

Check List for Grant of New License

GENERAL REQUIREMENTS OF DOCUMENTATIONS

- i) An application Form has been submitted in Form 24-D along with name of technical staff.
- ii) Two copies of map of premises (Blue print showing area of each room and indicating the purpose for which these are to be used).
- iii) List of machinery, equipments and lab testing equipments in two copies.
- iv) Ownership record of building where manufacturing unit is to be established.
- v) Copy of rent deed of premises if hired for establishment of manufacturing unit along with proof of ownership of building owner.
- vi) A treasury Challan amounting to Rs. 1000/- has been attached with depositing amount in following head :-
 - “0210 – Medical & Public Health
 - 03 – Medical Training & Research
 - 101 – Ayurvedic Receipt.”

WITH REGARD TO THE TECHNICAL PERSONS

- vii) An attested photocopies of qualifications, experience and registrations of technical staff along with attested/self signed photograph.
- viii) Affidavit from technical staff members with regard to working as full time employee in concerned manufacturing unit and statement with regard to non-conviction under Drugs and Cosmetics Act, 1940.

WITH REGARD TO THE PROPRIETOR AND PARTNER OF THE FIRMS

- ix) An affidavit from owner and partners with regard to the following submissions duly attested by 1st class Magistrate / Oath Commissioner / Public Notary
 - (a) That the premises shall not be utilized for any other purpose except manufacturing of drugs.
 - (b) That the premises shall not be used for residential purpose.
 - (c) That the all raw drugs shall be duly tested before their processing as per pharmacopoeial standard mention in Ayurvedic Pharmacopia.
 - (d) That all finished drugs shall be tested as per the specifications submitted under rule 1.1(N) of Schedule ‘T’ and the medicines shall be of standard quality.
 - (e) That the record of all testing of raw material and finished drugs shall be duly maintained.
 - (f) That the firm shall follow the all norms prescribed in Schedule ‘T’ of Drugs and Cosmetics Rules, 1945.
 - (g) That the owner and partners have never been convicted under the Drugs and Cosmetics Act, 1940 and rules made thereunder, 1945.
- x) A copy of the partnership deed (if applicable) on Rs. 10/- stamp paper duly attested by the 1st class Magistrate / Oath Commissioner or Public Notary.

WITH REGARD TO THE PRODUCT SUBMITTED FOR APPROVAL

- xi) Affidavit have been filed by the proprietor or authorized signatory of the firm for non-resemblance of products with regard to their name, formulations, packing and labeling etc.
- xii) Clinical trial report from two Govt. Dispensaries and one from private practitioner.
- xiii) Submission of quality control references of patent / proprietary formulations in pursuance of rule 1.1(N) of Schedule ‘T’.
- xiv) Proof of concept have been attached in case of patent / proprietary Ayurvedic medicines.
- xv) Five typed copies of the list of items to be manufactured.