**Government of Pakistan**
**Ministry of National Health Services, Regulations and Coordination**
**Drug Regulatory Authority of Pakistan**

Islamabad, the 16th November, 2026.

## NOTIFICATION

**S.R.O. 2117(I)/2026.-** In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, is pleased to make the following rules, namely:-

## CHAPTER 1
## PRELIMINARY

**1. Short title and commencement.-** (1) These rules shall be called the Alternative Medicines and Health Products Rules, 2026.

(2) These rules shall come into force at once.

**2. Definitions:** - (1) In these rules, unless there is anything repugnant in the subject or the context.-

(i) "Act" means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012);

(ii) "adulterated alternative medicine or health product" means an alternative medicine or health product,-

(a) which consists, in whole or in part, of any filthy, putrid or decomposed substance or which contains any foreign matter, vermin, worm, rodent or insect;

(b) the container of which is composed, in whole or in part, of any poisonous or deleterious substance;

(c) which contains any harmful, prohibited or toxic substance; or

(d) where any substance has been mixed therewith so as to reduce its quality or strength;

(iii) "baby milk and foods" means baby milk and foods for special medical conditions and therapeutic purposes excluding baby milk and food as substitute of mother feed and ordinary food;

(iv) "AMHP Board" means the Alternative Medicines and Health Products Board constituted under rule 3;

(v) "clinical trial" means clinical trial as defined under the Bio-Study Rules, 2017;

(vi) "contract" means a written agreement which should be drawn up and accepted between the contract giver and the contract acceptor specifying their respective responsibilities relating to the manufacture and quality control of the product;

(vii) "contract acceptor" means a manufacturer who manufactures the finished product under the label and brand of the contract giver;

(viii) "contract giver" means the person who awards the contract of particular products under their brand;

(ix) "counterfeit alternative medicine or health product" means an alternative medicine or health product the label or outer packing of which is an imitation of, or resembles or so nearly resembles as to be calculated to deceive, the label or outer-packing of a drug, alternative medicine or health product of another manufacturer;

(x) "dietetic foods intended for special medical purposes" means foods for special dietary use that are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foods or certain nutrients contained therein;

(xi) "Director" means in- charge of the division of Health and OTC Products (non-drugs) as specified in clause (h) of sub-section (1) of section 4 of the Act;

(xii) "division" means the division of Health and OTC Products (non-drugs) of the Authority;

(xiii) "experimental purposes" means manufacturing for clinical trial and product development purposes;

(xiv) "expiry date" means the date stated on the label of an alternative medicine or health product after which it is not permissible to sell the alternative medicine or health product;

(xv) "extract" means substances prepared by treating a plant or a plant material, an alga, a bacterium, a fungus or non-human animal material with solvents or pressure to remove any constituents;

(xvi) "finished product" means an alternative medicine or health product which is ready for use;

(xvii) "form' means form annexed to these rules;

(xviii) "generic product" means a product which has been previously approved by the Authority for marketing in Pakistan;

(xix) "health products or nutraceuticals" means products containing vitamins, pro-vitamins, multivitamins, minerals including a mineral salt, a naturally occurring mineral, metals and their salts, a lipid, including an essential fatty acid or phospholipids lipoproteins, amino-acids, proteins, fatty acids, carbohydrates, a mucopolysaccharide, plant or herbal material (or a synthetic duplicate of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll, herbal preparation, resins, balsams, volatile oils, non-human animal material (or a synthetic duplicate of that kind) including dried material, and cartilage, fats and oils and other extracts or concentrates, a microorganism, whole or extracted, except a vaccine, expressed juices, exudates etc., alone or their combinations and are presented in pharmaceutical dosage forms intended for the maintenance of good health;

(xx) "herbal medicines" include herbs, herbal materials, herbal preparations and finished herbal products, and-

(a) herbs include crude plant material such as leaves, flowers, fruit, seeds, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered presented in pharmaceutical dosage form;

(b) herbal materials are either whole plants or parts of medicinal plants in the crude state. They include herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs;

(c) herbal preparations are the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils, expressed juices and processed exudates of herbal materials. They are produced with the aid of extraction, distillation, expression, fractionation, purification, concentration, fermentation or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials;

(d) finished herbal products or herbal medicinal products containing as active substances exclusively herbal drugs or herbal drug preparations. They may consist of herbal preparations made from one or more herbs. If more than one herb is used, the term mixed herbal product can also be used. They may contain excipients in addition to the active ingredients. In some countries, herbal medicines may contain, by tradition, natural organic or inorganic active ingredients, which are not of plant origin (e.g. animal materials and mineral materials). Generally however, finished products or mixed products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal;

(e) medicinal plant – a plant, either growing wild or cultivated, used for its medicinal purposes; and

(f) medicinal plant materials (see herbal materials);

(xxi) "homeopathic medicinal product" includes any medicine which is prepared according to the techniques of homeopathic pharmacy and covers combination of ingredients of such homeopathic medicines but does not include a medicine which is administered by parenteral route. The homeopathic medicinal product must meet the criteria as mentioned in the below mentioned books as they are amended from time to time,-

(a) The European Pharmacopoeia (EP);

(b) British Pharmacopoeia (BP);

(c) Pharmacopée française or French Pharmacopoeia (Ph. fr.);

(d) Homeopathic Pharmacopoeia of United States (HPUS);

(e) Homöopathisches Arzneibuch (HAB) or German Homoeopathic Pharmacopoeia;

(f) Indian Homoeopathic Pharmacopoeia (IHP);

(g) Encyclopaedia of Homoeopathic Pharmacopoeia (EHP); or

(h) Any authoritative literature approved by the AMHP Board;

(xxii) "label" means any written, printed or graphic presentation that appears on or is attached to the container of the product or active ingredient or herbal preparation or any part of the packaging and includes informational sheet or leaflets that accompanies when finished product or active ingredient or preparation is being supplied;

(xxiii) "label claim" means any representation made on a product in relation to its indication, benefits or actions;

(xxiv) "manufacture" means all operations of production involved in the production of alternative medicines and health products or any part of the process of bringing the products to their final state, including engaging in the processing, packaging, labelling, storage, testing or releasing for supply of the products or of any component or ingredient of the product as part of the process but does not include dispensing or compounding of products;

(xxv) "markers" means chemically defined constituents or groups of constituents of a herbal substance, a herbal preparation or a herbal medicinal product which are of interest for control purposes independent of whether they have any therapeutic activity. Markers serve to calculate the quantity of herbal

substance(s) or herbal preparation(s) in the herbal medicinal product if the marker has been established for the relevant herbal substance or herbal preparation:

(a) active marker which are constituents or groups of constituents which are generally accepted to contribute to the therapeutic activity; and

(b) analytical marker which are constituents or groups of constituents that serve for analytical purposes;

(xxvi) "misbranded alternative medicine or health products" means an alternative medicine or health product which is:-

(a) not labelled in the prescribed manner or where any label or information is false or misleading;

(b) not packed according to the provisions of these rules; or

(c) which is bearing a design which is substantially identical with or deceptively similar to the design commonly used for the label of such drugs, in such manner that it is likely to cause harm to the health of the consumer;

(xxvii) "mother tincture or tincture" means the initial homoeopathic preparation made from source material that can be further potentized or obtained by a procedure prescribed by a recognized homoeopathic pharmacopoeia;

(xxviii) "new formulation or new product" means formulation, which has not been evaluated for quality, safety and efficacy nor sufficient standards of evidence have been defined regarding the recommended conditions for use excluding the products already in use indigenously for more than ten years;

(xxix) "nosode" means homoeopathic preparations of pathological organs or tissues, causative agents such as bacteria, fungi, ova, parasites, virus particles and yeast, disease products, excretions or secretions;

(xxx) "prohibited substance" means a substance that is not permitted to be contained in any alternative medicine or health product as decided by the AMHP Board;

(xxxi) "qualified person" means a person approved by the AMHP Board as a qualified technical person having prescribed qualification and experience;

(xxxii) "repacking" means all operations involved in the transfer of an alternative medicine or health product in bulk from a large container or packing into finished product including filling, packing, labelling, quality testing etc. for sale but doesn't include any compounding and dispensing;

(xxxiii) "Schedule" means schedules annexed to the rules;

(xxxiv) "Specials" means unregistered homeopathic medicinal products that are extemporaneously prepared by a licensed pharmacy, duly authorized for such preparation, to meet the special clinical needs of an individual patient upon the request of a registered homeopathic practitioner;

(xxxv) "specifications" means list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which health product or alternative medicines should conform to be considered acceptable for its intended use including specifications as approved by the AMHP Board;

(xxxvi) "specified publication" means any of the official publications recognized and notified by the Authority which contain material information regarding the manufacturing, analytical standards or recommended conditions for use of alternative medicines or health products as specified under these rules including British Pharmacopoeia or British Pharmaceutical Codex or British Herbal Pharmacopoeia, United States Pharmacopoeia, American Herbal Pharmacopoeia, European Pharmacopoeia, German Pharmacopoeia, Japanese Pharmacopoeia, Korean Pharmacopoeia, Codex Alimentarius, Indian Pharmacopoeia, Chinese Pharmacopoeia and China Drug Standards, Indian *Unani* Pharmacopoeia, Indian Ayurvedic Pharmacopoeia, and *Unani* and Ayurvedic Formulary, Homeopathic Pharmacopoeia of United States (HPUS), Homöopathisches Arzneibuch (HAB) or German Homoeopathic Pharmacopoeia, Indian Homoeopathic Pharmacopoeia (IHP), Encyclopedia of Homoeopathic Pharmacopoeia (EHP) India and any other publication to be notified by the Authority;

(xxxvii) "spurious alternative medicines or health products" means alternative medicines or health products which:-

(a) is imported under a name which belongs to another product;

(b) label or the container bears the name of an individual or company purporting to be the manufacturer of the medicine or health products, which individual or company is fictitious or does not exist;

(c) has been substituted wholly or in part by another drug, medicine, health product or substance; or

(d) is purports to be the product of a manufacturer of whom it is not truly a product.

(xxxviii) "sub-standard" means alternative medicine or health product, ingredient, raw material or finished product which does not conform to the specifications or prescribed standards of quality, identity, purity and strength as defined in the specified publication or prescribed under these rules;

(xxxix) "*unani* medicine" means a single or compound medicines of different origins (herbal, animal or mineral) that produce physiological effects when

administered according to *unani* description for the prevention of disease, promotion of health or treatment of disease or is in accordance with a formula prescribed in the authoritative books of *Tibb-e-Unani*; and

(xl) "unregistered alternative medicines or health product" means a product which is manufactured, imported, exported or sold without registration or which is not in accordance with the conditions of registration prescribed under these rules.

(2) The words and expressions used but not defined herein shall have the same meanings as are assigned to them in the Act, Codex Alimentarius of the Food and Agriculture Organization, World Health Organization, or International Conference on Harmonization Guidelines or the guidelines issued by the Authority for alternative medicines and health products.

**3. Alternative Medicines and Health Products Board.-** (1) The AMHP Board shall consist of the following members, namely:–

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|---|---|---|
| 1. | Director, Division of Health and OTC Products (non-drugs); | *Ex-Officio* Chairperson |
| 2. | Additional Director, Division of Health and OTC Products (non-drugs); | *Ex-Officio* Secretary cum Member |
| 3. | Chief Drug Control and Traditional Medicine Division, National Institute of Health; | *Ex-Officio* Member |
| 4. | Chief Nutrition Division, National Institute of Health; | *Ex-Officio* Member |
| 5. | One nominee each not below the rank of BS-18 to be nominated by the health department or drug control administration of Provinces and governments of Gilgit Baltistan, Azad Jammu and Kashmir and Islamabad Capital Territory; | *Ex-officio* Members |
| 6. | One expert of homeopathy having experience of seven years; | Member |
| 7. | One expert each of quality control and manufacturing having experience of seven years; | Members |
| 8. | One expert of *unani / tibb* having experience of seven years; | Member |
| 9. | One professor of pharmacognosy; | Member |
| 10. | One professor of veterinary pharmacology; | Member |
| 11. | Director, Division of Quality Assurance and Laboratory Testing; | Member |
| 12. | One nominee from relevant trade body or association duly registered by the Director, Directorate General of Trade Organization. | Observers |

(2) The AMHP Board may co-opt any expert member as and when required.

(3) The members of the AMHP Board, other than its ex-officio members, shall hold office for a term of three years and shall be eligible for re-nomination for further one term of the same period.

(4) A member may resign from his office by writing under his hand addressed to the Authority.

(5) The members from serial No. 6 to 10 provided in the sub-rule (1) shall be nominated by the Authority.

(6) No person who is a member of the Appellate Board or the Policy Board shall be a member of the AMHP Board.

(7) A simple majority of the total membership shall constitute the quorum for a meeting of the AMHP Board and in case of equality of votes, the Chairperson or the person presiding over the meeting shall have a casting vote.

(8) The Secretary shall call the meeting on the direction of the Chairperson or the Chief Executive Officer.

(9) The Secretary or authorized officer of the Division shall sign the correspondence on behalf of the AMHP Board.

(10) No act or proceeding of the AMHP Board shall be invalid by reason only of the existence of a vacancy, or any defect, in the constitution of the AMHP Board.

(11) The observers shall have no voting right.

(12) In case the Chairperson is absent or unavailable, the members of the AMHP Board may elect a person from amongst themselves as Chairperson of the AMHP Board for that particular meeting. The AMHP Board may authorise the Chairman or any of its members to perform any specific function of the Board for a specified period.

**4. Powers and functions of the AMHP Board.-** (1) The AMHP Board may appoint a panel of experts or inspectors or auditors for inspection or investigation and to submit a report to the AMHP Board.

(2) The AMHP Board may grant or renew, suspend or cancel a licence to manufacture alternative medicines and health products.

(3) The AMHP Board may grant or renew, suspend or cancel a registration for the manufacture of alternative medicines and health products.

(4) The AMHP Board may extend the sealing period and period of order not to dispose of up to three months for the licenced units on the request of an Inspector for the purpose of investigations:

Provided that investigations shall be completed within three months by the Inspector and the complete case shall be submitted for the consideration of the AMHP Board.

Provided further that the AMHP Board may extend the sealing period up to the decision of the case by the Drug Court in cases of unlicenced firms or where the licence has been cancelled or suspended by the AMHP Board.

(5) The AMHP Board may examine the investigation reports referred to it by the Federal Inspector and may pass appropriate orders including but not limited to granting permission to the Federal Inspector for lodging of first information report in case of manufacture of alternative medicines and health products in unlicenced premises or manufacture or sale of spurious alternative medicines and health products or manufacture or sale of unregistered alternative medicines and health products:

Provided that if any violation of these rules is found by the Provincial Drug Inspector, the case may be referred to the concerned provincial quality control Board for appropriate action under the law.

(6) The Provincial Quality Control Board may also refer the case regarding cancellation or suspension of the licence or registration to the AMHP Board for taking any action as deem appropriate.

(7) The AMHP Board may issue a show cause notice and provide an opportunity of personal hearing-

(a) before cancellation or suspension of licence or any section or area of a licenced unit;

(b) before cancellation or suspension of a registration;

(c) before granting permission for prosecution in the Drug Court; and

(d) for any other violations of the Act and these rules.

(8) The AMHP Board may exercise the power to call any person and seek any information which it believes is important for the conduct and disposal of the matter under consideration by the AMHP Board.

(9) The AMHP Board shall follow policy guidelines issued by the Policy Board or the Authority, as the case may be.

(10) The AMHP Board may, in case of minor contravention, advise the licencee for improvement or, if considered necessary, issue a warning or take other action as it may deem fit for the purpose of improvement.

(11) The AMHP Board may, in the public interest, recommend to the authority, dealing with the import of goods, to restrict or stop the import of any alternative medicine and health product, which is produced in sufficient quantity in Pakistan.



## CHAPTER 2
## LICENSING

**5. Types of licences.**- (1) Licence to manufacture or import alternative medicines and health products shall be of the following types, namely:--

(a) licence to manufacture bulk extract, mother tincture and isolate;

(b) licence to manufacture by way of formulation;

(c) licence to import finished product; and

(d) licence to manufacture for experimental purpose.

(2) If alternative medicines and health products are manufactured or imported on more than one premises, a separate licence shall be issued in respect of each such premises.

**6. Application for site suitability and layout plan for licence.-** (1) An application shall be made by a person (hereinafter referred to as "the applicant") on Form 1 for the site suitability and verification to the division for licence to manufacture bulk extract, mother tincture and isolate and licence to manufacture by way of formulation.

(2) Site suitability may be verified through an officer to be nominated by the Director:

Provided that such verification shall be exempted if the plot is located in a declared industrial area notified by the relevant government.

(3) The size and location of plot shall be determined in accordance with the guidelines issued by the Authority.

(4) After approval of site, the applicant may apply for the approval of layout plan, addressed to the division.

(5) The AMHP Board may, after affording the applicant an opportunity of personal hearing, reject an application if the applicant fails to provide information, particulars or documents as required under these rules and shall inform the applicant of its decision with reasons of such rejection.

**7. Procedure for grant and renewal of licence.**– (1) An application for the grant, after construction of building as per approved layout plan and installation of machinery and equipment or renewal of a licence referred to in clauses (i), (ii) and (iv) of sub-rule (1) of rule 5, shall be made on Form 2 and in case of licence to import finished product on Form 3 to the division.

(2) The AMHP Board may constitute a panel of inspectors or experts for the enquiry or verification of manufacturing and testing facilities or storage facility, before issuing a licence, to a manufacturer or importer of alternative medicines and health products, respectively.

(3) The panel of inspectors or experts appointed under sub-rule (2) shall forward a detailed inspection report with clear and candid recommendations to the AMHP Board.

(4) If the AMHP Board, after further enquiry, if any, as it may consider necessary, is satisfied that the requirements of the rules have been complied with, it may issue a licence.

(5) If the AMHP Board is not so satisfied, it shall reject the application and shall inform the applicant of its decision in writing with reasons of such rejection.

(6) If a person possesses, or applies for, more than one type of licences as prescribed under rule 5 or has a licenced unit of any other therapeutic good on the same premises, they may establish at least one quality control department, microbiology laboratory, and phyto-laboratory (in case of herbal products) for the purpose of the licences.

(7) On an application being made for renewal, the AMHP Board, may cause an inspection to be made and if satisfied that the conditions of the licence and the rules are fulfilled, may issue a certificate of renewal:

Provided that if decided by the AMHP Board, the licencee shall rectify the observations made during the inspection within a period as may be decided by the AMHP Board after affording the opportunity of hearing to the applicant and during such period, the manufacturing in that particular section or area or the premises may remain suspended as per the decision of the AMHP Board until after re-inspection, the AMHP Board grants renewal of the licence or otherwise rejects the application and informs the licencee accordingly.

**8. Certificate of licence to manufacture.-** (1) A licence to manufacture bulk extract, mother tincture or isolate or by way of formulation or by way of import of finished product or for experimental purpose, as the case may be, shall be issued on Form 4, Form 5, Form 6, and Form 7, respectively.

(2) If the original licence is defaced, damaged or lost, the licencee shall submit an application for issuance of a duplicate copy of such licence. Such copy of the licence shall bear the words "Duplicate Copy".

**9. Duration of licence.-** A licence issued under this Chapter, unless earlier suspended or cancelled, shall be in force for a period of five years from the date of issue and may thereafter be renewed for a period of five years at a time:

Provided that if an application for renewal is made before the expiry of the period of validity of a licence, the licence shall continue in force until orders are passed on such application even after the date of expiry of such licence.

Provided further that if an application for renewal is made after the expiry of the period of validity of a licence but within one year of its expiry, the licence shall continue to be in force on payment of additional surcharge as notified by the Authority under the Drug Regulatory Authority (Fee and Levy) Rules, 2022 for each day the application is delayed and thereafter the licence shall remain valid until orders are passed on such application.

**10. Conditions for the grant or renewal of licence.-** Before a licence to manufacture or import alternative medicines and health products is granted or renewed, the AMHP Board shall satisfy itself that the following conditions are being complied with by the applicant, namely:-

(a) conditions of licence to manufacture alternative medicines and health products except for experimental purpose:-

(i) the factory premises shall comply with the conditions as specified in Schedule-A. The applicant shall provide adequate space, plant and equipment for the manufacturing, quality assurance and testing operations as per guidelines issued by the Authority;

(ii) the manufacture shall be conducted under the active direction and personal supervision of technical staff consisting of at least one person who is a whole-time employee and who has a degree in pharmacy, homoeopathy or Bachelor of Eastern Medicine and Surgery (BEMS) from a university in Pakistan or any other institution recognized by the Council concerned or Higher Education Commission, as the case may be, for the purpose of these rules and has at least five years' experience in the manufacture of therapeutic goods related to the products being manufactured;

(iii) the applicant shall establish an independent quality control department and maintain separate staff, premises and adequate laboratory equipment for carrying out tests of purity, strength and quality of the substances being or to be used in the manufacture of the finished products or finished products intended to be manufactured;

(iv) the quality control department in-charge shall be a whole-time employee of the manufacturer and shall possess a degree in pharmacy or a degree in chemistry or homoeopathy or BEMS, with five years' experience in quality control of therapeutic goods related to the products being manufactured;

(v) an application for change in technical staff shall be submitted to the division with documentary evidence of qualification and experience for approval; and

(vi) the licencee shall comply with such further requirements, if any, as may be determined under guidelines issued by the Authority;

(b) special conditions of licence to import alternative medicines and health products:-

(i) the storage facility of the applicant for imported products shall be as per Schedule-B;

(ii) the facility for storage of imported alternative medicines and health products shall be supervised by a pharmacist having a degree in pharmacy from the University recognized by Higher Education Commission; and

(iii) the licencee shall comply with such further requirements as may be determined under guidelines issued by the Authority; and

(c) special conditions of licence to manufacture alternative medicines and health products for experimental purposes:-

(i) the licencee shall use the licence exclusively for experimental purposes; and

(ii) the licencee shall comply with such further requirements, if any, as determined under guidelines issued by the Authority.

**11. Cancellation or suspension of a licence.**- If a licencee does not comply with any of the conditions of a licence or violates any of the provisions of the Act or these rules, the AMHP Board may, after giving such licencee an opportunity of being heard, by an order in writing stating the reasons thereof, cancel a licence or suspend it for such period as it thinks fit, either wholly or in respect of some of the alternative medicines and health products to which it relates.

## CHAPTER 3
## REGISTRATION OF HEALTH PRODUCT

**12. Application for registration of health product.–** (1) An application, for registration of health product for the local manufacture for generic product made on Form 8, for new product on Form 9, import for generic product in Form 10 and for imported new product in Form 11, shall be submitted, addressed to the division.

(2) The applicant shall furnish information with documentary evidence and material as may be required by the AMHP Board for the proper evaluation of the application.

**13. Procedure for registration.**- (1) The AMHP Board may cause evaluation of the application for registration of health products by the officers in the division or by experts as it may deem appropriate.

(2) The AMHP Board may rely on the inspection report conducted for the purpose of the licence in respect of premises, plant and appliances or may constitute a panel of experts or inspectors to inspect the premises and submit its report to the AMHP Board for specific product under consideration by the AMHP Board.

(3) If the AMHP Board is satisfied that all requirements pertaining to the grant of registration of the applied product are fulfilled, it may register the product and issue a certificate of registration for local manufacture in Form 12 and for an imported product in Form 13:

Provided that if a product having the same formulation and route of administration has already been approved by the AMHP Board and has not been withdrawn from sale for reasons of safety or effectiveness, the subsequent application shall be decided by the Director on the basis of guidelines issued by the Authority. The decisions taken by the Director shall be placed before the AMHP Board for its information.

(4) The AMHP Board may, while registering a health product under sub-rule (3), approve the details as supplied by the applicant or approve them with amendments as it may deem fit in respect of the following particulars, namely:-

(a) the name under which the health product may be sold;

(b) the labelling; and

(c) the statement of all the representations to be made for the promotion of the health product in respect of-

(i) the claims to be made for the health product;

(ii) the route of administration;

(iii) the dosage; and

(iv) the contra-indications, the side effects and precautions, if any.

(5) If the AMHP Board is not satisfied as to the safety, efficacy or quality of the health product, the application for registration under these rules is rejected, the AMHP Board shall inform the applicant of its decision in writing with reasons for such decision.

**14. Duration of certificate of registration.-** (1) The registration, of the health product under sub-rule (3) of rule 13 shall be for a period of five years from the date of registration, unless earlier cancelled or suspended by the AMHP Board, however, it may thereafter be renewed for a period of five years at a time:

Provided that an application shall be made before the expiry of the registration and when an application has been made as aforesaid, the registration shall continue to be in force until orders are passed by the AMHP Board on such application.

(2) If an application is made after the expiry of the period of the registration, the AMHP Board may cancel the registration after affording the applicant an opportunity of a personal hearing.

**15. Conditions of registration of health product.-** (1) The import, manufacture and sale of a health product shall be in accordance with the information on the basis of which the product was registered:

Provided that deviations from any such information may be made only after obtaining prior approval of the AMHP Board.

(2) The indenter, importer or manufacturer's authorized agent shall issue a warranty in Form 14 for any health products intended or sold by him for the purpose of sale.

(3) If a health product or any of its ingredients, which is imported or manufactured by a company in Pakistan, is also approved for registration and free sale by its subsidiary, sister concern, associate or parent company in the country where it was originally developed or in any of the countries identified by the Authority, and-

(a) if that health product at any time, for safety reasons, is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or, as the case may be, the indenters or importers, to immediately withdraw the health products from the market in Pakistan or, as the case may be, to impose similar restrictions and to inform the AMHP Board within fourteen days of such information having come to their knowledge and having taken the necessary action. The AMHP Board, after getting the said intimation, shall take similar action for the same health product available from other sources within the shortest possible time;

(b) if clinical information for a health product is approved in any of the said countries, the same clinical information shall be considered as approved for registration in Pakistan unless modified by the AMHP Board on the basis of scientific data available to it and such clinical information may include indications, contra-indications, side effects, precautions, dosage, etc.; and

(c) if an adverse reaction not otherwise included in the application for registration is registered in any of the said countries, it shall be the responsibility of the concerned manufacturer or, in case of an imported health product, the indenters or manufacturer's agent in Pakistan to be aware of such adverse reaction and to report it to the AMHP Board within thirty days of becoming so aware.

(4) The manufacturer or, as the case may be, the indenters or importers shall supply the information in relation to safety, efficacy, production, quality or availability of the health product, as and when required by the AMHP Board with a view to ensuring the safety, efficacy or quality of the health product.

## CHAPTER 4
## REGISTRATION OF ALTERNATIVE MEDICINES INCLUDING *UNANI*, TRADITIONAL CHINESE MEDICINE, ETC. EXCLUDING HOMOEOPATHIC MEDICINE

**16. Application for registration of alternative medicines including *unani*, traditional Chinese medicine, etc. excluding homoeopathic medicines.-** (1) An application for registration of alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines for the local manufacture for generic product in Form 15, for new product in Form 16 or import for generic product in Form 17 and for imported new product in Form 18 shall be submitted, addressed to the division.

(2) The applicant shall furnish information with documentary evidence and material as may be required by the AMHP Board for the proper evaluation of the application.

**17. Procedure for registration.–** (1) The AMHP Board may cause evaluation of the application for registration by the officers in the division.

(2) The AMHP Board may rely on the inspection report conducted for the purpose of the licence in respect of premises, plant and appliances, process of manufacture intended to be employed and the means to be employed for standardizing and testing the substances to be manufactured, and also the professional qualifications of the technical staff employed.

(3) If the AMHP Board is satisfied that all requirements pertaining to the application have been met, it may register the product and issue a certificate of registration for local manufacture in Form 19 and for an imported product in Form 20:

Provided that if a product having the same formulation and route of administration has already been approved by the AMHP Board and has not been withdrawn from sale for reasons of safety or effectiveness, the subsequent application shall be decided by the Director on the basis of guidelines issued by the Authority. The decisions taken by the Director shall be placed before the AMHP Board for its information.

(4) The AMHP Board may, while registering an alternative medicine including *unani*, traditional Chinese medicine excluding homoeopathic medicines under sub-rule (3), approve the details as supplied by the applicant or approve them with amendments as it may deem fit in respect of the following particulars, namely:-

(a) the name under which the alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines may be sold;

(b) the labelling; and

(c) the statement of all the representations to be made for the promotion of the alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines in respect of:-

(i) the claims to be made for the alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines;

(ii) the route of administration;

(iii) the dosage; and

(iv) the contra-indications, the side effects and precautions, if any.

(5) If the AMHP Board is not satisfied as to the safety, efficacy or quality of the alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines, the application for registration under these rules is rejected and the AMHP Board shall inform the applicant of its decision in writing with reasons for such decision.

**18. Duration of certificate of registration.-** (1) The registration of the alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines under sub-rule (3) of rule 17 shall be for a period of five years from the date of registration, unless earlier cancelled or suspended by the AMHP Board, however, it may thereafter be renewed for a period of five years at a time:

Provided that an application shall be made before the expiry of the registration and when an application has been made as aforesaid, the registration shall, subject to the orders passed by the AMHP Board on the application for renewal, continue in force until such orders are passed.

(2) If an application is made after the expiry of the period of the registration, the AMHP Board may cancel the registration after affording the applicant an opportunity of a personal hearing.

**19. Conditions of registration of alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines.-** (1) The import, manufacture and sale of alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines shall be in accordance with the information on the basis of which the product was registered:

Provided that deviations from any such information may be made only after obtaining prior approval of the AMHP Board.

(2) The indenter, importer or manufacturer's authorized agent shall issue a warranty in Form 21 for any alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines intended or sold by him for the purpose of sale.

