CHECKLIST FOR INSPECTION OF MANUFACTURING UNITS OF ALTERNATIVE MEDICINES AND HEALTH PRODUCTS

1. Date of Inspection…….

2. Name of Manufacturing Unit…….

3. Complete Address……..……

4. Name of Managing Director ……..……..

5. Name of Proprietor (s) / Partner (s) ……..

6. Tel. No. ……... Fax No. ……..Cell No. …..……...

   Email ……. Website ……..

7. Category of products intended to be manufactured :

   (a) Alternative Medicines (Specify whether Homoeopathic / Biochemic or Unani / Herbal

   (b) Health Products (Specify whether Food Supplements / Nutritional Products / Baby Milk and Food & / or Medicated Cosmetics)

8. Technical Personnel :

   (a) Name of Production In charge with qualification and experience ……..

   .…….

   (b) Names, designation, qualification and experience of other technical personnel in production ……...……

   ……

   (c) Name of Q.C In charge with qualification and experience ……

   …….

   (d) Names, designation, qualification and experience of other technical personnel in Q.C

   ……

   ……

   (e) Training received by technical personnel, its periodicity and documentation ……..

   ……

S. No.	Facility / Activity	Observation	
		Yes	No
1.	**FACTORY PREMISES** Is layout plan with flow & covered area, attached?		
1.1	Does manufacturing unit has adequate space for receiving and storing raw materials and the areas given below?		
1.2	Manufacturing process areas. a…… b…….. c……. d……. …….. Is list of machinery and equipments in each section attached?		
1.3	Does the Quality Control Section has its own testing facilities and adequate space for: a) Chemistry lab. b) Pharmacognosy Lab. c) Microbiology Lab. d) Any other facility, if required e) Is list of instruments and equipments in QC attached?		
1.4	Office Rejected goods/drugs store		
2.	**LOCATION AND SURROUNDINGS**.		
2.1	Is the establishment located away from environmentally polluted areas?		
2.2	Is the establishment located away from areas adjacent to open sewerage, drain/public lavatory or any factory		

	which produces excessive, disagreeable odor?		
2.3	Are sewage, trash and other effluent disposal provided?		

3.	**BUILDINGS.**		
3.1	Do the internal design and layout of establishment permit good hygiene practices including protection from cross- contamination?		
3.2	Are surfaces of walls, partitions and floors made of impervious materials and capable of being kept clean?		
3.3	Do walls and partitions have smooth surfaces?		
3.4	Are floors constructedto allow adequate cleaning and drainage?		
3.5	Are doors, windows, ceiling and overhead fixtures constructed and finished to minimize buildup of dirt, condensation and shedding of particles and easy to clean?		
3.6	Are working surfaces that come into direct contact with drugs of sound condition, durable and easy to clean, maintain and disinfect?		
3.7	Are fire extinguishers or other appropriate system available and effective ?		
3.8	Are any products other than alternative medicines manufactured in the same building?		
3.9	Is there adequate space for equipment, materials and movement of personal and materials?		
3.10	Is there any programme / system to inhibit the entry of birds, rodents and insects?		
3.11	Are lightening and ventilation adequate?		
3.12	Are facilities for changing street clothes, footwear, washing and toilets adequately and satisfactorily maintained?		
3.13	Is the space for drying of raw materials satisfactory?		

4.	**WATER SUPPLY**		
4.1	Is there adequate supply of potable water?		
4.2	Does the potable water meet the specifications published API specifications?		
4.3	Is only potable water used in alternative medicines & health products?		
4.4	Nature of water purification system		
5.	**DISPOSAL OF WASTE**		
5.1	Are drainage and water disposal systems designed, constructed and maintained in such a way as to avoid contamination of alternative medicines & health products?		
5.2	Are the waste water and residues disposed of after suitable treatment as per guidelines of pollution control authorities?		
5.3	Disposal of solid/ semisolid waste, sewage and liquid laboratory waste?		
5.4	Disposal of Management of gaseous pollutants?		
5.5	Is efficient treatment plant in existence / if yes, give comment on it?		
5.6	Are fume hoods of adequate design in existence and used wherever necessary?		
6.	**CLEANING OF CONTAINERS**		
6.1	Is there proper arrangement for washing, cleaning and drying of containers?		
6.2	Is this area separated from manufacturing area?		
7.	**STORES**		
7.1	**Is** there independent adequate space for storage of different types of materials such as raw material, packaging materials and finished products?		

