ESTABLISHMENT OF PHARMACEUTICAL UNIT AND POST LICENSE CHANGES

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Drug Regulatory Authority of Pakistan
Islamabad-Pakistan

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1. HISTORY

This is the second edition of this document.

2. APPLICATION

This document is applicable to any applicant/firm/company who intends to establish a new pharmaceutical unit and for approval/endorsement of post license variances.

3. PURPOSE

This document is aimed to provide comprehensive information on the regulatory procedures for applicants/firms who are willing to apply for grant, renewal of Drug Manufacturing License and other post license variations.

4. INTRODUCTION

Division of Drug Licensing has been set up under the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) which is responsible for licensing drugs manufacturing facilities and performing other functions connected therewith.

5. DEFINITIONS& ACRONYMS:

5.1 Site: Area/location being selected for establishment of Pharmaceutical unit**.**

5.2 Drug Manufacturing License:

Drug Manufacturing License is a license to manufacture drugs. There are five types of the Drug Manufacturing Licenses which are as follow:

i) By way of Formulation
ii) By way of Basic Manufacturing
iii) By way of Semi-Basic Manufacturing
iv) By way of Re-packing
v) For Experimental purpose.

5.3 Technical staff: The production activities in any pharmaceutical unit are carried out in the presence of approved Production Incharge & Quality Control Incharge.

5.4 Active Pharmaceutical Ingredient (API's): A substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a pharmacologically active compound (ingredient).

5.5 Inspection Book: Inspection Book is the document- book issued at the time of grant of Drug Manufacturing License.

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

5.7 Central Licensing Board: Central Licensing Board is a statutory body for licensing of drug manufacturing facilities. CLB has been setup under section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with Clause (1) of Section 5 and Section 43 of the Drugs Act, 1976 (XXXI of 1976).

6. GUIDELINES FOR ESTABLISHMENT OF A PHARMACEUTICAL UNIT:

6.1. Site Verification:

6.1.1. The site/premises for establishment of pharmaceutical unit shall be located preferably in an industrial area and not in any residential or commercial area and size of the plot shall not be less than 2000 Sq Yards. The applicant submits the application along with documents as per check list attached as **Annexure-I** through this link https://eapp.dra.gov.pk/, (In case of any technical issues in submission of documents on https://eapp.dra.gov.pk/. hard form of the application shall be accepted in R & I section of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

6.1.2. The proposals/applications to establish a pharmaceutical unit on the rented premises shall 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 said required documents, the applicant will be informed in writing for doing the needful./completion of application.

6.1.3. On completion of the application, the field officers (Additional Director (E&M)/FID/Assistant Director/Authorized officer) will be asked for site verification with a copy of the letter to the firm for coordination with the concerned officers of the DRAP.

6.1.4. The field officer (Additional Director (E&M)/FID/Assistant Director) inspects the site of the proposed pharmaceutical unit to check / verify the requirements for suitability of site as laid down under the Drugs Act, 1976 and Schedule B of the Drugs (L, R & A) Rules 1976 framed under the Drugs Act,1976.

6.1.5. The field officer then sends the report to Licensing Division-in the light of provision of schedule B of the Drugs (Licensing, Registering and Advertising) Rules, 1976 either recommending or not recommending the site for establishment of Pharmaceutical Manufacturing Unit.

6.1.6. At present the Competent Authority for granting approval of Site for the establishment of a pharmaceutical unit is Chairman, Central Licensing Board as per delegation of powers approved by CLB under the Rules.

6.1.7. In case field officer recommends the site for establishment of Pharmaceutical Unit, the case/file is initiated / processed by the desk Officer for approval of Chairman CLB and same is communicated to the applicant/person/company.

6.1.8. In case of recommendations to reject the site for establishment of the Pharmaceutical unit by the field officer, the Chairman CLB may constitute a two-member panel for re-inspection. The report of two-member panel shall be placed before CLB to get final decision.

6.1.9. In case of approval of the site, the firm is advised to submit the layout plan of the proposed pharmaceutical unit.

6.1.10. The firm is informed accordingly in either case as applicant may file an appeal before Appellate Board under the Law against the decision of CLB.

6.1.11. The site verification of unclassified/agricultural area/premises shall be valid only for one year and for sites in industrial zones for 2 years. The firm shall apply afresh for approval after the lapse of the period.

6.2. Approval of the Building Layout Plan:

6.2.1. An applicant must get approval of building layout plan before construction from the Central Licensing Board.

6.2.2. Applicant submits application of proposed layout plan through this 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).

