DRUGS CONTROL DEPARTMENT

GOVERNMENT OF KERALA

Standard Operating Procedure – Product Certificatefor Ayurveda Drugs

Name of Department	Drugs Control Department

1. Standard Operating Procedure for Applicant

Application for	Product Certificatefor Ayurveda Drugs
Mandatory supporting documents required	1. Application with court fee stamp of rs.5/- 2. 25D,26D, GMP , Copy of approved product list 3. Payment of s. 830/- for each patent medicine
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 ofProduct Certificate for 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