(3) If an alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines or any of its ingredients, which is imported or manufactured by a company in Pakistan, is also approved for registration and free sale by its subsidiary, sister concern, associate or parent company in the country where it was originally developed or in any of the countries identified by the Authority, and-

(a) if that alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines at any time, for safety reasons, is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or, as the case may be, the indenters, to immediately withdraw the alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines from the market in Pakistan or, as the case may be, to impose similar restrictions and to inform the AMHP Board within fourteen days of such information having come to their knowledge and having taken the necessary action. The AMHP Board, after getting the said intimation, shall take similar action for the same alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines available from other sources within the shortest possible time;

(b) if clinical information for an alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines is approved in any of the said countries, the same clinical information shall be considered as approved for registration in Pakistan unless modified by the AMHP Board on the basis of scientific data available to it and such clinical information may include indications, contra-indications, side effects, precautions, dosage, etc.; and

(c) if an adverse reaction not otherwise included in the application for registration is registered in any of the said countries, it shall be the responsibility of the concerned manufacturer or, in case of an imported alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines, the indenters or manufacturer's agent in Pakistan to be aware of such

adverse reaction and to report it to the AMHP Board within thirty days of becoming so aware.

(4) The manufacturer or, as the case may be, the indenters or importers shall supply the information in relation to safety, efficacy, production, quality or availability of the alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines, as and when required by the AMHP Board, with a view to ensuring the safety, efficacy or quality of the alternative medicines including *unani*, traditional Chinese medicine etc. excluding homoeopathic medicines.

## CHAPTER 5
## REGISTRATION OF HOMOEOPATHIC PRODUCT

**20. Application for registration of homoeopathic medicines.**- (1) An application for registration of homoeopathic medicines, for the local manufacture of a generic product in Form 22, for a new product in Form 23, for import of a generic product in Form 24 and for an imported new product in Form 25, shall be submitted, addressed to the division.

(2) The applicant shall furnish information with documentary evidence and material as may be required by the AMHP Board for the proper evaluation of the application.

**21. Procedure for registration.-** (1) The AMHP Board may cause evaluation of the application for registration of homoeopathic medicines by the officers in the division.

(2) The AMHP Board may rely on the inspection report conducted for the purpose of the licence in respect of premises, plant and appliances, process of manufacture intended to be employed and the means to be employed for standardizing and testing the substances to be manufactured, and also the professional qualifications of the technical staff employed.

(3) A separate relevant application form as provided in sub-rule (1) of rule 20 shall be completed for each series of dilutions for which registration is sought. For combination products, a separate form shall be completed for each formulation. No application shall be entertained for parenteral dosage forms.

(4) If the AMHP Board is satisfied that all requirements pertaining to the application have been met, it may register the product and issue a certificate of registration for local manufacture in Form 26 and for an imported product in Form 27:

Provided that if a product having the same formulation and route of administration has already been approved by the AMHP Board and has not been withdrawn from sale for reasons of safety or effectiveness, the subsequent application shall be decided by the Director on the basis of guidelines issued by the Authority. The decisions taken by the Director shall be placed before the AMHP Board for its information.

(5) The AMHP Board may, while registering a homoeopathic medicine under sub-rule (4), approve the details as supplied by the applicant or approve them with amendments as it may deem fit in respect of the following particulars, namely:-

(a) the name under which the homoeopathic medicine may be sold;

(b) the labelling; and

(c) the statement of all the representations to be made for the promotion of the homoeopathic medicine in respect of:-

(i) the claims to be made for the homoeopathic medicine;

(ii) the route of administration;

(iii) the dosage; and

(iv) the contra-indications, the side effects and precautions, if any.

(6) If the AMHP Board is not satisfied as to the safety or efficacy of the homoeopathic medicine, the application for registration under these rules is rejected and the AMHP Board shall inform the applicant of its decision in writing with reasons for such decision.

**22. Duration of certificate of registration.-** (1) The registration of a homoeopathic medicine under sub-rule (4) of rule 21 shall be for a period of five years from the date of registration, unless earlier cancelled or suspended by the AMHP Board:, however, it may thereafter be renewed for a period of five years at a time:

Provided that an application shall be made before the expiry of the registration and when an application has been made as aforesaid, the registration shall, subject to the orders passed by the AMHP Board on the application for renewal, continue in force until such orders are passed.

(2) If an application is made after the expiry of the period of the registration, the AMHP Board may cancel the registration after affording the applicant an opportunity of a personal hearing.

**23. Conditions of registration of homoeopathic medicines.-** (1) The import, manufacture and sale of a homoeopathic medicine shall be in accordance with the information on the basis of which the product was registered:

Provided that deviations from any such information may be made only after obtaining prior approval of the AMHP Board.

(2) The indenter, importer or manufacturer's authorized agent shall issue a warranty in Form 28 for any homoeopathic medicines intended or sold by him for the purpose of sale.

(3) If homoeopathic medicines or any of its ingredients, which is imported or manufactured by a company in Pakistan is also approved for registration and free sale by its subsidiary, sister concern, associate or parent company in the country where it was originally developed or in any of the countries identified by the Authority, and-

(a) if homoeopathic medicines at any time, for safety reasons is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or as the case may be, the indentors, the immediately withdraw the homoeopathic medicines from the

market in Pakistan or, as the case may be to impose similar restriction and to inform the AMHP Board within fourteen days of such an information having come, to his knowledge and having taken the necessary action. The AMHP Board after getting the said intimation shall take similar action for the same homoeopathic medicines available from other sources within shortest possible time;

(b) if homoeopathic medicines is approved in any of the said countries, the same clinical information shall be considered as approved for homoeopathic medicines registration in Pakistan unless modified by the AMHP Board on the basis of scientific data available to it, and such clinical information may include indications, contra-indications, side effects precautions, dosage, etc.; and

(c) if an adverse reaction not otherwise included in the application for registration, is registered in any of the said countries, it shall be the responsibility of the concerned manufacturer or in case of imported homoeopathic medicines the indentors of manufacturer agent in Pakistan to be aware of such adverse action and to report to the AMHP Board within thirty days of becoming so aware.

(4) The Manufacturer or, as the case may be, the indentors or importers shall supply the information in relation to safety, efficacy, production, quality or availability of the homoeopathic medicines as and when required by the AMHP Board with a view to ensure safety, efficacy or quality of the homoeopathic medicines.

## CHAPTER 6
## MANUFACTURE OF BULK EXTRACTS, HOMOEOPATHIC TINCTURES OR ISOLATES

**24. Application for manufacture of bulk extract, homoeopathic tinctures or isolates.-** (1) An application for manufacture of a bulk extract, homoeopathic tinctures or isolates shall be submitted on Form 29 to the division.

(2) The AMHP Board may cause evaluation of the application for manufacture by the officers in the division.

(3) The AMHP Board may, rely on the inspection report conducted for the purpose of licence in respect of premises, plant and appliances, process of manufacture intended to be employed and the means to be employed for standardizing, and testing the substances to be manufactured and also professional qualification of the technical staff employed.

(4) If the AMHP Board, after such further enquiry, if any, as it may consider necessary, is satisfied that product meets the required criteria for licence to manufacture, it may approve the product and issue a certificate of registration in Form 30, subject to such specific conditions as it may specify.

(5) If the AMHP Board is not satisfied as to the process and quality of bulk extract, homoeopathic tinctures or isolates, it may reject the application and inform the applicant of the reasons for such rejection in writing within a period of thirty days.

(6) Rejection of an application under sub-rule (5) shall not debar an application from submitting a fresh application.

(7) A certificate of registration under this Chapter shall, unless earlier suspended or cancelled, be in force for a period of five years from the date of registration:

Provided that an application for renewal shall be made before expiry of the registration and when an application has been made as aforesaid, the registration shall subject to the orders passed on the application for the renewal, continue in force for the next period of five years.

(8) If an application is made after the expiry of the period of the registration, the AMHP Board may cancel the registration after affording the applicant an opportunity of a personal hearing.

**25. Conditions of registration of bulk extract, tinctures or isolates.-** (1) The manufacture and sale of bulk extract, homoeopathic tinctures or isolates shall be in accordance, with the information on the basis of which such product was registered by the AMHP Board:

Provided that deviations from any such information may be made only after obtaining prior approval of the AMHP Board.

(2) Every bulk extract, homoeopathic tinctures or isolates shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

## CHAPTER 7
## CONTRACT MANUAFCTURING

**26. Eligibility for contract manufacturing**.- Manufacture through contract, either for local sale or export purpose, shall be permissible for a contract giver who is:-

(a) a licenced pharmaceutical manufacturer having a licence to manufacture by way of formulation;

(b) a licenced alternative medicines and health products manufacturer having a licence to manufacture by way of formulation and does not possess the required section to manufacture the product;

(c) a licenced alternative medicines and health products manufacturer having a licence to manufacture by way of formulation, where the AMHP Board has been informed that the unit is under renovation or repair due to its expansion or improvement of good manufacturing practices (GMP) compliance or upgrade requirements:

Provided that contract manufacturing under this clause shall be for a maximum period of twelve months, extendable for a further period in case of *force majeure* to be decided by the AMHP Board on valid grounds;

(d) an importer for its already registered alternative medicine and health products in Pakistan for permission from finished drug product import to contract manufacturing by a licenced manufacturer by way of formulation, subject to

submission of no objection certificate from principal manufacturer abroad or marketing authorization holder; or

(e) a foreign pharmaceutical company (manufacturer or marketing authorization holder) having therapeutic goods sale licence in Pakistan for their research, innovator, originator products or products already registered for sale by any of reference regulatory authorities adopted by the AMHP Board.

**27. Application for contract manufacturing.**- (1) An application for contract manufacturing shall be submitted, addressed to the division in the following manner, namely:-

(a) application for manufacturing on contract basis by the contract giver shall be made in Form 31;

(b) application for the registration of the product shall be made on Form 32; and

(c) contract manufacturing approval shall be issued on Form 33 and shall be valid for a period of five years and may be renewable for a further period of five years, except for applications under the circumstances specified in clause (c) of sub-rule (1) of rule 26.

(2) The AMHP Board may approve testing and analysis of a product by one manufacturer at another manufacturer's facility or at any other testing laboratory approved by the Authority for a specific purpose which is specialized in nature and for a limited time in the public interest.

(3) The AMHP Board may revoke any approval granted under clause (c) of sub-rule (1) or sub-rule (2) at any time if it considers that the circumstances under which approval was granted no longer exist or that testing and analysis is not being carried out in accordance with the conditions:

Provided that before revoking the permission, an opportunity of being heard shall be provided to the applicant.

(4) Where any provision of the Act or the rules made thereunder, or any condition relating to contract manufacturing prescribed under these rules is contravened, both the contract giver and the contract acceptor shall be held responsible for such violation.

**28. Conditions for contract manufacturing.**- The eligibility for contract manufacturing, as provided in rule 26, shall be subject to the following conditions, namely:-

(a) the requirements of rules 15, 19, or 23, as the case may be, depending on the nature of the product, shall *mutatis mutandis* apply;

(b) contract manufacturing of controlled substances (narcotic drugs, psychotropic substances, or precursor chemicals) shall not be permitted; and

(c) contract manufacturing shall also be subject to the conditions laid down in Schedule-C.

## CHAPTER 8
## LABELLING OF ALTERNATE MEDICNES AND HEALTH PRODUCTS

**29. Minimum labelling requirements.-** (1) The manufacturer or importer of registered alternative medicines and health products, as the case may be, shall print the minimum following information on the product label in English and/or Urdu language, namely:-

(a) name of the product;

(b) name and quantity of active ingredients and name of excipients;

(c) dosage form;

(d) directions for use including dosage, mode of administration, duration of use and age group limitations. For human products, information on use during pregnancy and lactation shall be included where applicable and for veterinary health products and veterinary alternative products, target species and any species restrictions shall be included, if applicable;

(e) warning statements and relevant contraindications, adverse effects, if any, and overdose information when relevant;

(f) batch number;

(g) manufacturing date;

(h) expiry date;

(i) maximum retail price;

(j) storage conditions;

(k) name and address of the manufacturer and/or importer;

(l) manufacturing licence number;

(m) product registration number;

(n) the top of the label of an alternative medicine shall conspicuously bear the words "Alternative Medicine – Herbal/ Ayurvedic/ Homoeopathic/ Biochemic or as the case may be", in prominent bold ink; AND the top of label of Health products/ Nutraceuticals shall conspicuously bear the, words Health Product/Nutraceutical Not for The Treatment of Any Disease", in prominent bold ink;

(o) products for veterinary use shall be labelled conspicuously with the words "FOR VETERINARY USE ONLY" in prominent bold letters;

(p) products for external use shall be labelled conspicuously with the words "FOR EXTERNAL USE ONLY"; and

(q) any other information as directed by the AMHP Board.

(2) The scientific name of active ingredients, in addition to the common name, shall be used.

(3) The label and package insert shall be in English and/or Urdu and shall be easy to read and understand.

(4) The AMHP Board may decide further requirements for labelling, indications, and claims as and when necessary, including but not limited to track and trace system:

Provided decision in respect of track and trace system shall be subject to the approval of Policy Board.

**30. Labelling of alternative medicines and health products manufactured for experimental purposes.**– (1) Any alternative medicines and health products manufactured for experimental purposes shall be kept in containers bearing labels indicating the purpose for which they have been manufactured.

(2) If an alternative medicine or health product manufactured for experimental purposes is supplied by the manufacturer to any other person, the container shall bear a label on which shall be stated the name and address of the manufacturer, the accepted scientific name of the product, if known, or, if not known, a reference which shall enable the product to be identified and the purpose for which it has been manufactured. The label shall additionally state "FOR EXPERIMENTAL USE ONLY — NOT FOR COMMERCIAL SALE". For veterinary products manufactured for experimental purposes, the target species shall also be stated, if applicable.

## CHAPTER 9
## MISCELLANEOUS

**31. Cancellation or suspension of registration of registered alternate medicines and health product.**– Where any person has been found to have contravened any of the provisions of these rules in respect of any alternative medicines and health products, the AMHP Board may, after giving such person an opportunity of being heard, cancel the registration of such product or suspend such registration for a specified period.

**32. Post-marketing surveillance system.**- (1) For the purpose of post-marketing surveillance of marketed alternative medicines and health products, a licencee, shall establish, maintain and implement an appropriate and effective post-marketing surveillance system for the alternative medicines and health products they are dealing with, which shall include the following elements, namely:-

(a) distribution records;

(b) complaint handling system;

(c) mandatory problem reporting, including investigation of any problem or incident;

(d) corrective action; and

(e) recall procedure.

(2) Any person who, in compliance or purported compliance with sub-rule (1), furnishes to the AMHP Board or an authorized officer any record which is false or misleading, their licence or registration shall be cancelled or suspended as the AMHP Board may think fit, after affording him the opportunity of being heard.

(3) Pharmacovigilance of alternative medicines and health products shall be governed under the relevant rules made under the Act.

**33. Testing of alternative medicines and health products.-** (1) The standards for testing of alternative medicines and health products shall be in accordance with the standards as per guidelines issued by the Authority.

(2) The laboratory and government analyst, notified by the Authority in the official Gazette for the testing, analysis and reporting of therapeutic goods, shall perform testing, analysis and reporting of alternative medicines and health products:

Provided that until such time, the AMHP Board may send such samples for testing, analysis and reporting to any other laboratory as may be decided by the Authority.

Provided further that the provincial governments shall notify their respective laboratory as per their respective rules.

**34. Post licence and post registration variation.-** The licencee may make an application on Form 34 for change of title or management, within period of two months after completion of transaction and documentation and any correction or change in brand name, formulation etc, as the case may be, addressed to division.

**35. Fee.-** (1) Any application submitted under these rules shall be accompanied by the prescribed fee, as notified by the Authority under the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022.

(2) Any fee deposited under these rules shall in no case be refunded. However, the fee may be adjusted within the same financial year in accordance with the guidelines issued by the Authority.

**36. Appeal.-** Any person aggrieved by any decision under these rules may, within sixty days of such decision, prefer an appeal before the Appellate Board under section 12 of the Act.

**37. Powers to amend schedule and form.-** The Authority may, on the recommendation of AMHP Board, amend, delete or substitute any Schedule and Form so as to omit any entry therefrom, add any entry thereto or amend any entry therein.

**38. Repeal and savings.-** (1) The Alternative Medicines and Health Products (Enlistment) Rules, 2014, and all other rules, notifications, orders, guidelines and other

instruments made under the Act or the DRAP Act, in so far as they regulate alternative medicines and health products or any activity governed by these rules, are hereby repealed.

(2) Notwithstanding the repeal under sub-rule (1), any provisional certificate for enlistment as a manufacturer or importer, or any provisional certificate for enlistment of a product, issued under the Alternative Medicines and Health Products (Enlistment) Rules, 2014, shall continue to remain valid until a decision is made by the AMHP Board on the corresponding application for a fresh licence or registration, as the case may be:

Provided that such application is filed with the AMHP Board, after the notification of these rules, within—

(a) six months, in the case of an application for a licence; and

(b) eighteen months, in the case of an application for registration of a product.

(3) Notwithstanding the repeal under sub-rule (1), anything done, action taken, proceedings commenced, order made or notice issued under the Alternative Medicines and Health Products (Enlistment) Rules, 2014, before such repeal shall, in so far as it is not inconsistent with these rules, continue to have effect and may be continued, enforced or concluded as if the said rules had not been repealed.

## SCHEDULE A

*[See rule 10(a)(i)]*

## CHAPTER I

## GOOD MANUFACTURING PRACTICES AND REQUIREMENTS OF PREMISES, PLANT AND EQUIPMENT FOR HEALTH PRODUCTS

**1. Location and surroundings:**

The premises shall be situated at a clean place which shall not be adjacent to open drains, public lavatory or any factory producing pollution of any kind, garbage dump, slaughterhouse or any other source likely to cause contamination from the external environment. The premises shall be located away from railway lines so that the performance of sensitive electronic equipment is not affected by vibrations. There shall be no open drains inside or outside the manufacturing premises. It shall be so designed that the entry of rodents is checked. The drains shall facilitate easy flow of the effluent and shall be cleared periodically.

**2. Building:**

The premises shall not be used for any purpose other than manufacture of Nutraceuticals/ Health products, and no part of the manufacturing premises shall be used for any other purpose. Other facilities, if needed, could be provided in separate building (s) in the same campus. Crude raw materials, packing materials, etc. shall be stored and handled in places ear marked for them and shall not be taken inside areas where critical operations of manufacture are done excepting processed raw material. Heating, washing, drying, packing and labelling, etc. wherever needed, shall be done in dedicated ancillary areas adjacent to the manufacturing sections concerned. The walls and floorings of manufacturing areas shall be smooth and free from chinks, cracks and crevices and shall be washable. The design of the windows, windowpanes and all fittings shall be such that they will not facilitate accumulation/lodging of dust and other contaminants.

**3. General responsibility of Licensee:**

3.1. The Licensee shall follow Good Manufacturing Practices in production of Health products/ Nutraceuticals under which it shall be ensured that: -

3.1.1. all manufacturing processes which shall be defined are systematically reviewed in the light of experience, and shown to be capable of consistently manufacturing pharmaceutical products of the required quality that comply with their specifications;

3.1.2. critical steps of manufacturing processes and any significant change made to the processes are validated;

3.1.3. all necessary facilities are continued to be made available including: -

(i) appropriately qualified and trained personnel;

(ii) adequate premises and space;

(iii) suitable equipment and services;

(iv) correct materials, containers, and labels;

(v) approved procedures and instructions;

(vi) suitable storage and transport; and

(vii) adequate personnel, laboratories and equipment for in-process controls under the responsibility of the production management.

3.1.4. instructions and procedures are written in clear and unambiguous language, specifically applicable to the facilities provided and followed in letter and spirit;

3.1.5. operators receive training and refresher courses at regular intervals to carry out procedures correctly, and records of such training are maintained;

3.1.6. records are made, manually and or by recording instruments, during manufacture to show that all the steps required by the defined producers and instructions have in fact been taken and that the quantity and quality of the product are as expected, and any significant deviations are fully recorded and investigated;

3.1.7. records covering manufacture and distribution, which enable the complete history of a batch to be traced, are retained in a comprehensible and accessible form;

3.1.8. the proper storage and distribution of the products minimizes any risk to their quality; and

3.1.9. the written system to recall any batch of product from sale or supply is followed whenever a recall is necessitated.

**4. Personnel:**

4.1. **General. -** The licensee shall provide:

4.1.1. sufficient qualified personnel (at least one technical person for each section) to fulfil all its responsibilities required under these rules; and

4.1.2. organization chart.

4.2. **Written duties: -** All responsible staff shall have their specific duties recorded in written descriptions.

4.3. **Good manufacturing practices awareness: -** All personnel shall be aware of the principles of good manufacturing practices that affect them and receive initial and continuing training, including hygiene instructions, relevant to their needs.

4.4. **Prohibition of unauthorized persons: -** Steps shall be taken to prevent unauthorized people from entering production, storage, and quality control areas and personnel who do not work in these areas shall not use them as a passageway.

4.5. **Duties of head of departments: -** The head of the production and quality control department may have shared, or jointly exercised the following responsibilities relating to quality, namely:

4.5.1. the authorization of written procedures and other documents, including amendments;

4.5.2. the monitoring and control of the manufacturing environment;

4.5.3. plant hygiene;

4.5.4. process validation and calibration of analytical apparatus;

4.5.5. training, including the application and principles of quality assurance;

4.5.6. the approval and monitoring of suppliers of materials;

4.5.7. the approval and monitoring of contract manufacturers;

4.5.8. the designation and monitoring of storage conditions for materials and products;

4.5.9. the retention of records;

4.5.10. the monitoring of compliance with good manufacturing practices requirements; and

4.5.11. the inspection, investigation, and taking of samples in order to monitor factors that may affect product quality.

4.6. **Duties of production in-charge: -** The head of the production department may have the following responsibilities, namely: -

4.6.1. to ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality;

4.6.2. to approve the instructions relating to production operations including the in-process controls, and to ensure their strict implementation;
4.6.3. to ensure that the production records re-evaluated and signed by a designated person before they are made available to the quality control department;
4.6.4. to check the maintenance of the department, premises, and equipment;
4.6.5. to ensure that the appropriate process validations and calibrations of control equipment are performed and recorded and the reports made available; and
4.6.6. to ensure that the required initial and continuing training of production personnel is carried out and adapted according to need.

4.7. **Duties of Quality Control Incharge: -** The head of the quality control department shall have the following responsibilities, namely: -
4.7.1. to approve or reject starting materials, packaging materials, and intermediate, bulk, and finished products;
4.7.2. to evaluate batch records;
4.7.3. to ensure that all necessary testing is carried out;
4.7.4. to approve sampling instructions, specifications, test methods, and other quality control procedures;
4.7.5. to approve and monitor analyses carried out under contract;
4.7.6. to check the maintenance of the department, premises and equipment;
4.7.7. to ensure that the appropriate validation, including those of analytical procedures and calibrations of control equipment are done; and
4.7.8. to ensure that the required initial and continuing training of quality control personnel is carried out and adapted according to need.

4.8. **Training:**
4.8.1. **Written programme: -** The training shall be provided in accordance with a written program for all the personnel whose duties require them to work in the production areas, as the case may be, in the control laboratories (including the technical, maintenance, and cleaning personnel), and for other personnel whose activities could affect the quality of the product.
4.8.2. **Training appropriate to duties: -** Besides basic training on the theory and practice of good manufacturing practices, newly recruited personnel shall receive training appropriate to the duties assigned to them., continuing training shall also be given, and its practical effectiveness shall be periodically assessed, training programs shall be available, approved by the head of either production or quality control, as appropriate, and training records shall be kept.
4.8.3. **Specific training: -** Personnel working in areas where contamination is a hazard, such as clean areas or areas where highly active, toxic, infectious, or sensitizing materials are handled, shall be given specific training.
4.8.4. **Understanding concepts: -** The concept of quality assurance and all the measures capable of improving its understanding and implementation shall be fully discussed during the training sessions.
4.8.5. **Visitors or untrained personnel discouraged: -** Visitors or untrained personnel shall be discouraged entry into the production and quality control areas.

4.9. **Personnel hygiene**
4.9.1. **Health Examination: -** All personnel prior to and during employment as may be appropriate, shall undergo health examinations and personnel conducting visual inspections shall also undergo periodic eye examinations.
4.9.2. **Practices in personal hygiene: -** All personnel shall be trained in the practices of personal hygiene, a high level of personal hygiene shall be observed by all

those concerned with manufacturing processes, personnel shall be instructed particularly to wash their hands before entering production areas, and signs to this effect shall be pasted and instructions observed.

4.9.3. **Illness:** - Any person down at any time to have an apparent illness or open lesions that may adversely affect the quality of products shall not be allowed to handle starting materials, packaging materials, in process materials, or Health products/ Nutraceuticals products until the condition is no longer judged to be a risk.

4.9.4. **Reporting health problems:** - All employees shall be instructed and encouraged to report to their immediate supervisor any conditions, relating to plant, equipment, or personnel, that they consider may adversely affect the products.

4.9.5. **Avoiding direct contact with materials:** - Direct contact shall be avoided between the operator's hands and starting materials, primary packaging materials, and intermediate or bulk product.

4.9.6. **Appropriate clothing and covering:** - To ensure protection of the product from contamination, personnel shall war clean body coverings appropriate to the duties they perform, including appropriate hair cover, and used clothes, if re-usable, shall be stored in separate closed containers until properly laundered and, if necessary, disinfected or sterilized

4.9.7. **Foods and drinks prohibited:** - Smoking eating, drinking, chewing and keeping plants, food, drink, smoking material, and personal medicine shall not be permitted in production, laboratory, and storage areas or in any other areas where they might adversely influence product quality

## 5. Material:

### 5.1. General:

5.1.1. **Quarantine:** - All incoming materials and finished products shall be quarantined immediately after receipt or processing, until they are released for use or distribution

5.1.2. **Appropriate storage:** - All materials and products shall be stored under the appropriate conditions established by the manufacturer and in an orderly manner to permit batch segregation and stock rotation by a first-in, first-out rule.

### 5.2. Starting materials:

5.2.1. **Purchase:** - The purchase of starting materials is an important operation that must involve staff who have a particular and thorough knowledge of the products and suppliers and a pharmacist with some experience of production may be preferred.

5.2.2. **Purchase from producer or established supplies:** - Staring materials shall be purchased directly from the producer or only form established suppliers.

5.2.3. **Checking of containers:** - For each consignment, the containers shall be checked for integrity of package and seal and for correspondence between the order, the delivery note, and the supplier's labels, and, containers shall be cleaned where necessary and labelled, if required, with the prescribed data.

5.2.4. **Damaged container:** - Damage to containers and any other problem that might adversely affect the quality of a material shall be recorded and reported to the quality control department and investigated.

5.2.5. **Delivery from different batches:** - If a delivery of material is made up of different batches, each batch shall be considered as separate for sampling, testing and release

5.2.6. **Labelling:** - Starting materials in the storage area shall be appropriately labelled, and labels shall bear at least the following information, namely: -

5.2.6.1. the designated name of the product and the internal code reference where applicable;

5.2.6.2. the batch number(s) given by the supplier and on receipt by the manufacturer, if any.

5.2.6.3. where appropriate, the status of the contents such as on quarantine, on test, released, rejected returned, and recalled, and;

5.2.6.4. where appropriate an expiry date or a date beyond which retesting is necessary. When fully computerized storage systems are used appropriate system shall be developed for the identification of above referred information.

5.2.7. **Identity of contents:** - There shall be appropriate procedures or measures to ensure the identity of the contents of each container of staring material, but bulk containers form which samples have been drawn shall be identified

5.2.8. **Released materials to be used:** - Only starting materials released by or quality control department and within their self-life shall be used. Procedure to ensure that the correct materials are accurately weighted or measured into clean and properly labelled containers.

5.2.9. **Checking:** - Each dispensed material and its weight or volume shall be independently checked and the check recorded

5.2.10. **Labelling:** - Materials dispensed for each batch of the final product shall be kept together and conspicuously labelled as such.

5.3. **Packaging materials:**

5.3.1. **Purchase:** - The purchase, handling and control of primary and printed packaging materials shall be as for starting materials.

5.3.2. **Printed materials:** - Particular attention shall be paid to printed packaging materials which shall be stored in secure conditions so as to exclude the possibility of unauthorized access, cut labels, and other loose printed materials shall be stored and transported in separate closed containers so as to avoid mix-ups and packaging materials shall be used for use only by designated personnel following an approved and documented procedure.

5.3.3. **Reference numbers:** - Each delivery or batch of printed or primary packaging material shall be given a specific reference number or identification mark.

5.3.4. **Obsolete materials:** - Outdated or obsolete primary packaging material or printed packaging material shall be destroyed, and its disposal be recorded.

5.3.5. **Checking before delivery:** - All products and packaging materials to be used shall be checked on delivery to the packaging department for quantity, identity, and conformity with the packaging instructions

5.4. **Intermediate and bulk products:**

5.4.1. **Storage:** - Intermediate and bulk products shall be kept under appropriate conditions.

5.4.2. **Handling:** - Intermediate and bulk products purchased as such shall be handled on receipt as though they were starting materials.

5.5. **Finished pharmaceutical products:**

5.5.1. **Quarantine:** - Finished pharmaceutical products shall be held in quarantine until their final release, and thereafter they shall be stored as usable stock under conditions established by the manufacturer.

5.5.2. **Release:** - The evaluation of finished products and the documentation necessary for release of a product for sale, as per requirement of these rules, shall be followed

5.6. **Rejected and recovered materials:**

5.6.1. **Storage and disposal:** - Rejected materials and products shall be clearly marked as such and stored separately in restricted areas, and they shall either be returned to the suppliers, or, where appropriate, reprocessed or destroyed and then action shall be approved by authorized personnel and recorded.