6.2.3. The requirements for building layout plan are attached as **Annexure-II.**

6.2.4. 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 function of Chairman of committee for approval of layout plan. The Layout Plan is approved by the committee in case it is found compliant to the requirement of Schedule-B of Drugs (Licensing, Registering&

Advertising) rules, 1976 as per facilities being constructed and drawn on the proposed layout plan.

6.2.5 In case of major shortcomings in the layout plan, the observations will be communicated to the applicant or a technical expert or representative of the firm will be asked to discuss the layout plan with the licensing directorate. However, the minor shortcomings will be rectified by the licensing directorate in the joint meeting.

6.2.6. After approval, the duly signed and stamped layout plan will be sent to the firm for construction of the unit as per approved layout plan and further necessary action. However, if approval is granted, the applicant will be informed/ advised to construct proper building structure with proper provision of safety exits, HVAC system etc under intimation / seek approval of the relevant building control authorities too.

6.2.7. The approval of lay out plans shall be for one (01) year for additional section and (02) years for a new unit. If the firm do not complete the construction and installation of the machines and equipment within prescribed timeframe, then the firm shall apply afresh for the purpose.

6.3. Grant of Drug Manufacturing License:

6.3.1 After construction of the building, the firm will submit application for grant of Drug Manufacturing License through this link https://eapp.dra.gov.pk/. The hard copies of mandatory documents of the application shall be accepted in R & I section of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing)on prescribed Form 1 (**Annexure-III)**, after completion of construction of the unit as per approved layout plan, installation of machinery, equipment, HVAC system, engagement of the required technical personnel and completing other requirements as per the Drugs Act, 1976 and rules framed there under.

6.3.2. The application will be scrutinized and evaluated by the licensing division. If there will be any shortcoming in the application, the same will be 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 is constituted by the Chairman, Central Licensing Board for inspection of the unit and evaluation of the provided facilities as required under the rules.

6.3.3. The field officer (Additional Director (E&M)/FID/authorized officer) will be 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.

6.3.4. The panel of experts & Inspectors will inspect the proposed pharmaceutical unit and will 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.

6.3.5. The authorized officer will submit the report to Licensing Division which is presented before the Central Licensing Board for decision.

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

6.3.7. Drug Manufacturing License (DML) will be issued on Form-2, with an inspection book and covering letter detailing about manufacturing facilities to the firm.

7. GUIDELINES FOR POST LICENSURE VARIANCES.

7.1. Renewal of Drug Manufacturing License:

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

7.1.2. The application will be scrutinized and evaluated by the Licensing Division. If there is any shortcoming in the application, the same will be 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 will be processed further and as per delegation of powers, a panel of experts/ Inspectors will be 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.

7.1.3. The field officer (Additional Director (E&M)/FID/authorized officer) will be 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.

7.1.4. The panel of experts / inspectors will inspect the proposed pharmaceutical unit and will 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.

7.1.5. The authorized officer will forward the report with their recommendations to Licensing Division. The inspection report will be 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.

7.1.6. 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.

7.2. Change of Qualified Staff (Production Incharge & Quality Control Incharge & Quality Assurance Incharge):

7.2.1. As per Rule 15 & 16 of Drugs (Licensing, Registering & Advertising) rules, 1976, the manufacturing of Drugs shall be conducted under active directions and personal supervisions of qualified staff. The firm shall submit application for the approval of qualified staff (Production Incharge/Quality Control Incharge/Quality Assurance Incharge) in case, already approved qualified staff resign or terminated by the firm as per **Annexure-V** through this link https://eapp.dra.gov.pk/. Hard form of the application shall be accepted in R &

I section of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

7.2.2. The Central Licensing Board has delegated the power to Secretary, Central Licensing Board for approval of qualified staff. In case the application is complete, approval letter will be issued to the firm and if there is any shortcoming in the application, the same is communicated to the applicant for doing the needful.

7.3. Grant of Active Pharmaceutical Ingredient(s) (APIs):

7.3.1. A pharmaceutical firm having Drug Manufacturing License by way of Basic manufacture or Semi Basic Manufacture intends to manufacture active pharmaceutical ingredient (s) submit application for the grant of Active Pharmaceutical Ingredient (s) (APIs) as per **Annexure-VI** through this link https://eapp.dra.gov.pk/. Hard form of the application shall be accepted in R & I section of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

7.3.2. The application is scrutinized by the licensing division and if found as per requirements, it will be processed further and as per delegation of powers, a panel of experts will be constituted by the Chairman, Central Licensing Board/any other officer authorized by CLB for inspection of the unit.

