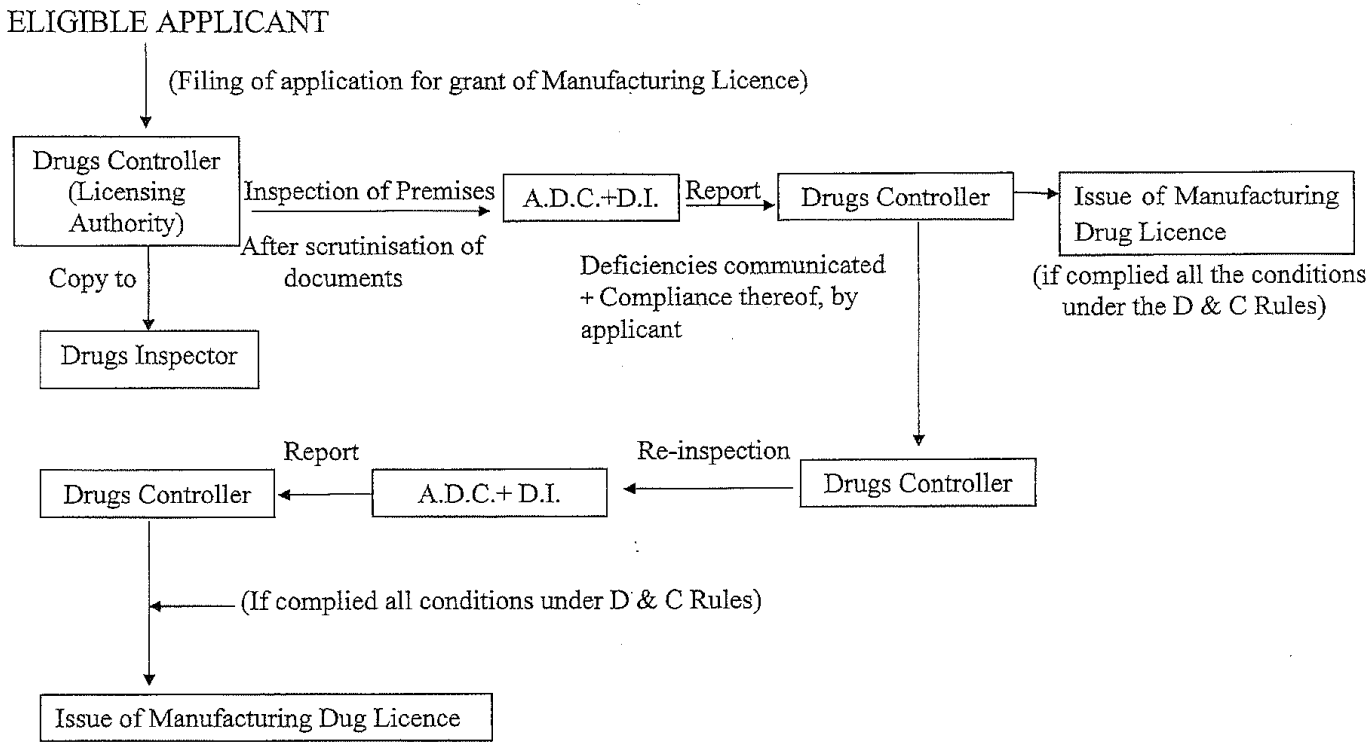
PROCESS FLOW FOR GRANT OF MANUFACTURING DRUG LICENCE



DOCUMENTS/CHECKLIST FOR MANUFACTURING

- Covering Letter (Introduction of applicant with address of the Plant and Administration office and his requirement)
- Application (statutory) in
  Form- 24 with fee – Rs. 6000/- Licence Fees & 1500/- (for every inspection)
  Form- 24-A with fee – Rs. 6000/- Licence Fees & 1500/- (for every inspection))
  Form- 24-B with fee – Rs. 500/- Licence Fees & 200/- (for every inspection)
  Form-27 with fee - Rs. 6000/- Licence Fees & 1500/- (for every inspection)
  Form- 27-A with fee – Rs. 6000/- Licence Fees & 1500/- (for every inspection)
  Form- 27-B with fee – Rs. 6000/- Licence Fees & 1500/- (for every inspection)
  Form- 27-D with fee – Rs. 6000/- Licence Fees & 1500/- (for every inspection)
  Form- 27-DA with fee – Rs. 6000/- Licence Fees & 1500/- (for every inspection)
  Form- 31 with fee – Rs. 2500/- Licence Fees & 1000/- (for every inspection)
  Form- 31A with fee – Rs. 2500/- Licence Fees & 1000/- (for every inspection) duly signed by the Proprietor / Managing Partner / Managing Director/ Person declared as responsible under Sec.34/ Person Authorized by the Board of Directors accompanied by Company Board Resolution.
- Challan in original remitting the required amount of fee in the Head of Account
  0210-Medl. and Ph
  04-Ph-104 – Fees & Fines etc.
  0049-Fines and Confiscations
  02071-Licence Fees under the D & C Rules
- Proof of Identity of the applicants(Copy of Passport/Aadhar Card/Driving Licence)
- Constitution of Firm (Propeietorship/partnership/Pvt. Ltd comp/Public Ltd. Company/ Registered Society/Govt. Agency)
- Documents Required/ Registered Partnership Deed/Registered under I.G.R, Odisha/Articles of Association /Memorandum of Association as per company Act.
- Resolution Copy passed by the Board of Directors for obtaining of License. If Govt. Agency, (Legal Authorization from Competent Higher Authority)
- Power of Attorney/Letter of authorization(wherever applicable)
- Detail list of manufacturing and analytical equipment with copies of purchase bill.
- Copy of SMF (Site Master File)
- List of SOP (Standard Operating Procedure)
- Calibration Validation certificate of Equipments wherever necessary
- List of drugs intended to be manufactured including formula, pack size and details of primary packing material, literature and insert (if any), draft label of product intended to manufacture.