5.6.2. **Reprocessing:** - The reprocessing of rejected products shall be exceptional, it is permitted only if the quality of the final product is not affect, if the specifications are met, and if it is done in accordance with a defined and authorized procedure after evaluation of the risks involved and record shall be kept of the reprocessing and a reprocessed batch shall be given a new batch number.

5.6.3. **Batch recovery:** - The introduction of all or part of earlier batches, conforming to the required quality, into a batch of the same product at a defined stage of manufacture shall be authorized beforehand, this recovery shall be carried out in accordance with a defined procedure after evaluation of the risks involved including any possible effect on shelf-life and the recovery shall be recorded.

5.6.4. **Additional testing of reprocessed materials:** - The need for additional testing of any finished product that has been reprocessed, or into which a recovered product has been incorporated, shall be considered by the quality control department

5.7. **Recalled and returned products:**

5.7.1. **Recalled products:** - Recalled products shall be identified, clearly marked as such and stored separately in a secure area until a decision is taken on their fate.

5.7.2. **Returned goods:** - Products returned from the market shall be destroyed unless it is certain that their quality is satisfactory, they may be considered for resale, relabelling, or bulking with a subsequent batch only after they have been critically assessed by the quality control department in accordance with a written procedure. The nature of the product, any special storage conditions, it requires, its condition and history, and the time elapsed since it was issued shall all be taken into account in this assessment, where any doubt arises over the quality of the product, it shall not be considered suitable for reissue or re-use, although basic chemical reprocessing to recover the active ingredient may be possible, and any action taken shall be appropriately recorded.

5.8. **Reagents and culture media:**

5.8.1. All reagents and culture media shall be recorded upon receipt or preparation.

5.8.2. Reagents made up in the laboratory shall be prepared according to written procedures and appropriately labelled, the label shall indicate the concentration, standardization factor, shelf-life, the date when re-standardization is due, and the storage conditions and the label shall be signed and dated by the person preparing the reagent.

5.8.3. Both positive and negative controls shall be applied to verify the stability of culture media and the size of the inoculum used in positive controls shall be appropriate to the sensitivity required.

5.9. **Reference standards:**

5.9.1. **Testing of prepared reference standard:** - Reference standards may be available in the form of official reference standards and reference standards prepared by the producer shall be tested, released, and then stored in the same way as official standards, and they shall be kept under the responsibility of a designated person in a secured area.

5.9.2. **Use:** - Official reference standards shall be used only for the purpose described in the appropriate testing method submitted for registration purposes.

5.9.3. **Working standards:** - Secondary or working standards may be established by the application of appropriate tests and checks at regular intervals to ensure standardization, and all in-house reference standards shall be based on official reference standards, when available

5.9.4. **Storage:** - All reference standards shall be stored and used in a manner that will not adversely affect their quality

5.10. **Waste materials:**

5.10.1. **Storage:** - Provision shall be made for the proper and safe storage of waste materials awaiting disposal, and toxic substances and flammable materials shall be stored in suitably designed and separate enclosed cupboards.

5.10.2. **Disposal:** - Waste material shall not be allowed to accumulate, and it shall be collected in suitable receptacles for removal to collection points outside the buildings and disposed of safely and in a sanitary manner at regular and frequent intervals.

5.10.3. **Effluent Control:** - There shall be a effluent control system.

5.11. **Miscellaneous:**

5.11.1. Rodenticides, insecticides, fumigating agents and sanitizing materials shall not be permitted to contaminate equipment, starting materials, packaging, materials, in-process materials, or finished products

**6. Processing operations:**

6.1. **General:** - Production operations must follow clearly defined procedures with the objective of obtaining products of the requisite quality.

6.1.1. **Material handling:** - All handling of materials and products such as receipt and quarantine, sampling, storage, labelling dispensing, processing, packaging, and distribution shall be done in accordance with written procedures or instructions and, where necessary, recorded.

6.1.2. **Avoiding deviation:** - Any deviation from instructions or procedures shall be avoided as far as possible and if deviations occur, they shall be approved in writing by a designated person, with the involvement of the quality control department.

6.1.3. **Yield checks:** - Check on yields and re-conciliation of quantities shall be carried out as necessary to ensure that yields are within acceptable limits.

6.1.4. **Avoiding mix-ups:** - Operations on different products shall not be carried out simultaneously or consecutively in the same room unless there is no risk of mix-up or cross-contamination.

6.1.5. **Labelling:** - At all times during processing, all materials, bulk containers, major items of equipment, and where appropriate the rooms used shall be labelled or otherwise identified with an indication of the product or material being processed and its strengths, where applicable, and the batch number, and where applicable this indication shall also mention the stage of production.

6.1.6. **Un-authorized entry prohibited:** - Access to the production premises shall be restricted to authorized personnel.

6.1.7. **In-process controls:** - In process controls are mostly performed within the production are and they shall not carry any risk for the quality of the product.

6.2. **Prevention of cross-contamination and bacterial contamination in production:**

6.2.1. **Precautions against dust:** - When dry materials and products are used in production, special precautions shall be taken to prevent the generation and dissemination of dust. This applies particularly to the handling of highly active or sensitizing materials.

6.2.2. **Measures against contamination:** - Contamination of a starting material or of a product by another material or product shall also be avoided and similarly, cross-contamination shall be avoided by appropriate technical or organizational measures, as may be necessary by production segregated areas, namely: -

6.2.2.1. conducting production in segregated areas;

6.2.2.2. providing appropriate airlock, pressure differentials and dust extraction;

6.2.2.3. minimizing the risk of contamination caused by re-circulation or re-entry of untreated or insufficiently treated air;

6.2.2.4. wearing and keeping protective clothing in areas where products with special risk of cross-contamination re processed;

6.2.2.5. using, cleaning and decontamination procedures of known effectiveness, as in-effective cleaning of equipment is a common source of cross-contamination;

6.2.2.6. encourage using a 'closed system" of production;

6.2.2.7. testing for residues where necessary;

6.2.2.8. using cleanliness status labels on equipment, showing the name of the previous product.

6.2.3. **Cross-contamination checks:** - Measures to prevent cross-contamination and their effectiveness shall be checked periodically according to standard operating procedures.

6.2.4. **Microbiological monitoring:** - Production areas where susceptible products are processed shall undergo periodic microbiological monitoring and the bio-burden shall be kept within the specified limits.

6.3. **Processing operations, intermediate and bulk products:**

6.3.1. **Pre-processing cleanliness checks:** - Before any processing operation is started, steps shall be taken to ensure that the work area and equipment are clean and free from any starting materials, products, product residues, labels, or documents not required for the current operation.

6.3.2. **In-process controls:** - Necessary in-process controls and environmental controls shall be carried out and recorded. Defective equipment: - Means shall be instituted for indicating failures of equipment or of services, such as water or gas, to equipment. Defective equipment shall be withdrawn from use until the defect has been rectified.

6.3.3. **Cleaning containers:** - Containers for filling shall be cleaned before filing and attention shall be given to avoiding and removing any contaminants such as glass fragments and metal particles. Production equipment shall be cleaned according to detailed written procedures and stored only under clean and dry conditions.

6.3.4. **Yield deviations:** - Any significant deviation from expected yield shall be recorded and investigated.

6.3.5. **Product pipelines:** - Checks shall be carried out to ensure that pipelines and other pieces of equipment used for the transportation of products from one are to another are connected in a correct manner.

6.3.6. **Water pipes:** - Pipes used for conveying distilled or deionized water and, where appropriate, other water-pipes shall be sanitized according to written procedures that detail the action and limits for microbiological contamination and the measures to be taken.

6.3.7. **Equipment calibration:** - Measuring, weighing, recording control equipment and instruments shall be serviced and calibrated at pre-specified intervals and records maintained. To ensure satisfactory functioning instruments shall be checked daily or prior to use for performing analytical tests and the date of calibration and the date when re-calibration is due shall be clearly indicated.

6.3.8. **Repair and maintenance:** - Repair and maintenance operations shall present any hazard to the quality of the products.

6.4. **Packaging operations:**

6.4.1. **Avoiding mix-ups:** - When the program for packaging operations is being set up particular attention shall be given to minimizing the risk of cross-contamination, mix-up, or substitutions, and different products shall not be packaged in close proximity unless there is physical segregation or the use of electronic surveillance.

6.4.2. **Pre-packaging checks:** - Before packaging operations are begun, steps shall be taken to ensure that the work area, packaging lines, printing machines, and other equipment are clean and free from any products, materials, or documents previously used and not required for the current operation, and the line clearance shall be performed according to an appropriate checklist and recorded.

6.4.3. **Labelling of packaging line:** - The name and batch number of the product being handled shall be displayed at each packaging station or line.

6.4.4. **Process continuity.** - Normally, filling and sealing shall be followed as quickly as possible by labelling and if labelling is delayed, appropriate procedures shall be applied to ensure that no mix-up or mis-labelling can occur.

6.4.5. **Printing operation checks:** - The correct performance of any printing, mode numbers or expiry dates, done separately or in the course of the packaging shall be checked and recorded, and attention shall be paid to printing by hand which shall be re-checked at regular intervals.

6.4.6. **Label verification:** - Special care shall be taken when cut labels are used and when over-printing is carried out off-line and in hand-packaging operations, roll-feed labels are normally preferable to cut labels in helping to avoid mix-up. On-line verification of all labels by automated electronic means can be helpful in preventing mix-up, but checks shall be made to ensure that electronic code readers, label counters, or similar devices are operating correctly.

6.4.7. **Fast colour printing on labels:** - Printed and embossed information on packaging materials shall be distinct and resistant to fading or erasing.

6.4.8. **On-line packaging checks:** - On-line control of the product during packaging shall include at least check on: -

6.4.8.1. the general appearance of the packages;

6.4.8.2. whether the packages are complete;

6.4.8.3. whether the correct products and packaging materials are used;

6.4.8.4. whether any over-printing is correct;

6.4.8.5. the correct functioning of line monitors; and

6.4.8.6. samples taken from the packaging line shall not be returned unless inspection is done in close the packaging proximity of line.

6.4.9. **Product re-introduction on packaging line:** - Products that have been involved in an un-usual event during packaging shall be re-introduced into the process only after special inspection, investigation, and approval by authorized personnel and a detailed record shall be kept of this operation.

6.4.10. **Discrepancies to be investigated:** - Any significant or un-usual discrepancy observed during reconciliation of the amount of bulk product and printed packaging materials and the number of units produced shall be investigated and satisfactorily accounted for before release

6.4.11. **Destruction of un-used packaging materials:** - Upon completion of a packaging operation, un-used batch-coded packaging materials shall be destroyed and the destruction recorded, and a documented procedure shall be followed if encoded printed materials are returned to stock.

## 7. Sanitation and hygiene:

7.1. **General:** - A high level of sanitation and hygiene shall be practiced in every aspect of the manufacture of Health products/ Nutraceuticals products, the scope of sanitation and hygiene covers personnel, premises, equipment and apparatus, production materials and containers, product for cleaning and disinfection, and anything that could become a source of contamination to the product, and potential sources of contamination shall be eliminated through an integrated comprehensive program of sanitation and hygiene

## 8. Documents:

8.1. **General:**

8.1.1. **Maintenance of documents:** - Documents, as required under these rules, shall be meticulously maintained and regularly reviewed and kept up to date, and when a document has been revised, a system shall exist to prevent inadvertent use of the superseded version.

8.1.2. **Records of action:** - Records shall be made or completed when any action is taken and in such a way that all significant activities, concerning the manufacture of pharmaceutical products are traceable. The batch record shall be retained for at least one year after the expiry date of the finished product.

8.1.3. **Documentation systems:** -Data may be recorded by electronic data processing systems or by photographic or other reliable means. Master formulate and detailed standard operating procedures relating to the system in use shall be available and the accuracy of the records shall be checked and if documentation is handled by electronic data-processing method, only authorized persons shall be able to enter or modify data in the computer, and there shall be a record of changes, and deletions, access shall be restricted by passwords or their means and the entry of critical data shall be independently checked and data shall also be readily available.

8.1.4. **Status identification:** - Labels applied to containers, equipment, or premises shall be unambiguous and in the company's agreed format. The labels of different colours may also be used in addition to the working to indicate the status such as "quarantined," "accepted," "rejected," or "clear."

8.1.5. **Product labelling:** - All finished products shall be labelled in accordance with the Rules

8.1.6. **Reference standards identification:** - For reference standards, the label or accompanying documents shall indicate concentration, date of manufacture, expiry, date, and storage conditions, where appropriate.

8.1.7. **Specification approvals:** - Each specification, shall be approved and maintained by the quality control unit.

8.1.8. **Revision of specification:** - Periodic revisions of the specifications may be necessary to comply with new editions of the national pharmacopoeia or other official compendia or the health products / nutraceuticals (Specifications) Rules 1978.

8.1.9. **Packaging material specification:** - Packaging material shall conform to specifications, with emphasis placed on the compatibility of the material with the Health products/ Nutraceuticals product it contains.

8.1.10. **Starting material re-assay:** - Documents describing testing procedures shall state the required frequency for re-assaying each starting material, as determined by its stability

8.1.11. **Analytical records:** - Analysis records shall include at least the following namely: -

8.1.11.1. the name of the material or product and, where applicable, dosage form;

8.1.11.2. the batch number and, where appropriate, the manufacturer and/or supplier;

8.1.11.3. references to the relevant specifications and testing procedures;

8.1.11.4. test results, including observations and calculations, and reference to any specifications (limits);

8.1.11.5. dates of testing;

8.1.11.6. the initials of the persons who performed the testing;

8.1.11.7. the initials of the persons who verified the testing and the calculations, where appropriate; and

8.1.11.8. a clear statement of release or rejection (or other status decision) and the dated signature of the designated responsible person.

8.1.12. **Finished product release procedure:** - Written release and rejection procedures shall be available for materials and products, and in particular for the release for sale of the finished product by an authorized person.

8.1.13. **Recording batch distribution:** - Records shall be maintained of the distribution of each batch of a product in order to facilitate the recall of the batch if necessary.

8.1.14. **Standard operating procedures:** - Standard operating procedures and associated records of actions taken or, where appropriate, conclusions reached shall be available at the premises for: -

8.1.14.1. equipment assembly and validation;

8.1.14.2. analytical apparatus and calibration;

8.1.14.3. maintenance, cleaning, and sanitization;

8.1.14.4. personnel matters including qualification, training, clothing, and hygiene;

8.1.14.5. environmental monitoring;

8.1.14.6. pest control;

8.1.14.7. complaints;

8.1.14.8. recalls; and

8.1.14.9. status.

8.1.15. **Equipment logbooks:** - Logbooks shall be kept with major and critical equipment as identified by the Licensee and shall record, as appropriate, any

validations, calibrations, maintenance, cleaning, or repair operations including dates and the identity of the people who carried out these operations.

8.1.16. **Equipment utilization record:** - The use of major and critical equipment and the areas where products have been processed shall be appropriately recorded in chronological order.

8.2. **Particulars to be shown in manufacturing records:**

8.2.1. **General:**

8.2.1.1. Serial Number.
8.2.1.2. Name of the Health products/ Nutraceuticals.
8.2.1.3. Batch Size
8.2.1.4. Batch number.
8.2.1.5. Date of commencement of manufacture and date when manufacture was completed,
8.2.1.6. Name of all ingredients, quantities required for the batch size, quantities actually used. (All weighing and measurements shall be checked initiated by the competent person in the section).
8.2.1.7. Control reference numbers in respect of raw materials used in formulation.
8.2.1.8. Date of mixing in case of dry products, e.g., powder, powder mixture for capsule products, etc.
8.2.1.9. Date of granulation wherever applicable.
8.2.1.10. Weight of granules.
8.2.1.11. Date of compression in case of tablets/date of filling in case of capsules.
8.2.1.12. Dates of coating wherever applicable.
8.2.1.13. Records of test to be carried out in case of tablets as under:
8.2.1.13.1. Average weight every thirty minutes.
8.2.1.13.2. Disintegration time as often as practicable.
8.2.1.14. Records of readings taken to check weight variation in case of capsules,
8.2.1.15. Reference to Analytical Report number stating whether of standard quality or otherwise.
8.2.1.16. Records on the disposal of rejected batches and batches with-drawn from the market.
8.2.1.17. Actual production and packing particulars indicating the size and quantity of finished packings,
8.2.1.18. Date of release of finished packings for distribution or sale,
8.2.1.19. Signature of the expert staff responsible for the manufacture

8.3. **Records of raw materials:**

8.3.1. Records in respect of each raw material shall be maintained indicating the quantity received, control reference numbers, the quantities issued from time to time, the names and batch Nos. of the products for the manufacture of which the quantities have been issued and the particulars relating to the proper disposal of the stocks.

8.4. **Particulars to be recorded in the analytical records:**

8.4.1. **General (specific for Dosage form may be noted separately):**

8.4.1.1. Analytical report number.
8.4.1.2. Name of the sample.
8.4.1.3. Date of receipt of sample,
8.4.1.4. Batch number.
8.4.1.5. Protocols of tests applied:
8.4.1.5.1. Description.
8.4.1.5.2. Identification.

8.4.1.5.3. Uniformity of weight.
8.4.1.5.4. Uniformity of diameter (if applicable).
8.4.1.5.5. Disintegration test (time in minutes).
8.4.1.5.6. Any other tests.
8.4.1.5.7. Results of assay.
8.4.1.6. Signature of the Analyst.
8.4.1.7. Opinion and signature of the approved Analyst.

8.4.2. **Raw materials:**
8.4.2.1. Serial number
8.4.2.2. Name of the material
8.4.2.3. Name of the manufacturer/supplier.
8.4.2.4. Quantity received.
8.4.2.5. Invoice/Challan number and date.
8.4.2.6. Protocols of tests applied.

8.4.3. **Container, packing material, etc.:**
8.4.3.1. Serial number.
8.4.3.2. Name of the item.
8.4.3.3. Name of the manufacturer/supplier.
8.4.3.4. Quantity received.
8.4.3.5. Invoice/Challan number and date.
8.4.3.6. Results of tests applied.

Note: Particulars regarding various tests applied shall be maintained and necessary reference to these records shall be entered serial No. 6 wherever necessary.

8.4.3.7. Remarks.
8.4.3.8. Signature of the examiner.

**9. Quality control**

Quality control department exists which is independent of other departments and under the authority of a person with the required qualifications and experience and with adequate facilities.

9.1. **Basic requirements:**

9.1.1. During the period of validity of licence, adequate facilities, trained personnel and approved procedures are available for sampling, inspecting, testing starting materials, packaging materials, intermediate, bulk, and finished products, and where appropriate for monitoring environmental conditions for good manufacturing practices purposes;

9.1.2. Samples of starting materials, packaging materials, intermediate products, bulk products and finished products are taken by methods, and personnel approved of by the quality control department.

9.1.3. Testing methods are validated;

9.1.4. Records are made that all the required sampling, inspecting and testing procedures have actually been carried out and that any deviation has been fully recorded and investigated;

9.1.5. The finished products contain ingredients complying with the qualitative and quantitative composition of the product described in the marketing authorization.

9.1.6. Records are made of the results of inspecting and testing materials and intermediate, bulk and finished products against specifications and product assessment.

9.1.7. No batch of product is released for sale prior to certification by the authorized person(s) that it is in accordance with the requirement of the rules;

9.1.8. Sufficient samples of starting materials and products are retained to permit future examination of the product.

9.1.9. All quality control procedures are established, validated and implemented; the reference standards for substances are evaluated maintained, and stored; correct labelling of containers of materials and products is ensured; the stability of the active pharmaceutical ingredients and products is monitored. Complaints related to the quality of the product are investigated.

9.1.10. All these operations shall be carried out in accordance with written procedures

9.2. **Control Procedures:**

9.2.1. **General: -** All tests and analysis conducted shall be in accordance with the instructions given in the relevant written test procedures. The result shall be checked by the supervisor before the material or product is released or rejected.

9.2.2. **Sampling: -** The samples shall:

9.2.2.1. be representative of the batches of material from which they are taken and in accordance with the approved written procedure;

9.2.2.2. be taken in a manner so as to avoid contamination or other adverse effect on quality.

9.2.2.3. be taken with care to guard against contamination or mix-up. All sampling equipment that comes into contact with the material shall be clean.

9.2.2.4. be taken with equipment which shall be cleaned and, if necessary, sterilized before and after each use and stored separately from other laboratory equipment.

9.2.3. **Test requirement for starting and packaging materials:**

9.2.3.1. **Test before use: -** Before releasing a starting or packaging material for use, the quality control manager ensure that the materials have been tested for conformity with specifications for identity, strength, purity, and other quality parameters.

9.2.3.2. **Identity from each container: -** An identity test shall be conducted on a sample from each container of starting material.

9.2.3.3. **Examination of each batch: -** Each batch (lot) of printed packaging materials shall be examined following receipt

9.2.4. Test requirement for in-process control

9.2.4.1. **Records of testing: -** In process control records shall be maintained and form a part of the batch records.

9.2.5. **Test requirements for finished products:**

9.2.5.1. **Testing each batch: -** For each batch of Health products/ Nutraceuticals product, there shall be an appropriate laboratory determination of satisfactory conformity to its finished product specifications prior to release.

9.2.5.2. **Rejection of failed products: -** Product failing to meet the established specifications or any other relevant quality criteria may be revalidated and shall be rejected if they do not qualify revalidation protocols.

9.2.5.3. **Reprocessing: -** Reprocessing may be performed, if feasible, but the reprocessed product shall meet all specifications and other quality criteria prior to its acceptance and release.

9.2.6. **Production record and batch review:**

9.2.6.1. **Review of Records: -** Production and control records shall be reviewed.

9.2.6.2. **Retention of Samples:** - Retention samples from each batch of finished product shall be kept for at least one year after the expiry date.

**10. Stability studies:**

10.1. **The quality control department shall: -**

10.1.1. Evaluate the quality and stability of finished pharmaceutical products and, of starting materials and intermediate products; and, of starting materials and intermediate products;

10.1.2. Establish expiry dates and shelf-life specifications on the basis of stability tests related to storage conditions.

10.1.3. A written program for ongoing stability determination shall be developed and implemented to include elements such as: -

10.1.3.1. Stability of the finished product shall be evaluated and documented prior to marketing.

**11. Quality assurance system:**

11.1. Health products/ Nutraceuticals are designed and developed as per requirements of good manufacturing practices;

11.2. production and control operations are clearly specified in a written form and good manufacturing practices requirements are adopted and followed;

11.3. managerial responsibilities are clearly specified in job descriptions;

11.4. arrangements are made for the manufacture, supply, and use of the correct starting and packaging materials;

11.5. all necessary controls on starting materials, intermediate products, and bulk products and other in process controls calibrations and validations are carried out;

11.6. the finished products are correctly processed and checked, according to the defined procedures;

11.7. finished Health products/ Nutraceuticals are not sold or supplied before the authorized person(s) has certified that each production batch has been produced and controlled in accordance with the requirements of the good manufacturing practices and the relevant rules made under the Act relevant to the production, control and release of Health products/ Nutraceuticals as well as of conditions of registration;

11.8. satisfactory arrangements exist to store in appropriate storage conditions;

11.9. Procedure for self-inspection and or quality audit exists and documented

11.10. written Standard Operating Procedure available according to which complaints about marketed products are examined, the causes of quality defects investigated, and appropriate measures taken in respect of the defective products and to prevent recurrence and that system is followed.

**12. Self-inspection:**

12.1. General: - The management shall appoint a self-inspection team. The team responsible for self-inspection shall consist of personnel who can evaluate the implementation of good manufacturing practices objectively; all recommendations for corrective action shall be implemented; The procedure for self-inspection shall be documented and there shall be an effective follow-up program. Self-inspections shall be performed routinely.

12.2. Items for self-inspection: - Written instructions for self-inspection shall be established to provide a minimum and uniform standard of requirements.

12.3. Frequency of self-inspection: - it shall be at least once every year.

12.4. Self-inspection report: - A report shall be made at the completion of self-inspection which shall include: -

12.4.1. self-inspection results;

12.4.2. evaluation and conclusions; and

12.4.3. recommended corrective actions.

**13. Complaints:**

13.1. Review of complaints: - All complaints must be carefully reviewed according to written procedures.

13.2. Person authorized: - A person responsible for handling the complaints.

13.3. Written procedures: - There shall be written procedures describing the action to be taken including the need to consider a recall, in the case of a complaint concerning a possible product defect.

13.4. Recording defects and investigation: - Any complaint concerning a product defect shall be recorded with all the original details and thoroughly investigated.

13.5. Investigation: - If a product defect is discovered or suspected in a batch, consideration shall be given to whether other batches shall be checked in order to determine whether they are also affected.

13.6. Follow-up action: - Where necessary, appropriate follow-up section, possibly including product recall, shall be taken after investigation and evaluation of the complaint.

13.7. Recording measures: - All the decisions and measures taken as a result of a complaint shall be recorded and referenced to the corresponding batch records.

13.8. Review for recurring problems: - Complaint record shall be regularly reviewed for any indication of specific or recurring problems that require attention.

**14. Product recalls:**

14.1. System: - There shall be a system to promptly and effectively recall from the market the products known or suspected to be defective.

14.2. Authorized person: - A person responsible for the execution and coordination of recalls shall be designated.

14.3. Written procedure: - There shall be established written procedures, regularly checked and updated for the organization of any recall activity.

14.4. Recall with promptness: - All competent authorities to whom a given product may have been distributed shall be promptly informed of any intention to recall the product.

14.5. Distribution records: - The distribution records shall be readily available to the person(s) responsible for recall.

14.6. Recording of progress: - The progress of the recall process shall be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.

14.7. Evaluation: - The effectiveness of the arrangements for recalls shall be evaluated from time to time.

14.8. Storage of recalled Health products/ Nutraceuticals: - An instruction shall be included to store recalled products in a secure segregated area while their fate is decided.



## CHAPTER II

## GOOD MANUFACTURING PRACTICES AND REQUIREMENTS OF PREMISES, PLANT AND EQUIPMENT FOR ALTERNATIVE MEDICINES INCLUDING TRADITIONAL CHINESE MEDICINE EXCLUDING HOMOEOPATHIC MEDICINE

### 1. General Requirements

1.1. The herbal products shall be processed from suitable quality raw materials as per method of production and composition defined in the (official books as approved by the Enlistment Evaluation Committee in its 13th meeting).

1.2. The raw materials used shall comply to requirements for raw materials specified in the pharmacopoeia /books specified by the EEC.

1.3. The finished Herbal products shall comply with requirements specified in the official books.

1.4. Herbal products shall be processed, handled, packaged under hygienic conditions adhering to the Good Manufacturing Practices detailed below;

### 2. Personal hygiene

2.1. All personnel, prior to and during employment, shall undergo health examinations at least once per year. Personnel conducting visual inspections shall also undergo periodic eye examinations.

2.2. All personnel shall be trained in the practices of personal hygiene. A high level of personal hygiene should be observed by all those concerned with manufacturing processes. In particular, personnel should be instructed to wash their hands before entering production areas. Signs to this effect should be posted and instructions observed.

2.3. Any person shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products shall not be allowed to handle starting materials, packaging materials, in-process materials or drug products until the condition is no longer judged to be a risk.

2.4. All employees should be instructed and encouraged to report to their immediate supervisor any conditions (relating to plant, equipment or personnel) that they consider may adversely affect the products.

2.5. Direct contact shall be avoided between the operator's hands and starting materials, primary packaging materials and intermediate or bulk product.

2.6. To ensure protection of the product from contamination, personnel shall wear clean body coverings appropriate to the duties they perform, including appropriate hair covering. Used clothes, if reusable, shall be stored in separate closed containers until properly laundered and, if necessary, disinfected or sterilized.

2.7. Smoking is not permitted on the premises (except in designated areas) . Eating, drinking, chewing, and keeping plants, food, drink, personal medicines, incense sticks, garlands etc shall not be permitted in production, laboratory and storage areas, or in any other areas where they might adversely influence product quality.

2.8. Personal hygiene procedures including the use of protective clothing shall apply to all persons entering production areas, whether they are temporary or full-time employees or non-employees, e.g. contractors' employees, visitors, senior managers, and inspectors.

3. **Premises:**
   3.1. Premises must be located, designed, constructed, adapted, and maintained to suit the operations to be carried out.
   3.2. The layout and design of premises shall be such that it minimizes the risk of errors and permit effective cleaning and maintenance in order to avoid cross contamination, build-up of dust or dirt, and, in general, any adverse effect on the quality of products.
   3.3. Where dust is generated (e.g. during sampling, weighing, mixing and processing operations, packaging of powder), measures shall be taken to avoid cross-contamination and facilitate cleaning.
   3.4. Premises should be situated in an environment that, when considered together with measures to protect the manufacturing process, presents minimum risk of causing any contamination of materials or products.
   3.5. Premises used for the manufacture of finished products shall be suitably designed and constructed to facilitate good sanitation.
   3.6. Premises shall be carefully maintained, and it shall be ensured that repair and maintenance operations do not present any hazard to the quality of products. g) Premises shall be cleaned and, where applicable, disinfected.
   3.7. Electrical supply, lighting, temperature, humidity and ventilation shall be appropriate and such that they do not adversely affect, directly or indirectly, either the Herbal products/alternative medicine during their manufacture and storage, or the accurate functioning of equipment.
   3.8. Premises should be designed and equipped so as to afford maximum protection against the entry of insects, birds or other animals. There shall be a procedure for rodent and pest control.
   3.9. Premises shall be designed to ensure the logical flow of materials and personnel.

4. **Ancillary areas:**
   4.1. Rest and refreshment rooms shall be separate from manufacturing and control areas.
   4.2. Facilities for changing and storing clothes and for washing and toilet purposes shall be easily accessible and appropriate for the number of users. Toilets shall not communicate directly with production or storage areas and may preferably be separated from these areas.
   4.3. Maintenance workshops should if possible be separated from production areas. Whenever parts and tools are stored in the production area, they should be kept in rooms or lockers reserved for that use.
   4.4. Animal houses should be well isolated from other areas, with separate entrance (animal access) and air-handling facilities.

