



GUIDELINES ON ESTABLISHMENT OF PHARMACEUTICAL UNIT, GRANT AND RENEWAL OF DRUG MANUFACTURING LICENCE THEREOF

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1. HISTORY

This is the fourth edition of this document.

2. APPLICATION

This document is applicable to any applicant/firm/company/person/institution who intends to establish a pharmaceutical unit and apply for grant or renewal Drug Manufacturing License (DML) of license and submit application for approval of renewal of DML.

3. PURPOSE

This document is aimed to provide comprehensive information on the regulatory procedures for applicants/firms who intend to establish a pharmaceutical unit and apply for grant of DML or renewal of DML.

4. INTRODUCTION

Division of Drug Licensing under Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) is responsible for licensing of drug manufacturing facilities and to perform other functions connected therewith.

5. DEFINITIONS:

5.1 Site: Area/location/premises, selected for establishment of a pharmaceutical unit.

5.2 Drug Manufacturing License: Drug Manufacturing License is a permission from the competent authority to manufacture drugs. The five types of Drug Manufacturing Licenses are as follows:

- (i) Licence to manufacture by way of formulation;
- (ii) Licence to manufacture by way of basic manufacture;
- (iii) Licence to manufacture by way of semi-basic manufacture;
- (iv) Licence to manufacture by way of repacking;
- (v) Licence to manufacture for experimental purposes.

5.3 Technical staff: The production activities in any pharmaceutical unit are carried out in the presence of technical staff approved Production In-charge and Quality Control In-charge.

5.4 Active Pharmaceutical Ingredient (APIs): A substance or compound that is intended to be used in the manufacture of a pharmaceutical/bio-pharmaceutical product as a pharmacological active compound (ingredient).

Active Pharmaceutical Ingredients of Biological Origin: API of biological origin produced by biological systems and which require standardization by biological assays according to the relevant and updated recommendations of the World Health Organization published in



Technical Report Series and Biological Standardization Report, and includes the products as defined in Schedule-I of the DRAP Act, 2012.

5.5 Inspection Book: A document/book issued at the time of grant of Drug Manufacturing License for recording the expression of inspections conducted.

5.6 Repacking Products/Drugs: The products/drugs which are enlisted in Schedule-D of the Drugs (Licensing, Registration & Advertising) Rules, 1976.

5.7 Central Licensing Board: Central Licensing Board is a statutory body established for licensing of drug manufacturing facilities.

5.8 Intermediate : Products produced /manufactured from basic materials and processed for manufacturing of Active Manufacturing Ingredients.

ACRONYMS

S. No.	Acronym	Full Form
1	DRAP	Drug Regulatory Authority of Pakistan
5	DML	Drug Manufacturing License
6	API	Active Pharmaceutical Ingredient
8	CLB	Central Licensing Board
9	E&M	Evaluation and Monitoring
10	FID	Federal Inspector of Drugs
11	R&I	Receipt & Issue
12	LOP	Layout Plan
13	HVAC	Heating, Ventilation and Air Conditioning
14	PIC/S	Pharmaceutical Inspection Co-operation Scheme
16	SRO	Statutory Regulatory Order
17	NOC	No Objection Certificate
18	CEO	Chief Executive Officer
19	MD	Managing Director
20	CRF	Central Research Fund
21	QC	Quality Control
22	QA	Quality Assurance
23	CNIC	Computerized National Identity Card
24	SECP	Securities and Exchange Commission of Pakistan
25	SMC	Single Member Company
27	NHSR&C	National Health Services, Regulations & Coordination
28	eApp / eapp	https://eapp.dra.gov.pk
29	Lic.	Licensing
30	Sq. ft.	Square Feet
31	ft.	Feet
32	S. No.	Serial Number



