Permission for Drug Manufacturing License

1	**Name of Approval / NoC/ Licence/ Registration**	**Grant of manufacturing licenses(excluding LVP/Sera/Vaccines/r-DNA derived drugs and Blood Banks)**
2	**Competent Authority**	Director (Licensing Authority), Drug Control Administration
3	**Applicability Criteria**	Once the factory is ready with its manufacturing & testing facilities as required under the Drugs & Cosmetic Act, 1940 & Rules 1945
4	**Stage**	Pre-Operation
5	**SLA/ Number of Days**	15 Days
6	**Documents Required**	1. Statutory Form 24/27. 2. Affidavit-II (enclosed with online form) attested by Notary regarding the name, address and other details of the persons responsible to the day-to-day affairs of the company and for the conduct of business along with his photograph duly attested. 3. Attested copies of certificates academic qualifications, experience certificates, Bio-data and declarations of Technical Staff in the prescribed proforma with attested photos. 4. Attested copies of documents relating to the ownership/rent/lease 5. Attested copy of Ration Card or Passport or Electoral Card in support of the residential address of the responsible person. 6. Brief manufacturing procedure and Flow Chart along with consumption coefficient of effluents generated and their treatment for the drug applied for along with the method and procedure of Test/Analysis 7. Clearance from Drugs Controller General (India), New Delhi in case of new drugs (Either Bulk Drug or Formulation) New drugs are defined under Rule 122 E of the Drugs and Cosmetic Rules 1945. 8. Declaration of the proprietor/Partnership/Director etc, in Affidavit-I (enclosed with online form), attested copies of Partnership Deed/Memorandum and Articles of Association. 9. Detailed list of Manufacturing and Analytical Equipment with copies of purchase bills. 10. Plan and layout of the premises showing the installation of Machinery and Equipment. 11. Copies of monographs of drugs, which are not included in I.P

		12. Consolidated list of formulations with packing particulars 13. Labels of similar products in respect of non-pharmacopeia products 14. Method of test/analysis for the finished products and also for the ingredients which are not official in any pharmacopoeia or any official compendia or Drug Standards 15. Specimen labels
7	**Form Submission**	https://www.apindustries.gov.in/APIndus/Default.aspx
8	**Procedure for getting license**	**Drug Manufacturing License** **Step 1:** Applicant submits application from the State Single Desk portal with relevant document and pays the fee online **Step 2:** Receipt of Application by Director in SLS email **Step 3:** Forwarding of Application by Director to Area Drugs Inspector and CDSCO for joint inspection through SLS/e-Office **Step 4:** Inspection by concerned Area Drugs Inspector and CDSCO **Step 6:** Forwarding of Inspection Report along with Remarks by Drugs Inspector to Assistant Director in SLS/e-Office **Step 7:** Forwarding of remarks by Drugs Inspector by Assistant Director to Joint Director through SLS/e-Office **Step 8:** Forwarding of remarks by Joint Director to Director through SLS/e-Office **Step 7:** Issuing of License by Director to applicant electronically through Single Desk Portal. **Retention of Sales License** **Step 1:** Applicant pays the retention fees online. An acknowledgement slip / renewal certificate is generated instantly.
9	**Fee & Mode of Payment**	**Mode of Payment:** Online through CFMS payment gateway Fee: **8 categories for Drug Manufacturing** • Upto 10 products per each category – Rs. 6000 + • More than 10 products per category – Rs. 300 per product + Premises Inspection Fees – Rs. 1500