5. **Storage areas:**
   5.1. Storage areas should be of sufficient capacity to allow orderly storage of the various categories of materials and products with proper separation and segregation: starting and packaging materials, intermediates, bulk and finished products, products in quarantine, and released, rejected, returned or recalled products.
   5.2. Storage areas should be designed or adapted to ensure good storage conditions. In particular, they shall be clean, dry, sufficiently lit and maintained within acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity) these shall be provided, controlled, monitored and recorded where appropriate.



5.3. Receiving and dispatch bays shall be separated, and materials and products be protected from the weather. Receiving areas shall be designed and equipped to allow containers of incoming materials to be cleaned, if necessary, before storage.
5.4. Where quarantine status is ensured by storage in separate areas, these areas shall be clearly marked and their access restricted to authorized personnel. Any system replacing the physical quarantine shall give equivalent security.
5.5. Segregation shall be provided for the storage of rejected, recalled, or returned materials or products.
5.6. Highly active and radioactive materials, narcotics, other dangerous drugs, and substances presenting special risks of abuse, fire or explosion should be stored in safe and secure areas.
5.7. Printed packaging materials are considered critical to the conformity of the pharmaceutical product to its labelling and special attention shall be paid to sampling and the safe and secure storage of these materials.
5.8. There should normally be a separate sampling area for starting materials.
5.9. If sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross-contamination.

**6. Weighing areas:**

6.1. The weighing of starting materials and the estimation of yield by weighing shall be carried out in separate weighing areas designed for that use, for example with provisions for dust control. Such areas may be part of either storage or production areas.

**7. Production areas:**

7.1. Premises should preferably be laid out in such a way as to allow the production to take place in areas connected in a logical order corresponding to the sequence of the operations and to the requisite cleanliness levels.
7.2. The adequacy of the working and in-process storage space shall permit the orderly and logical positioning of equipment and materials so as to minimize the risk of confusion between different Herbal products or their components, to avoid cross-contamination, and to minimize the risk of omission or wrong application of any of the manufacturing or control steps.
7.3. Where starting and primary packaging materials and intermediate or bulk products are exposed to the environment, interior surfaces (walls, floors and ceilings) shall be smooth and free from cracks and open joints, shall not shed particulate matter, and shall permit easy and effective cleaning and, if necessary, disinfection.
7.4. Pipework, light fittings, ventilation points and other services shall be designed and sited to avoid the creation of recesses that are difficult to clean. As far as possible, for maintenance purposes, they should be accessible from outside the manufacturing areas.
7.5. Drains should be of adequate size and designed and equipped to prevent back-flow. Open channels should be avoided where possible, but if they are necessary, they shall be shallow to facilitate cleaning and disinfection.
7.6. Production areas shall be effectively ventilated, with air control facilities (including filtration of air to a sufficient level to prevent contamination and cross-contamination, as well as control of temperature and, where necessary, humidity) appropriate to the products handled, to the operations undertaken and to the external environment.
7.7. Premises for the packaging of Herbal products shall be specifically designed and laid out so as to avoid mix-ups or cross-contamination.

7.8. Production areas shall be well lit, particularly where visual on-line controls are carried out.

**8. Quality control areas:**

8.1. The organisation shall have in-house testing facilities / Quality control laboratories, and these shall be separated from production areas. Areas where biological, or microbiological test methods are employed shall be separated from each other and from other laboratories.

8.2. Quality control laboratories shall be designed to suit the operations to be carried out in them. Sufficient space shall be given to avoid mix-ups and cross-contamination of samples and reagents. There should be adequate suitable storage space for samples, reference standards (if necessary, with cooling), solvents, reagents and records.

8.3. The design of the laboratories should take into account the suitability of construction materials, prevention of fumes and ventilation. There shall be separate air supply to laboratories and production areas. Separate air-handling units and other provisions are needed for biological, and microbiological laboratories.

8.4. A separate room may be needed for instruments to protect them against electrical interference, vibration, contact with excessive moisture and other external factors, or where it is necessary to isolate the instruments.

**9. Equipment:**

9.1. Equipment must be located, designed, constructed, adapted, and maintained to suit the operations to be carried out. The layout and design of equipment shall aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt, and, in general, any adverse effect on the quality of the products.

9.2. Equipment shall be installed, cleaned, maintained and operated in such a way as to minimize any risk of error or of contamination.

9.3. Fixed pipework should be clearly labelled to indicate the contents and, where applicable, the direction of flow.

9.4. All service piping and devices should be adequately marked and special attention paid to the provision of non-interchangeable connections or adaptors for dangerous gases and liquids.

9.5. Balances and other measuring equipment of an appropriate range and precision should be available for production and control operations and should be calibrated on a scheduled basis.

9.6. Production equipment should be thoroughly cleaned on a scheduled basis.

9.7. Laboratory equipment and instruments shall be suited to the testing procedures undertaken.

9.8. Washing, cleaning and drying equipment should be chosen and used so as not to be a source of contamination.

9.9. Production equipment should not present any hazard to the products. The parts of the production equipment that come into contact with the product shall not be reactive, additive, or absorptive to an extent that would affect the quality of the product. Justification that equipment will not contaminate the product shall be provided by the manufacturer. Non-wooden equipment should be used unless tradition demands wooden material. Where it is necessary to use traditional equipment (such as wooden implements, clay pots, pallets, hoppers, etc.), this should be dedicated, unless otherwise justified. When such equipment is used, it is advisable that it does not come into direct contact with chemicals or contaminated material. If the use of wooden

equipment is unavoidable, special consideration must be given to its cleaning as wooden materials may retain odours, be easily discoloured and are easily contaminated. Defective equipment shall be removed from production and quality control areas. If this is not possible, it shall be clearly labelled as defective to prevent use.

9.10. Closed equipment should be used whenever appropriate. Where open equipment is used or equipment is opened, precautions shall be taken to minimize contamination.

9.11. Non-dedicated equipment shall be cleaned according to validated cleaning procedures between production of different pharmaceutical products to prevent cross-contamination.

9.12. Vacuum or wet-cleaning methods are preferred. If wet cleaning is done, the equipment should be dried immediately after cleaning to prevent the growth of microorganisms. Cleaning with compressed air and brushes should be used with care and avoided if possible, as these methods increase the risk of product contamination.

9.13. Current drawings of critical equipment and support systems should be maintained.

**10. Materials:**

10.1. **General:**

10.1.1. No materials used for operations such as cleaning, lubrication of equipment and pest control, should come into direct contact with the starting material, packing material, work in process or finished product. Where possible, such materials should be of a suitable grade (e.g. food grade) to minimize health risks.

10.1.2. All incoming materials and finished products should be quarantined immediately after receipt or processing, until they are released for use or distribution.

10.1.3. All materials and products should be stored under the appropriate conditions established by the manufacturer and in an orderly fashion to permit batch segregation and stock rotation by a first-in, first-out rule.

10.1.4. Water used in the manufacture of pharmaceutical products shall comply with WHO guidelines for drinking (potable) water quality.

10.2. **Starting materials:**

10.2.1. Starting materials should be purchased only from approved suppliers and, where possible, directly from the producer. The specifications established by the manufacturer for the starting materials should be discussed with the supplier All incoming materials should be checked to ensure that the consignment corresponds to the order. Containers should be cleaned where necessary and labelled, if required, with the prescribed information. Where additional labels are attached to containers, the original information should not be lost.

10.2.2. Damage to containers and any other problem that might adversely affect the quality of a material should be recorded and reported to the quality control department and investigated. c) If one delivery of material is made up of different batches, each batch must be considered as separate for sampling, testing and release.

10.2.3. Starting materials in the storage area should be appropriatcly labelled.

10.2.4. Only starting materials released by the quality control department and within their shelf-life shall be used. Reference to WHO guidelines on stability studies for herbal materials or herbal preparations should be made.

10.2.5. Materials dispensed for each batch of the final product shall be kept together and conspicuously labelled as such.

10.2.6. Labels shall bear at least the following information:

10.2.6.1. the designated name of the product and the internal code reference where applicable;

10.2.6.2. the batch number given by the supplier and, on receipt, the control or batch number given by the manufacturer, if any, documented so as to ensure traceability;

10.2.6.3. the status of the contents (e.g. in quarantine, on test, released, rejected, returned, recalled);

10.2.6.4. where appropriate, an expiry date or a date beyond which retesting is necessary.

10.2.6.5. analytical Report no. on label of approved material

10.2.6.6. No. of container upon total no. of containers.

10.3. **Packaging materials:**

10.3.1. The purchase, handling and control of primary and printed packaging materials should be as for starting materials.

10.3.2. Printed packaging materials shall be stored in secure conditions so as to exclude the possibility of unauthorized access. Roll-feed labels should be used wherever possible. Cut labels and other loose printed materials should be stored and transported in separate closed containers so as to avoid mix-ups. Packaging materials should be issued for use only by designated personnel following an approved and documented procedure.

10.3.3. Each delivery or batch of printed or primary packaging material shall be given a specific reference number or identification mark.

10.3.4. Outdated or obsolete primary packaging material or printed packaging material shall be destroyed and its disposal recorded.

10.3.5. All products and packaging materials to be used shall be checked on delivery to the packaging department for quantity, identity and conformity with the packaging instructions.

10.4. **Intermediate and bulk products:**

10.4.1. Intermediate and bulk products should be kept under appropriate conditions.

10.4.2. Intermediate and bulk products purchased as such shall be handled on receipt as though they were starting materials.

10.5. **Finished products:**

10.5.1. Finished products should be held in quarantine until their final release, after which they should be stored as usable stock under conditions established by the manufacturer.

10.6. **Rejected, recovered, reprocessed and reworked materials:**

10.6.1. Rejected materials and products should be clearly marked as such and stored separately in restricted areas. They should either be returned to the suppliers or, where appropriate, reprocessed or destroyed in a timely manner.

10.6.2. Whatever action is taken should be approved by authorized personnel and recorded.

10.6.3. The reworking or recovery of rejected products should be exceptional. It is permitted only if the quality of the final product is not affected, if the specifications are met, and if it is done in accordance with a defined and authorized procedure after evaluation of the risks involved. A record shall be kept of the reworking or recovery. A reworked batch shall be given a new batch number.

10.6.4. The introduction of all or part of earlier batches, conforming to the required quality, into a batch of the same product at a defined stage of manufacture shall be authorized beforehand. This recovery shall be carried out after evaluation of the risks involved, including any possible effect on shelf-life. The recovery shall be recorded.

10.6.5. Any finished product that has been reprocessed reworked or into which a recovered product has been incorporated, shall be retested for all requirements.

10.7. **Recalled products:**

10.7.1. Recalled products shall be identified and stored separately in a secure area until a decision is taken on their fate. The decision should be made as soon as possible.

10.8. **Returned goods:**

10.8.1. Products returned from the market shall be destroyed unless it is certain that their quality is satisfactory; in such cases they may be considered for resale or relabelling, or alternative action taken only after they have been critically assessed. The nature of the product, any special storage conditions it requires, its condition and history, and the time elapsed since it was issued should all be taken into account in this assessment. Where any doubt arises over the quality of the product, it shall not be considered suitable for reissue or reuse. Any action taken should be appropriately recorded.

10.9. **Waste materials:**

10.9.1. Toxic substances and flammable materials shall be stored in suitably designed, separate, enclosures, as required by national legislation.

10.9.2. Waste material shall not be allowed to accumulate. It should be collected in suitable receptacles for removal to collection points outside the buildings and disposed of safely and in a sanitary manner at regular and frequent intervals. Waste material shall be disposed as required by national legislation.

10.10. **Miscellaneous:**

10.10.1. Rodenticides, insecticides, fumigating agents and sanitizing materials shall not be permitted to contaminate equipment, starting materials, packaging materials, in-process materials or finished products.

**11. Reference samples and standards**:

11.1. The reference standard for a herbal medicine may be a botanical sample of the herbal material; a sample of the herbal preparation, e.g. extract; or a chemically defined substance, e.g. a known active constituent, a marker substance or a known impurity. The reference standard should be of a quality appropriate to its purpose. If the herbal medicine is not described in a recognized pharmacopoeia, a herbarium sample of the flowering or fruiting top of the whole medicinal plant or part of the medicinal plant (e.g. if the whole medicinal plant is a tree) should be available. All reference standards should be stored under appropriate conditions to prevent degradation. Their expiry and/or revalidation date should be determined and indicated.

**12. Documentation**:

12.1. Documents should be approved, signed and dated by the appropriate responsible persons. No document should be changed without authorization and approval.

12.2. Documents should have unambiguous contents: the title, nature and purpose should be clearly stated. Reproduced documents should be clear and legible.

12.3. Documents should be regularly reviewed and kept up to date. When a document has been revised, a system should exist to prevent inadvertent use of the superseded version. Superseded documents should be retained for a specific period of time.

12.4. Records should be made or completed when any action is taken and in such a way that all significant activities concerning the manufacture of the Herbal products are traceable. Records should be retained for at least one year after the expiry date of the finished product.

**13. Labels:**

13.1. Labels applied to containers, equipment or premises should be clear, unambiguous and in the company's agreed format.

13.2. For reference standards, the label and/or accompanying document should indicate potency or concentration, date of manufacture, expiry date, date the closure is first opened, storage conditions and control number, as appropriate.

**14. Packaging instructions:**

14.1. Packaging instructions for each product, pack size and type shall be defined. These should include, or make reference to:

14.1.1. the name of the product;

14.1.2. a description of its pharmaceutical form, strength and directions for use;

14.1.3. the pack size expressed in terms of the number, weight or volume of the product in the final container;

14.1.4. a complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types, with the code or reference number relating to the specifications for each packaging material;

14.1.5. where appropriate, an example or reproduction of the relevant printed packaging materials and specimens, indicating where the batch number and expiry date of the product have been marked; special precautions to be observed, including a careful examination of the packaging area and equipment in order to ascertain the line clearance before and after packaging operations;

14.1.6. a description of the packaging operation, including any significant subsidiary operations, and equipment to be used;

14.1.7. details of in-process controls with instructions for sampling and acceptance limits.

**15. Batch processing records:**

15.1. A batch processing record shall be kept for each batch processed. It shall be based on the relevant parts of the currently approved specifications on the record.

15.2. Before any processing begins, a check should be made that the equipment and work station are clear of previous products, documents, or materials not required for the planned process, and that the equipment is clean and suitable for use. This check should be recorded.

15.3. During processing, the following information shall be recorded at the time each action is taken, and after completion the record shall be dated and signed by the person responsible for the processing operations:

15.3.1. the name of the product; the number of the batch being manufactured;

15.3.2. and times of commencement, of significant intermediate stages, and of completion of production;

15.3.3. the name of the person responsible for each stage of production;

15.3.4. the initials of the operator(s) of different significant steps of production and, where appropriate, of the person(s) who checked each of these operations (e.g. weighing);
15.3.5. the batch number and/or analytical control number and the quantity of each starting material actually weighed (including the batch number and amount of any recovered or reprocessed material added);
15.3.6. any relevant processing operation or event and the major equipment used;
15.3.7. the in-process controls performed, the initials of the person(s) carrying them out, and the results obtained;
15.3.8. the amount of product obtained at different and pertinent stages of manufacture (yield), together with comments or explanations for significant deviations from the expected yield;
15.3.9. notes on special problems including details, with signed authorization for any deviation from the master formula.

**16. Batch packaging records:**

16.1. A batch packaging record shall be kept for each batch or part batch processed.
16.2. Before any packaging operation begins, checks should be made that the equipment and workstation are clear of previous products, documents or materials not required for the planned packaging operations, and that equipment is clean and suitable for use. These checks should be recorded.
16.3. The following information shall be recorded at the time each action is taken, and the date and the person responsible should be clearly identified by signature or electronic password:
16.3.1. the name of the product, the batch number and the quantity of bulk product to be packed, as well as the batch number and the planned quantity of finished product that will be obtained, the quantity actually obtained and the reconciliation;
16.3.2. the date(s) and time(s) of the packaging operations;
16.3.3. the name of the responsible person carrying out the packaging operation;
16.3.4. the initials of the operators of the different significant steps;
16.3.5. the checks made for identity and conformity with the packaging instructions, including the results of in-process controls;
16.3.6. details of the packaging operations carried out, including references to equipment and the packaging lines used, and, when necessary, the instructions for keeping the product unpacked or a record of returning product that has not been packaged to the storage area;
16.3.7. whenever possible, samples of the printed packaging materials used, including specimens bearing the approval for the printing of and regular check (where appropriate) of the batch number, expiry date, and any additional overprinting;
16.3.8. notes on any special problems, including details of any deviation from the packaging instructions, with written authorization by an appropriate person;
16.3.9. the quantities and reference number or identification of all printed packaging materials and bulk product issued, used, destroyed or returned to stock and the quantities of product obtained to permit an adequate reconciliation.

**17. Standard operating procedures (SOPs) and records:**

17.1. Standard operating procedures and associated records of actions taken or, where appropriate, conclusions reached should be available for:
17.1.1. Equipment assembly and validation;

17.1.2. Analytical apparatus and calibration;
17.1.3. maintenance, cleaning and sanitization;
17.1.4. personnel matters including qualification, training, clothing and hygiene;
17.1.5. Environmental monitoring;
17.1.6. Pest control;
17.1.7. Complaints
17.1.8. Recalls;
17.1.9. Returns;
17.1.10. Reprocessing of a batch handling of hazardous materials like cleaning liquids, pesticides, disinfectants, gases, flammable materials, solvents etc entry into and exit from production areas preparation, handling, using and standardization and frequency of retesting of reagents handling of materials with out of specification results of analysis.

17.2. There should be standard operating procedures and records for the receipt of each delivery of starting material and primary and printed packaging material.

17.3. The records of the receipts should include:
17.3.1. The name of the material on the delivery note and the containers;
17.3.2. the "in-house" name and/or code of material if different from (i);
17.3.3. the date of receipt;
17.3.4. the supplier's name and, if possible, manufacturer's name;
17.3.5. the manufacturer's batch or reference number;
17.3.6. the total quantity, and number of containers received;
17.3.7. the batch number assigned after receipt;
17.3.8. any relevant comment (e.g. state of the containers).

17.4. There should be standard operating procedures for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate.

17.5. Standard operating procedures should be available for each instrument and piece of equipment (e.g. use, calibration, cleaning, maintenance) and placed in close proximity to the equipment.

17.6. There should be standard operating procedures for sampling, which specify the person(s) authorized to take samples.

17.7. The sampling instructions should include:
17.7.1. The method of sampling and the sampling plan;
17.7.2. The equipment to be used;
17.7.3. any precautions to be observed to avoid contamination of the material or any deterioration in its quality
17.7.4. the amount(s) of sample(s) to be taken;
17.7.5. instructions for any required subdivision of the sample;
17.7.6. the type of sample container(s) to be used, and whether they are for aseptic sampling or for normal sampling, and labelling;
17.7.7. any specific precautions to be observed, especially in regard to the sampling of sterile or noxious material.

17.8. There shall be a standard operating procedure describing the details of the unique batch (lot) numbering system, with the objective of ensuring that each batch of intermediate, bulk or finished product is identified with a specific batch number. The batch numbering applied to the processing stage and to the respective packaging stage should be related to each other.

17.9. Batch-number allocation shall be recorded, with details of at least the date of allocation, product identity and size of batch.

17.10. There should be written procedures for testing materials and products at different stages of manufacture, describing the methods and equipment to be used. The tests performed should be recorded.

17.11. Analysis records shall include at least the following data:

17.11.1. the name of the material or product and, where applicable, dosage form;

17.11.2. the batch number and, where appropriate, the manufacturer and/or supplier;

17.11.3. references to the relevant specifications and testing procedures;

17.11.4. test results, including observations and calculations, and reference to any specifications (limits);

17.11.5. date(s) and reference number(s) of testing;

17.11.6. the initials of the persons who performed the testing;

17.11.7. the date and initials of the persons who verified the testing and the calculations, where appropriate;

17.11.8. a clear statement of release or rejection (or other status decision) and the dated signature of the designated responsible person. Written release and rejection procedures should be available for materials and products, and in particular for the release for sale of the finished product by an authorized person.

17.12. Records shall be maintained of the distribution of each batch of a product in order, e.g. to facilitate the recall of the batch if necessary.

17.13. Records shall be kept for major and critical equipment, as appropriate, of any validations, calibrations, maintenance, cleaning, or repair operations, including dates and the identity of the people who carried these operations out.

17.14. The use of all equipment and the areas where products have been processed should be appropriately recorded in chronological order.

17.15. There shall be written procedures assigning responsibility for cleaning and sanitation and describing in sufficient detail the cleaning schedules, methods, equipment and materials to be used and facilities and equipment to be cleaned, and these shall be followed.

**18. Good practices in production:**

18.1. **General:**

18.1.1. All handling of materials and products, such as receipt and cleaning, quarantine, sampling, storage, labelling, dispensing, processing, packaging and distribution shall be carried out under good hygienic and good manufacturing practices.

18.1.2. Checks on yields and reconciliation of quantities shall be carried out as necessary to ensure that there are no discrepancies outside acceptable limits.

18.1.3. Operations on different products shall not be carried out simultaneously or consecutively in the same room or area unless there is no risk of mix-up or cross-contamination.

18.1.4. At all times during processing, all materials, bulk containers, major items of equipment, and where appropriate, the rooms and packaging lines being used should be labelled or otherwise identified with an indication of the product or material being processed, its strength (where applicable) and the batch number.

18.1.5. Access to production premises shall be restricted to authorized personnel.

18.2. **Prevention of cross-contamination and bacterial contamination during production:**

18.2.1. When dry materials and products are used in production, special precautions shall be taken to prevent the generation and dissemination of dust. Provision

shall be made for proper air control (e.g. supply and extraction of air of suitable quality).

18.2.2. Contamination of a starting material or of a product by another material or product shall be avoided. This risk of accidental cross-contamination arises from the uncontrolled release of dust, gases, particles, vapours, sprays or organisms from materials and products in process, from residues on equipment, from intruding insects, and from operators' clothing, skin, etc.

18.2.3. Cross-contamination should be avoided by taking appropriate technical or organizational measures, for example:

i. carrying out production in dedicated and self-contained areas, conducting campaign production (separation in time) followed by appropriate cleaning in accordance with a validated cleaning procedure;
ii. providing appropriately designed airlocks, pressure differentials, and air supply and extraction systems;
iii. minimizing the risk of contamination caused by recirculation or re-entry of untreated or insufficiently treated air;
iv. wearing protective clothing where products or materials are handled;
v. using cleaning and decontamination procedures of known effectiveness;
vi. using a "closed system" in production;
vii. testing for residues;
viii. using cleanliness status labels on equipment.

18.2.4. Measures to prevent cross-contamination and their effectiveness should be checked periodically according to standard operating procedures. e) Production areas where susceptible products are processed should undergo periodic environmental monitoring (e.g. for microbiological monitoring and particulate matter where appropriate).

18.3. **Processing operations:**

18.3.1. Before any processing operation is started, steps shall be taken to ensure that the work area and equipment are clean and free from any starting materials, products, product residues, labels or documents not required for the current operation.

18.3.2. Defective equipment shall be withdrawn from use and appropriately labelled and preferably covered until the defect has been rectified. After use, production equipment shall be cleaned without delay according to detailed written procedures and stored under clean and dry conditions in a separate area or in a manner that will prevent contamination.

18.3.3. Time limits for storage of equipment after cleaning and before use should be stated, be based on data and scheduled by the manufacturer. Containers for filling shall be cleaned before filling. Attention should be given to avoiding and removing any contaminants such as glass fragments and metal particles.

18.3.4. Any significant deviation from the expected yield should be recorded and investigated.

18.3.5. Measuring, weighing, recording, and control equipment and instruments shall be serviced and calibrated at prespecified intervals and records maintained. To ensure satisfactory functioning, instruments should be checked at appropriate intervals or prior to use for performing analytical tests. The date of calibration and servicing and the date when recalibration is due shall be clearly indicated, preferably on a label attached to the instrument.

18.3.6. Repair and maintenance operations should not present any hazard to the quality of the products.

18.4. **Packaging operations:**

18.4.1. Different products shall not be packaged in close proximity unless there is physical segregation or an alternative system that will provide equal assurance.

18.4.2. Before packaging operations are begun, steps shall be taken to ensure that the work area, packaging lines, printing machines and other equipment are clean and free from any products, materials or documents used previously and which are not required for the current operation.

18.4.3. The name and batch number of the product being handled shall be displayed at each packaging station or line.

18.4.4. Normally, filling and sealing shall be followed as quickly as possible by labelling. If labelling is delayed, appropriate procedures should be applied to ensure that no mix-ups or mislabelling can occur.

18.4.5. The correct performance of any printing (e.g. of code numbers or expiry dates) done separately or in the course of the packaging shall be checked and recorded. Printing by hand, should be rechecked at regular intervals.

18.4.6. Special care should be taken when cut labels are used and when overprinting is carried out off-line, and in hand-packaging operations. Roll-feed labels are normally preferable to cut labels in helping to avoid mix-ups. On-line verification of all labels by automated electronic means can be helpful in preventing mix-ups, but checks should be made to ensure that any electronic code readers, label counters, or similar devices are operating correctly. When labels are attached manually, in-process control checks should be performed more frequently.

18.4.7. Printed and embossed information on packaging materials should be distinct and resistant to fading or erasing.

18.4.8. Regular on-line control of the product during packaging shall include at least checks on the general appearance of the packages.

18.4.9. whether the packages are complete; whether the correct products and packaging materials are used; whether any overprinting is correct; the correct functioning of line monitors. Samples taken away from the packaging line shall not be returned.

18.4.10. Products that have been involved in an unusual event during packaging shall be reintroduced into the process only after special inspection, investigation and approval by authorized personnel. A detailed record shall be kept of this operation.

18.4.11. Any significant or unusual discrepancy observed during reconciliation of the amount of bulk product and printed packaging materials and the number of units produced shall be investigated, satisfactorily accounted for, and recorded before release.

18.4.12. Upon completion of a packaging operation, any unused batch-coded packaging materials shall be destroyed and the destruction recorded. A documented procedure requiring checks to be performed before returning unused materials should be followed if uncoded printed materials are returned to stock.

**19. Good practices in quality control:**

19.1. **General:**

19.1.1. Quality control is concerned with sampling, specifications and testing, and with the organization, documentation and release procedures which ensure that the

necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory.

19.1.2. The quality control function should have adequate resources available so as to ensure that all the quality control arrangements are effectively and reliably carried out, which includes;

19.1.2.1. sampling of starting materials, packaging materials, intermediate products, bulk products and finished products by approved methods;

19.1.2.2. performance of qualification and validation;

19.1.2.3. recording for demonstrating that all the required sampling, inspecting and testing procedures have actually been carried out and that any deviations have been fully recorded and investigated;

19.1.2.4. the finished products must contain ingredients complying with the qualitative and quantitative composition of the product described in the relevant regulatory requirements;

19.1.2.5. the ingredients shall be of the required purity, in their proper container and correctly labelled;

19.1.2.6. records shall be made of the results of inspecting and testing the materials and intermediate, bulk and finished products against specifications;

19.1.2.7. product assessment must include a review and evaluation of the relevant production documentation and an assessment of deviations from specified procedures;

19.1.2.8. no batch of product is to be released for sale or supply prior to certification by the authorized person(s) that it is in accordance with the requirements of the relevant regulatory requirement;

19.1.2.9. sufficient samples of starting materials and products shall be retained to permit future examination of the product if necessary; the retained product shall be kept in its final pack unless the pack is exceptionally large.

19.1.3. Assessment of finished products includes checking the production conditions, the results of in-process testing, the manufacturing (including packaging) documentation, compliance with the specification for the finished product, and an examination of the finished pack.

19.2. **Control of starting materials and intermediate, bulk and finished products:**

19.2.1. All tests shall follow the instructions given in the relevant written test procedure for each material or product as specified in the API or the importing country Regulation. The result should be checked by the supervisor before the material or product is released or rejected.

19.2.2. Samples shall be representative of the batches of material from which they are taken in accordance with the approved written procedure.

19.2.3. Sampling shall be carried out to avoid contamination or other adverse effects on quality. The containers that have been sampled should be marked accordingly and carefully resealed after sampling. Samples drawn for checking/testing shall not be released for sale.

19.2.4. Sampling equipment shall be cleaned and, if necessary, sterilized before and after each use and stored separately from other laboratory equipment.

19.2.5. Each sample container should bear a label indicating:

19.2.5.1. the name of the sampled material;

19.2.5.2. the batch or lot number;

19.2.5.3. the number of the container from which the sample has been taken;
19.2.5.4. the number of the sample;
19.2.5.5. the signature of the person who has taken the sample;
19.2.5.6. the date of sampling.

19.2.6. Out-of-specification results obtained during testing of materials or products shall be investigated in accordance with an approved procedure. Records should be maintained.

19.3. **Test requirements - Starting and packaging materials:**

19.3.1. Before releasing a starting or packaging material for use, they shall be tested for conformity with specifications for identity, strength, purity and other quality parameters.

19.3.2. In lieu of testing by the manufacturer, a certificate of analysis may be accepted from the supplier, provided that the manufacturer establishes the reliability of the supplier's analysis through appropriate periodic validation of the supplier's test results and through on-site audits of the supplier's capabilities.

19.4. **Test requirements - In-process control:**

19.4.1. In-process control records should be maintained and form a part of the batch records.

19.5. **Test requirements - Finished products:**

19.5.1. For each batch of Herbal product, there shall be an appropriate laboratory determination of satisfactory conformity to its finished product specification prior to release.

