

DRUGS CONTROL DEPARTMENT

GOVERNMENT OF KERALA

Standard Operating Procedure – One time retention of loan license for Ayurvedic medicine

Name of Department	Drugs Control Department
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1. Standard Operating Procedure for Applicant

Application for	One time retention of loan license for Ayurvedic medicine
Mandatory supporting documents required	<ol style="list-style-type: none">1. Covering letter with court fee stamp of Rs.52. Filled 24 E application3. Filled Questionnaire (Applicant's photograph affixed)4. Drug Licence- Classical medicine- 2000/- Chalan Head of account (0210-04-104-99) Drug License- Patent & Proprietary medicine 3000/- for upto 10 medicines 2000/- for every additional medicines each additional product GMP Retention- 5000/-5. Copy of letter issued for permission to the establishment intending to manufacture the drug.6. Consent letter from the establishment intending to manufacture the drug7. Detailed building plan prepared and signed by a registered draftsman and signed by the applicant8. Affidavit in prescribed form in 200/- stamped paper attested by notary under seal.9. Ownership certificate of the building10. In the case of rented building, copy of attested lease agreement in 200/- stamped paper11. Attested Certificate of joint venture agreement/Memorandum of Association of the company, Articles of Association and attested identity

	<p>of directors and partners.</p> <p>12. Copy of 25 D, 26D, GMP Certificate of the establishment intending to manufacture the drug.</p> <p>13. Applicant's identity document and self-addressed postal cover</p> <p>14. List of lab equipment in the drug manufacturing unit</p> <p>15. List of machinery and vessels in the drug manufacturing unit</p> <p>16. Affidavit of technical experts of the establishment intending to manufacture the medicine attested by Drugs Inspector, qualification certificate, identity documents.</p>
Process description	<p>1. Submit the complete set of application at the concerned DI office.</p> <p>2. Prepare the premises and related records for Pre-licensing inspection of concerned DI.</p> <p>3. If any defects are detected and informed in the application or at the premises during the verification of the drug inspector, rectify the same as early as possible and initiate it to the office of the drug inspector.</p> <p>4. Keep in touch with department through official mail or official website.</p>
Procedure for Fees payment	<p>Payment can be done through e-treasury. Select – drugs control department – select the district as Thiruvananthapuram and then the office of Deputy Drugs Controller (Ayurveda). All payment should be remitted to office the Deputy drugs controller Thiruvananthapuram.</p>

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List of Reference Documents	Drugs & Cosmetics Act,1940 & Rules,1945
Time line for completing the process Checking of Application Status	60days
Checking of Application Status	Online provision currently available " Click here "
Key Contact Person from department	Deputy Drugs Controller- Ayurveda

2. Standard Operating Procedure for Approver

Application for	Grant of One time retention of loan license for Ayurvedic medicine
Mandatory supporting documents required	Mentioned as SOP for Applicant.
List of Reference Documents	Drugs & Cosmetics Act, 1940 & Rules, 1945
Time line for completing the process	60days
Departmental Work Flow	<ol style="list-style-type: none">1. Receiving of the entire application through the concerned DI office forwarded to Office of Deputy Drugs Controller Thiruvananthapuram.2. Verification of the documents by the concerned Regional/Senior Drugs Inspector Ayurveda.3. Pre-licensing inspection to be conducted by the Drugs Inspector Ayurveda.4. Issue of Manufacturing Licence by the State licensing authority (Deputy Drugs Controller Ayurveda)

3. Verification/Inspection Procedure:

Verification – Verification of application form and supporting documents

Inspection – Inspection of the premises by the concerned Drugs Inspector