Procedure to obtain Drug Manufacturing License

License for manufacturing of drugs are issued online at the state portal sso.rajasthan.gov.in as per the provisions of Drugs & Cosmetics Act and Rules. The Licensing Authority for such licenses is the Drugs Controller of the state.

Step 1

Application for grant of Manufacturing Licence (The unit should be in industrial area).
The applicant has to make application online in the requisite Form No. 24, or 27, or as applicable (Form 24C for Homoeopathic medicines) and pay necessary fees as given under 'Forms & Fees'. Fee can be paid through the application portal itself or through Government Treasurychallan, under Head of Account-
0210- 04-800-02-00 Other receipts
Department Name: Commissionerate, Food Safety and Drug Control Jaipur
Office Name: Commissioner Food Safety & Drug Control
On-line application portal: Drug Control Organization (DCO) at sso.rajasthan.gov.in

Documents to be uploaded along with the application form:
(Aadhar card number with valid mobile number is mandatory)

1. Application Form.
2. Receipt of fees challan, if not paid through online portal
3. Affidavit/ Declaration of Proprietor/ Partners/ Director(s)/ Managing Director
4. List of all the Partners/ Directors with age & complete postal & residential address.
5. Specific Power of attorney in favour of Authorised Signatory for submitting Application on behalf of the Company on Rs 10/- Non-judicial Stamp paper duly attested by Notary Public.
6. Affidavit / Declaration of Manufacturing Chemist.
7. Affidavit / Declaration of Analytical Chemist.
8. Documents of educational qualification, experience and approval certificates of proposed Manufacturing Chemist & Analytical Chemist; Appointment Letters; Id Proof; Registration certificate issued by Pharmacy Council (if applicable).
9. Site Master File duly signed.
10. Product sheets in specified proforma for approval of products.
11. Section wise list of Plant and machineries, analytical instruments, apparatus for physico chemical, microbiological , biological testing along with attested photocopies of their purchase invoices. List of safety equipments.
12. Details of AHUs (Air Handling Units) including Qualification details and Schematic Diagram. Details of Water System including Qualification details and Schematic diagram; Water testing reports.
13. Medical examination Certificate of technical staff & employees includes absence of contagious disease.
14. Registration from District Industries Center.
15. Consent to establish & consent to operate from Rajasthan State Pollution Control Board.
16. List of Reference books and literature provided.

17. Document pertaining to ownership for the proposed site of the unit & documents in its support.
18. Partnership deed / Memorandum & Article of Association.
19. Specific resolution for commencing Drugs Manufacturing activities (if not already included in Memorandum of Association)
20. Section wise lay-out /blue print of location of plant and machineries (dimensions in metric system), & site plan.
21. NOC from Fire Safety Office, and/ or NOC from Controller of Explosives (as applicable) if dealing with explosive / inflammable material.
22. List of Products alongwith their manufacturing process, analysis procedure, stability data and standard operating procedures.
23. Consent letter from government approved laboratory for sophisticated tests. (If applicable).

Following additional documents are required if applied for loan license on Form 24-A or 27-A or any other form as applicable:

1. Consent letter from principal manufacturing unit in case of loan license.
2. Wholesale licenses of the applicant loan licensee.
3. Statement of production capacity, and capacity utilization of the principal manufacturer.
4. Valid manufacturing licenses and copies of product permission of the product in question (if applicable) of the principal manufacturer.
5. Id Proof of Directors, PAN Card copies, TIN no / GST reg. certificate of applicant firm.

* For proforma of affidavits, see under 'Downloads'.

Step 2

Scrutiny of application. In case any shortcoming / discrepancy is noted, query shall be raised. Further action shall be taken upon receipt of clarification from the applicant. In case the application is found in order, it will be processed for inspection of factory premises. CDSCO will be informed about the application and it will be requested to depute an inspector for joint inspection of the premises.

Step 3
Inspection of proposed premises.

Step 4
If shortcomings / discrepancies are observed during inspection, the applicant shall be intimated to rectify the same and submit compliance report.

Step 5
Upon receipt of the compliance report from the applicant, it will be sent to the concerned officer for verification. If found satisfactory, it will be forwarded for the next step.

Step 6
Products Scrutiny. The details of the products applied for shall be scrutinized and if they are found to comply with the norms, the application will be considered for grant of license.

Step 7
Grant of Licence
If all the prescribed conditions are complied with, licence is granted.