DRUGS CONTROL DEPARTMENT

GOVERNMENT OF KERALA

Standard Operating Procedure – Onetime retention of Ayurvedic medicine manufacturing license

Name of Department	Drugs Control Department

1. Standard Operating Procedure for Applicant

Application for	Onetime retention of Ayurvedic medicine manufacturing license
Mandatory supporting documents required	1. The application should be submitted to Deputy Drugs Controller through the respective Regional Office with a courtfee stamp of Rs.5 2. Properly filled 24 D 3. Properly filled 24 E1 4. Drug Licence- Classical medicine-1000/- Chalan Head of account (0210-04-104-99) Drug License- Patent & Proprietary medicine 1000/- for upto 10 medicines 1000/- for every additional medicines each additional product GMP Retention- 1000/- 5. Detailed building plan prepared and signed by a registered draftsman and signed by the applicant (only if the existing building plan has been modified) 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. Original 26D, Original GMP certificate, original and one copy of approved list of products. 18. Stability study of approved Patent & Proprietary medicine should be submitted for renewal purpose. 19. Quality test report of the last batch products. 20. Schedule TA report for last 5 yrs should be submitted 21. In case of change in ownership, building or partnership deed applicant for the new license should be made as soon as possible by submitting back existing license, GMP list, renewal certificate, Original list of approved products.
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 ofOnetime retention of Ayurvedic medicine manufacturing license
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