6. GUIDELINES FOR ESTABLISHMENT OF A PHARMACEUTICAL UNIT:

6.1 Site Verification for Grant of DML by Way of Formulation:

- 6.1.1. The site/premises for establishment of a pharmaceutical unit shall be located ,preferably in an industrial area and not in any residential or commercial area. The size of the plot may be more than 2000 Sq. Yards. The applicant submits the application along with documents as per the checklist attached as **Annexure-I** through <https://eapp.dra.gov.pk/>.
- 6.1.2. The applications to establish a pharmaceutical unit on the rented premises may not be entertained. At least one of the owners of the plot should be part of management of the firm as a director/partner/owner. In case of shortcomings in the above-mentioned required documents, the applicant will be informed in writing for doing the needful/completing the application.
- 6.1.3. On completion of the application, an officer is asked for site verification, and the applicant is informed for coordination with the concerned officer of the DRAP.
- 6.1.4. The authorized officer inspects the site of the proposed pharmaceutical unit to check/verify the requirements for the suitability of the site as laid down under the Drugs Act, 1976 and the provision of Annexure-B of Compliance Framework Document-I approved by CLB issued by Licensing Division vide Circular No.F.6-1/2026-LIC(M-314) in light of SRO. 1587(I)/2025 dated 25-08-2025 under Drugs (Licensing, Registering and Advertising) Rules, 1976.
- 6.1.5. After inspection of the site, the officer submits the report to Licensing Division with his/her recommendations as to whether the site is suitable for establishment of Pharmaceutical Manufacturing Unit or not.
- 6.1.6. Approval of the site for establishment of a Pharmaceutical Manufacturing Unit is granted by the Chairman, CLB as per powers delegated to him by CLB under the Drugs (Licensing, Registration & Advertising) Rules, 1976.
- 6.1.7 In case of recommendations to reject the site for establishment of the pharmaceutical unit by the officer, the Chairman CLB may constitute a two-member panel for re-inspection. The report of two-member panel is placed before CLB for a final decision.



- 6.1.8. After approval of the site, the firm is directed to submit the layout plan of the proposed pharmaceutical unit.
- 6.1.9. The firm is informed accordingly in either case and the applicant may file an appeal before Appellate Board under the law against the decision of CLB.
- 6.1.10. The site verification of unclassified/agricultural area/premises remains valid only for one year and for sites in industrial zones for two years. The firm has to apply afresh for approval after the lapse of the period.
- 6.1.11 CLB is the competent forum to bring changes in the procedure not in consistent with the Act.

6.2 Site Verification for Grant of DML by Way of Basic and Semi-Basic Manufacturing:

- 6.2.1. The applicant provides site/premises/building which is suitable for the intended use, in size and construction, and is located in an area free from offensive or obnoxious odors and other possible sources of contamination. The applicant submits the application along with documents as per the checklist attached as Annexure-I through this link , “<https://eapp.dra.gov.pk/>”
- 6.2.2. The proposals/applications to establish a pharmaceutical unit on the rented, leased and ownership premises/building is entertained. In case of shortcomings in the above-mentioned required documents, the applicant is informed in writing for doing the needful/completing the application.
- 6.2.3. On completion of the application, an officer is asked for site verification with a copy of the letter to the firm for coordination with the concerned officer of DRAP.
- 6.2.4. The officer inspects the site of the proposed pharmaceutical unit to check/verify the requirements for the suitability of the site as laid down under the Drugs Act, 1976 and Drugs (Licensing, Registering and Advertising) Rules, 1976.
- 6.2.5. The officer after inspection sends the report to Licensing Division, either recommending or not recommending the site for establishment of a Pharmaceutical Manufacturing Unit by way of Basic or Semi-Basic manufacturing.



- 6.2.6. The Competent Authority for granting approval of Site for the establishment of a pharmaceutical unit is the Chairman, Central Licensing Board as per the delegation of powers approved by CLB under the Rules.
- 6.2.7. In case the field officer recommends the site for establishment of a Pharmaceutical Unit, the case/file is initiated/processed by the Licensing division for approval of the Chairman, CLB, and the same is communicated to the applicant/person/company.
- 6.2.8 Approval is also granted on google map provision ,showing suitability of the premises to encourage the local manufacturing of intermediates and APIs.
- 6.2.9. In case of recommendations to reject the site for establishment of the Pharmaceutical unit by the officer, the Chairman CLB may constitute a two-member panel for re-inspection. The report of two-members panel is placed before CLB for a final decision.
- 6.2.10. In case of approval of the site, the firm is advised to submit the layout plan of the proposed pharmaceutical unit for acknowledgment and record.
- 6.2.11 The firm is informed accordingly in either case and the applicant may file an appeal before Appellate Board under the law against the decision of CLB.
- 6.2.12. The site verification of unclassified/agricultural area/premises/building remains valid only for one year and for sites in industrial zones for two years. The firm has to apply afresh for approval after the lapse of the period.