- Layout plan of the premises (Blue print alongwith details of area of each section duly signed by applicant and owner of house)
- Design and layout of HVAC systems if applicable (validation thereof).
- Documentary Evidence in support of Ownership & Building
- House Rent Agreement in Case of Tenancy or declaration of House Owner if same as applicant for specific Purpose
- Educational Certificate of the person incharge of Manufacturing, Testing and Quality Assurance
- Consent Letter of Person Incharge of Manufacturing, Testing & Quality Assurance for their Specific Job.
- Experience Certificate of the person Incharge of Manufacturing, Testing, Quality Assurance from where respective Ex-Employees.
- Declaration/Affidavit of their person Incharge of Manufacturing, Testing, QA regarding their Non-Engagement elsewhere & their previous engagements in the concerned Fields

- Line Diagram of AHU (Air Handling Unit)/AC/De-Humidifier/ Purified Water Supply/Portable Water Supply/Drainage/Return Air Vent etc.
- Fire Safety measures provided (No. Of fire extinguishers) Provide with their validity & other steps taken for safety.
- Provision made for disposal of Waste water Management.
- Pollution Control Certificate (Wherever applicable).
- Consent Letter Approved Institution to carry out Test & Analysis of Manufacturing Drugs and Raw Materials prior to release of the batch along with the copy of Valid License/thereof where the Applicant had not provided own Testing facilities (which require sophisticated instrument)
- Fire Safety Certificate obtained from Fire Officer.
- Compliance of Schedule M, M-I, M-II, M-III) as the case may be.
- Protocol for testing in case of Patent & Proprietary medicine whenever necessary.
- Stability studies data of drugs (Stability studies for all products is to be submitted in case of renewal of licence. In case of grant of licence only established pharmacopoeial products will be allowed. However, real time/accelerated studies has to be commenced immediately after the products are manufactured).
- Permission obtained from the Municipal Authorities/ Panchayat authorities / Certificate in conformity with Factories Act for construction and starting the Unit.
- Clearance from Drugs Controller General (India), New Delhi in case of new drugs (Either Bulk drug or Formulation) – New Drugs as defined under Rule 122 E of Drugs and Cosmetics Rules 1945.
- **Technical Data in respect of the products for manufacture of:-**

