DRUGS CONTROL DEPARTMENT

GOVERNMENT OF KERALA

Standard Operating Procedure – Additional Product

Name of Department	Drugs Control Department

1. Standard Operating Procedure for Applicant

Application for	Additional product
Mandatory supporting documents required	1. Covering letter with Court fee stamp of Rs.5 mentioning the purpose of application in detail. 2. Properly filled additional medicine questionnaire 3. Fee structure : *Drug Licence*- Classical medicine-2000/- Chelan Head of account (0210-04-104-99)(if already paid submit the copy of the paid chalan) Drug License- Patent & Proprietary medicine up to 10 products and for 3000/-, After the approval of ten products Rs: 2000/- per each additional product 4. Affidavit in prescribed form 200/- stamped paper attested by notary Public under seal(for Patent & Proprietary medicine) 5.List of drugs in prescribed format,2 set 1 set signed by the Licensee & Manufacturing Technical Staff (P &P drugs 14 column format, Classical drug four columns) of drugs to be approved. 6. 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. 7. Copy of the Drug License &GMP
Process description	1. Submit the complete set (1 set original & 1 set copy) of application at the concerned DI office. 2. Prepare the premises and related records for 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
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. Additonal medicine inspection to be conducted by the Drugs Inspector Ayurveda. 4. For P&P medicines Expert committee verification and acceptance needed 4. Issue of the additional medicines 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