6.3 Site Verification for Grant of DML by Way of Repacking:

- 6.3.1. The applicant provide site/premises which is suitable for the intended use, in size and construction, and is located in an area free from offensive or obnoxious odors and other possible sources of contamination. The applicant submits the application along with documents as per the checklist attached as Annexure-I through this link
- 6.3.2. The proposals/applications to establish a pharmaceutical unit on the rented premises is not entertained. At least one of the owners of the plot should be part of the management of the firm as a director/partner/owner. In case of shortcomings in the above-mentioned required documents, the applicant is informed in writing for doing the needful/completing the application.



- 6.3.3. On completion of the application, an officers will be asked for site verification with a copy of the letter to the firm for coordination with the officer of DRAP.
- 6.3.4. The officer inspects the site of the proposed pharmaceutical unit to check/verify the requirements for the suitability of the site as laid down under the Drugs Act, 1976 and Drugs (Licensing, Registering and Advertising) Rules, 1976.
- 6.3.5. The officer then sends the report to Licensing Division, either recommending or not recommending the site for establishment of a Pharmaceutical Manufacturing Unit by way of repacking.
- 6.3.6. The Competent Authority for granting approval of Site for the establishment of a pharmaceutical unit is the Chairman, Central Licensing Board as per the delegation of powers approved by CLB under the Rules.
- 6.3.7. In case the officer recommends the site for establishment of a Pharmaceutical Unit, the case/file is initiated/processed by the Licensing division for approval of the Chairman, CLB, and the same is communicated to the applicant/person/company.
- 6.3.8. In case of recommendations to reject the site for establishment of the Pharmaceutical unit by the officer, the Chairman CLB may constitute a two-members panel for re-inspection. The report of two-members panel is placed before CLB for a final decision.
- 6.3.9. In case of approval of the site, the firm is advised to submit the layout plan of the proposed pharmaceutical unit for acknowledgment and record.
- 6.3.10. The firm is informed accordingly in either case and the applicant may file an appeal before Appellate Board under the law against the decision of CLB.
- 6.3.11. The site verification of unclassified/agricultural area/premises remains valid only for one year and for sites in industrial zones for two years. The firm has to apply afresh for approval after the lapse of the period.
- 6.3.11 CLB is the competent authority to change any procedure accordingly.

6.4 Acknowledgement of the Building Layout Plan for Grant of Drug Manufacturing by Way of Formulation:

- 6.4.1. An applicant obtains acknowledgement of the building layout plan before construction from the Central Licensing Board.



- 6.4.2. The applicant submits an application for the proposed layout plan through the link, “ <https://eapp.dra.gov.pk/>.” Two hard copies of the proposed LOP shall be provided through R & I office/section of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).
- 6.4.3. The requirements for the building layout plan are attached as **Annexure-II**.
- 6.4.4. The layout plan is scrutinized by the scrutiny committee as constituted by the Central Licensing Board. The Chairman of the Central Licensing Board is also performing the function of Chairman of committee for acknowledgement of layout plan. The Layout Plan is acknowledgement by the committee in case it is found compliant with the requirements of Annexure - B of Compliance Framework document-I,II & IV, issued by Licensing Division vide circular No.F.6-1/2026-LIC(M-314) in light of SRO. 1587(I)/2025 dated 25-08- 2025 under Drugs (Licensing, Registering and Advertising) Rules, 1976 as per facilities being constructed and drawn on the proposed layout plan.
- 6.4.5. In case of major shortcomings in the layout plan, the observations are communicated to the applicant or a technical expert or representative of the firm are asked to discuss the layout plan with the licensing directorate. However, the minor shortcomings are rectified by the licensing directorate in the joint meeting.
- 6.4.6. After acknowledgement , the duly signed and stamped layout plan is sent to the firm for construction of the unit as per the approved layout plan and further necessary action. However, if acknowledgment is performed, the applicant will be informed/advised to construct a proper building structure with proper provision of safety exits, HVAC system etc., under intimation to/subject to approval by of the relevant building control authorities too.
- 6.4.7. The acknowledgement of layout plans is for one (01) year for additional section and (02) years for a new unit. If the firm does not complete the construction and installation of the machines and equipment within the prescribed time frame, then the firm has to apply afresh for the purpose.