(a) Technical Documents to be submitted for Bulk Drugs:

(i) Manufacturing procedure of each product
(ii) Flow Chart with structural Formula of reactions as per Master Formula record and analytical procedure of each applied product with mode of procurement of official reference standards or working standards.
(iii) Official Monographs copies.
(iv) Consumption coefficients of Raw Materials.(as per Format)
(v) Details of effluents generated and their treatment followed.
(vi) Specimen labels of all applied products.

(b) Technical Documents to be submitted for Formulations

(i) Consolidated list of Formulations with packing particulars separately Category wise Viz. Tablets, Capsules, Injectables etc.
(ii) Details of biopharmaceutical classification of each drug to be manufactured (Oral Dosage Form) with result of bioequivalence study of drug (Oral Dosage Form under category II & IV)
(iii) Manufacturing & Analytical procedure of each product (This may not be submitted during renewal of licence).
(iv) Specimen labels
(v) Labels of the similar products moving in the market for formulations not include in IP
(vi) Copies of monographs of drugs which are not included in IP

ADDITIONAL REQUIREMENT IN CASE OF LOAN LICENCE

(i) Consent letter from Principal manufacturing unit
(ii) Copy of valid drug licence of manufacturing unit
(iii) Production capacity of drug for which applied for loan licence
(iv) Copy of GMP if any

- **Additional Requirements In case of Renewal**

(i) Drug Licence with list of products approved in the last licensing period.
(ii) Consolidated List of the Products.
(iii) Production particulars for the last Licensing Period.
(iv) Declaration regarding the changes in the premises, constitution, (Directors/ Partners), Technical Staff of the firm/ Company.
(v) Original labels.

CHECK LIST FOR LAY OUT PLAN FOR MANUFACTURING ALLOPATHIC DRUGS

Sl. No.	Manufacturing Section	Area Provided	Minimum Required Area (Sch. M)	Other Requirement
1	**External Preparation** (Ointments, Emulsion , Creams, Lotions, Paste, Dusting Powder		30 sq.mt + 10 sq. mt Ancillary Area Separate area for formulation Meant for external use & internal use	Air handling system, Airlock, Air Conditioning & Air Supply through 20 Micron filter & Exhaust system, installation of Fly Catcher / air curtain
2	**Liquid Orals** (Syrups, Elixirs, Suspensions, Emulsion etc.)		30 sq. mt + 10 sq. mt Ancillary Area	Air handling system, Airlock, In primary packaging area 5-micron air supply & temp .below 30 degree Celsius installation of Fly Catcher / air curtain
3	**Oral Powder**		30 sq. mt	Air handling system, Exhaust system, and Separate Section. For Blending.
4	**Tablets.** A. Granulation B. Compression C. Packing D. Coating		60 sq. mt 20 sq. mt Anc. Area 30 sq. mt+ 10 sq. mt anc.	Air handling system, Dehumidifier & Air Conditioning as required and Suitable Exhaust system Cubicle for each tablet machine
	E. Beta Lactum		Separate manufacturing & packing Section Area as required for general tablet section	Suitable Measures to avoid cross contamination, Air handing System
	F. Hypodermic Tablets		Separate manufacturing & Packing Section Area as required	Aseptic condition with A/C