7.3.3. If there will be any shortcoming in the application, the same will be communicated to the applicant for doing the needful in the light of observation made by the concerned officer (s) as per requirement of Rules. As the required information / documents provided, the case will be processed as stated above

7.3.4. The field officer (Additional Director (E&M)/FID/authorized officer) will be advised for coordinating with the other members of the panel and the firm's representative and he will conduct the panel inspection of the firm as per checklist / evaluation form and submit the report of inspection thereof.

7.3.5. The panel of experts / inspectors shall inspect the proposed pharmaceutical unit and will 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.

7.3.6. The authorized officer will send the report to Licensing Division, and same will be placed before the Central Licensing Board for approval of Active Pharmaceutical Ingredient (APIs) then approval letter will be issued to firm.

7.4. Grant of Additional /Revised/Regularized Section's:

7.4.1. A licensed pharmaceutical firm intends to develop new sections or amend the already approved sections or regularize their existing facility submits application for grant of additional /Revised/Regularized Section (s) as per **Annexure-VII** through this link https://eapp.dra.gov.pk/. Hard form of the application shall be accepted in R & I section of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

7.4.2. The application/ layout plan will be scrutinized by the scrutiny committee as per requirements of Schedule-B of Drugs (Licensing, Registering& Advertising) rules, 1976. The Chairman of the Central Licensing Board also performs function of Chairman of the scrutiny committee for layout plan. The Layout Plan is approved by the committee in case it is found compliant to the requirement of Schedule-B of Drugs (Licensing, Registering& Advertising) rules, 1976 as per facilities being constructed and drawn on the proposed layout plan.

7.4.3. In case of shortcomings in the layout plan, the observations will be communicated to the applicant or a technical expert or representative of the firm will be asked to discuss the layout plan with the licensing directorate.

7.4.4. After approval, the duly signed and stamped layout plan will be sent to the firm for construction of the unit as per approved layout plan and further necessary action. However, if approval is granted, the applicant will be informed/ advised to construct proper building structure with proper provision of safety exits under intimation /seek approval of the relevant building control authorities too.

7.4.5. The panel of experts / inspectors will inspect the proposed pharmaceutical unit/facility and will 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.

7.4.6. The authorized officer then sends the report to Licensing Division, and same will be placed before the Central Licensing Board for approval of Grant of additional /Revised/Regularized Section's by the panel then approval letter will be issued to firm.

7.5. Issuance of Inspection Book:

7.5.1. A licensed Pharmaceutical firm shall submit application for the issuance of inspection book as per **Annexure-VIII** through this https://eapp.dra.gov.pk/ Hard form of the application shall be accepted in R & I section of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing) in case the already issued inspection book is lost or damaged or finished.

7.5.2. The Central Licensing Board has delegated the power to Secretary, Central Licensing Board for approval of issuance of inspection book. In case the application is complete, inspection book will be issued to the firm and if there is any shortcoming in the application, the same will be communicated to the applicant for doing the needful.

7.6. Change of Management/ Title of Firm:

7.6.1. A licensed pharmaceutical firm shall submit application for the change of management/title of the firm as per **Annexure-IX** through this link https://eapp.dra.gov.pk/., Hard form of mandatory documents shall be accepted in R & I section of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

7.6.2. If the application is found complete, case will be placed before the Central Licensing Board and letter will be issued to the firm afterwards. If there is any shortcoming in the application, the same will be communicated to the applicant for doing the needful.

7.7. Issuance of NOC for import of reduced customs duty (5%) plant, machinery & equipment for registered Pharmaceutical Manufacturers

A licensed pharmaceutical shall apply on Firm's Letter Head signed by CEO / Director and should accompany following documents:

7.7.1.1. Section approval letter approved by CLB along with Approval letter of layout plan of the section where machinery to be installed.

7.7.1.2. Invoice of Machine/Equipment being imported.

7.7.1.3. Picture of imported Machine/Equipment.

7.7.1.4. Previous installation report of the machine imported by the firm verified by the Area Federal inspector of Drugs.

7.7.1.5. The scientific reason / justification for import of the machine.

7.7.1.1. Notarized Undertaking on Stamp Paper issued in the name of the firm/company or signatory & signed by the MD/CEO) of the firm/company containing following contents:

7.7.1.1.1. Name, Model, Quantity of Machine/Equipment to be imported.

7.7.1.1.2. Name of section in which imported machinery/equipment is to be installed.

7.7.1.1.3. Total Cost of machinery as on Invoice of the machine / equipment to be imported.

7.7.1.1.4. Fulfilment of following Clauses in the light of the decision of DRAP (Authority);

a. The machine(s) will be imported for their own use as per spirit of heading of 38 of the amended 5th schedule of the Customs Act 1969.

b. The conditions specified in amended 5th schedule of the Customs Act 1969 shall be abide by.

c. In case of any violation, firm will be responsible.