6.5 Acknowledgment of the Building Layout Plan for Grant of Drug Manufacturing by Way of Basic or Semi-Basic Manufacturing:

- 6.5.1. The applicant has to submit building layout plan before construction.
- 6.5.2. The applicant submits an application for the proposed layout plan through the link, “ <https://eapp.dra.gov.pk/>”



- 6.5.3. The building layout design, size and flow requires to be suitable for the intended purpose in light of Annexure-IV and IV-A. Adequate space, plant and equipment for the manufacturing operations are required.
- 6.5.4. The layout plan is scrutinized by the scrutiny committee as constituted by the Central Licensing Board. The Chairman of the Central Licensing Board performs the function of Chairman of Building Layout Plan Committee.
- 6.5.5. In case of major shortcomings in the layout plan, the observations are communicated to the applicant/ technical expert / representative of the firm and asked to discuss the layout plan with the licensing directorate. However, the minor shortcomings are rectified by the licensing directorate in the joint meeting.
- 6.5.6. In case the Building Layout fulfills the requirements and the shortcomings are rectified as required in the light of Annexure-IV and IV-A, the proposed Building Layout is retained for record and acknowledgement is issued through e-app.

6.6 Acknowledgment of the Building Layout Plan for Grant of Drug Manufacturing by Way of Repacking:

- 6.6.1. The applicant has to submit building layout plan before construction.
- 6.6.2. The applicant submits an application for the proposed layout plan through the link, “ <https://eapp.dra.gov.pk/>. “
- 6.6.3. The building layout design, size and flow requires to be suitable for the intended purpose in light of Annexure-IV and IV-A. Adequate space, plant and equipment for the manufacturing operations are required.
- 6.6.4. The layout plan is scrutinized by the scrutiny committee as constituted by the Central Licensing Board. The Chairman of the Central Licensing Board is also performing the function of Chairman of Building Layout Plan Committee.
- 6.6.5. In case of major shortcomings in the layout plan, the observations are communicated to the applicant / technical expert / representative of the firm is asked to discuss the layout plan with the licensing directorate. However, the minor shortcomings are rectified by the licensing directorate in the joint meeting.
- 6.6.6. In case the Building Layout fulfills the requirements and the shortcomings have been rectified as required in the light of Annexure-IV and IV-A, the



proposed Building Layout is to retained for record and acknowledgement is issued.

6.7 Grant of Drug Manufacturing License by Way of Formulation:

6.7.1. After construction of the building, the firm submits an application for grant of Drug Manufacturing License through the link, “<https://eapp.dra.gov.pk/>.” The hard copies of the mandatory documents of the application are accepted in R & I section of DRAP, Islamabad only after verification by Director (Licensing)/Additional Director (Licensing) on the prescribed Form 1 (Annexure-III), after completion of the construction of the unit as per the acknowledged layout plan, installation of machinery, equipment, HVAC system, engagement of the required technical personnel, and completion of other requirements as per the Drugs Act, 1976 and rules framed thereunder.

6.7.2. The application is scrutinized and evaluated by the Licensing Division. If there is any shortcoming in the application, the same is communicated to the applicant for doing the needful in the light of observation made by the authorized officer(s) as per the requirements of the Rules.