19.5.2. Products failing to meet the established specifications or any other relevant quality criteria shall be rejected.

19.6. **Batch record review:**

19.6.1. Production and quality control records shall be reviewed as part of the approval process of batch release. Any divergence or failure of a batch to meet its specifications shall be thoroughly investigated. The investigation should, if necessary, extend to other batches of the same product and other products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and should include the conclusion and follow-up action.

19.6.2. Retention samples from each batch of finished product shall be kept for at least one year after the expiry date. Finished products should usually be kept in their final packaging and stored under the recommended conditions. Samples of active starting materials shall be retained for at least one year beyond the expiry date of the corresponding finished product. Other starting materials (other than solvents, gases, and water) shall be retained for a minimum of two years if their stability allows. Retention samples of materials and products should be of a size sufficient to permit at least two full re-examinations.

**20. Stability studies:**

20.1. The quality and stability of finished Herbal products and, when necessary, of starting materials and intermediate products shall be evaluated.

20.2. Expiry dates and shelf-life specifications shall be established on the basis of stability tests related to storage conditions.

20.3. A written programme for ongoing stability determination should be developed and implemented to include elements such as:

20.3.1. a complete description of the Herbal product involved in the study;

20.3.2. the complete set of testing parameters and methods, describing all tests for potency, purity, and physical characteristics and documented evidence that these tests indicate stability;

20.3.3. Provision for the inclusion of a sufficient number of batches;

20.3.4. the testing schedule for each Herbal product;

20.3.5. provision for special storage conditions;

20.3.6. provision for adequate sample retention;

20.3.7. a summary of all the data generated, including the evaluation and the conclusions of the study.

20.4. Stability should be determined prior to marketing and following any significant changes in processes, equipment, packaging materials, etc.

**21. Qualification and validation:**

21.1. The company should identify what qualification and validation work is required to prove that the critical aspects of their particular operation are controlled.

21.2. The key elements of a qualification and validation programme of a company should be clearly defined and documented in a validation master plan.

21.3. Qualification and validation should establish and provide documentary evidence that:

21.3.1. The premises, supporting utilities, equipment and processes have been designed in accordance with the requirements for GMP;

21.3.2. The premises, supporting utilities and equipment have been built and installed in compliance with their design specifications;

21.3.3. the premises, supporting utilities and equipment operate in accordance with their design specifications;

21.3.4. a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

21.4. Any aspect of operation, including significant changes to the premises, facilities, equipment or processes, which may affect the quality of the product, directly or indirectly, should be qualified and validated.

21.5. The ongoing programme should follow their first implementation and should be based on an annual review. On review any changes to the initial programme to be justified.

21.6. The responsibility of performing validation should be clearly defined.

21.7. Validation studies should be conducted in accordance with predefined and approved protocols.

21.8. A written report summarizing the results recorded and the conclusions reached should be prepared and stored.

21.9. Processes and procedures should be established on the basis of the results of the validation performed.

**22. Complaints:**

22.1. All complaints including those of adverse side effects and other information concerning potentially defective products should be carefully reviewed according to written procedures and the corrective action should be taken.

22.2. The person responsible for handling complaints and deciding on the measures to be taken to deal with them shall have appropriate training and/or experience in the specific features of the quality control of herbal medicines.

22.3. There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint concerning a possible product defect.
22.4. Any complaint concerning a product defect shall be recorded with all the original details and thoroughly investigated. The person responsible for quality control shall be involved in the review of such investigations.
22.5. If a product defect is discovered or suspected in a batch, other batches that may contain reprocessed product from the defective batch should also be investigated.
22.6. Where necessary, appropriate follow-up action, possibly including product recall, should be taken after investigation and evaluation of the complaint.
22.7. All decisions made and measures taken as a result of a complaint shall be recorded and referenced to the corresponding batch records.
22.8. Complaints records shall be regularly reviewed for any indication of specific or recurring problems that require attention and might justify the recall of marketed products.
22.9. The competent authorities should be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, counterfeiting or any other serious quality problems with a product.

**23. Product recalls:**

23.1. There should be a system to recall from the market, promptly and effectively, products known or suspected to be defective.
23.2. The authorized person should be responsible for the execution and coordination of recalls.
23.3. There should be established written procedures, which are regularly reviewed and updated, for the organization of any recall activity. Recall operations should be capable of being initiated promptly down to the required level in the distribution chain.
23.4. Recalled products shall be stored in a secure segregated area while their fate is decided.
23.5. All customers / competent authorities of all countries to which a given product has been distributed should be promptly informed of any intention to recall the product because it is, or is suspected of being, defective.
23.6. The distribution records should be readily available to the authorized person, and they should contain sufficient information on wholesalers and directly supplied customers (including, for exported products, those who have received samples for clinical tests and medical samples) to permit an effective recall.
23.7. The progress of the recall process should be monitored and recorded.
23.8. Records should include the disposition of the product. A final report should be issued, including a reconciliation between the delivered and recovered quantities of the products.
23.9. The effectiveness of the arrangements for recalls should be tested and evaluated from time to time.

**24. Personnel:**

24.1. The organization structure and the responsibilities and authorities of personnel shall be defined. The manufacturer shall have adequate number of personnel with the necessary qualifications and practical experience. Individual responsibilities and authorities should be clearly defined and understood by the persons concerned and recorded as written descriptions.

24.2. There should be no gaps or unexplained overlaps in the responsibilities of personnel concerned with the application of GMP.

24.3. All personnel should be aware of the principles of GMP that affect them and receive initial and continuing training, including hygiene instructions, relevant to their needs.

24.4. Key personnel responsible for supervising the manufacturing and quality control of herbal products shall possess the qualifications as specified vide rule 10(a).

24.5. The release of herbal medicines shall be authorized by a person (known as Responsible Person) who has been trained in the specific features of processing and quality control of herbal substances, herbal preparations and finished herbal products. Personnel dealing with the production and quality control of herbal medicines shall have adequate training in the specific issues relevant to herbal medicines.

**25. Training:**

25.1. The personnel should have adequate training in appropriate fields such as pharmaceutical technology, taxonomic botany, phytochemistry, pharmacognosy, hygiene, microbiology and related subjects (such as traditional use of herbal medicines).

25.2. Training records should be maintained and periodic assessments of the effectiveness of training programmes should be made.

**26. Packing:**

26.1. The products shall be packed in clean, hygienic bottles / containers / made of materials suitable for the respective dosage form and confirmed with suitable stability studies as per regulations.

**27. Labelling:**

27.1. The Herbal products/ alternative medicine shall be marked legibly on the label of the bottle / package:

27.1.1. Name of the Herbal Product;

27.1.2. List of active Ingredients, showing the amount of each present and a statement of the net contents (e.g. number of dosage units, weight, volume);

27.1.3. Dosage form;

27.1.4. Batch number assigned by the manufacturer;

27.1.5. the expiry date in an uncoded form;

27.1.6. any special storage conditions or handling precautions that may be necessary;

27.1.7. directions for use, and warnings and precautions that may be necessary;

27.1.8. the name and address of the manufacturer or the company or the person responsible for placing the product on the market;

27.1.9. Any others as required by the Regulation.

## CHAPTER III

## GOOD MANUFACTURING PRACTICES AND REQUIREMENTS OF PREMISES, PLANT AND EQUIPMENT FOR HOMOEOPATHIC MEDICINES

**1. Location and surroundings: -**

The premises shall be situated at a clean place which shall not be adjacent to open drains, public lavatory or any factory producing pollution of any kind, garbage dump, slaughter house or any other source likely to cause contamination from the external environment. The premises shall be located away from railway lines so that the performance of sensitive electronic equipment is not affected by vibrations. There shall be no open drains inside or outside the manufacturing premises. It shall be so designed that the entry of rodents is checked. The drains shall facilitate easy flow of the effluent and shall be cleared periodically.

**2. Building:**

**2.1 General: -** The premises shall not be used for any purpose other than manufacture of homoeopathic drugs, and no part of the manufacturing premises shall be used for any other purpose. Other facilities, if needed, could be provided in separate building (s) in the same campus. Crude raw materials, packing materials, etc. shall be stored and handled in places ear marked for them and shall not be taken inside areas where critical operations of manufacture are done excepting processed raw material. Heating, washing, drying, packing and labelling, etc. wherever needed, shall be done in dedicated ancillary areas adjacent to the manufacturing sections concerned. The walls and floorings of manufacturing areas shall be smooth and free from chinks, cracks and crevices and shall be washable. The design of the windows, windowpanes and all fittings shall be such that they will not facilitate accumulation/lodging of dust and other contaminants.

**2.2 Rooms:** – The rooms shall be airy, ventilated, and maintained at temperatures which are moderate and comfortable. Sections which are required to be sterile, air-conditioned and provided with air handling systems shall be designed accordingly. All sections shall be free from insects, birds, rodents, worms etc. and suitable measures shall be taken to prevent the same from finding ways to the sections and equipment.

**2.3 Water:** – The water used for manufacture of drugs shall be of the quality as prescribed in the rules or in the Homoeopathic Pharmacopoeia concerned, as the case may be, and shall be prepared from pure drinking quality water, free from pathogenic organisms.

**2.4 Disposal of waste:** – Effluents, organic and inorganic wastes shall be disposed of in such a manner as may be prescribed in the laws pertaining to pollution control and if no such law exists in the place of manufacture, they shall be rendered harmless and shall be disposed of in such a manner that they are not hazardous to health of the public or cattle or plants.

**2.5 Factories Act:** – The provisions of the Factories Act, as applicable shall be adhered to.

**2.6 Medical services:** – All persons concerned with any activity pertaining to manufacture of drugs including handling of raw material, packing material, packing and labelling of drugs, etc. shall be medically examined for fitness at the time of employment and subsequently at periodic and records thereof shall be maintained. Intervals.

**2.7 Safety measures:** – First-aid facilities shall be provided in such a manner that they are easily accessible, and the staff shall be imparted knowledge and training in first-aid measures as may be needed. Fire control equipment in suitable numbers shall be provided at easily accessible places near all sections including stores and warehouses.

2.8 **Workbenches:** - workbenches suitable to the nature and quantum of the work involved shall be provided in all sections. Such work benches in general, shall have smooth, washable and impervious tops and the parts shall not be rough or rusty or damaged otherwise. (h)Container management. – Proper arrangements shall be made for receiving containers, closures and packing materials in secluded areas and for dusting the same, removal of wastes, washing, cleaning and drying. Suitable equipment shall be provided as may be needed, considering the nature of work involved. Where soaps and detergents are used to wash containers and closures used for primary packing, suitable procedure shall be prescribed and adopted for total removal of such closures. Plastic containers which are which are likely to contaminate the materials from the containers and likely to absorb active principles or contents may not be used. Glass containers used shall be made of neutral glass. The closures and washers used shall be of inert materials which shall not absorb the active principles or contaminate the contents, or which may otherwise be likely to cause deterioration of quality. The containers, closures and packing materials shall protect the properties of the medicines. Tablets, if blister-packed, shall have secondary protective packaging to protect the medicines from moisture, odour etc. Neutral glass phials and epoxy-coated closures shall be used for eyedrops. Transparent plastic containers may be used for eye drops containing only aqueous preparations. Sterile plastic nozzles may be provided to eye drops, separately along with the medicine, whatever needed.

3. **Plant and equipment:**

3.1 **General**: - The design of the plant shall be suitable for the nature and quantum of the activates involved. Equipment shall be installed in such a manner as to facilitate easy flow of materials and to check criss-cross movement of the personnel. The entry to all manufacturing sections shall not have access to them. There shall be arrangements for personal cleanliness of workers and toilets. These shall be separate for men and women, to change from their outside dress and footwear into the factory dress and footwear. Uniforms of suitable colours and fabric which facilitate proper washing and which do not shed fibres other contaminants shall be provided. Suitable head-covers and gloves shall be provided to the workers. The manufacturing premises shall not be used for dining. There shall be separate area for the personnel to take food or rest. Toilets shall not be located in or adjacent to any of the areas concerned with any manufacturing activity. Spitting, smoking, chewing, littering, etc. in the manufacturing or ancillary areas shall not be permitted. Standard operating Practices (SOPs) for cleaning and sanitation, personal hygiene of the workers, general and specific upkeep of the plant, equipment and premises and every activity associated with manufacture of drugs including procurement, quarantine, testing and warehousing of materials shall be written and adopted. No person with any contagious disease shall be involved in any of the manufacturing activates. There shall be proper arrangements for maintenance of the equipment and systems. The performance of every equipment and system shall be properly validated, and their use shall be monitored. Dos and don'ts in the matter of the use of the plant and equipment as may be applicable shall be written and displayed in all places. There shall be separate dedicated areas for each ancillary activity such as receipt, cleaning, warehousing and issue of raw materials, packaging materials, container and closures, finished goods etc. Adequate measures shall be taken to prevent entry/ presence etc of insects, rodents, birds, lizards and other animals into the raw material handling areas. Every material shall have proper identification and control numbers and inventory tags and labels displaying status of the quality being used, etc. There shall be proper arrangements and SOPs for preventing mix-up of materials at

every stage of handling. There shall be separate arrangements for handling and warehousing of materials of different origins. Materials with odour shall be kept in tightly closed containers and shall be well protected from other materials. Fresh materials and odorous materials shall, preferably be stored in separate dedicated areas. Where bonded manufacturing and or warehousing facilities are required as per Excise laws, the facilities required shall be provided without compromise on the requirements specified above. A well-equipped laboratory for quality control/quality assurance of raw materials and finished products and for carrying out in- process controls shall be provided.

**4. Personnel:**

Manufacture of drugs shall be under the control of approved technical staff that shall possess the qualifications as prescribed in Rule 10(a).

**5. Requirement of equipment and facilities:**

**5.1 Mother tinctures and mother solutions:** - The following equipment and facilities shall be provided:

5.1.1 Disintegrator;
5.1.2 Sieved separator;
5.1.3 Balances, weights and fluid measures, all in metric system;
5.1.4 Chopping table/Board and knives;
5.1.5 Macerators with lids (all made of stainless steel of grade 304 or neutral glass);
5.1.6 Percolators (all made of stainless steel of grade 304);
5.1.7 Moisture determination apparatus;
5.1.8 Filter press/Sparkler filter (all metal parts shall be of stainless steel);
5.1.9 Mixing and Storage vessels (Stainless steel of grade 304);
5.1.10 Portable stirrers (Rod, blades and screws shall be of stainless steel);
5.1.11 Water still/water purifier;
5.1.12 Macerators and percolators for preparing mother solutions of materials of chemical origin. These shall be of material, which will not react with the chemicals, used and which do not bleach;
5.1.13 Filling and sealing machine. The area and facilities for manufacture of mother tinctures and mother solutions shall be separate and shall be 55 square meters for each for basic installations.

**5.2 Potentisation section:** – The section shall have the following facilities:

5.2.1 Work benches with washable impervious tops;
5.2.2 Facilities for orderly storage of different potencies and back-potencies of various drugs;
5.2.3 Suitable devices for measuring and dispensing of potencies/back-potencies into the potentisation phials;
5.2.4 Potentiser with counter. An area of 20 square meters shall be provided for basic installations.

Note – (a) The requirement of potentiser is not mandatory. The process may be done manually also with proper SOPs. Potentiser, if used, shall be properly validated and shall be calibrated every time before commencement of work for proper performance.
(b) The manufacturer shall use back-potencies procured from Licenced manufacturer and the firm shall maintain proper records of purchase or shall prepare own back-potencies. Every container of potencies and back-potencies shall be kept properly labelled and there shall not be mix-up of different medicines and different potencies.

**5.3 Containers and Closures Section:**

5.3.1 Separate area for preparation of containers and closures shall be provided adjacent to the potentisation section. This area shall have the following facilities:

5.3.1.1 Washing tanks with suitable mechanical or hand operated brushes;

5.3.1.2 Rinsing tanks. Purified water shall be used for rinsing;

5.3.1.3 Closures washing/macerating tanks;

5.3.1.4 Driers;

5.3.2 Different droppers shall be used only for each different medicine and different potency.

5.3.3 All measures shall be in metric system. Measures used shall be of neutral glass. Metal droppers and plastic droppers shall not be used.

5.3.4

5.3.5 Glass droppers shall be reused only after proper cleaning and sterilization.

5.3.6 Potentisation shall be done by the method(s) prescribed in the Homoeopathic Pharmacopoeia.

**5.4 Trituration, Tableting, Pills and Globules making sections:**

5.4.1 The following basic equipment and facilities shall be provided: -

5.4.1.1 Triturating Machine;

5.4.1.2 Disintegrator;

5.4.1.3 Mass Mixer;

5.4.1.4 Granulator;

5.4.1.5 Electrical oven;

5.4.1.6 Tablets punching Machine;

5.4.1.7 Kettle (steam or electrically heated) for preparing solutions;

5.4.1.8 Driers for drying granules and tablets;

5.4.1.9 Sieved separator (stainless steel);

5.4.1.10 Tablet counter;

5.4.1.11 Balances;

5.4.1.12 Coating Pan with spray-gun;

5.4.1.13 Multi-sifter;

5.4.1.14 Mill with perforations.

5.4.2 An area of 55 square meters shall be provided for basic installations. The area shall be suitably divided into cubicles to minimize cross contamination, mix-up etc.
Note: The section shall be free from insects, worms, rodents dust and other floating particles and moisture.

**5.5 Syrups and other oral liquids section: -**

5.5.1 The following basic equipment and facilities shall be provided:

5.5.1.1 Mixing and storage tanks. (stainless steel of grade 304);

5.5.1.2 Portable stirrer (rod. Blades and screws shall be of stainless steel);

5.5.1.3 Filter press/Sparkler filter (all metal parts shall be of stainless steel);

5.5.1.4 Filling and sealing machine; pH meter.

5.5.2 An area of 20 square meters shall be provided for basic installations. The section shall be free from dust and other floating particles, cobwebs, flies, ants and other insects, birds, lizards and rodents. Adequate number of workbenches shall be provided. Visual inspection table shall be provided. This shall comprise of a colour contrast background with lamp for providing diffused light, mounted on a suitable table.

**5.6 Ointments and lotions section: -**

5.6.1 The following basic equipment and facilities shall be provided: -

5.6.1.1 Mixing tanks (Stainless steel) Kettle (steam or electrically heated) for preparing solutions;
5.6.1.2 Suitable powder/planetary Mixer;
5.6.1.3 Ointment mill/colloidal Mill/Emulsifier;
5.6.1.4 Filling and sealing machine/crimping machine;
5.6.1.5 Filtering equipment;
5.6.1.6 Balance and weights.

5.6.2 A minimum area of 20 square meters shall be provided for basic installations. An ancillary area for washing vessels and equipment shall be provided. An ancillary area for heating purposes shall also be provided.

**5.7 Ophthalmic preparations section: –**

5.7.1 The following basic equipment and facilities shall be provided:

5.7.1.1 Hot air oven, electrically heated, with thermostatic control;
5.7.1.2 Laminar Air Flow bench;
5.7.1.3 Air Handling Unit with HEPA filters to provide filtered air and positive pressure to the section and air locks;
5.7.1.4 Ointment mill/colloidal Mill;
5.7.1.5 Mixing and storage tanks (stainless steel of grade 304);
5.7.1.6 Pressure vessels, as may be needed;
5.7.1.7 Sintered glass funnels, Seitz Filter/Filter candle;
5.7.1.8 Vacuum pump;
5.7.1.9 Filling machines for liquids ointments etc.;
5.7.1.10 Autoclaves with pressure and temperature gauges;
5.7.1.11 and Necessary workbenches, visual inspection bench, etc.;

5.7.2 Area: Minimum area of 20 square meters shall be provided for basic installations.

Note:

i. The section shall have a clean room facility of class 100 specification.
ii. The section shall be air-conditioned and humidity controlled.
iii. Entry to the sections shall be regulated through air-locks with differential air pressures with the air-lock adjacent to the section having higher pressure and the first one through which entry is made with the least pressure.
iv. Materials shall be passed to the sections through suitable hatches.
v. The personnel shall wear sterile clothing including headgear, which shall not shed fibre.
vi. Washing of phials shall be done in separate areas with proper equipment. Proper facilities shall be provided in the area for washing vessels.
vii. Separate area shall be provided for packing and labelling.

**6. Quality control division:**

**6.1 Functions:** - A separate quality control division shall be provided in the premises. The section shall be under the control of an approved technical officer, independent of the manufacturing division and directly responsible to the management. The section shall be responsible for ensuring the quality of all raw materials, packing materials and finished goods. The section shall also carry out in-process quality checks of the products. The section shall be responsible for the stability of the products and for prescribing their shelf life wherever applicable. The functions of the division shall include: -

6.1.1 To test the identity, quality and purity of the raw materials and to recommend rejection of the material of poor quality and approve materials of the prescribed quality only.

6.1.2 To test the identity, quality and purity of the finished products and to recommend rejection of the material of poor quality and approve materials of the prescribed quality only.

6.1.3 To prepare and validate the methods of analysis, validate the equipment, monitor their use, take steps for proper maintenance etc.

6.1.4 To approve or reject containers, closures and packaging materials in accordance with the prescribed norms.

6.1.5 To exercise/carry out in-process control of products.

6.1.6 To prescribe SOPs on all matters concerning quality of materials and products.

6.1.7 To monitor the storage and handling of raw materials, finished products, containers, closures and packaging materials.

6.1.8 To investigate complains on quality of products and take/recommend appropriate measures and to examine returned goods and recommend their proper disposal.

**6.2 Personnel:** – The quality control staff shall be full-time personnel. Analysis and tests of drugs, raw materials, etc. shall be done by qualified and approved technical staff. The technical staff shall have the minimum qualification and experience as prescribed vide Rule 10(a) in the test and analysis of medicine including handling of instruments.

**6.3 Equipment:** – The following equipment shall be provided: -

6.3.1 Microscope of suitable magnification and photographic device;

6.3.2 Dissecting microscope;

6.3.3 TLC apparatus;

6.3.4 UV lamp viewer;

6.3.5 Monopan Digital Electronic Balance;

6.3.6 Hot air oven;

6.3.7 Distillation apparatus;

6.3.8 Water Bath;

6.3.9 Polarimeter; Refractometer;

6.3.10 Melting point apparatus; PH meter;

6.3.11 Magnetic stirrer;

6.3.12 Table Centrifuge;

6.3.13 Muffle furnace/electric Bunsen;

6.3.14 Moisture determination apparatus;

6.3.15 U.V. Spectrophotometer;

6.3.16 Rotary microtome/Section cutting facilities;

6.3.17 Tablet Disintegration Machine.

**7. Raw materials:**

**7.1 Raw materials of Plant Origin:**

7.1.1 The raw materials of plant origin used for manufacture of drugs shall be of the following specification:

7.1.1.1 The materials shall be those recently collected and dried and shall be free from moisture so as to eliminate the risk of deterioration and infestation with pests moulds, etc. The materials shall be collected when the atmospheric temperature is suitable where its active constituents are not changed/damaged/destroyed;

7.1.1.2 When fresh materials are to be used, the time lapse from the time of collection to use shall be minimized to the extent possible;

7.1.1.3 The material should be taken from healthy plants and shall be free from parasites, moulds, etc.;

7.1.1.4 The materials shall be free of inorganic or organic foreign matter;

7.1.1.5 When dry materials are procured, they shall be from healthy plants and shall be in un-processed form, free from all extraneous matters such as fungus, insects, moulds, pathogenic organisms, etc. and should not be more than six months old. Plant materials of Agaricaceae, which are perishable shall be used within one week of collection.

7.1.2 To facilitate proper identification and purity of the material and to exercise proper quality control of the material, the following conditions must be satisfied:

7.1.2.1 a small twig of the plant with leaves shall be available if the part used is bark of the plant; an entire plant or part or aerial twig with leaves and some uncut roots/rhizomes/bulbs shall be available if the part used is a root/rhizome/bulb;

7.1.2.2 if plants with flowers are to be used, a few dry flowers shall also be available with the aerial twig;

7.1.2.3 if the material used is a mould or of the plant families Agaricaceae, Polyporaceae/ amanitacaea/ Boletaceae/ Russulaceae, a whole specimen plant mould shall be available in properly dried form;

7.1.2.4 the materials shall be free from insecticides, fungicides, etc.;

7.1.2.5 the materials shall be in open mesh bags or in suitable material which permits the passage of air inside;

7.1.2.6 each consignment of the material shall be accompanied by a statement of the supplier's name;

7.1.2.7 name of the plant with description of the part 5.2 5.3 5.4 supplied;

7.1.2.8 the pharmacopoeial reference, place of collection/harvest, date and time of collection and packaging and weight.

7.2 **Raw material of Chemical origin:**

7.2.1 They shall be of respective pharmacopoeial standards or their specification shall accompany the materials.

7.3 **Raw materials of animal origin:**

7.3.1 The materials shall be those collected from healthy animals and shall be of pharmacopoeial specifications. The materials shall be those collected, packed and transported under proper hygienic conditions and well protected from all contamination. In case of drugs derived from a whole insect, bulk of such drugs along with some uncut whole insect should be provided/maintained for records.

7.3.2 Sarcodes. – The materials shall be those collected from healthy animals and shall be of pharmacopoeial specification. The materials shall be those collected, packed and transported under proper hygienic conditions and well protected from all contamination. The materials shall be tested to see that they are free from pathogenic organisms such as E. Coli,

7.3.3 Nosodes. – These shall be of pharmacopoeial specifications. As these are derived from diseased animals or human beings, they shall be autoclaved immediately after collection and preserved and transported under proper hygienic conditions and well protected from all contamination. Before use, these shall be sterilized by autoclaving and shall comply with the test for sterility as specified in the Homoeopathic Pharmacopoeia.

## 8. Procedures:

8.1 **Manufacture of Mother Tinctures**:

8.1.1 Every material shall be identified and checked for its purity. They shall be cleaned and process by cutting, chopping, etc. for use in macerators/percolators. A

specimen of the material shall be preserved till approval of the product for release for sale.

8.1.2 The design and procedures adopted shall ensure reproduction of the product of the same quality every time. c) Mother tinctures shall be preserved in tight closed neutral containers at temperatures preferably below 25° C, protected from light.

8.2 **Manufacture of Attenuations:**

8.2.1 Attenuations shall be prepared in a clean room environment with filtered air and positive pressure inside suitable for the operations.

8.2.2 The methods used shall be reproducible and shall be validated.

8.2.3 The containers, tubings, etc. of the machines used for manufacture of attenuations shall be thoroughly washed, cleaned and dried after attenuation of a drug. Regular checks shall be carried out on the materials.

8.2.4 The parts of the equipment that come into contact with the attenuation materials shall be of neutral quality and shall not cause any contamination to the material.

8.2.5 Attenuations shall be preserved in properly labelled glass containers.

8.2.6 Alcohol and other vehicles used shall be of Homoeopathic Pharmacopoeia specification and shall be free from impurities.

8.3 **Trituration**: - Trituration technique is used to manufacture drugs from insoluble strains. The procedure/method specified in the Homoeopathic Pharmacopoeia shall be adopted.

8.4 **Formulations: -** Compound formulations shall preferably be in liquid and solid forms and the potency of the ingredients shall be in detectable quantity preferably be in 3X except in case of highly poisonous material and toxins which should not be below 6X. The ingredients shall be compatible to each other. Complete pharmacopoeial name of each ingredient shall be printed on the label along with composition.

8.5 **Medicated Insert pellets:**

8.5.1 Pellets shall be manufactured in clean rooms free from particulate contaminants. The equipment used shall enable prevention of contamination and cross-contamination.

8.5.2 The procedures shall be validated.

8.6 **Laboratory Controls**: - Tests as per the pharmacopoeia and requirements shall be carried out on products and materials. The stability of the products shall be established by proper methods. Sterility test, wherever applicable, shall be carried out. Control samples shall be preserved for not less than three years after the last sales.

8.7 **Packing and Labelling**: - A minimum area (per rules) shall be provided for packing and labelling section.

**9. Expiry Date: -** Not exceeding sixty (60) months from the date of manufacture.

**10. Standard Operating Practices: -** Standard Operating Practices (SOPs) shall be developed for various activities such as receipt, identification, cleaning, drying, warehousing, issue, handling, sampling etc of all materials. Labels and packing materials shall be examined for correctness and compliance with rules. Rules shall be maintained for their printing, use, destruction etc.

**11. Records and Registers: -** Records shall be maintained for all the activities. These shall include records of production, records of raw materials, records of testing, records of sales and other supplies, records of rejection, complaints and actions taken, SOPs and records in respect of compliance thereof, log books of equipment, master formula records, records of medical examination and fitness of personnel etc. All records shall be maintained for a period of one year after the expiry of a batch or for three years whichever is later.

## SCHEDULE B

*[See rule 10(b)(i)]*

## REQUIREMENTS FOR ESTABLISHMENT OF A GODWON AS IMPORTER FOR ALTERNATIVE MEDICINE AND HEALTH PRODUCTS

An importer shall follow the good storage practice and supply chain management accordingly detailed below:

1. A minimum area of 500sq ft. should be required for an importer in a non-residential area to establish a godown/warehouse for imported alternative medicine and health products.

2. There shall be adequate segregation to eliminate the risk of cross contamination.

3. There shall be proper cleanliness and hygiene. The humidity and temperature shall be maintained within acceptable limits of respective products.

4. Goods and materials shall be stored off the floor, suitably spaced to permit ventilation, cleaning and inspection.

5. The vehicles deployed to distribute, store or handle drugs shall be properly designed and equipped to ensure protection from different environmental and weather conditions.

6. It will be ensured that alternate medicines and health products due to expire first are sold and/or distributed first.

7. Adequate controls shall be in place to prevent the sale/distribution of expired products.

8. Expired, broken or damaged items shall be kept/ stored separately, properly labelled and marked in the warehouse.

9. Thermolabile products shall be kept in refrigerator with proper temperature recording like thermometer, and its temperature shall be monitored to ensure its consistency within the required limits.