5	**Capsule Section** A. General (Non-Penicillin)		25 sq. mt + 10 sq. mt ancillary.	Air handling system, Airlock Exhaust Dehumidifier & A/C
	B. Beta Lactum Group		25 sq. mt + 10 sq. mt ancillary.	Air handling system, Provisions to avoid Cross contamination
	C. Soft Gelatin Capsule		30 sq. mt	Air handling system, A/C, Dehumidifier
6	**Surgical Dressings** A. Surgical Bandages (Excluding Cotton wool)		30 sq. mt 30 sq. mt	} Air handling } System
	B. Medicated Dressings		Separate Prevision	
	G. Efferrascent Tablets		Adequate Space	A/C and Dehumidifier
7	**Opthalmic Preparation** (Eye ointments, Eye Lotions etc.)		25. sq. mt + 10 sq. mt. anc.	Sterile, Air conditioned Dehumidified & Air Lock Separate area for preparation meant for external & internal use.
8	**Pesseries & Suppositories** (if manufactured by Granulation & compression area required is as per tablet section)		30 sq. mt	Other requirement as per Tablet section
9	**Metered Dose inhalers**		20 sq. mt	Air handling system With following subsections Change room, Container preparation bulk preparation & filling Quarantine spray testing
10	**Basic drugs**			
A	General		30 sq. mt	a .Construction above this is not allowed Air handling system 5 micron air supply
B	Sterile		30 sq. mt	All provisions required for manufacture of sterile formulation
11	**Disinfectant**		30 sq. mt 30 sq. mt	Air lock
12	**Repacking of Drugs**		30 sq. mt	Air handling system

13	**Medicinal gases**		30 sq. mt	
14	**Cotton Wool**		100 sq. mt	
15	**Hard gelatin capsule**		75 sq. mt	Air handling system
16	**Mechanical contraceptives** a. Condoms b. copper T c. Tubal rings		30 sq. mt 25 sq. mt 25 sq. mt	Air handling System Aseptic area
17	**Bottle washing Cleaning**		15 sq. mt	Air handing system
18	**Parenteral Preparations** (Following Subsections are required for Glass containers) a Water management area b Containers & closures prep. c Solution prep d Filling capping sealing e Sterilization f Quarantine g Visual inspection h Packing area		150	Air handling system Environmental Monitoring & other Special Provisions as per Sch M Part I A 100 sq. mt ancillary area for small volume parenteral 150 sq.mt. ancillary area large volume parental Minimum 100 sq. mt for packing material store for large volume parietals
19	**For parenteral preparation in plastic container Mfgd by FFS/BFS Technology for metered dose required**			
-	Water management Area		250 sq. mt Separate area for formulation meant for external & internal use	As per Sch M Part I Air handling unit, Environment monitoring & Special Provision 150 Ancillary Area for Large volume parental preparation Minimum 100 Sq. Mt for Packing material stores for LVP
-	Solution preparation Area			
-	Container moulding, filling & sealing Area			
-	Sterilization Area			
-	Quarantine Area			
-	Visual inspection Area Packaging Area			
20	**Quality Control**			
A	Chemical Testing		20 sq. mt	
B	Instrument room		15 sq. mt	Air conditioned
C	Microbiology		10 sq. mt	Air Lock Air handling unit LAF
D	Pyrogen Testing		15 sq. mt	Air conditioned

E	Sterility testing		20 sq. mt	Air Lock, Air handling unit LAF
F	Animal house		15 sq. mt	Air conditioned
21	**Workers room**		Adequate Space	
22	**Raw material Section**		Adequate Space	• Provision for Humidity Control • A/C for thermo labile drugs Separate sampling area Separate area for Sampling/ Dispensing & storing of Betalactum, cytotoxic & sex hormones
23	**Quarantine Raw Material**		10 sq. mt	A/C for the thermolabile drugs
24	**Finished Goods Store**		Adequate Space	A/C for the thermolabile drugs
25	**Quarantine for finished product**		15 sq. mt	A/C
26	**Packing & labeling**	Air handling system for primary packing section		
27	**Packing Materials**		Adequate Space	Air conditioned or air handling system