If the application is found complete, it is processed further and as per delegation of powers, a panel of experts is constituted by the Chairman, Central Licensing Board for inspection of the unit and evaluation of the facilities provided as required under the rules and circular No.F.6-1/2026-LIC(M-314) in light of SRO. 1587(I)/2025 dated 25-08- 2025 under Drugs (Licensing, Registering and Advertising) Rules, 1976 for the following annexures;

Annexure-A

Chapter 4 (Documentation) of PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part-I (PE 009-17)

Annexure - B

Compliance Framework Document-I, II, II & IV

6.7.3. An officer of DRAP is advised for coordinating with the other members of the panel and the firm’s representative and conduct a panel inspection of the firm as per checklist / evaluation form and submits the inspection report.

6.7.4. The panel of experts and inspectors inspect the proposed pharmaceutical unit and carry out a detailed evaluation of the requirements as laid down in the



criteria/checklist under the Drugs Act, 1976, rules framed thereunder and practice in vogue.

- 6.7.5. In case all the required facilities are available and in order, the panel recommends the grant of Drug Manufacturing License for approval by the Central Licensing Board and vice versa.
- 6.7.6. The officer submits the report to Licensing Division which is presented to the Central Licensing Board for decision.
- 6.7.7. Drug Manufacturing License (DML) is issued on Form-2 generated through E-app, with an inspection book and covering letter, detailing the manufacturing facilities of the firm.

6.8 Grant of Drug Manufacturing License by Way of Basic or Semi-Basic Manufacturing:

- 6.8.1. After completion of construction of the unit as per the layout plan, installation of machinery, equipment, HVAC system where required, engagement of the required technical personnel, and completion of other requirements as per the Drugs Act, 1976 and rules framed thereunder, the firm submits an application for grant of Drug Manufacturing License by way of Basic or Semi-Basic manufacturing through the link, "<https://eapp.dra.gov.pk/>" on Form 1 (Annexure-III), along with details of APIs to be manufactured as per Annexure-IV and IV-A.
- 6.8.2. The application is scrutinized and evaluated by the Licensing Division. If there is any shortcoming in the application, the same is communicated to the applicant for doing the needful in the light of observation made by the authorized officer(s) as per the requirements of the Rules.
- 6.8.3. If the application is found complete, it is processed further and as per delegation of powers, a panel of experts is constituted by the Chairman, Central Licensing Board for inspection of the unit and evaluation of the facilities provided as required under the rule of Drugs (Licensing, Registering and Advertising) Rules, 1976
- 6.8.4. An officer is advised for coordinating with the other members of the panel and the firm's representative and conduct a panel inspection of the firm as per checklist / evaluation form and submit the inspection report.
- 6.8.5. The panel of experts and inspectors is inspects the proposed pharmaceutical unit and carry out a detailed evaluation of the requirements as laid down in the



criteria/checklist under the Drugs Act, 1976, rules framed thereunder and practice in vogue.

- 6.8.6. In case all the required facilities are available and in order, the panel recommends the grant of Drug Manufacturing License for approval by the Central Licensing Board and vice versa.
- 6.8.7. The officer submits the report to Licensing Division which is presented to the Central Licensing Board for decision.
- 6.8.8. Drug Manufacturing License (DML) is issued on Form-2 generated through E-app, with an inspection book and covering letter, detailing the manufacturing facilities of the firm.

6.9 Grant of Drug Manufacturing License by Way of Repacking:

- 6.9.1. After completion of construction of the unit as per the layout plan, installation of machinery, equipment, HVAC system, engagement of the required technical personnel, and completion of other requirements as per the Drugs Act, 1976 and rules framed thereunder, the firm submits an application for grant of Drug Manufacturing License by way of repacking through the link, <https://eapp.dra.gov.pk/> on Form 1 (Annexure-III).
- 6.9.2. The application is scrutinized and evaluated by the Licensing Division. If there is any shortcoming in the application, the same is communicated to the applicant for doing the needful in the light of observation made by the authorized officer(s) as per the requirements of the Rules.
- 6.9.3. If the application is found complete, it is processed further and as per delegation of powers, a panel of experts is constituted by the Chairman, Central Licensing Board for inspection of the unit and evaluation of the facilities provided as required under the rules and circular No.F.6-1/2026-LIC(M-314) in light of SRO. 1587(I)/2025 dated 25-08- 2025 under Drugs (Licensing, Registering and Advertising) Rules, 1976 for the following annexures;