7.2	Are alternative medicines & health products storage facilities designed and constructed to permit adequate maintenance and cleaning?		
7.3	Avoid pest ace and harborage?		
7.4	Enable medicines to be effectively protected from contamination?		
7.5	Provided the necessary environment to prevent spoilage?		
7.6	Are storage facilities deigned, constructed and maintained to ensure that malicious or accidental contamination of alternative medicines or health products with harmful materials is prevented?		
8.	**RAW MATERIALS STORES**		
8.1	Are raw materials or ingredients checked for parasites, undesirable microorganisms, pesticides or decomposed or extraneous substances?		
8.2	Are raw materials or ingredients inspected and tested before processing?		
8.3	Are raw materials or ingredients subjected to effective stock rotation?		
8.4	Is the area adequate?		
8.5	Are the ventilation and lighting of stores adequate?		
8.6	Is the raw materials store segregated for different types of raw material? a) Raw materials of metallic origin b) Raw materials of mineral origin c) Raw materials of animal source d) Fresh herbs, dry herbs or plant parts excepients etc. e) Volatile oils/perfumes and flavours f) Plant extracts and exudates /resins		

	g) Others		
8.7	Is special area with special condition provided for special raw materials?		
8.8	Are there labels for material of different status i.e. quarantine, tested and releases for use and rejected?		
8.9	Are these labels of different colours?		
8.10	Are labels on containers of raw materials to be used in manufacture checked with regard to identity, quantity and QA approval?.If not give detail.		
8.11			
8.12	Is the following information available on the labels? 1) Name of material 2) Batch Number 3) Analysis number 4) Date of release/ rejection? 5) Date of testing? 6) Date of expiry?		
8.13	Is the sampling performed by quality control personnel?		
8.14	Are there sampling procedures?		
8.15	Are the containers provided for storage of raw materials suitable to preserve the quality?		
8.16	Is exterior storage available for solvent storage area?		
8.17	Available of inflammable materials storage area?		
8.18	Whether safety measures provided have been assessed by regulatory agency if any?		
8.19	Is SOP's available for handling of these materials?		
8.20	Are SOP's for cleaning of containers and closures available before packing of products?		
8.21	Is the dispensing area segregated?		

8.22	Are lighting and ventilation adequate?		
8.23	Is the area clean?		
8.24	Do the personal wear appropriate clothing?		
8.25	Is there danger of cross contamination during dispensing?		
8.26	Are the scales and balance calibrated regularly and record maintained?		
8.27	Are the containers of the raw materials to be dispensed, cleaned before opening?		
8.28	After dispensng, are these containers sealed?		
8.29	Are the raw materials for each batch, after dispensing properly identified and checked?		
8.30	Are adequately cleaned and dried equipment used for dispensing materials from the containers?		
8.31	Is FIFO principle adopted?		
9	**PACKING MATERIALS**		
9.1	Is the area adequate with reference to packing materials?		
9.2	Are the containers and closures adequately cleared and checked?		
10	**FINISHED GOODS STORES**.		
10.1	Is the area adequate with reference to materials stored?		
10.2	Are lighting and ventilation adequate?		
10.3	Are there available inventory record to show? Quantities, Batch number, Date of receipt, and other required information.		
10.4	Has the distribution record been maintained?		
10.5	Does distribution record provide sufficient		

	information for drug recall purpose?		
10.6	Is there segregation area for retrieved goods?		
10.7	Is record available for the retrieved goods?		
10.8	Is there any marked quarantine area?		
10.9	Is there space for materials requiring special storage conditions (environmental conditions), if required?		
10.10	**WORKING SPACE**		
10.11	Is space adequate as per manufacturing operations?		
10.12	Is machinery along with working manual orderly placed with adequate space?		
10.13	Are there adequate precautions to check cross contamination?		
10.14	**HEALTH, CLOTHING, SANITATION AND HYGIENE OF WORKERS**		
10. 15	Are workers free from contagious disease?		
10.16	Are workers properly uniformed?		
10.17	Are there separate lavatories for men and women?		
10.18	Is there provision for changing their cloth and to keep personal belongings?		
10.19	Are adequate facilities like wash-basin with running water hand drier & clean towels, etc., available for personal hygiene before entering into production area?		
10.20	Are SOPs available for personnel to observe personal hygiene?		
10.21	Are hygiene instructions displayed in change rooms and strategic locations?		
10.22	Is the sanitation system monitored for effectiveness?		