7.7.2. The application will be marked from Director (Lic.) /Additional Director (Lic.) to the respective officer.

7.7.3. Once the case is complete as per checklist the evaluator/desk officer will forward the case (e-office / e-application / hard file) for perusal and approval of the Additional Director (Lic.).

7.7.4. The Additional Director will review the case and if found incomplete, the case will be returned back to the concerned Desk Officer for requisite information from the firm. If the case is found complete, it will be forwarded to the Director (Lic.). for approval.

7.7.5. The Director Licensing after perusal of the case will approve/ defer /reject the case mentioning the reasons thereof and return the case to the Additional Director (Lic.).

7.7.6. The Additional Director (Lic.) will convey the approval to the respective Desk Officer.

7.7.7. The Desk officer will issue the recommendation letter to the Section Officer, Ministry of National Health Services Regulations & Coordination (M/o NHSR&C), Islamabad for issuance of the NOC for import of machines under heading 38 of the amended 5th schedule of the Customs Act 1969.

7.7.8. The Section Officer, M/o NHSR&C after completing the codal formalities will issue the NOC to the firm and copy of same will be sent to the Division of Licensing, DRAP.

8. SUBMISSION OF REGULATORY FEE

DRAP has introduced an online fee challan system, available on the link provided at the official website of DRAP. This system will help user (s) 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.

9.3 The DRAP Act, 2012.

9.2 The Drugs (Licensing, Registering & Advertising) Rules, 1976.

ANNEXURE -I

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

Following listed documents / information's required for processing the request / application;

i. Proper application on 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 etc.

iv. Copy of Partnership deed duly executed in the court of competent jurisdiction/registrar of the firms & Copy of Certificate of Registration (Form-C) with Registrar of firms in case of partnership.

v. Copy (s) of CNIC of Chief Executive Officer / Managing Director /Directors/ Partners.

vi. Declaration of firm on stamp paper, In case of Sole Proprietorship Company.

vii. Complete documents of proposed land / plot in the name of firm or its all Directors/partners (purchase document of land/plot, allotment letter, transfer letter/ possession letter, Fard, copy of site map or Aks Shajrah etc.) The proposed land should not be rental place and no grey structure be present in proposed land.

viii. In case if firm is Private Limited, the Certificate of Incorporation with SECP, Memorandum and Article of Association, Form-A, Form-21 and Form-29 should also be furnished. (Attested by SECP)

ix. All documents submitted should be duly attested by Notary Public /SECP/Registrar of firms, office as the case may be.

*As per requirement of paragraph 1.1 of Schedule B under the Drugs (Licensing, Registering and Advertising) Rules 1976, the proposed site shall be located preferably in Industrial area and in any case not in any Residential or commercial area and as per paragraph 1.3 of schedule 'B' the size of plot shall not be less than 2000 Sq. Yards.

ANNEXURE -II

DOCUMENTS / INFORMATION REQUIRED FOR APPROVAL OF BUILDING LAYOUT PLAN.

1. Proper application on covering letter on letter head.
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 copy of approved master layout plan.

REQUIREMENTS OF AREA ACCORDING TO SCHEDULE B-1

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.	
12	Hypodermic Disposable Syringes	900 Sq. ft.	
13	Hypodermic Disposable needles	600 Sq. ft.	
14	Infusion Set	900 Sq. ft.	
	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 radiopharmaceutical 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 maybe intimated 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 legal status of the applicant (i.e. in case of proprietorship the name(s) of proprietors and their address(es), in the case of firm the name and names and addresses of its partners and in the case of 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 Incharge and Quality Control Incharge for supervising manufacturing processes and 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 RENEWAL OF DRUG MANUFACTURING LICENSE

FORM-1A

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

1. 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).
2. There have been / have not been any change in respect of: -I enclose: -
   i. Name of the proprietor (s) / directors (s)/ partner (s).
   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 Quality Control Department, and other technical staff working in these departments.
3. Statement of the Central Research Fund.
   Following statement, as per audited accounts/ based on Income Tax Return for the last five years:-

Year	Investment	Turn-over***	CRF due	C.R.F. ** paid as per Col.4.
1	2	3	4	5

*If there is any change it should be furnished.
**(Original Challan attached).
***Central Research Fund at the rate of 1% of gross profit before deduction of income tax.