Annexure-A

Chapter 4 (Documentation) of PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part-I (PE 009-17)

Annexure - B

Compliance Framework Document-I, II, III & IV



- 6.9.4. The officer is advised for coordinating with the other members of the panel and the firm's representative and conduct a panel inspection of the firm as per checklist / evaluation form and submits the inspection report.
- 6.9.5. The panel of experts and inspectors inspects the proposed pharmaceutical unit and carry out a detailed evaluation of the requirements as laid down in the criteria/checklist under the Drugs Act, 1976, rules framed thereunder and practice in vogue.
- 6.9.6. In case all the required facilities are available and in order, the panel recommends the grant of Drug Manufacturing License for approval by the Central Licensing Board and vice versa.
- 6.9.7. The officer submits the report to Licensing Division which is presented to the Central Licensing Board for decision.
- 6.9.8. Drug Manufacturing License (DML) is issued on Form-2 generated through E-app, with an inspection book and covering letter, detailing the manufacturing facilities of the firm.

6.10 Grant of Drug Manufacturing License by Way of Experimental Purposes:

- 6.10.1. The applicant submits an application through E-App along with the following documents prior to inspection of the premises for the purpose of grant of a license to manufacture drugs for experimental purposes at new premises:
 - i. Application on prescribed Form-3 under Rule 21 of Drugs (L, R &A) Rules, 1976 countersigned by the Head of Institution.
 - ii. Names and qualifications of qualified persons responsible for manufacturing for experimental purposes.
 - iii. List of machinery and equipment in the Production and Quality Control departments.
 - iv. Facility Layout Plan for the manufacturing and Quality Control of Experimental Drug.
 - v. Manufacturing Process.
 - vi. Testing Method.
 - vii. Working SOPs.
 - viii. Affidavit on stamp paper in light of Rules 21-23 of Drugs (L, R &A) Rules, 1976.
- 6.10.2. The application is scrutinized and evaluated by the Licensing Division. If there is any shortcoming in the application, the same is communicated to the applicant for doing the needful in the light of observation made by the authorized officer (s) as per requirements.



6.10.3. If the application is found complete, it is processed further and as per delegation of powers, a panel of experts is constituted by the Chairman, Central Licensing Board for inspection of the unit and evaluation of the provided facilities

i. 6.10.4. An field is advised for coordinating with the other members of the panel and the firm's representative and conduct a panel inspection of the firm as per checklist / evaluation form and submit the inspection report.

6.10.5. The panel of experts/ inspectors inspects the proposed pharmaceutical unit and carry out a detailed evaluation of the requirements as laid down in the criteria/checklist under the Drugs Act, 1976, rules framed thereunder and practice in vogue.

6.10.6. In case all the required facilities are available and in order, the panel recommends the grant of Drug Manufacturing License for approval by the Central Licensing Board and vice versa.

6.10.7. The officer submits the report to Licensing Division which is presented to the Central Licensing Board for decision.

6.10.8. Drug Manufacturing License (DML) is issued on Form-4 for two years, along with covering letter, detailing the manufacturing facilities/Products of the firm.

7. Renewal of Drug Manufacturing Licenses:

Drug Manufacturing License by way of Formulation, Basic, Semi-Basic and Repacking are valid for 05 years after the date of issue. The firm has to submit the DML renewal application for further period of 05 years before the expiry of previous tenure. In case of late submission up to 60 days after expiry firms can submit DML renewal application along with surcharge fee per day. After expiry of 60 days the DML shall stand in valid.

7.1 The Licensed firm before expiry of tenure submits application for the renewal of Drug Manufacturing License on prescribed Form 1A, as per Annexure-IV through the link, "<https://eapp.dra.gov.pk/>."The hard copies of mandatory documents of the application is accepted in R & I section of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

7.2 The application is scrutinized and evaluated by the Licensing Division. If there is any shortcoming in the application, the same is communicated to the applicant for doing the needful in the light of observation, made by the concerned officer (s) as per requirement of rules. If the application is found complete, it is processed further and as per delegation of powers, a panel of experts/ Inspectors is constituted by the Chairman, Central Licensing Board/any other officer authorized by CLB for inspection of the unit and evaluation of the provided facilities as required under the rules.