10. Storage conditions for products and materials shall be in compliance with the labelling instructions and requirements.

11. All the medicines must be kept on racks and shelves to allow access for cleaning and to avoid harbouring pests. The stores may be arranged in the storeroom and shelves as per following general guidelines, pallets are being used stake the carton:

    (a) at least ten cm (4inches) of the floor;
    (b) at least thirty cm (1 foot) away from the walls and other stakes;
    (c) not more than 2.5 meter (8 feet) high.

12. Products shall be protected from excessive climatic conditions during storage and transport such as heat frost, moisture and direct sunlight.

13. Buildings shall be kept free of vermin, insects, birds and other pests.

14. Temperature above 40 degree and relative humidity above 70 percent are considered to be the extremes of temperature and humidity respectively.

15. Health products that must be stored under defined conditions require appropriate storage instructions. Unless otherwise specifically stated, deviation may be tolerated only during short terms interruptions or during local transportation.

16. It is important to follow manufacturers recommend storage conditions printed on label of products:

    **Store Frozen:** some products, like certain vaccines, need to be transported within a cold chain and stored at -20° C (4° F). Frozen storage is normally for longer-term storage at higher level facilities;

    **Store at 2-8° C (36°-46° F):** some products are very heat sensitive but must not be frozen. These are usually kept in the first and second part of refrigerator and never in the freezer. This temperature is appropriate for storing vaccines for a short period of time:

    **Keep Cool: Store between 8°-15° C (45°-59° F)**

    Store at room temperature:
    Store at ambient temperature:
    Store at the surrounding temperature. This term is not widely used due to significant variation in ambient temperatures. It means "room temperature" or normal storage conditions, which means storage in a dry, clean, well-ventilated area at room temperatures between 15° to 26° C (59°-77° F) or up to 30° C, depending on climatic conditions.

    **Protect from Moisture:** no more than 60° relative humidity. In normal storage condition; to be provided to the patients in a light-resistant container.

17. There shall not be any leaks from roofs of storage sites.

18. The storage facility shall be clean and free from litter, dust and pests.

19. Adequate precautions shall be taken against spillage and breakage, attack by microorganisms and cross contamination.

20. The importers shall ensure the deliveries only to authorized retailers, wholesalers or distributors under a valid warranty under the law.

21. For all supplies a document shall be enclosed making it possible to identify the stocks to ascertain the date, the name and pharmaceutical form of the alternative medicine and Health product, quantity supplied, the name and address of the supplier and addressee.

22. The alternative medicine and health products shall be transported in such a way that:

    (a) their identification is not lost;

(b) adequate precautions are taken against spillage, breakage or theft; and
(c) they are secure and not subjected to unacceptable degree of heat, cold, light, moisture and such like other factors.

23. Alternative medicine and health products requiring controlled temperature storage shall be transported by appropriately specialized means.

24. Defective alternative medicine and health products which have been returned shall be kept apart from saleable stock to prevent sale/ redistribution until a decision has been reached regarding the disposal.

## SCHEDULE C

*[See rule 28(c)]*

## CONDITIONS FOR CONTRACT MANUFACTURING

1. General conditions for contract shall be as under:-

   (a) Technical aspects of the contract should be drawn up by competent persons suitably knowledgeable in Alternative Medicines and Health Products technology, analysis and Good Manufacturing Practice (GMP);

   (b) All arrangements for manufacture and analysis must be in accordance with the marketing authorization and agreed by both parties;

   (c) The contract should specify the way in which the Qualified Person releasing the batch for sale ensures that each batch has been manufactured and checked for compliance with the requirements of Marketing Authorization;

   (d) The contract should describe responsibility for purchasing materials, testing and releasing materials, undertakingproduction and quality controls, including in-process controls, and who has responsibility for sampling and analysis;

   (e) Manufacturing, analytical and distribution records, and reference samples should be kept by, or be available to, the Contract Giver. Any records relevant to assessing the quality of a product in the event of complaints or a suspected defect must be accessible and specified in the defect or recall procedures of the Contract Giver; and

   (f) The Contract should permit the Contract Giver to visit the facilities of the Contract Acceptor. In the case of contract analysis, the Contract Acceptor should understand that he is subject to Inspection by the competent Authorities;

2. Contract Acceptor shall be responsible for the following, namely:-

   (a) He must have adequate premises and equipment, knowledge and experience, and competent personnel to carry out satisfactorily the work ordered by the Contract Giver. Contract manufacture may be undertaken only by a manufacturer who is the holder of a manufacturing authorization;

   (b) He should ensure that all products or materials delivered to him are suitable for their intended purpose;

   (c) He should not pass to a third party any of the work entrusted to him under the contract; and

   (d) He should refrain from any activity which may adversely affect the quality of the product manufactured or analyzed for the Contract Giver;

3. Contract Giver shall be responsible for the following, namely:-

(a) Assessing the competence of the Contract Acceptor to carryout successfully the work required and for ensuring by means of the Contract that the principles and guidelines of GMP are followed;

(b) The Contract Giver should provide the Contract Acceptor with all the information necessary to carry out the contracted operations correctly in accordance with the marketing authorization and any other legal requirements;

(c) The Contract Giver should ensure that the Contract Acceptor isfully aware of any problems associated with the product or the work which might pose a hazard to his premises, equipment,personnel, other materials or other products; and

(d) The Contract Giver should ensure that all processed products and materials delivered to him by the Contract Acceptor comply with their specifications or that the products have been released by a Qualified Person.

**FORM 1**

*[See rule 6(1)]*

**APPLICATION FOR SITE SUITABILITY AND LAYOUT APPROVAL FOR ESTABLSIHMENT OF UNIT FOR MANUAFCTURE OF ALTERNATIVE AND HEALTH PRODUCTS**

I, ..... (MD / Chief executive / Proprietor)
of M/s ..... Address .....
hereby apply for establishment of firm/ company located at (Address of the premises)
.....

I do herby attach following documents:

| S. No. | Description | Document | Attachment |
|---|---|---|---|
| 1 | Fee deposit bank receipt for site verification | Original receipt | |
| 2 | Ownership of Plot with size and location (Industrial / Un-specified ) | i. Certified copy of Allotment letter / Fard. Etc | |
| | | ii. In case of rental property ownership documents along with lease agreement with the landlord (lease shall not be less than 15 years). | |
| | | iii. Exemption from site verification request in case Industrial Site | |
| 3 | Legal Status of the Establishment | | |
| | (a) sole proprietorship concern | i. Copy of CNIC | |
| | | ii. Certified true copies of NTN and Online FBR Certificate mentioning business activity as manufacturer of alternative medicines and/or health products; | |
| | | iii. Undertaking on notarized stamp paper declaring the applicant is a sole proprietor; | |
| | (b) Firm | i. Certified true copies of Certificate by Registrar of Firms, | |
| | | ii. Certified true copy of Partnership Deed, | |
| | | iii. NTN, Online FBR Certificate mentioning business activity as manufacturer of alternative medicines and/or health products; | |
| | | iii. copies of CNICs | |
| | | iv. Name and Signature of Partner (s) | (Signature) |

| | | | |
|---|---|---|---|
| | | | (Signature) |
| | | | (Signature) |
| | | | |
| | (C) Company | i. Certified true copies of incorporation certificate (Form II) alongwith Article of Association; Memorandum of Association; | |
| | | ii. copies of CNICs of CEO; directors | |
| | | iii. Name and Signature of MD/ CEO and director(s) | (Signature) |
| | | | (Signature) |
| 4 | Fee deposit bank receipt for layout approval (per section(s), stores nutraceuticals, stores herbal, stores homoeopathic, or any dedicated/segregated store/area (etc.) & testing laboratory) | Fee Challan | |
| 5 | Type(s) of licence to manufacture alternative medicines and health products intended to be manufactured by the applicant | i. licence to manufacture bulk extract, mother tincture and isolate | |
| | | ii. licence to manufacture by way of formulation | |
| 6 | Details of type(s) / class (es) of alternative medicines and health products intended to be manufactured | i. Alternative Medicines. | |
| | | ii. Health Products | |
| 7 | If applicant is already Licenced for manufacturing of any other therapeutic goods, | Applicant shall submit site approval, copy of already approved layout plan, sections details, licence validity evidence and undertaking that my licence is valid as well as the proposed area in the proposed layout plan is not included in the already Licenced premises | |
| 8 | Lay Out Plan | Two (02) copies of proposed layout plan of the manufacturing unit. | |
| 9 | Undertaking | i. Undertaking on notarized stamp paper, about the feasibility that the premises is situated in an environment that, when considered together with measures to protect the manufacturing processes, presents minimum risk of causing any contamination of materials or products. It shall be away from filthy surroundings and shall not be | |

| | | | |
|---|---|---|---|
| | | adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odour or fumes or large quantities of soot, dust or smoke which may contaminate the alternative medicines or health products being manufactured or adversely affect their quality | |
| | | ii. I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper). | |

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 2**

*[See rule 7(1)]*

**APPLICATION FOR THE GRANT OR RENEWAL OF LICENCE FOR MANUAFCTURE OF ALTERNATIVE AND HEALTH PRODUCTS**

I, ..... (MD / Chief executive / Proprietor) of M/s ..... Address ..... hereby apply for grant / renewal of licence of firm/ company located at (Address of the premises) .....

I do herby attach following documents:

| S. No. | Description | Document | Attachment |
|---|---|---|---|
| 1 | Fee deposit bank receipt for grant / renewal of licence | Original receipt | |
| 2 | Application is for type and grant or renewal | Mention type(s) of licence to manufacture alternative medicines and health products intended to be manufactured by the applicant:<br>a. licence to manufacture Herbal Extract, Homoeopathic Tincture or Isolate;<br>b. licence to manufacture by way of formulation;<br>c. licence to manufacture for experimental purpose | |
| | | For renewal of manufacturer licence to alternative medicine and health products | |
| | | (i) Licence number and date of issue: | |
| | | (ii) Validity date: | |
| | | (iii) Last renewal date and its validity: | |
| | | (iv) Attach certificate of licence and last renewal: | |
| 3 | Manufacturing premises details | i. Site Master File | |
| | | ii. Copy of approved layout plan. | |
| | | iii. List of Sections ready for inspection | |
| | | iv. List of products intended to be manufactured [along with formula, pack size etc.] | |
| | | v. Details of section wise equipment and machinery for | |

| | | | |
|---|---|---|---|
| | | manufacturing and instruments for quality control: | |
| 4 | Detail of Qualified Person for Production | i. Photograph and certified copies of CNIC, | |
| | | ii. Certified Degrees Certificate | |
| | | iii. Certified Registration Certificate of Council | |
| | | iv. Experience Certificate | |
| 5 | Detail of Qualified Person for Quality Control | i. Photograph and certified copies of CNIC, | |
| | | ii. Certified Degrees Certificate | |
| | | iii. Certified Registration Certificate of Council | |
| | | iv. Experience Certificate | |
| 6 | Detail of other qualified persons with name, qualification and designations appointed. | | |
| 7 | **Additional documents in case of grant of licence to manufacture licence to manufacture Herbal Extract, Homoeopathic Tincture or Isolate;** | | |
| (i) | List of products intended to be manufactured | | |
| (ii) | Detailed manufacturing and testing methods for each product | | |
| (iii) | Any other relevant information that may be required by the AMHP Board. | | |
| 8 | **Additional documents in case of grant of licence to manufacture by way of Experimental purpose;** | | |
| (i) | Details of experiment | | |
| (ii) | List of products intended to be manufactured | | |
| (iii) | Detailed manufacturing and testing methods for each product | | |
| (iv) | Any other relevant information that may be required by the AMHP Board. | | |
| 9 | List of products intended to be manufactured | | |
| 10 | Letter from Manufacturer being ready for inspection on company letter head. | | |
| 11 | **DECLARATION ON AFFIDAVIT**<br><br>Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided. | | |
| 12 | **UNDERTAKING ON AFFIDAVIT**<br><br>affidavit binding of the partners/proprietors/Director and qualified persons, duly verified to the effect that they:— | | |

| | | |
|---|---|---|
| | i. shall comply with the provisions of DRAP Act, 2012 and the rules made there under,<br>ii. have not been convicted of any offence from any court of law.<br>iii. shall inform AMHP Board and the inspector as soon as possible when either of the party ceases to have interest in the licence issued under these rules<br>iv. shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any alternative medicines and health products in violation of the DRAP Act, 2012 and the rules made there under.<br>v. the contents stated above are correct and true to the best of my knowledge. | |
| 11 | Name, CNIC and Signatures of all Director /Partners / Sole Proprietor | |

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 3**

*[See rule 7(1)]*

**APPLICATION FOR THE GRANT OR RENEWAL OF LICENCE TO IMPORT ALTERNATIVE MEDICINES AND HEALTH PRODUCTS**

I, ..... (MD / Chief executive / Proprietor)
of M/s ..... hereby apply for grant
/ renewal of licence of firm/ company located at (Address of the premises) .....
having storage facility at .....

I do herby attach following documents:

| S. No. | Description | Document | Attachment |
|---|---|---|---|
| 1 | Fee deposit bank receipt for grant / renewal of licence | Original receipt | |
| 2 | Application is for type and grant or renewal | Import | |
| | | For renewal of import licence to alternative medicine and health products | |
| | | i. Licence number and date of issue: | |
| | | ii. Validity date: | |
| | | iii. Last renewal date and its validity: | |
| | | iv. Attach certificate of licence and last renewal: | |
| 3 | Legal Status of the Establishment | | |
| | (a) sole proprietorship concern | i. Copy of CNIC | |
| | | ii. Certified true copies of NTN and Online FBR Certificate mentioning business activity as importer of alternative medicines and/or health products; | |
| | | iii. Undertaking on notarized stamp paper declaring the applicant is a sole proprietor; | |
| | (b) Firm | i. Certified true copies of Certificate by Registrar of Firms, | |
| | | ii. Certified true copy of Partnership Deed, | |
| | | iii. NTN, Online FBR Certificate mentioning business activity as importer of alternative medicines and/or health products; | |
| | | iii. copies of CNICs | |
| | | iv. Name and Signature of Partner (s) | (Signature) |

| | | | |
|---|---|---|---|
| | | | (Signature) |
| | | | (Signature) |
| | (C) Company | i. Certified true copies of incorporation certificate (Form II) along with Article of Association; Memorandum of Association; | |
| | | ii. copies of CNICs of CEO; Directors | |
| | | iii. Name and Signature of MD/ CEO and Director (s) | (Signature) |
| | | | (Signature) |
| 4 | **Detail Of Qualified technical Person in storage facility**<br>(Attached copies of CNIC, Photographs, Degrees, Experience Certificate and Certificate of Concerned council)<br>a. Names of Qualified Technical Person for supervising sale, distribution or wholesale of Alternative Medicines and Health Products in storage facility.<br>Other technical staff working in the facility. | | |
| 5 | Any other relevant information that may be required by the AMHP Board. | | |
| 6 | **DECLARATION ON AFFIDAVIT**<br><br>Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided. | | |
| 7 | **UNDERTAKING ON AFFIDAVIT**<br><br>affidavit binding of the partners/proprietors/Director and qualified persons, duly verified to the effect that they:—<br>i. shall comply with the provisions of DRAP Act, 2012 and the rules made there under,<br>ii. have not been convicted of any offence from any court of law.<br>iii. shall inform AMHP Board and the inspector as soon as possible when either of the party ceases to have interest in the licence issued under these rules<br>iv. shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any alternative medicines and health products in violation of the DRAP Act, 2012 and the rules made there under.<br>v. the contents stated above are correct and true to the best of my knowledge. | | |

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 4**

*[See rule 8(1)]*

**GOVERNMENT OF PAKISTAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**Licence No.** _____
**Grant / renewal date:** _____

## LICENCE TO MANUFACTURE BULK EXTRACTS, HOMOEOPATHIC TINCTURES AND ISOLATE

M/s.....
is hereby licenced to manufacture Bulk Extract, Homoeopathic Tinctures and Isolate at the following premises: .....

2. This licence permits the manufacture of alternative medicines and health products registered under the DRAP Act, 2012 and rules framed thereunder in following section(s):

(i) .....
(ii) .....

3. This licence shall, in addition to the conditions specified in the Alternative Medicines and Health Products Rules, 2026 under the DRAP Act, 2012, be subject to the following conditions namely:-

(a) The licence shall be in force for a period of **five years** from the date of issue unless earlier suspended or cancelled.
(b) This licence shall be displayed at the premises of the given address mentioned above.
(c) The licence authorizes the sale of Alternative Medicines and Health Products manufactured under this licence.
(d) Name of the approved technical staff.

.....(NAME).....
Production Incharge

.....(NAME).....
Quality Control Incharge

**CHAIRPERSON**
Alternative Medicine & Health Products Board

**SECRETARY**
Alternative Medicine & Health Products Board

No. F.....

**FORM 5**

*[See rule 8(1)]*

**GOVERNMENT OF PAKISTAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**Licence No.** _____
**Grant / renewal date:** _____

## LICENCE TO MANUFACTURE ALTERNATIVE MEDICINES & HEALTH PRODUCTS BY WAY OF FORMULATION

M/s.....
is hereby licenced to manufacture alternative medicines and health products by way of formulation at the following premises: .....

2. This licence permits the manufacture of alternative medicines and health products registered under the DRAP Act, 2012 and rules framed thereunder in following section(s):

i. .....
ii. .....

3. This licence shall, in addition to the conditions specified in the Alternative Medicines and Health Products Rules, 2026 under the DRAP Act, 2012, be subject to the following conditions namely:-

(a) The licence shall be in force for a period of **five years** from the date of issue unless earlier suspended or cancelled.
(b) This licence shall be displayed at the premises of the given address mentioned above.
(c) The licence authorizes the sale of Alternative Medicines and Health Products manufactured under this licence.
(d) Name of the approved technical staff.

.....(NAME).....
Production Incharge

.....(NAME).....
Quality Control Incharge

**CHAIRPERSON**
Alternative Medicine & Health Products Board

**SECRETARY**
Alternative Medicine & Health Products Board

No. F.....

**FORM 6**
*[See rule 8(1)]*

**GOVERNMENT OF PAKISTAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**Licence No.** _____
**Grant / renewal date:** _____

## LICENCE TO IMPORT ALTERNATIVE MEDICINES & HEALTH PRODUCTS

M/s [Complete title with Business Address] .....
having storage facility at .....
approved by the AMHP Board.

2. This licence permits the Licencee to import and store for sale alternative medicines and health products registered under the DRAP Act, 2012 and rules framed thereunder.

3. This licence shall, in addition to the conditions specified in the Alternative Medicines and Health Products Rules, 2026 under the DRAP Act, 2012, be subject to the following conditions namely:-

(a) The licence shall be in force for a period of **five years** from the date of issue unless earlier suspended or cancelled.
(b) This licence shall be displayed at the premises of the given address mentioned above.
(c) Name of the approved technical staff.

.....(NAME).....
Qualified Person

**CHAIRPERSON**
Alternative Medicine & Health Products Board

**SECRETARY**
Alternative Medicine & Health Products Board

No. F.....

**FORM 7**
*[See rule 8(1)]*

**GOVERNMENT OF PAKISTAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**Licence No.** _____
**Grant / renewal date:** _____

**LICENCE TO MANUFACTURE ALTERNATIVE MEDICINES AND HEALTH PRODUCTS FOR EXPERIMENTAL PURPOSE**

M/s.....
is hereby licenced to manufacture alternative medicines and health products by way of experimental purpose at the following premises: .....

2. This licence permits the manufacture of alternative medicines and health products registered under the DRAP Act, 2012 and rules framed thereunder in following section(s):

i. .....
ii. .....

3. This licence shall, in addition to the conditions specified in the Alternative Medicines and Health Products Rules, 2026 under the DRAP Act, 2012, be subject to the following conditions namely:-

(a) The licence shall be in force for a period of **five years** from the date of issue unless earlier suspended or cancelled.
(b) This licence shall be displayed at the premises of the given address mentioned above.
(c) The licence authorizes the sale of Alternative Medicines and Health Products manufactured under this licence.
(d) Name of the approved technical staff.

.....(NAME).....
Production Incharge

.....(NAME).....
Quality Control Incharge

**CHAIRPERSON**
Alternative Medicine & Health Products Board

**SECRETARY**
Alternative Medicine & Health Products Board

No. F.....

**FORM 8**

*[See rule 12(1)]*

**APPLICATION FOR REGISTRATION OF LOCALLY MANUFACTURED GENERIC HEALTH PRODUCT**

I/We..... Owner (s) of M/s.....hereby apply for registration/ renewal of registration of following product manufactured by my firm/company located at the premises .....

**Administrative Information**

| | |
|---|---|
| Name and address of the manufacturer | |
| Licence Number and Date of Grant / Renewal | |
| Approved Sections (Attach copy) | |

**Product Profile**

| | | |
|---|---|---|
| **1.** | Name under which the product is proposed to be sold. | |
| **2.** | Dosage and Directions for use. | |
| **3.** | Route of Administration. | |
| **4.** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | |
| **5.** | Composition of the product, stating quantity of each active and non-active ingredient(s) per unit or as a percentage of total formulation. | |
| **6.** | Formulation and evidence of competitor availability in the local or international market | |
| **7.** | Safety and Efficacy data of proposed product or usage within local community for minimum 10 years | |
| **8.** | Recommended Conditions for use. | |

1. Master Formula.
2. Manufacturing process.
3. Testing specifications (Raw materials and Finished Product).
4. Shelf life and storage.
5. Stability Summary

   (a)The shelf life for all the pack types shall be supported by stability data. Information shall also include shelf life before first opening, after reconstitution and/or after opening where applicable. Stability data to support such shelf life shall be available.

   (b)Evidence is required to demonstrate that the product is stable (meets the finished product shelf-life specifications throughout its proposed shelf-life in the specified container closure system).

(c) Type of container/package, with the nature of material, package testing (chemical, mechanical, environmental).

6. Labelling: Specimen or draft with color scheme, along with the undertaking to refrain from counterfeiting shall also be submitted.
7. Packaging and pack Size.
8. Template of BMR of Commercial Batch.
9. Fee deposit receipt.

**Product Summary**

| **S. No** | | **Brand Name of Product.** | | | | |
|---|---|---|---|---|---|---|
| | List of ingredients With Quantities | Specifications of Raw Materials | Common Name of ingredients | Recommended use | Pack size | |
| | | | | | | |

## Declaration

I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper).

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 9**

*[See rule 12(1)]*

**APPLICATION FOR REGISTRATION OF LOCALLY MANUFACTURED NEW HEALTH PRODUCT**

I/We..... Owner (s) of M/s.....hereby apply for registration/ renewal of registration of following products manufactured by my firm/company located at the premises as under .....

**Administrative Information**

| | |
|---|---|
| Name and address of the manufacturer | |
| Licence Number and Date of Grant/ Renewal | |
| Approved Sections | |

**Product Profile**

| | | |
|---|---|---|
| 1. | Name under which the product is proposed to be sold. | |
| 2. | Dosage and Directions for use. | |
| 3. | Route of Administration. | |
| 4. | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | |
| 5. | Formulation | |
| 6. | Safety, efficacy and quality data as per recognized evidence and standards | |
| 7. | Recommended Conditions for use along with evidence for therapeutic or disease reduction claims as per standards of evidence | |
| 8. | Composition of the drug, stating quantity of each active and non-active ingredient(s) per unit or as a percentage of total formulation. | |

1. Master Formula.
2. Manufacturing process.
3. Testing specifications (Raw materials and Finished Product).
4. Shelf life and storage.
5. Stability Summary

   (a)The shelf life for all the pack types shall be supported by stability data. Information shall also include shelf life before first opening, after reconstitution and/or after opening where applicable. Stability data to support such shelf life shall be available.

   (b)Evidence is required to demonstrate that the product is stable (meets the finished product shelf life specifications throughout its proposed shelf-life in the specified container closure system).

   (c) Type of container/package, with the nature of material, package testing (chemical, mechanical, environmental).

6. Labelling: Specimen or draft with colour scheme, along with the undertaking to refrain from counterfeiting shall also be submitted.
7. Packaging and pack Size.
8. Template of BMR of Commercial Batch.
9. Fee deposit receipt.

**Product Summary**

| **S. No** | | **Brand Name of Product.** | | | | |
|---|---|---|---|---|---|---|
| | List of ingredients With Quantities | Specifications of Raw Materials | Common Name of ingredients | Recommended use | Pack size | Maximum Retail price |
| | | | | | | |

**Declaration**

I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper).

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 10**

*[See rule 12(1)]*

**APPLICATION FOR REGISTRATION OF GENERIC IMPORTED HEALTH PRODUCT**

I/We..... Owner (s) of M/s..... having storage facility at..... hereby apply for registration/ renewal of registration of following product manufactured by M/s ..... situated at ..... and exported by ..... Country of origin of principal manufacturer .....

**Administrative Information**

| | |
|---|---|
| Name and address of the Importer | |
| Licence Number and Date of issuance/ Renewal | |
| Name and Address of Exporter | |
| Name and Address of Principal Manufacturer | |

**Product Profile**

| | | |
|---|---|---|
| **1.** | Name under which the product is proposed to be sold. | |
| **2.** | Dosage and Directions for use. | |
| **3.** | Route of Administration. | |
| **4.** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | |
| **5.** | Recommended Conditions for use. | |
| **6.** | Composition of the drug, stating quantity of each active and non-active ingredient(s) per unit or as a percentage of total formulation. | |

1. Batch manufacturing formula or Master Formulation.
2. Manufacturing process and In-process controls.
3. Testing specifications of starting materials and finished products
4. Certificate of analysis of finished product
5. Shelf life and storage. (Evidence of long term and accelerated Stability data)
6. Packaging and labelling (label mock up and package leaflet insert approved in the country of origin)
7. Import documents

   **"Import documents shall be duly attested, notarized and embassy attested / apostille in the country of origin."**

   a. Free sale certificate in the country of origin and in other countries being marketed (certificate of pharmaceutical product (CPP on WHO Format) as replacement for Free Sale, GMP and Registration or marketing Authorization)
   b. G.M.P Certificate of Principal Manufacturer by the local regulatory Authority
   c. Certification with any Organization or Authority.
   d. Agreement between the importer and principal manufacturer.

e. Letter of Authorization for export, If exporter is other than manufacturer.
f. Last inspection report by the local regulatory Authority or body authorized in this behalf by the local regulatory Authority.

8. Fee deposit receipt.

**Product Summary**

| **S. No** | | **Brand Name of Product.** | | | | |
|---|---|---|---|---|---|---|
| | List of ingredients With Quantities | Specifications of Raw Materials | Common Name of ingredients | Recommended use | Pack size | Maximum Retail price |
| | | | | | | |

**Declaration**

I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper).

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 11**

*[See rule 12(1)]*

**APPLICATION FOR REGISTRATION OF IMPORTED NEW HEALTH PRODUCT**

I/We..... Owner (s) of M/s.....having storage facility at..... hereby apply for registration/ renewal of registration of following products manufactured by M/s ..... situated at ..... and exported by ..... Country of origin of principal manufacturer.....

**Administrative Information**

| | |
|---|---|
| Name and address of the Importer | |
| Licence Number and Date of issuance/ Renewal | |
| Name and Address of Exporter | |
| Name and Address of Principal Manufacturer | |

**Product Profile**

| | | |
|---|---|---|
| **1.** | Name under which the product is proposed to be sold. | |
| **2.** | Dosage and Directions for use. | |
| **3.** | Route of Administration. | |
| **4.** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | |
| **5.** | Recommended Conditions for use along with evidence for therapeutic or disease reduction claims as per standards of evidence | |
| **6.** | Evidence of clinical safety and efficacy based on Pre-clinical and clinical studies along with data. | |
| **7.** | Composition of the drug, stating quantity of each active and non-active ingredient(s) per unit or as a percentage of total formulation. | |

1. Name under which the product is proposed to be sold.
2. Batch manufacturing formula or Master Formulation.
3. Manufacturing process and In-process controls.
4. Testing specifications of starting materials and finished products
5. Certificate of analysis of finished product.
6. Shelf life and storage. (Evidence of long term and accelerated Stability data)
7. Recommended conditions for use (with evidence of quality, safety and efficacy data).
8. Packaging and labelling (label mock up and package leaflet insert approved in the country of origin)
9. Import documents
   **"Import documents shall be duly attested, notarized and embassy attested / apostille in the country of origin."**

a. Free sale certificate in the country of origin and in other countries being marketed (certificate of pharmaceutical product (CPP on WHO Format) as replacement for Free Sale, GMP and Registration or marketing Authorization)
b. G.M.P Certificate of Principal Manufacturer by the local regulatory Authority.
c. Agreement between the importer and principal manufacturer.
d. Letter of Authorization for export, If Exporter is other than manufacturer.
e. Last inspection report by the local regulatory Authority or agency or organization authorized by the Regulatory Authority of that country.

10. Fee deposit receipt.

**Product Summary**

| **S. No** | | **Brand Name of Product.** | | | | |
|---|---|---|---|---|---|---|
| | List of ingredients With Quantities | Specifications of Raw Materials | Common Name of ingredients | Recommended use | Pack size | Maximum Retail price |
| | | | | | | |

**Declaration**

I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper).