10.23	Is the sanitation system periodically verified by inspections?		
10.24	Is microbiological sampling of environment and AM&HP contact surfaces carried out?		
10.25	Is the sanitation system regularly reviewed and adapted to reflect changed circumstances?		
11	**MEDICAL SERVICES**		
11 .1	**Is** medical file of each worker maintained separately?		
11. 2	Is recruitment of an employee preceded by medical examinations?		
11. 3	What is the periodicity of subsequent medical examinations?		
11. 4	Is an employee whose state of health is doubtful immediately removed from work site until he is fully recovered?		
12	**MACHINERY AND EQUIPMENT**		
12. 1	Is manually operated or semi-operated or automatic machines are used for crushing, grinding, powdering, boiling, mashing, burning, roasting, filtering, drying, filling, labeling and packing?		
12. 2	Are equipment and containers coming into contact with alternative medicines or health products designed such that they can be adequately cleaned, disinfected and maintained?		
12.3	Are equipment made of nontoxic materials?		
12. 4	Is equipment used to cook, heat, treat, cool and store designed to achieve the required temperature as rapidly as necessary?		
12.5	Are equipments used to cook, heat, treat, cool and store designed to monitor and control the required		

	temperature?		
12.6	Are containers for waste suitably identified?		
12.7	Are containers for waste closable to prevent malicious or accidental contamination of Alternative Medicines or Health Products?		
12.8	Is the equipment adequate for intended use?		
12.9	Is it constructed in such a way that lubricants, coolant, etc. cannot contaminate the drug product?		
12.10	Does the equipment permit cleaning and maintenance?		
12.11	Does the equipment show its status i.e. clean, dirty, batch contents etc?		
12.12	Do all apparatus /equipment bear appropriate labels to identify the product for which the equipment is used, its batch no., date of manufacturing etc?		
12.13	Are SOPS available for cleaning, maintenance and sanitation of major equipment?		
12.14	Are log books maintained for cleaning, maintenance and sanitation of major equipment?		
12.15	Are SOP's readily available to operators?		
12.16	If automatic electronic or mechanical equipment is used are there written programs for calibration/ inspection?		
12.17	Checks to ensure that changes are made only by authorized persons		

12.18	Are suitable closures or lids available to protect the changes in properties of materials exposed to outside atmosphere?		
13	**BATCH MANUFACTURING RECORD**		
13. 1	Are appropriate records of processing, production and distribution kept?		
13. 2	Are SOP's available for the following?		
	1) Receipt of raw materials and other components? 2) Quarantine and storage? 3) Quality control system and approval/rejection 4) Release for production 5) In process testing and control 6) Finished products? 7) Storage of finished products? 8) Distribution returned goods 9) Recalls and complaints 10) Cleaning and maintenance? 11) Quality control of water 12) For reworking of non-conforming batches in existence?		
13.3	Are there additional documents like log books, note books or other similar records available to show execution of various functions?		
13.4	Are there record of receipts of materials and do these have following information?		
13.5	Goods Receipt Note (GRN) and GRN documents		

	number?		
13.6	1) Date of receipt? 2) Supplier? 3) Manufacturer? 4) Manufacture's batch number? 5) Type and size of containers? 6) Number of containers and conditions? 7) Are specifications available for all materials? 8) Are test methods validated? 9) Are periodic reviews of specification carried out to ensure compliance with new /revised recognized international pharmacopoeia?		
13.7	Are there record of stock and issue of raw materials and do these have following information: 1) Opening balance? 2) Date of receipt? 3) Quantity received? 4) Name and batch number assigned by the manufacturer? 5) Invoice number, date, name and address of supplier? 6) Analysis receipt no. and date? 7) Date of expiry, if any? 8) Name and batch number of product for manufacture for which issued? 9) Balance? 10) Signature of issuing person?		
13.8	Are there master formulation record for each drug		

	product being produced?		
13. 9	Is there a separate master production documents for each dosage form/batch size?		
13. 10	Are there master production record signed and dated by competent person?		
13.11	Is batch production record prepared for every batch produced?		
13.12	Is it reproduction of the appropriate master production documents or it has all critical information about the batch?		
13.13	IS batch record retained for at least one year after expiry date?		
13.14	Has it been checked for accuracy, signed and dated by a responsible person?		
13.15	Is the record maintained by QC for all the tests carried out?		
13. 16	Does the record include?		