(a) Attested copies of the last two income tax assessment order of the Income Tax Department attached.

Dated…… Signed……
Place …… Name Designation & Address……..

ii). Copy of fee Challan as notified by the Authority.

All documents submitted should be duly attested.

ANNEXURE -V

DOCUMENTS / INFORMATION REQUIRED FOR CHNAGE OF QUALIFIED STAFF (PRODUCTION INCHARGE/QUALITY CONTROL INCHARGE/ QUALITY ASSURANCE INCHARGE)

1. Proper application on covering letter on letter head.
2. Prescribe fee as notified by the Authority for proposed Production or Q.C Incharge.
3. Appointment letter.
4. Job acceptance letter by the appointee.
5. Copy of CNIC of appointee.
6. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
7. Registration certificate from Pharmacy Council (in case of Production Incharge).
8. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
9. Resignation / retirement of earlier Production Incharge / QC Incharge.
10. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
11. Status of renewal of DML.
12. Copy of approval letter of previous Incharge.
13. Undertaking as whole time employee on stamp paper.

LETTER OF UNDERTAKING FOR PRODUCTION INCHARGE

I ----------, S/O ---------- CNIC No. ---------- and Managing Director ---------- CNIC No. ---------- For the management of ---------- ---------- do here by agree that proposed Production Incharge ---------- is whole time employee of the firm and not working anywhere else. We hereby confirm that the information / documents provided for academic qualification and experience as per Rule 16-c of Drugs (Licensing, Registering & Advertising) Rules, 1976 are correct and up-to-date.

Management signature / Date **Production Incharge signature / date**

LETTER OF UNDERTAKING FOR QUALITY CONTROL INCHARGE

I ----------, S/O ---------- CNIC No. ---------- And Managing Director ---------- CNIC No. ---------- For the management of ---------- ---------- do here by agree that proposed Quality Control Incharge ---------- is whole time employee of the firm and not working anywhere else. We hereby confirm that the information / documents provided for academic qualification and experience as per Rule 16-e of Drugs (Licensing, Registering & Advertising) Rules, 1976 are correct and up-to-date.

Management signature **Q.C Incharge Signature**

12.All documents should be attested by gazette officer or Notary Public.

ANNEXURE -VI

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

1. Proper application on covering letter on letter head.
2. Prescribed fee as notified by the Authority per API.
3. Names and quantities of chemicals to be used in manufacturing.
4. Names and quantities of chemicals to 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 equipments
10. Shelf life of API
11. Material safety data sheet
12. **All documents should be duly attested/verified by approved technical staff along with Company stamp.**

ANNEXURE -VII

DOCUMENTS / INFORMATION REQUIRED FOR APPROVAL OF ADDITIONAL/REVISED/REGULARIZED SECTION(S)

1. Proper application on covering letter on letter head.
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 copy of approved master layout plan.

REQUIREMENTS OF AREA ACCORDING TO SCHEDULE B-1

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	
12	Hypodermic Disposable Syringes	900 Sq. ft	
13	Hypodermic Disposable needles	600 Sq. ft	
14	Infusion Set	900 Sq. ft	
	Sterilization	401 . 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 radiopharmaceutical 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 maybe intimated in different colored arrows.

ANNEXURE -VIII

DOCUMENTS / INFORMATION REQUIRED FOR ISSUANCE OF INSPECTION BOOK

i). Proper application on covering letter on letter head.

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 News Paper (in case of lost / damaged inspection book).
v). All documents should be attested by gazetted officer or Notary Public.

ANNEXURE -IX

DOCUMENTS / INFORMATION REQUIRED FOR CHANGE OF MANGEMENT/TITLE OF FIRM

1. Proper application on covering letter on letter head.
2. A Fee equivalent to fee for renewal of DML.
3. Copy of revised partnership deed, Agreement of Sale and Transfer of Share/ Transfer Deeds and NOC from Previous Owners on Stamp Paper (In Case of Partnership firm).
4. Undertaking as sole proprietor on stamp paper and NOC from Previous Owner on Stamp Paper (In Case Of sole proprietor firm).
5. Latest certified true copy of Form-29 or Form-A duly attested from S.E.C.P (In Case of SMC/Private/Public Limited)
6. Copies of CNIC'S (Previous and New Management).
7. Approval letter of previous management from CLB, if applicable.
8. All documents should be attested by gazetted officer or Notary Public.

Drug Regulatory Authority of Pakistan
Prime Minister National Health Complex, Park Road
Islamabad-Pakistan
Email: dir.lic@dra.gov.pk Contact: 92 51 9255974
www.dra.gov.pk