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**GOVERNMENT OF PAKISTAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**FORM 12**
*[See rule 13(3)]*

**No. F**.....

**CERTIFICATE FOR REGISTRATION OF HEALTH PRODUCT(S) FOR LOCAL MANUFACTURE**

**M/s (complete address)** ..... having Licence Number ..... is hereby authorized to manufacture following health products which are registered under the Alternative Medicines and Health Products Rules, 2026.

| Registration Number | Products Name and composition (with excipients) | Common Name | Pack Size |
|---|---|---|---|
| | | | |
| | | | |

**Conditions for registration:**

a) The product conforms to all the relevant provisions of the Drug Regulatory Authority of Pakistan Act, 2012 and rules framed thereunder.

b) The product shall be sold as per recommended use.

c) The finished products shall be tested and released before sale by the Quality Control Department of the unit or contract laboratory approved by the Authority.

d) The products shall remain safe, effective and retain its quality during the whole shelf life.

e) The import, manufacture and sale, of alternative medicines and health products shall be in accordance with the information on the basis of which such certificate for registration was granted by the AMHP Board.

f) Every health product shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

g) The manufacture of any health product shall not, without the prior approval of the AMHP Board, be discontinued for a period which may result in its shortage.

h) The Manufacturer shall supply the information in relation to safety, efficacy, production, quality, or availability of the health product as and when required by the

Alternate Medicine & Health Products AMHP Board with a view to ensure safety; efficacy or quality of the health product.

i) It shall be the responsibility of the manufacturer to report to the Alternate Medicine & Health Products AMHP Board within thirty days if an adverse reaction not otherwise included in the application for registration, is registered in any of the reference countries.

j) The product is not contaminated with any type of ingredient not enlisted in the formula approved by the Authority.

k) The product does not contain any prohibited substance or Allopathic or any western ingredient which is not part of approved formulation.

l) The product shall not contain any toxic or dangerous materials which are injurious to health.

m) The content of the heavy metals in the finished product shall be within the prescribed limits as defined in the rules.

n) The manufacturer shall be responsible for immediately withdrawing any health and OTC product at any time, for safety reasons, if the same is withdrawn or banned or certain restrictions are imposed in any of the countries namely, U.S.A. European Union |Countries, Canada, Japan, Australia or any other country identified by the Authority, from the market in Pakistan or, as the case may be to impose similar restriction and to inform the AMHP Board within fourteen days of such an information.

o) If clinical information for a health product is approved in any of the said countries, the same clinical information shall be considered as approved for registration in Pakistan unless modified by the Alternate Medicine & Health Products AMHP Board on the basis of scientific data available to it, and such clinical information may include indications, contra-indications, side effects precautions, dosage, etc;

p) The recommended conditions for use shall be permissible only through valid evidence based on standards of evidence as prescribed under the rules.

q) This certificate of registration, shall unless earlier suspended or cancelled, be in force for a period of five years from the date of Registration.

r) Certificate of registration shall be surrendered to the Authority within 15 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

s) Shelf life of health product shall be determined by the AMHP Board

t) Finished health products shall conform to the guidelines described in the specifications monographs prescribed in the relevant category and dosage form.

u) Product registration holder shall be liable to change the brand name, if it resembles with the already registered products.

SECREATARY OR DESIGNATED
OFFICER
Alternate Medicine & Health Products
Board
Drug Regulatory Authority of Pakistan

Dated: _____

**GOVERNMENT OF PAKISTAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**FORM 13**
*[See rule 13(3)]*

**No. F**.....

**CERTIFICATE FOR REGISTRATION OF HEALTH PRODUCT(S) FOR IMPORT**

**M/s (complete address)** ..... having Licence Number ..... is hereby authorized to import from M/s ..... manufactured by ..... following health products which are registered under the Alternative Medicines and Health Products Rules, 2026.

| Registration Number | Products Name and composition | Common Name | Pack Size |
|---|---|---|---|
| | | | |
| | | | |

**Conditions for registration:**

a) The product conforms to all the relevant provisions of the Drug Regulatory Authority of Pakistan Act, 2012 and rules framed thereunder.

b) The product shall be sold as per recommended use.

c) The finished products shall be tested and released before sale by the Quality Control Department of the unit or contract laboratory approved by the Authority.

d) The products shall remain safe, effective and retain its quality during the whole shelf life.

e) The import, manufacture and sale, of alternative medicines and health products shall be in accordance with the information on the basis of which such certificate for registration was granted by the AMHP Board.

f) Every health product shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

g) The manufacture of any health and OTC product shall not, without the prior approval of the AMHP Board, be discontinued for a period which may result in its shortage.

h) The Manufacturer shall supply the information in relation to safety, efficacy, production, quality, or availability of the health product as and when required by the AMHP Board with a view to ensure safety; efficacy or quality of the alternative medicine and health product.

i) It shall be the responsibility of the manufacturer to report to the AMHP Board within thirty days if an adverse reaction not otherwise included in the application for registration, is registered in any of the reference countries.

j) The product is not contaminated with any type of ingredient not enlisted in the formula approved by the Authority.

k) The product does not contain any prohibited substance or Allopathic or any western ingredient which is not part of approved formulation.

l) The product shall not contain any toxic or dangerous materials which are injurious to health.

m) The content of the heavy metals in the finished product shall be within the prescribed limits as defined in the rules.

n) The manufacturer shall be responsible for immediately withdrawing any health product at any time, for safety reasons, if the same is withdrawn or banned or certain restrictions are imposed in any of the countries namely, U.S.A. European Union |Countries, Canada, Japan, Australia or any other country identified by the Authority, from the market in Pakistan or, as the case may be to impose similar restriction and to inform the AMHP Board within fourteen days of such an information.

o) If clinical information for a health product is approved in any of the said countries, the same clinical information shall be considered as approved for registration in Pakistan unless modified by the AMHP Board on the basis of scientific data available to it, and such clinical information may include indications, contra-indications, side effects precautions, dosage, etc;

p) The recommended conditions for use shall be permissible only through valid evidence based on standards of evidence as prescribed under the rules.

q) This certificate of registration, shall unless earlier suspended or cancelled, be in force for a period of five years from the date of registration.

r) Certificate of registration shall be surrendered to the Authority within 15 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

s) Shelf life of health product shall be determined by the Board.

t) Finished health products shall conform to the guidelines described in the specifications monographs prescribed in the relevant category and dosage form.

u) Product registration holder shall be liable to change the brand name, if it resembles with the already registered products.

SECREATARY / DESIGNATED
OFFICER
Alternate Medicine & Health Products
Board
Drug Regulatory Authority of Pakistan

Dated: _____

**FORM 14**

*[See rule 15(2)]*

**WARRANTY HEALTH PRODUCT(S) (IMPORTED / LOCAL)**

Invoice No ..... dated.....
to M/s ..... situated at .....
It is certified that I Mr ..... S/o ..... of
M/s ..... having CNIC No
..... being manufacturer or importer or (authorized agent *vide*
authority letter No ..... dated ..... on
behalf of M/s .....

1. It is hereby certified that following finished products have been supplied by me, namely:-

| **S. No.** | **Detail of Health product sold.** | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Name of product and pack size** | **Batch number (or lot No.)** | **Mfg. date** | **Expiry date** | **No. of units sold** | **Distribution price** | **Retail price** |
| | | | | | | | |

**Grant total** .....

2. It is hereby certified and I undertake that above mentioned finished products of specified batch number (or lot number) supplied by me do not contravene any provision of the DRAP Act, 2012 and rules framed there under. The authorized agent (with valid distribution authority letter) shall pass on this warranty to the retailers in his area of jurisdiction during the supply health products.

a.....
b.....

Date.....
Signature.....
Place ..... Qualified person Name.....
Designation.....

Seal of manufacture or /importer

**FORM 15**

*[See rule 16(1)]*

**APPLICATION FOR REGISTRATION/ RENEWAL OF LOCALLY MANUFACTURED GENERIC ALTERNATIVE MEDICINES INCLUDING UNANI, TRADITIONAL CHINESE MEDICINE, ETC EXCLUDING HOMOEOPATHIC MEDICINE**

I/We ..... Owner (s) of M/s ..... hereby apply for registration/ renewal of registration of following product manufactured by my firm/company located at the premises .....

**Administrative Information**

| | |
|---|---|
| Name and address of the manufacturer | |
| Licence Number and Date of Grant / Renewal | |
| Approved Sections (Attach copy) | |
| Renewal of Registration No. (in case of renewal application) | |

**Product Profile**

| **Brand Name of Product** | | | | | |
|---|---|---|---|---|---|
| **1** | List of ingredients With strength and monograph | scientific /botanical name of plant Common Name of ingredients | Common name of plant in regional language | Plant part used | Pack size |
| | | | | | |
| **2** | Name under which the product is proposed to be sold. | | | | |
| **3** | Dosage and directions for use. | | | | |
| **4** | Route of administration. | | | | |
| **5** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | | | | |
| **6** | Formulation and evidence of competitor availability in the local or international market | | | | |
| **7** | Safety and efficacy data of proposed product or usage within local community for minimum 10 years | | | | |
| **8** | Recommended conditions for use. | | | | |
| **8** | Safety category<br>Class;1<br>Class;11 | | | | |

| | | |
|---|---|---|
| | class;111 | |

1. Master formula.
2. Manufacturing process.
3. Testing specifications (ingredients and Finished product).
4. Shelf life and storage.
5. Recommended conditions/indication for use.
6. Contra-indication.
7. Side effect.
8. Packaging and labelling.
9. Fee deposit receipt (challan number and fee amount).
10. Additional Information (in case of renewal of registration).

**Declaration**

I undertake, certify and confirmed that the contents and all existing data which are relevant to the registration supplied in the dossier, as appropriate, stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper). If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications.

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 16**

*[See rule 16(1)]*

**APPLICATION FOR REGISTRATION OF LOCALLY MANUFACTURED NEW PRODUCT / NEW FORMULATION OF ALTERNATIVE MEDICINES INCLUDING UNANI, TRADITIONAL CHINESE MEDICINE, ETC. EXCLUDING HOMOEOPATHIC MEDICINE**

I/We ..... Owner (s) of M/s ..... hereby apply for registration of following product manufactured by my firm/company located at the Premises .....

**Administrative Information**

| | |
|---|---|
| Name and address of the manufacturer | |
| Licence Number and Date of Grant / Renewal | |
| Approved Sections (Attach copy) | |
| Renewal of Registration No. (in case of renewal application) | |

**Product Profile**

| **Brand Name of Product** | | | | | |
|---|---|---|---|---|---|
| **1** | List of ingredients with strength and monograph | scientific /botanical name of plant Common Name of ingredients | Common name of plant in regional language | Plant part used | Pack size |
| | | | | | |
| **2** | Name under which the product is proposed to be sold. | | | | |
| **3** | Dosage and directions for use. | | | | |
| **4** | Route of administration. | | | | |
| **5** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | | | | |
| **6** | Formulation and evidence of competitor availability in the local or international market | | | | |
| **7** | Safety and efficacy data of proposed product | | | | |
| **8** | Recommended conditions for use. | | | | |
| **8** | Safety category<br>Class;1<br>Class;11<br>class;111 | | | | |

1. Master formula.
2. Manufacturing process.
3. Testing specifications (ingredients and finished product).
4. Shelf life and storage.
5. Recommended conditions/indication for use.
6. Contra-indication.
7. Side effect.
8. Packaging and labelling.
9. Fee deposit receipt (challan number and fee amount).
10. Additional Information (in case of renewal of registration).

**Declaration**

I undertake, certify and confirmed that the contents and all existing data which are relevant to the registration supplied in the dossier, as appropriate, stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper). If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications.

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 17**

*[See rule 16(1)]*

**APPLICATION FOR REGISTRATION / RENEWAL OF GENERIC IMPORTED ALTERNATIVE MEDICINES INCLUDING UNANI, TRADITIONAL CHINESE MEDICINE, ETC. EXCLUDING HOMOEOPATHIC MEDICINE**

I/We ..... Owner (s) of M/s ..... having storage facility at ..... hereby apply for registration/ renewal of registration of following product manufactured by M/s ..... situated at ..... and exported by ..... Country of origin of principal manufacturer .....

**Administrative Information**

| | |
|---|---|
| Name and address of the Importer | |
| Licence Number and Date of issuance/ Renewal | |
| Name and Address of Exporter | |
| Name and Address of Principal Manufacturer | |

**Product Profile**

| **Brand Name of Product** | | | | | |
|---|---|---|---|---|---|
| **1** | List of ingredients with strength and monograph | scientific /botanical name of plant Common Name of ingredients | Common name of plant in regional language | Plant part used | Pack size |
| | | | | | |
| **2** | Name under which the product is proposed to be sold. | | | | |
| **3** | Dosage and Directions for use. | | | | |
| **4** | Route of Administration. | | | | |
| **5** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | | | | |
| **6** | Formulation and evidence of competitor availability in the local or international market | | | | |
| **7** | Safety and Efficacy data of proposed product or usage within local community for minimum 10 years | | | | |
| **8** | Recommended Conditions for use. | | | | |
| **9** | Safety category<br>Class;1 | | | | |

| | | |
|---|---|---|
| | Class;11<br>class;111 | |

1. Master Formula.
2. Manufacturing process.
3. Testing specifications (ingredients and Finished product)
4. Shelf life and storage.
5. Recommended Conditions/indication for use.
6. Contra-indication
7. Side Effect
8. Packaging and labelling.
9. Import documents shall be duly attested, notarized and embassy attested / apostille in the country of origin–
   (a) Free sale certificate in the country of origin and in other countries being marketed (certificate of pharmaceutical product (CPP on WHO Format) as replacement for Free Sale, GMP and Registration or marketing Authorization)
   (b) G.M.P Certificate of Principal Manufacturer by the local regulatory Authority
   (c) Certification with any Organization or Authority.
   (d) Agreement between the importer and principal manufacturer.
   (e) Letter of Authorization for export, If Exporter is other than manufacturer.
   (f) Last inspection report by the local regulatory Authority or body authorized in this behalf by the local regulatory Authority
10. Fee deposit receipt (challan number and fee amount)
11. Additional Information (in case of renewal of registration)

**Declaration**

I undertake, certify and confirmed that the contents and all existing data which are relevant to the registration supplied in the dossier, as appropriate, stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper). If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications.

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 18**

*[See rule 16(1)]*

**APPLICATION FOR REGISTRATION OF IMPORTED NEW PRODUCT/ NEW FORMULATION OF ALTERNATIVE MEDICINES INCLUDING UNANI, TRADITIONAL CHINESE MEDICINE, ETC. EXCLUDING HOMOEOPATHIC MEDICINE**

I/We..... Owner (s) of M/s.....having storage facility at..... hereby apply for registration of following product manufactured by M/s ..... situated at ..... and exported by ..... Country of origin of principal manufacturer .....

**Administrative Information**

| | |
|---|---|
| Name and address of the Importer | |
| Licence Number and Date of issuance/ Renewal | |
| Name and Address of Exporter | |
| Name and Address of Principal Manufacturer | |

**Product Profile**

| | **Brand Name of Product** | | | | |
|---|---|---|---|---|---|
| **1** | List of ingredients with strength and monograph | scientific /botanical name of plant Common Name of ingredients | Common name of plant in regional language | Plant part used | Pack size |
| | | | | | |
| **2** | Name under which the product is proposed to be sold. | | | | |
| **3** | Dosage and directions for use. | | | | |
| **4** | Route of administration. | | | | |
| **5** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | | | | |
| **6** | Formulation and evidence of competitor availability in the local or international market | | | | |
| **7** | Safety and efficacy data of proposed product | | | | |
| **8** | Recommended Conditions for use. | | | | |
| **8** | Safety category<br>Class;1<br>Class;11 | | | | |

| | | |
|---|---|---|
| | class;111 | |

1. Master formula.
2. Manufacturing process.
3. Testing specifications (ingredients and Finished product)
4. Shelf life and storage.
5. Recommended conditions/indication for use.
6. Contra-indication.
7. Side effect.
8. Packaging and labelling.
9. Import documents shall be duly attested, notarized and embassy attested / apostille in the country of origin–
    (a) Free sale certificate in the country of origin and in other countries being marketed (certificate of pharmaceutical product (CPP on WHO Format) as replacement for Free Sale, GMP and Registration or marketing Authorization)
    (b) G.M.P Certificate of Principal Manufacturer by the local regulatory Authority
    (c) Certification with any Organization or Authority.
    (d) Agreement between the importer and principal manufacturer.
    (e) Letter of Authorization for export, If Exporter is other than manufacturer.
    (f) Last inspection report by the local regulatory Authority or body authorized in this behalf by the local regulatory Authority
10. Fee deposit receipt (challan number and fee amount).

**Declaration**

I undertake, certify and confirmed that the contents and all existing data which are relevant to the registration supplied in the dossier, as appropriate, stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper). If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications.

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**GOVERNMENT OF PAKISTAAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**FORM 19**
*[See rule 17(3)]*

**No. F**.....

## CERTIFICATE FOR REGISTRATION OF ALTERNATIVE MEDICINES INCLUDING UNANI, TRADITIONAL CHINESE MEDICINE, ETC EXCLUDING HOMOEOPATHIC MEDICINE

**M/s (complete address)** ..... having Licence Number ..... is herby authorized to manufacture following alternative medicines including *unani*, traditional Chinese medicine, etc excluding homoeopathic medicines which are registered under the Alternative Medicines and Health Products Rules, 2026.

| Registration Number | Products Name and composition (with excipients) | Common Name | Pack Size |
|---|---|---|---|
| | | | |
| | | | |

**Conditions for registration:**

a) The product conforms to all the relevant provisions of the Drug Regulatory Authority of Pakistan Act, 2012 and rules framed thereunder.

b) The product shall be sold as per recommended use.

c) The finished products shall be tested and released before sale by the Quality Control Department of the unit or contract laboratory approved by the Authority.

d) The products shall remain safe, effective and retain its quality during the whole shelf life.

e) The import, manufacture and sale, of alternative medicines and health products shall be in accordance with the information on the basis of which such certificate for registration was granted by the AMHP Board.

f) Every health and OTC product shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

g) The manufacture of any alternative medicines including traditional Chinese medicine excluding homoeopathic medicines shall not, without the prior approval of the AMHP Board, be discontinued for a period which may result in its shortage.

h) The Manufacturer shall supply the information in relation to safety, efficacy, production, quality, or availability of the nutraceutical product, health product, food supplement etc, as and when required by the AMHP Board with a view to ensure safety; efficacy or quality of the alternative medicine and health product.

i) It shall be the responsibility of the manufacturer to report to the AMHP Board within thirty days if an adverse reaction not otherwise included in the application for registration, is registered in any of the reference countries.

j) The product is not contaminated with any type of ingredient not enlisted in the formula approved by the Authority.

k) The product does not contain any prohibited substance or Allopathic or any western ingredient which is not part of approved formulation.

l) The product shall not contain any toxic or dangerous materials which are injurious to health.

m) The content of the heavy metals in the finished product shall be within the prescribed limits as defined in the rules.

n) The manufacturer shall be responsible for immediately withdrawing any health and OTC product at any time, for safety reasons, if the same is withdrawn or banned or certain restrictions are imposed in any of the countries namely, U.S.A. European Union |Countries, Canada, Japan, Australia or any other country identified by the Authority, from the market in Pakistan or, as the case may be to impose similar restriction and to inform the AMHP Board within fourteen days of such an information.

o) If clinical information for an Alternative Medicines excluding homoeopathic medicines is approved in any of the said countries, the same clinical information shall be considered as approved for registration in Pakistan unless modified by the AMHP Board on the basis of scientific data available to it, and such clinical information may include indications, contra-indications, side effects precautions, dosage, etc;

p) The recommended conditions for use shall be permissible only through valid evidence based on standards of evidence as prescribed under the rules.

q) This certificate of registration, shall unless earlier suspended or cancelled, be in force for a period of five years from the date of Registration.

r) Certificate of registration shall be surrendered to the Authority within 15 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

s) Shelf life of alternative medicines including traditional Chinese medicine excluding homoeopathic medicines shall be determined by the AMHP Board

t) Finished alternative medicines including traditional Chinese medicine excluding homoeopathic medicines shall conform to the guidelines described in the specifications monographs prescribed in the relevant category and dosage form.

u) Product registration holder shall be liable to change the brand name, if it resembles with the already registered products.

SECREATARY OR DESIGNATED
OFFICER
Alternate Medicine & Health Products
Board
Drug Regulatory Authority of Pakistan

Dated: _____

**GOVERNMENT OF PAKISTAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**FORM 20**
*[See rule 17(3)]*

**No. F** .....

**CERTIFICATE FOR REGISTRATION OF ALTERNATIVE MEDICINES INCLUDING UNANI, TRADITIONAL CHINESE MEDICINE, ETC EXCLUDING HOMOEOPATHIC MEDICINES**

**M/s (complete address)** ..... having Licence Number ..... is herby authorized to import from M/s ..... manufactured by ..... following alternative medicines including *unani*, traditional Chinese medicine, etc. excluding homoeopathic medicines which are registered under the Alternative Medicines and Health Products Rules, 2026.

| Registration Number | Products Name and composition | Common Name | Pack Size |
|---|---|---|---|
| | | | |
| | | | |

**Conditions for registration:**

a) The product conforms to all the relevant provisions of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI) of 2012 and rules framed thereunder.

b) The product shall be sold as per recommended use.

c) The finished products shall be tested and released before sale by the Quality Control Department of the unit or contract laboratory approved by the Authority.

d) The products shall remain safe, effective and retain its quality during the whole shelf life.

e) The import, manufacture and sale, of alternative medicines and health products shall be in accordance with the information on the basis of which such certificate for registration was granted by the Alternate Medicine & Health Products AMHP Board.

f) Every alternative medicines including traditional Chinese medicine excluding homoeopathic medicines shall be imported in sufficient quantity so as to ensure its regular and adequate supply in the market.

g) The manufacture of any alternative medicines including traditional Chinese medicine excluding homoeopathic medicines shall not, without the prior approval of the AMHP Board, be discontinued for a period which may result in its shortage.

h) The Manufacturer shall supply the information in relation to safety, efficacy, production, quality, or availability of the alternative medicines including traditional Chinese medicine excluding homoeopathic medicines as and when required by the AMHP Board with a view to ensure safety; efficacy or quality of the alternative medicine and health product.

i) It shall be the responsibility of the manufacturer to report to the AMHP Board within thirty days if an adverse reaction not otherwise included in the application for registration, is registered in any of the reference countries.

j) The product is not contaminated with any type of ingredient not enlisted in the formula approved by the Authority.

k) The product does not contain any prohibited substance or Allopathic or any western ingredient which is not part of approved formulation.

l) The product shall not contain any toxic or dangerous materials which are injurious to health.

m) The content of the heavy metals in the finished product shall be within the prescribed limits as defined in the rules.

n) The manufacturer shall be responsible for immediately withdrawing any alternative medicines including traditional Chinese medicine excluding homoeopathic medicines at any time, for safety reasons, if the same is withdrawn or banned or certain restrictions are imposed in any of the countries namely, U.S.A. European Union Countries, Canada, Japan, Australia or any other country identified by the Authority, from the market in Pakistan or, as the case may be to impose similar restriction and to inform the AMHP Board within fourteen days of such an information.

o) If clinical information for an Alternative Medicines excluding homoeopathic medicines is approved in any of the said countries, the same clinical information shall be considered as approved for registration in Pakistan unless modified by the AMHP Board on the basis of scientific data available to it, and such clinical information may include indications, contra-indications, side effects precautions, dosage, etc;

p) The recommended conditions for use shall be permissible only through valid evidence based on standards of evidence as prescribed under the rules.

q) This certificate of registration, shall unless earlier suspended or cancelled, be in force for a period of five years from the date of Registration.

r) Certificate of registration shall be surrendered to the Authority within 15 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

s) Shelf life of alternative medicines including traditional Chinese medicine excluding homoeopathic medicines shall be determined by the AMHP Board

t) Finished alternative medicines including traditional Chinese medicine excluding homoeopathic medicines shall conform to the guidelines described in the specifications monographs prescribed in the relevant category and dosage form.

u) Product registration holder shall be liable to change the brand name, if it resembles with the already registered products.

SECREATARY / DESIGNATED
OFFICER
Alternate Medicine & Health Products
Board
Drug Regulatory Authority of Pakistan

Dated: _____

**FORM 21**

*[See rule 19(2)]*

**WARRANTY**

Invoice No ..... Dated .....
to M/s ..... situated at .....
It is certified that I, ..... S/o .....
of M/s ..... having CNIC No.....
being manufacturer or importer or (authorized agent *vide* authority letter No.....
dated ..... on behalf of M/s .....

1. It is hereby certified that following finished products have been supplied by me, namely:-

| **S. No.** | | | **Detail of health product sold** | | | | |
|---|---|---|---|---|---|---|---|
| | **Name of product and pack size** | **Batch number (or lot No.)** | **Mfg. date** | **Expiry date** | **No. of units sold** | **Distribution price** | **Retail price** |
| | | | | | | | |

**Grant total** .....

2. It is hereby certified and I undertake that above mentioned finished products of specified batch number (or lot number) supplied by me do not contravene any provision of the DRAP Act, 2012 and rules framed there under. The authorized agent (with valid distribution authority letter) shall pass on this warranty to the retailers in his area of jurisdiction during the supply health products.

a.....
b.....

Date.....
Signature.....
Place ..... Qualified person Name.....
Designation.....
Seal of manufacture or /importer

**FORM 22**

*[See rule 20(1)]*

**APPLICATION FOR REGISTRATION / RENEWAL OF LOCALLY MANUFACTURED GENERIC HOMOEOPATHIC MEDICINE**

I/We ..... Owner (s) of M/s ..... hereby apply for registration/ renewal of registration of following product manufactured by my firm/company located at the premises .....

**Administrative Information**

| | |
|---|---|
| Name and address of the manufacturer | |
| Licence Number and Date of Grant / Renewal | |
| Approved Sections (Attach copy) | |
| Renewal of Registration No. (in case of renewal application) | |

**Product Profile**

| **Brand Name of Product** | | | | | |
|---|---|---|---|---|---|
| **1** | List of ingredients with strength and monograph | Scientific /botanical name of plant Common Name of ingredients | Common name of plant in regional language | Plant part used | Pack size |
| | | | | | |
| **2** | Name under which the product is proposed to be sold. | | | | |
| **3** | Dosage and directions for use. | | | | |
| **4** | Route of administration. | | | | |
| **5** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | | | | |
| **6** | Formulation and evidence of competitor availability in the local or international market. | | | | |
| **7** | Safety and efficacy data of proposed product or usage within local community for minimum 10 years. | | | | |
| **8** | Recommended conditions for use. | | | | |
| **9** | Safety category<br>Class;1<br>Class;11<br>class;111 | | | | |

1. Master Formula.
2. Manufacturing process.
3. Testing specifications (ingredients and finished product).
4. Shelf life and storage.
5. Recommended conditions/indication for use.
6. Contra-indication.
7. Side effect.
8. Packaging and labelling.
9. Fee deposit receipt (challan number and fee amount).
10. Additional Information (in case of renewal of registration).

**Declaration**

I undertake, certify and confirmed that the contents and all existing data which are relevant to the registration supplied in the dossier, as appropriate, stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper). If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications.

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 23**

*[See rule 20(1)]*

**APPLICATION FOR REGISTRATION OF LOCALLY MANUFACTURED NEW PRODUCT/ NEW FORMULATION OF HOMOEOPATHIC MEDICINE**

(Attach readable soft copy with application)

I/We ..... Owner (s) of M/s ..... hereby apply for registration of following product manufactured by my firm/company located at the premises .....

**Administrative Information**

| | |
|---|---|
| Name and address of the manufacturer | |
| Licence Number and Date of Grant / Renewal | |
| Approved Sections (Attach copy) | |
| Renewal of Registration No. (in case of renewal application) | |

**Product Profile**

| **Brand Name of Product** | | | | | |
|---|---|---|---|---|---|
| **1** | List of ingredients with strength and monograph | Scientific /botanical name of plant Common Name of ingredients | Common name of plant in regional language | Plant part used | Pack size |
| | | | | | |
| **2** | Name under which the product is proposed to be sold. | | | | |
| **3** | Dosage and Directions for use. | | | | |
| **4** | Route of Administration. | | | | |
| **5** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | | | | |
| **6** | Formulation and evidence of competitor availability in the local or international market | | | | |
| **7** | Safety and Efficacy data of proposed product | | | | |
| **8** | Recommended Conditions for use. | | | | |
| **8** | Safety category<br>Class;1<br>Class;11<br>class;111 | | | | |

1. Master Formula.
2. Manufacturing process.
3. Testing specifications (ingredients and finished product).
4. Shelf life and storage.
5. Recommended conditions/indication for use.
6. Contra-indication.
7. Side effect.
8. Packaging and labelling.
9. Fee deposit receipt (challan number and fee amount).
10. Additional Information (in case of renewal of registration).

**Declaration**

I undertake, certify and confirmed that the contents and all existing data which are relevant to the registration supplied in the dossier, as appropriate, stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper). If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications.

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 24**

*[See rule 20(I)]*

**APPLICATION FOR REGISTRATION/ RENEWAL OF GENERIC IMPORTED HOMOEOPATHIC MEDICINE**

(Attach readable soft copy with application)

I/We ..... Owner (s) of M/s .....having storage facility at ..... hereby apply for registration/ renewal of registration of following product manufactured by M/s ..... situated at ..... and exported by ..... Country of origin of principal manufacturer .....

