



Test License to Manufacture Allopathic Drugs from Food Safety and Drug Administration Department

Procedure, List of Supporting Documents and Fees

Table of Contents

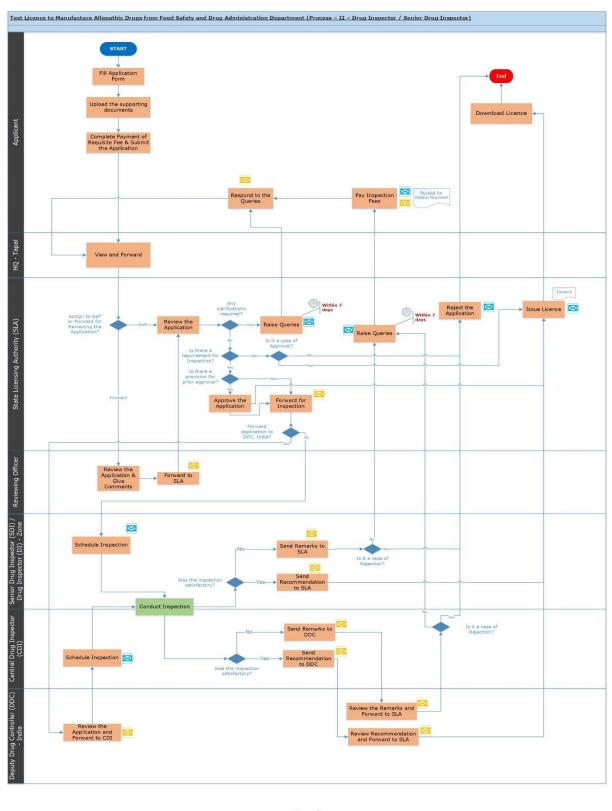
1 F	Procedure	3
2 (Checklist of Supporting Documents	5
3 F	ees	6

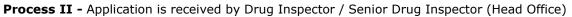
1 Procedure

Test Licence to Manufacture Allopathic Drugs from Food Safety and Drug Administration Department (Process – I – Assistant Director Drugs Control) STAR oad the supporting documents Download Licence Applicant uisite Fee & Sub Pay Inspection Receipt for Fees Respond to the Queries Tapal View and Forward Licence Within 7 Within 7 Ways Within 7 days Issue Licence 🖂 Assign to Self or Forward for Reviewing the Application? Raise Que Raise Queries State Licensing Authority Is it a case o equireme Is there a provision f Reviewing Officer Forward to 1 & Director (AD) Review the Application and Forward the Application to Review the Remarks a Forward to SLA Is it a case of Rejection? eview Recommendation and Forward to SLA SDI) X Remarks to AD Schedule Inspection Senior Drug Inspector AD Conduct Inspe ctor Send Remarks to DDC Is it a case of Rejection? Deputy Drug Controller (DDC) Central Drug 1 - India Schedule Inspection 🔀 Recommendatio to DDC Was the inspection satisfactory? Review the Remarks and Forward to SLA Review the Application and Forward to CDI Review Recommendation and Forward to SLA

Process I: Application is received by Assistant Director (Zone)

Legend Online System 🗾 Offline System 🔀 SMS & Email Alert Sent to the Department Official 🔀 SMS & Email Alert Sent to the Applicant





Legend
Online System Official 🔀 SMS & Email Alert Sent to the Department Official 🔀 SMS & Email Alert Sent to the Applicant

2 Checklist of Supporting Documents

S. No.	S. No. Document					
	For Existing Drug Manufacturing License Holders					
1.	Filled Form 30 as specified in the Drugs and Cosmetics Rules, 1945					
2.	Authorization letter for the signatory of the application form (Board Resolution / Authorisation Letter)					
3.	Drug manufacturing licences Copy					
4.	Previously issued Form 29 Copy, if any					
5.	Copy of valid DSIR (Department of Scientific and industrial research) approval certificate (if any)					
6.	Product dossier (for each product)					
7.	Any other relevant details or documents to establish the correctness of the details or documents or claims made with regard to the above items					
	For those who do not have a Drug Manufacturing License					
8.	Document relating to constitution of concerned firm/ Company/ LLP and others. Proprietorship : Declaration Form Partnership Firm : Partnership Deed Limited Liability Partnership : LLP deed, Registration Certificate of ROC Pvt. Ltd. / Ltd: Memorandum and articles of association, Registration Certificate of ROC, Copy of Board resolution Trust : Trust deed Society : Registration Certificate, By Laws, Copy of Resolution passed Hindu Undivided Family : HUF deed					
9.	Biodata (with photograph) of the Applicant (s)					
10.	Address / ID Proof of the Applicant (s) e.g. Passport, Driving License, Election Commission ID Card, Aadhaar Card/e-Aadhaar letter downloaded from UIDAI website, Income Tax PAN					
11.	Card. Biodata (with photograph) of the Technical Staff (s)					
12.	Educational qualification certificate(s) of the Technical Staff (s) (Starting from Minimum Educational Qualification as specified in the Drugs and Cosmetics Rules, 1945)					
13.	Experience Certificate of the Technical Staff (s)					
14.	Digitally Signed Self-Certification by each Technical Staff stating that He / She is a fulltime employee of the Firm under consideration					
15.	Address / ID Proof of the Technical Staff (s) e.g. Passport, Driving License, Election Commission ID Card, Aadhaar Card/e-Aadhaar letter downloaded from UIDAI website, Income Tax PAN Card					
16.	Ownership document of the premises (Registered Sale Deed / Registered General Power of Attorney / Conveyance Deed / Latest Property Tax Receipt)					
17.	Rental agreement of the premises, if applicable					
18.	Plan of the premises- with details of partitions, measurements - Section wise with location of machineries					
19.	List of machineries and equipment, Air Handling Units, and water system provided Section wise for the manufacturing					

S. No.	Document	
20.	List of analytical instruments and equipment for analysis	
21.	Purchase invoices with the details like production capacity, make etc. if applicable	

3 Fees

S. No.	Fee Туре	Amount(INR)
1	Fees per Product	250

<This space has been left intentionally blank>