- 7.3 The officer is advised for coordinating with the other members of the panel and the firm's representative and conduct the panel inspection of the firm as per checklist / evaluation form and submit the report of inspection thereof.
- 7.4 The panel of experts / inspectors inspects the proposed pharmaceutical unit and carry out detailed evaluation of the requirements as laid down as per criteria/checklist under the Drugs Act, 1976, rules framed there under and practice in vogue.
- 7.5 The officer forwards the report with their recommendations to Licensing Division. The inspection report is placed before the Central Licensing Board for grant of renewal of Drug Manufacturing License, then the DML on Form-2 with covering letter will be issued to the firm
- 7.6 Provided that if directed by the Central Licensing Board, the licensee shall rectify the observations made during the inspection within the period which shall not be less than one (01) month and more than three (03) months from the date of receipt of orders in this regard and during this period the manufacturing in that particular area or the premises, as the case may be, shall remain suspended and until after re-inspection the Board grants the renewal of license or otherwise reject the application and inform the licensee accordingly.

8. SUBMISSION OF REGULATORY FEE

DRAP has introduced an online fee challan system, available on the link provided at the official website of DRAP. The system helps users in the selection of applicable regulatory fee for the required service(s) under the respective regulatory function. The applicant can generate the fee challan(s) for any required purpose. The regulatory fees of DRAP can be submitted on any branch of the banks listed on the fee challan.

9. REFERENCES:

- 9.1 The Drugs Act, 1976.
- 9.2 The DRAP Act, 2012.
- 9.3 The Drugs (Licensing, Registering & Advertising) Rules, 1976.
- 9.4 SRO 1582(I)/2025 dated 25-08-2025 for Implementation of PIC/S Guide to Good Manufacturing practice for Medicinal Products Part-I (PE 009).
- 9.5 Circular letter No.F.6-1/2026-Lic(M-314) dated 24-02-2026 (Annexure A and B/Compliance Framework Document No.I,II,III &IV)



ANNEXURE -I

DOCUMENTS / INFORMATION REQUIRED FOR SITE VERIFICATION FOR ESTABLISHMENT OF A PHARMACEUTICAL UNIT

The following documents/information are required for processing the request/application;

- i. Proper application with a covering letter on letter head.
- ii. Prescribed fee as notified by the Authority for site verification.
- iii. Disclosure of status of firm: proprietorship, partnership, public limited or private Limited, institution, etc.
- iv. Copy of the Partnership Deed duly executed in the court of competent jurisdiction/Registrar of Firms & Copy of Certificate of Registration (Form-C) with Registrar of firms in case of partnership.
- v. Copies of CNIC of Chief Executive Officer / Managing Director /Directors/ Partners.
- vi. Declaration of firm on stamp paper, In case of a sole proprietorship.
- vii. Complete documents of the proposed land/plot, in the name of the firm or all its directors/partners (purchase document of land/plot, allotment letter, transfer letter/ possession letter, Fard, copy of site map or Aks Shajrah ,etc) / Agreement deed.
- viii. In case the firm is Private Limited, the Certificate of Incorporation with SECP, Memorandum and Articles of Association, Form-A, Form-21 and Form-29 shall also be furnished. (Attested by SECP)
- ix. All documents submitted shall be duly attested by Notary Public /SECP/Registrar of firms, office, as the case may be.



ANNEXURE -II

DOCUMENTS / INFORMATION REQUIRED FOR APPROVAL OF BUILDING LAYOUT PLAN.

1. Proper application with a covering letter on letterhead.
2. Prescribed fee as notified by the Authority for each section/facility.
3. Two (02) copies of proposed layout plan.
4. Highlight the proposed amendments on a copy of approved master layout plan.