**Administrative Information**

| | |
|---|---|
| Name and address of the Importer | |
| Licence Number and Date of issuance/ Renewal | |
| Name and Address of Exporter | |
| Name and Address of Principal Manufacturer | |

**Product Profile**

| | **Brand Name of Product** | | | | |
|---|---|---|---|---|---|
| **1** | List of ingredients with strength and monograph | scientific /botanical name of plant Common Name of ingredients | Common name of plant in regional language | Plant part used | Pack size |
| | | | | | |
| **2** | Name under which the product is proposed to be sold. | | | | |
| **3** | Dosage and directions for use. | | | | |
| **4** | Route of administration. | | | | |
| **5** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | | | | |
| **6** | Formulation and evidence of competitor availability in the local or international market | | | | |
| **7** | Safety and Efficacy data of proposed product or usage within local community for minimum 10 years | | | | |
| **8** | Recommended conditions for use. | | | | |
| **9** | Safety category<br>Class;1 | | | | |

| | | |
|---|---|---|
| | Class;11<br>class;111 | |

1. Master Formula.
2. Manufacturing process.
3. Testing specifications (ingredients and finished product)
4. Shelf life and storage.
5. Recommended conditions/indication for use.
6. Contra-indication
7. Side Effect
8. Packaging and labelling.
9. Import documents shall be duly attested, notarized and embassy attested / apostille in the country of origin–
    (a) Free sale certificate in the country of origin and in other countries being marketed (certificate of pharmaceutical product (CPP on WHO Format) as replacement for Free Sale, GMP and Registration or marketing Authorization)
    (b) G.M.P Certificate of Principal Manufacturer by the local regulatory Authority
    (c) Certification with any Organization or Authority.
    (d) Agreement between the importer and principal manufacturer.
    (e) Letter of Authorization for export, If Exporter is other than manufacturer.
    (f) Last inspection report by the local regulatory Authority or body authorized in this behalf by the local regulatory Authority
10. Fee deposit receipt (challan number and fee amount)
11. Additional Information (in case of renewal of registration)

**Declaration**

I undertake, certify and confirmed that the contents and all existing data which are relevant to the registration supplied in the dossier, as appropriate, stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper). If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications.

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 25**

*[See rule 20(1)]*

**APPLICATION FOR REGISTRATION OF IMPORTED NEW PRODUCT/ NEW FORMULATION OF HOMOEOPATHIC MEDICINE**

(Attach readable soft copy with application)

I/We ..... Owner (s) of M/s ..... having storage facility at ..... hereby apply for registration of following product manufactured by M/s ..... situated at ..... and exported by ..... Country of origin of principal manufacturer .....

**Administrative Information**

| | |
|---|---|
| Name and address of the Importer | |
| Licence Number and Date of issuance/ Renewal | |
| Name and Address of Exporter | |
| Name and Address of Principal Manufacturer | |

**Product Profile**

| **Brand Name of Product** | | | | | |
|---|---|---|---|---|---|
| **1** | List of ingredients With strength and monograph | scientific /botanical name of plant Common Name of ingredients | Common name of plant in regional language | Plant part used | Pack size |
| | | | | | |
| **2** | Name under which the product is proposed to be sold. | | | | |
| **3** | Dosage and Directions for use. | | | | |
| **4** | Route of Administration. | | | | |
| **5** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | | | | |
| **6** | Formulation and evidence of competitor availability in the local or international market | | | | |
| **7** | Safety and Efficacy data of proposed product | | | | |
| **8** | Recommended Conditions for use | | | | |
| **9** | Safety category<br>Class;1<br>Class;11 | | | | |

| | | |
|---|---|---|
| | class;111 | |

1. Master Formula.
2. Manufacturing process.
3. Testing specifications (ingredients and finished product)
4. Shelf life and storage.
5. Recommended conditions/indication for use.
6. Contra-indication
7. Side Effect
8. Packaging and labelling.
9. Import documents shall be duly attested, notarized and embassy attested / apostille in the country of origin–
   (a) Free sale certificate in the country of origin and in other countries being marketed (certificate of pharmaceutical product (CPP on WHO Format) as replacement for Free Sale, GMP and Registration or marketing Authorization)
   (b) G.M.P. Certificate of Principal Manufacturer by the local regulatory Authority
   (c) Certification with any Organization or Authority.
   (d) Agreement between the importer and principal manufacturer.
   (e) Letter of Authorization for export, If Exporter is other than manufacturer.
   (f) Last inspection report by the local regulatory Authority or body authorized in this behalf by the local regulatory Authority
10. Fee deposit receipt. (Challan number and fee amount)

**Declaration**

I undertake, certify and confirmed that the contents and all existing data which are relevant to the registration supplied in the dossier, as appropriate, stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper). If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications.

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**GOVERNMENT OF PAKISTAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**FORM 26**
*[See rule 21(4)]*

**No. F**.....

**CERTIFICATE FOR REGISTRATION OF HOMOEOPATHIC MEDICINES LOCAL**

**M/s (complete address)** ..... having Licence Number ..... is hereby authorized to manufacture following homoeopathic medicines which are registered under the Alternative Medicines and Health Products Rules, 2026.

| Registration Number | Products Name and composition (with excipients) | Common Name | Pack Size |
|---|---|---|---|
| | | | |
| | | | |

**Conditions for registration:**

(a) The product conforms to all the relevant provisions of the Drug Regulatory Authority of Pakistan Act, 2012 and rules framed thereunder.

(b) The product shall be sold as per recommended use.

(c) The finished products shall be tested and released before sale by the Quality Control Department of the unit or contract laboratory approved by the Authority.

(d) The products shall remain safe, effective and retain its quality during the whole shelf life.

(e) The import, manufacture and sale, of homoeopathic medicines shall be in accordance with the information on the basis of which such certificate for registration was granted by the Alternate Medicine & Health Products AMHP Board.

(f) Every health and OTC product shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

(g) The manufacture of any homoeopathic medicines shall not, without the prior approval of the AMHP Board, be discontinued for a period which may result in its shortage.

(h) The Manufacturer shall supply the information in relation to safety, efficacy, production, quality, or availability of the nutraceutical product, health product, food supplement etc, as and when required by the AMHP Board with a view to ensure safety; efficacy or quality of the homoeopathic medicine.

(i) It shall be the responsibility of the manufacturer to report to the AMHP Board within thirty days if an adverse reaction not otherwise included in the application for registration, is registered in any of the reference countries.

(j) The product is not contaminated with any type of ingredient not enlisted in the formula approved by the Authority.

(k) The product does not contain any prohibited substance or Allopathic or any western ingredient which is not part of approved formulation.

(l) The product shall not contain any toxic or dangerous materials which are injurious to health.

(m) The content of the heavy metals in the finished product shall be within the prescribed limits as defined in the rules.

(n) The manufacturer shall be responsible for immediately withdrawing any health and OTC product at any time, for safety reasons, if the same is withdrawn or banned or certain restrictions are imposed in any of the countries namely, U.S.A. European Union |Countries, Canada, Japan, Australia or any other country identified by the Authority, from the market in Pakistan or, as the case may be to impose similar restriction and to inform the AMHP Board

(o) within fourteen days of such an information.

(p) If clinical information for an homoeopathic medicines is approved in any of the said countries, the same clinical information shall be considered as approved for registration in Pakistan unless modified by the AMHP Board on the basis of scientific data available to it, and such clinical information may include indications, contra-indications, side effects precautions, dosage, etc;

(q) The recommended conditions for use shall be permissible only through valid evidence based on standards of evidence as prescribed under the rules.

(r) This certificate of registration, shall unless earlier suspended or cancelled, be in force for a period of five years from the date of Registration.

(s) Certificate of registration shall be surrendered to the Authority within 15 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

(t) Shelf life of homoeopathic medicines shall be determined by the AMHP Board

(u) Finished homoeopathic medicines shall conform to the guidelines described in the specifications monographs prescribed in the relevant category and dosage form.

(v) Product registration holder shall be liable to change the brand name, if it resembles with

the already registered products.

SECREATARY OR DESIGNATED
OFFICER
Alternate Medicine & Health Products
Board
Drug Regulatory Authority of Pakistan

Dated: _____

**GOVERNMENT OF PAKISTAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**FORM 27**
*[See rule 21(4)]*

**No. F.** .....

## CERTIFICATE FOR REGISTRATION OF HOMOEOPATHIC MEDICINES FOR IMPORT

**M/s (complete address)** ..... having Licence Number ..... is hereby authorized to import from M/s ..... manufactured by ..... following homoeopathic medicines which are registered under the Alternative Medicines and Health Products Rules, 2026.

| Registration Number | Products Name and composition | Common Name | Pack Size |
|---|---|---|---|
| | | | |
| | | | |

**Conditions for registration:**

(a) The product conforms to all the relevant provisions of the Drug Regulatory Authority of Pakistan Act, 2012 and rules framed thereunder.

(b) The product shall be sold as per recommended use.

(c) The finished products shall be tested and released before sale by the Quality Control Department of the unit or contract laboratory approved by the Authority.

(d) The products shall remain safe, effective and retain its quality during the whole shelf life.

(e) The import, manufacture and sale, of homoeopathic medicines shall be in accordance with the information on the basis of which such certificate for registration was granted by the AMHP Board.

(f) Every homoeopathic medicine shall be imported in sufficient quantity so as to ensure its regular and adequate supply in the market.

(g) The manufacture of any homoeopathic medicines shall not, without the prior approval of the AMHP Board, be discontinued for a period which may result in its shortage.

(h) The Manufacturer shall supply the information in relation to safety, efficacy, production, quality, or availability of the homoeopathic medicines as and when required by the AMHP Board with a view to ensure safety; efficacy or quality of the homoeopathic medicine.

(i) It shall be the responsibility of the manufacturer to report to the AMHP Board within thirty days if an adverse reaction not otherwise included in the application for registration, is registered in any of the reference countries.

(j) The product is not contaminated with any type of ingredient not enlisted in the formula approved by the Authority.

(k) The product does not contain any prohibited substance or Allopathic or any western ingredient which is not part of approved formulation.

(l) The product shall not contain any toxic or dangerous materials which are injurious to health.

(m) The content of the heavy metals in the finished product shall be within the prescribed limits as defined in the rules.

(n) The manufacturer shall be responsible for immediately withdrawing any homoeopathic medicines at any time, for safety reasons, if the same is withdrawn or banned or certain restrictions are imposed in any of the countries namely, U.S.A. European Union |Countries, Canada, Japan, Australia or any other country identified by the Authority, from the market in Pakistan or, as the case may be to impose similar restriction and to inform the AMHP Board within fourteen days of such an information.

(o) If clinical information for an homoeopathic medicines is approved in any of the said countries, the same clinical information shall be considered as approved for registration in Pakistan unless modified by the AMHP Board on the basis of scientific data available to it, and such clinical information may include indications, contra-indications, side effects precautions, dosage, etc;

(p) The recommended conditions for use shall be permissible only through valid evidence based on standards of evidence as prescribed under the rules.

(q) This certificate of registration, shall unless earlier suspended or cancelled, be in force for a period of five years from the date of Registration.

(r) Certificate of registration shall be surrendered to the Authority within 15 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

(s) Shelf life of homoeopathic medicines shall be determined by the AMHP Board.

(t) Finished homoeopathic medicines shall conform to the guidelines described in the specifications monographs prescribed in the relevant category and dosage form.

(u) Product registration holder shall be liable to change the brand name, if it resembles with the already registered products.

SECREATARY / DESIGNATED
OFFICER
Alternate Medicine & Health Products
Board
Drug Regulatory Authority of Pakistan

Dated: _____

**FORM 28**

*[See rule 23(2)]*

**WARRANTY OF HOMOEOPATHIC PRODUCTS (LOCAL / IMPORT)**

Invoice No. ..... Dated .....
to M/s ..... situated at .....
It is certified that I Mr. ..... S/o .....
of M/s ..... having CNIC No. .....
being manufacturer or importer or (authorized agent *vide* authority letter No. ..... dated ..... on behalf of M/s .....)

1. It is hereby certified that following finished products have been supplied by me, namely:-

| **S. No.** | **Detail of homoeopathic product sold.** | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Name of product and pack size** | **Batch number (or lot No.)** | **Mfg. date** | **Expiry date** | **No. of units sold** | **Distribution price** | **Retail price** |
| | | | | | | | |

**Grant total** .....

2. It is hereby certified and I undertake that above mentioned finished products of specified batch number (or lot number) supplied by me do not contravene any provision of the DRAP Act, 2012 and rules framed there under. The authorized agent (with valid distribution authority letter) shall pass on this warranty to the retailers in his area of jurisdiction during the supply health products.

a.....
b.....

Date.....
Signature.....
Place ..... Qualified person Name.....
Designation.....

Seal of manufacture or /importer

**FORM 29**

*[See rule 24(1)]*

**APPLICATION FOR GRANT AND RENEWAL OF THE REGISTRATION OF BULK EXTRACT, HOMOEOPATHIC TINCTURE OR ISOLATE**

I/We..... Owner (s) of M/s.....hereby apply for registration of following product manufactured by my firm/ company located at the premises .....

**Administrative Information**

| | |
|---|---|
| Name and address of the manufacturer | |
| Licence Number and Date of Grant / Renewal | |
| Approved Sections (Attach copy) | |
| Renewal of Registration No. (in case of renewal application) | |

| Sr. No. | Description |
|---|---|
| **1.** | **Purpose of application, whether;** |
| (i) | Fresh / New Application |
| (ii) | For renewal of registration of Bulk Extract, Homoeopathic Tincture or Isolate |
| | (i) Registration number and date of issue: |
| | (ii) Validity date: |
| | (iii) Last renewal date and its validity: |
| | (iv) Attach certificate of registration and last renewal: |
| (iii) | Proposed change of any particular of a registered Bulk Extract, Homoeopathic Tincture or Isolate |
| **2.** | Details of products intended to be manufactured<br>• Name of the product(s)<br>• Batch Size<br>• Product category [e.g., Alternative Medicines *(Herbal, Unani, Ayurvedic, Homoeopathic, Chinese, etc.)* & Health Products *(Vitamins, Minerals, Extracts, etc.)*].<br>• List of all ingredients present in the product, including other active substances, heavy metals, residual solvents etc.<br>• Specifications for the purity and quality of ingredients.<br>• Information on the source of ingredients (e.g., plant-based etc.).<br>• Scientific data on the safety of each ingredient, including any potential risks associated with their use.<br>• Information on the safety assessment process, which may include toxicological studies, exposure assessments, and potential interactions. |
| **3.** | Master Formula. |
| **4.** | Manufacturing process.<br>(a) Names and quantities of chemicals to be used in manufacturing.<br>(b) Names and quantities of chemicals to recycled in manufacturing.<br>(c) Manufacturing process steps and flow chart.<br>(d) Theoretical yield of manufacturing process. |

| | |
|---|---|
| **5.** | Testing specifications (starting materials and final product). |
| **6.** | Trial batches record and stability data along with validation (if available) |
| **7.** | Reference monograph and Testing method |
| **8.** | List of Testing equipment |
| **9.** | Shelf life and storage. |
| **10.** | Stability Summary<br>(a)The shelf life for all the pack types shall be supported by stability data. Information shall also include shelf life before first opening, after reconstitution and/or after opening where applicable. Stability data to support such shelf life shall be available.<br>(b)Evidence is required to demonstrate that the product is stable (meets the finished product shelf-life specifications throughout its proposed shelf-life in the specified container closure system).<br>(c) Type of container/package, with the nature of material, package testing (chemical, mechanical, environmental). |
| **11.** | Labelling: Specimen or draft with colour scheme shall also be submitted. |
| **12.** | Packaging and pack Size. |
| **13.** | Template of BMR of Commercial Batch. |
| **14.** | Fee deposit receipt. |
| **15.** | Any other relevant information that may be required by the AMHP Board. |

## DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided.

I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper).

Name of the owner
Signature
Seal of the Firm/ Company
Dated.....

**GOVERNMENT OF PAKISTAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**FORM 30**
*[See rule 24(4)]*

**No. F.** .....

## CERTIFICATE FOR REGISTRATION OF BULK EXTRACT, HOMOEOPATHIC TINCTURE OR ISOLATE

Following Bulk Extract, Homoeopathic Tincture or Isolate of **M/s**.....
**Licence Number** ..... are registered to be manufactured at the premises located at .....

| Registration Number | Products Name and composition | Pack Size | Shelf life |
|---|---|---|---|
| | | | |
| | | | "-" |
| | | | "-" |

**Conditions for Registration:**

(a) The product shall not contain any toxic or dangerous materials which are injurious to health.

(b) The finished products shall be tested and released before sale by the Quality Control Department of the unit or contract laboratory approved by the Authority.

(c) The products shall remain safe, effective and retain its quality during the whole shelf life.

(d) The product conforms to all the relevant provisions of the Drug Regulatory Authority of Pakistan Act, 2012.

(e) The product is not contaminated with any type of ingredient not enlisted in the formula approved by the Authority.

(f) The product does not contain any prohibited substance or Allopathic or any western ingredient which is not part of approved formulation.

(g) The product(s) shall be tested for microbial contamination, and it is verified that these products do not contain any type of pathogenic microbial contamination. Provided that

disinfectants and homoeopathic medicines containing 50% or above concentration of ethanol shall be exempted from such microbial testing.

(h) The content of the heavy metals in the finished product shall be within the prescribed limits.

(i) The manufacture and sale, of Bulk Extract, Homoeopathic Tincture or Isolate shall be in accordance with the information on the basis of which such certificate for registration was granted by the AMHP Board.

(j) Every Bulk Extract, Homoeopathic Tincture or Isolate manufacturing shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

(k) The manufacture of Bulk Extract, Homoeopathic Tincture or Isolate shall not be discontinued for a period which may result in its shortage.

(l) The Manufacturer shall supply the information in relation to safety, efficacy, production, quality, or availability of the Bulk Extract, Homoeopathic Tincture or Isolate as and when required by the AMHP Board with a view to ensure safety; efficacy or quality of the nutraceutical product, health product, food supplement etc.

(m) It shall be the responsibility of the manufacturer to report to the AMHP Board within thirty days if an adverse reaction not otherwise included in the application for registration, is registered in any of the reference countries.

(n) This certificate of registration, shall unless earlier suspended or cancelled, be in force for a period of **five years** from the date of Registration of the nutraceutical product, health product, food supplement etc.

(o) Certificate of registration shall be surrendered to the Authority within 7 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

SECRETARY
Division of Health & OTC
Drug Regulatory Authority of Pakistan

Dated:

**FORM 31**

*[See rule 27(1)(a)]*

**APPLICATION FOR CONTRACT MANUFACTURING OF ALTERNATIVE MEDICINES OR HEALTH PRODUCTS BY THE CONTRACT GIVER FOR CARRYING OUT CONTRACT MANUFACTURING**

I, ..... (MD / Chief executive / Proprietor) of M/s ..... hereby apply for grant / renewal of contract manufacturing as a contract giver located at (Address of the premises) ..... I do herby attach following documents:

| S. No. | Description | Document | Attachment |
|---|---|---|---|
| 1 | Fee deposit bank receipt for grant / renewal of licence | Original receipt | |
| 2 | Mention type(s) of licence to manufacture alternative medicines and health products intended to be manufactured by the applicant: | Licence to manufacture by way of formulation; | |
| | | For renewal of manufacturer licence to alternative medicine and health products | |
| | | Licence number and date of issue: | |
| | | Validity date: | |
| | | Last renewal date and its validity: | |
| | | Attach certificate of licence and last renewal: | |
| 3 | Details of Contract Giver | Licence No. | |
| | | Approved Sections: | |
| 4 | Manufacturing premises details of Contract Acceptor | Site Master File | |
| 5 | | Copy of approved layout plan. | |
| 6 | | List of Approved Sections | |
| 7 | | Details of section wise equipment and machinery for manufacturing and instruments for quality control: | |
| 8 | Detail of Qualified Person for Production Contract Acceptor | | |
| | | | |
| | | | |
| | | | |
| 9 | Detail of Qualified Person for Quality Control Contract Acceptor | | |
| | | | |
| | | | |
| | | | |
| 10 | Detail of other qualified persons with name, qualification and designations appointed by Contract Acceptor. | | |

| | | |
|---|---|---|
| 11 | Contract Manufacturing Agreement on stamp paper with the contract acceptor duly signed and notarized **(Original)** | |
| 12 | **DECLARATION ON AFFIDAVIT**<br>Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided. | |
| 13 | **UNDERTAKING ON AFFIDAVIT**<br>affidavit binding of the partners/proprietors/Directors and qualified persons, duly verified to the effect that they:—<br>(i) shall comply with the provisions of DRAP Act, 2012 and the rules made there under,<br>(ii) have not been convicted of any offence from any court of law.<br>(iii) shall inform AMHP Board and the inspector as soon as possible when either of the party ceases to have interest in the licence issued under these rules<br>(iv) shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any alternative medicines and health products in violation of the DRAP Act, 2012 and the rules made there under.<br>(v) the contents stated above are correct and true to the best of my knowledge. | |
| 14 | Name, CNIC and Signatures of all Director /Partners / Sole Proprietor of Contact Giver and Acceptor | |

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**FORM 32**

*[See rule 27(1)(b)]*

**APPLICATION FOR REGISTRATION OF ALTERNATIVE MEDICINES OR HEALTH PRODUCTS PRODUCT BY CONTRACT MANUFACTURING**

I/We..... Owner (s) of
M/s (Contract Giver complete address) .....
hereby apply for registration/ Renewal of Registration of following product manufactured by M/s (Contract Acceptor complete address) .....

**Administrative Information**

| | |
|---|---|
| Name and address of the manufacturer | |
| Licence Number and Date of Grant / Renewal | |
| Approved Sections (Attach copy) | |
| Renewal of Registration No. (in case of renewal application) | |

**Product Profile**

| **Brand Name of Product** | | | | | |
|---|---|---|---|---|---|
| **1** | List of ingredients With strength and monograph | scientific /botanical name of plant Common Name of ingredients | Common name of plant in regional language | Plant part used | Pack size |
| | | | | | |
| **2** | Name under which the product is proposed to be sold. | | | | |
| **3** | Dosage and Directions for use. | | | | |
| **4** | Route of Administration. | | | | |
| **5** | Proposed dosage:<br>(a) for adults. (b) children by age group. (c) infant (d) special groups. | | | | |
| **6** | Formulation and evidence of competitor availability in the local or international market | | | | |
| **7** | Safety and Efficacy data of proposed product or usage within local community for minimum 10 years | | | | |
| **8** | Recommended conditions for use. | | | | |
| **9** | Safety category<br>Class;1<br>Class;11 | | | | |

| | | |
|---|---|---|
| | Class;111 | |

1. Master Formula.
2. Manufacturing process.
3. Testing specifications (ingredients and Finished product)
4. Shelf life and storage.
5. Recommended conditions/indication for use.
6. Contra-indication
7. Side Effect
8. Packaging and labelling.
9. Fee deposit receipt (Challan number and fee amount)
10. Additional Information (in case of renewal of registration)

**RENEWAL OF REGISTRATION**

**NAME AND REGISTRATION NUMBER:**

| |
|---|
| |

**Declaration**

I undertake, certify and confirm that the contents and all existing data which are relevant to the registration supplied in the dossier, as appropriate, stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper). If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications.

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

**GOVERNMENT OF PAKISTAN**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**DIVISION OF HEALTH AND OTC PRODUCTS**

**FORM 33**
*[See rule 27(1)(c)]*

**No. F.** .....

## CERTIFICATE FOR CONTRACT MANUFACTURING OF ALTERNATIVE MEDICINES OR HEALTH PRODUCTS

**M/s (complete address)** ..... having Licence Number ..... is hereby authorized to manufacture following alternative medicines which are registered under the Alternative Medicines and Health Products Rules, 2026 for M/s..... on contract.

| Registration Number | Products Name and Composition (with excipients) | Common Name | Pack Size |
|---|---|---|---|
| | | | |
| | | | |

**Conditions for registration:**

(a) The product conforms to all the relevant provisions of the Drug Regulatory Authority of Pakistan Act, 2012 and rules framed thereunder.

(b) The product shall be sold as per recommended use.

(c) The finished products shall be tested and released before sale by the Quality Control Department of the unit or contract laboratory approved by the Authority.

(d) The products shall remain safe, effective and retain its quality during the whole shelf life.

(e) The import, manufacture and sale, of alternative medicines and health products shall be in accordance with the information on the basis of which such certificate for registration was granted by the AMHP Board.

(f) Every health and OTC product shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

(g) The manufacture of any alternative medicines including traditional Chinese medicine excluding homoeopathic medicines shall not, without the prior approval of the AMHP Board, be discontinued for a period which may result in its shortage.

(h) The Manufacturer shall supply the information in relation to safety, efficacy, production, quality, or availability of the nutraceutical product, health product, food supplement etc, as and when required by the AMHP Board with a view to ensure safety;

efficacy or quality of the alternative medicine and health product.

(i) It shall be the responsibility of the manufacturer to report to the AMHP Board within thirty days if an adverse reaction not otherwise included in the application for registration, is registered in any of the reference countries.

(j) The product is not contaminated with any type of ingredient not enlisted in the formula approved by the Authority.

(k) The product does not contain any prohibited substance or allopathic or any western ingredient which is not part of approved formulation.

(l) The product shall not contain any toxic or dangerous materials which are injurious to health.

(m) The content of the heavy metals in the finished product shall be within the prescribed limits as defined in the rules.

(n) The manufacturer shall be responsible for immediately withdrawing any health and OTC product at any time, for safety reasons, if the same is withdrawn or banned or certain restrictions are imposed in any of the countries namely, U.S.A. European Union |Countries, Canada, Japan, Australia or any other country identified by the Authority, from the market in Pakistan or, as the case may be to impose similar restriction and to inform the AMHP Board within fourteen days of such an information.

(o) If clinical information for an Alternative Medicines excluding homoeopathic medicines is approved in any of the said countries, the same clinical information shall be considered as approved for registration in Pakistan unless modified by the AMHP Board on the basis of scientific data available to it, and such clinical information may include indications, contra-indications, side effects precautions, dosage, etc;

(p) The recommended conditions for use shall be permissible only through valid evidence based on standards of evidence as prescribed under the rules.

(q) This certificate of registration, shall unless earlier suspended or cancelled, be in force for a period of five years from the date of Registration.

(r) Certificate of registration shall be surrendered to the Authority within 15 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

(s) Shelf life of alternative medicines including traditional Chinese medicine excluding homoeopathic medicines shall be determined by the AMHP Board

(t) Finished alternative medicines including traditional Chinese medicine excluding homoeopathic medicines shall conform to the guidelines described in the specifications monographs prescribed in the relevant category and dosage form.

(u) Product registration holder shall be liable to change the brand name, if it resembles with the already registered products.

SECREATARY OR DESIGNATED
OFFICER
Alternate Medicine & Health Products
Board
Drug Regulatory Authority of Pakistan

Dated: _____

**FORM 34**

*[See rule 34]*

**POST LICENCE AND POST REGISTRATION VARIATION**

I, ..... (MD / Chief executive / Proprietor) of M/s ..... hereby apply for change of title / management of firm/ company located at (Address of the premises) ..... I do herby attach following documents:

| S. No. | Description | Document | Attachment |
|---|---|---|---|
| 1 | Fee deposit bank receipt for site verification | Original receipt | |
| 2 | Existing Legal Status and title of the Establishment | | |
| | (a) Sole proprietorship concern | i. Copy of CNIC | |
| | | ii. Certified true copies of NTN and Online FBR Certificate mentioning business activity as manufacturer of alternative medicines and/or health products; | |
| | | iii. Undertaking on notarized stamp paper declaring the applicant is a sole proprietor; | |
| | (b) Firm | i. Certified true copies of Certificate by Registrar of Firms, | |
| | | ii. Certified true copy of Partnership Deed, | |
| | | iii. NTN, Online FBR Certificate mentioning business activity as manufacturer of alternative medicines and/or health products; | |
| | | iii. copies of CNICs | |
| | | iv. Name and Signature of Partner (s) | (Signature) |
| | | | (Signature) |
| | | | (Signature) |
| | | | |
| | (C) Company | i. Certified true copies of incorporation certificate (Form II) alongwith Article of Association; Memorandum of Association; | |
| | | ii. copies of CNICs of CEO; Directors | |
| | | iii. Name and Signature of MD/ CEO and Director(s) | (Signature) |
| | | | (Signature) |

| | | | |
|---|---|---|---|
| 3 | **New Legal Status and title of the Establishment** | | |
| | (a) Sole proprietorship concern | i. Copy of CNIC | |
| | | ii. Certified true copies of NTN and Online FBR Certificate mentioning business activity as manufacturer of alternative medicines and/or health products; | |
| | | iii. Undertaking on notarized stamp paper declaring the applicant is a sole proprietor; | |
| | (b) Firm | i. Certified true copies of Certificate by Registrar of Firms, | |
| | | ii. Certified true copy of Partnership Deed, | |
| | | iii. NTN, Online FBR Certificate mentioning business activity as manufacturer of alternative medicines and/or health products; | |
| | | iii. copies of CNICs | |
| | | iv. Name and Signature of Partner (s) | (Signature) |
| | | | (Signature) |
| | | | (Signature) |
| | | | |
| | (C) Company | i. Certified true copies of incorporation certificate (Form II) along with Article of Association; Memorandum of Association; | |
| | | ii. copies of CNICs of CEO; Directors | |
| | | iii. Name and Signature of MD/ CEO and Director(s) | (Signature) |
| | | | (Signature) |
| 4 | Post Registration Variation | | |
| | Existing name and Composition | Proposed correction | |
| | | | |
| 5 | Undertaking | i. Undertaking on notarized stamp paper, about the feasibility that the premises is situated in an environment that, when considered together with measures to protect the manufacturing processes, presents minimum risk of causing any contamination of materials or products. It shall be away from filthy surroundings and shall not be adjacent to an open sewerage, drain, public | |

| | | | |
|---|---|---|---|
| | | lavatory or any factory which produces a disagreeable or obnoxious odour or fumes or large quantities of soot, dust or smoke which may contaminate the alternative medicines or health products being manufactured or adversely affect their quality | |
| | | ii. I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper). | |

(Name of the signatory)
Seal of the Firm / Company
Dated: _____

To,

The Director (H&OTC)
Drug Regulatory Authority of Pakistan,
Islamabad.

[No. F.13-8/2025-LA]

**AAMAR LATIF,**
*Director (Legal Affairs).*

**The Manager,**
Printing Corporation of Pakistan Press,
Islamabad.