	1) The name of the product 2) Number of the batch being manufactured? 3) Issue slip with lab ref. No. and Job cards? 4) Graphs, chart, spectra, etc? 5) List of major equipment used? 6) In-process testing reports? 7) Calculations of yield? 8) Notes on deviations with signed authorization? 9) Signature of individuals of who performed the tests? 10) Material returns to store slip? 11) Lab report of final product? 12) Review of results for any raw material issued under "positive Recall"? 13) Signature of the designated person responsible for the review of records for accuracy and compliance with established standards? 14) Are other associated records available? 15) Is documentation available readily for examination? 16) Is batch production record capable of giving complete history of the batch right from the raw materials stage to the distribution of finished products?		
14	**DISTRIBUTION RECORD**		
14. 1	Is record of sale and distribution of each batch of alternative medicines maintained?		

14. 2	Is record maintained at least up to 5 years of the exhausting of stock?		
15	**RECORD OF MARKET COMPLAINTS**		
15.1	Are thefirms maintaining a record of complaint received from market?		
15 .2	Does the firm has investigated the complaint and has taken any corrective action?		
15.3	Does the firm has intimated such complaint six monthly to the Authority?		
15.4	Does the firm maintain register of any ADR report received?		
15.5	Are written procedure available for receipt and control of return products?		
15.6	Are returned or salvaged drug products destroyed unless QC determines their reprocessing?		
15.7	Are records of the returned products maintained including their disposition?		
15.8	Is a safety manual available?		
16	**QUALITY CONTROL**		
16.1	Is the QC area adequate?		
16. 2	Has Quality Control section minimum of in-process controls.		
16.3	Are master control procedures signed and stated by authorized persons?		
16. 4	Do these control procedures include specifications, test procedures or other control procedures for:		
16.5	1) Raw materials 2) In process materials 3) Packaging and labeling materials? 4) Finished products?		

16. 6	Are the procedures in written form and readily available for acceptance of reprocessed material?		
16.7	Do these control procedures include specifications test procured or other control procedures for 1) Raw materials 2) In process materials 3) Packaging and labeling materials 4) Finished products?		
16.8	Are samples collected by QC personal per SOP		
16.9	Is there special room for microbiological and sterility testing?		
16.10	Is the environment of room controlled?		
16.11	Are only materials, containers and appliance necessary for the job in handstored in the vicinity of the manufacturing areas and are these properly labeled with name of the product, batch no. date etc.?		
16.12	Are all raw materials, containers, closures, labels and printed packaging material approved and released by QC for use in manufacture of drugs products		
16.13	Are in-process controls carried out by QC personnel?		
16.14	Are semi-finished products tested for appropriate tests when necessary?		
16.15	Is bulk finished product tested for established specifications before packing?		
16.16	Is every finished product tested for established specifications before release for sale?		
16.17	Does the QC maintain record of all the tests carried out?		
16.18	Does the QC review all production and control		

	record to ensure compliance with established written procedures before a batch of the product is released for sale?		
17	**Reference standards:**		
17.1	Are standards (R.S) available?		
17.2	Are these RS or working standards (WS)?		
17.3	Are WS standardized against RS or CRS? Are quality control procedures validated?		
17.4	Are RS stored properly (at appropriate temperature under dehumidified conditions)?		
17.5	Are record of R.S and their standard maintained?		
17.6	Are samples insufficient quantity for testing twice retained of starting materials and finished products for future examination, in case ofneed?		
17.7	Is a written program available for stability including the following?		
17.8	Sample storage room temperature?		
17.9	Sample size and test intervals?		
17.10	Reliable and specific test methods?		
17.11	Testing in the same containers closure system in which it is marketed?		
17.12	Date of manufacture and expiration date if any?		
17.13	Establishment of in-house specification? –		

17.14	Does the firm provide the equipment as recommended in Part II C ?		
18	**REQUIREMENT FOR STERILE PRODUCT**?		
18.1	**Manufacturing areas**		
18.2	Is there separate manufacturing area?		
18.3	Are there air locks for entry		
18.4	. Is there dust free and ventilated air supply?		
18.5	Precautions against contaminations and mix.		
18.6	Are manufacturing operations being carried out in a separate block of adequately isolated building		
18.7	Is there appropriate pressure differential in the process area.		
18.8	Is suitable exhaust system provided?		
18.9	For aseptic manufacturing proper air supply (filtered through HEPA) provided?		
19	**MASTER FILE**		
19.1	Is master file prepared by the Manufacturer?		

Names of the dosage forms having the required facilities

……

……..

1. Name & signature of Production In-charge.

2. Name & signature of QC In-Charge.

Comments of the Managing Director/General Manager

……

Name & Signature of Managing Director/General Manager

Stamp & Seal

Concluding Remarks and Recommendations of the Inspecting Panel

Name, Designation & Signature of Inspecting Panel Member

1.

2.

3.