REQUIREMENTS OF AREA ACCORDING TO ANNEXURE-B

S. No	Section	Minimum Area	Remarks
1	External Appliances or Suspension	200 Sq. ft.	
2	Syrups, Elixirs & Solutions	300 Sq. ft.	
3	Compressed Tablets	900 Sq. ft.	Should be divided into three distinct subsections situated in different rooms (Granulation, Compression, Coating) Hypodermic Tablets in aseptic & separate room
5	Hard Gelatin Capsules	200 Sq. ft.	
7	Eye ointments, Eye drops, Eye lotions and other use	250 Sq. ft.	Manufacture and filling shall be in aseptic conditions
8	Pessaries and Suppositories	200 Sq. ft.	If compression is involved, a separate room with min. 300 Sq. ft
9	Inhaler and Vitrallae	200 Sq. ft.	
10	Repacking	300 Sq. ft.	
13	Cream/Ointment/Gel/Lotion	Adequate	
14	Sterilization	400. ft./unit of sterilizer	

5. Dedicated and self-contained facilities for the production of particular drugs shall be provided in addition to the general facilities such as highly sensitizing materials (e.g. penicillin) or biological preparations (e.g. live microorganisms) or cytotoxic substances or radio pharmaceutical or veterinary immunological preparations or sterile products or, for that matter, such other highly active pharmaceutical products, antibiotics, hormones, as may be identified by the Central Licensing Board at any stage.
6. Men and material flow may be indicated in different colored arrows.

ANNEXURE -III



**DOCUMENTS / INFORMATION REQUIRED FOR GRANT OF DRUG
MANUFACTURING LICENSE**

“FORM-1

[See rule 5(1)]

**APPLICATION FORM FOR GRANT OF A LICENSE TO MANUFACTURE DRUGS BY
WAY OF FORMULATION/BASIC MANUFACTURE/ SEMI-BASIC MANUFACTURE/RE-
PACKING.**

I/We _____ of _____ hereby
apply for the grant of a license to manufacture by way of _____ on
premises situated at _____.

2. The drug(s) or class(es) of drugs intended to be manufactured: -
 - (I) Class(es) of drugs
 - (II) Dosage form(s) of drugs.
 - (III) Name of drug(s).
3. I enclose: -
 - (i) Particulars regarding the legal status of the applicant (i.e. in case of proprietorship the name(s) of proprietors and their address(es), in the case of a firm, the names and addresses of its partners and in the case of a company, the name and address of the company and its directors).
 - (ii) Details of the premises including layout plan of the factory.
 - (iii) Details of the section-wise equipment and machinery for manufacture and quality control.
 - (iv) Names and qualifications of the Production In-charge and Quality Control In-charge for supervising manufacturing processes and the Quality Control Department, and other technical staff working in these departments.
4. The premises and plant will be ready for inspection on or
are ready for inspection.

Date.....Signed.....
Place Name, designation and address of the
signatory.....



ANNEXURE -IV

DOCUMENTS / INFORMATION REQUIRED FOR GRANT OF ACTIVE PHARMACEUTICAL INGREDIENT(S)/INTERMEDIATES

1. Proper application with a covering letter on letterhead.
2. Prescribed fee as notified by the Authority per API/Intermediate
3. Names and quantities of chemicals to be used in manufacturing.
4. Names and quantities of chemicals to be recycled in manufacturing.
5. Manufacturing process steps and flow chart.
6. Theoretical yield of manufacturing process.
7. Trial batches record and stability data along with validation (if available).
8. Reference monograph and testing method
9. List of Testing equipment
10. Shelf life of API
11. Material safety data sheet
12. **All documents should be duly attested/verified by approved technical staff along with the Company stamp.**



ANNEXURE – IV (A)

**REQUIREMENTS FOR GRANT OF DRUG MANUFACTURING LICENSE BY THE WAY
OF BASIC & SEMI-BASIC MANUFACTURING FOR BLOOD/ PLASMA
ESTABLISHMENTS**

ANNEXURE -VIII

**DOCUMENTS / INFORMATION REQUIRED FOR ISSUANCE OF INSPECTION
BOOK**

- i). Proper application with a covering letter on letterhead.
- ii). Prescribed fee as notified by the Authority for Issuance of Inspection Book.
- iii). Copy of last three pages of previous inspection book.
- iv). Copy of FIR and Advertisement in national newspaper (in case of lost/damaged inspection book).
- v). All documents should be attested by a gazetted officer or Notary Public.

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