

DRUGS CONTROL ORGANISATION, RAJASTHAN

Check List for documents to be submitted for Grant of Manufacturing Licence – Drugs.

- (1) Application on prescribed form (Form 24 and/or 27 or as applicable) along with requisite fees to be deposited through treasury challan in the Head- 0210- 04-800-02-00 Other receipts
Department Name: Drugs Controller, Rajasthan, Jaipur
Office Name: Asstt. Drugs Controller, NDNP, Jaipur, Rajasthan.
On-line application portal: Drug Control Organization (DCO) at sso.rajasthan.gov.in
- (2) Affidavit of Proprietor/ Partners/ Director(s)/ Managing Director on Rs 10/- Non Judicial Stamp Paper duly attested by Notary Public
- (3) List of all the Partners/ Directors with age & complete postal & residential address.
- (4) 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.
- (5) Affidavit / Declaration of Manufacturing Chemist & Analytical Chemist.
- (6) Copies of documents of educational qualification, experience and approval certificates of proposed Manufacturing Chemist & Analytical Chemist; Appointment Letters; Id Proof.
- (7) Registration issued by Pharmacy Council in the name of Manufacturing Chemist &/or Analytical Chemists. (If any)
- (8) Site Master File duly signed.
- (9) Product approval sheets duly signed with undertaking.
- (10) 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.
- (11) 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.
- (12) Medical examination Certificate of technical staff & employees including absence of contagious disease.
- (13) Registration from District Industries Center.
- (14) Consent to establish & consent to operate from Rajasthan State Pollution Control Board.
- (15) List of Reference books and literature provided.
- (16) Document pertaining to ownership for the proposed site of the unit / Rent deed. Site should be in industrial area.
- (17) Attested copies of partnership deed / Memorandum & Article of Association.
- (18) Specific resolution for commencing Drugs Manufacturing activities (if not already included in Memorandum of Association)
- (19) Section wise blue print of location of plant and machineries (dimensions in metric system), & site plan.
- (20) NOC from Fire Safety Office, and/ or NOC from Controller of Explosives (as applicable) if dealing with explosive / inflammable material.
- (21) List of Products alongwith their manufacturing process, analysis procedure, stability data and standard operating procedures.
- (22) Consent letter from government approved laboratory for sophisticated tests. (If applicable).