DRUGS CONTROL DEPARTMENT

GOVERNMENT OF KERALA

Standard Operating Procedure – Manufacturing Licence for Ayurveda Drugs

Name of Department	Drugs Control Department

1. Standard Operating Procedure for Applicant

Application for	Manufacturing Licence for Ayurveda Drugs
Mandatory supporting documents required	1. Covering letter with Court fee stamp of Rs.5 mentioning the purpose of application in detail. 2. Properly filled 24 D form 3. Properly filled 24 E1 form 4. Fee structure : *Drug Licence*- Classical medicine-2000/- Chelan Head of account (0210-04-104-99) Drug License- Patent & Proprietary medicine up to 10 products and for 3000/-, After the approval of ten products Rs: 2000/- per each additional product *GMP* - 5000/- 5. Detailed building plan prepared and signed by a registered draftsman with the signatureof the applicant. 6. Affidavit in prescribed form 200/- stamped paper attested by notary Public under seal 7. Ownership certificate of the building 8. In case of tenancy, attested copy of tenancy agreement prepared on Rs.200 stamp paper 9. Attested partnership deed/Memorandum of Association of the establishment and articles of association of the company and attested identity document of Directors and partners. 10. Attested copy of Applicant's identity card 11. Duly filled questionnaire with photograph 12. Self-written affidavit in prescribed format, attested by Drugs Inspector with photograph of technical experts (One in pharmaceutical manufacturing department & two in quality control department. 13. Attested copy of technicians, qualification certificate, Registration Certificate and identity card. 14. Copy of water tested report/copy of invoice card of water authority. 15. List of collection of lab equipment, Machinery & utensils belonging to the applicant with his signature.

	16. Stamped envelope with applicant's address 17. List of drugs in prescribed format (P &P drugs 14 column format, Classical drug four columns) of drugs to be approved. 18. Pilot study report, Stability study report, report of drug testing in AYUSH approved lab, page copy of reference books should also be submitted for approval of Patent & Proprietary drugs. 19. Pharmaceutical manufacturing establishment's SOP (for GMP) 20. In case of fresh application due to death of licensee application should be submitted along with copy of Death Certificate, copy of inheritance certificate, existing license, GMP and their renewal certificates, original list of approved medicines.
Process description	1. Submit the complete set of application at the concerned DI office. 2. Prepare the premises and related records for Pre-licensing inspection of concerned DI. 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. 4. Keep in touch with department through official mail or official website.
Procedure for Fees payment	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.

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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 Licence for Manufacturing Ayurveda Drugs
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	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