

DRUGS CONTROL DEPARTMENT  
GOVERNMENT OF KERALA

**Standard Operating Procedure and Checklist – Homeopathic Drugs Manufacturing Licence**

Application for	Manufacturing Licence for Homeopathic Drugs
Mandatory supporting documents required	<ol style="list-style-type: none"> <li>1. Application in Form 24C</li> <li>2. Licence fee of Rs.300/- for manufacture of Homeopathic mother tincture &amp; potentised preparation, Licence fee of Rs.300/- for manufacture of potentised preparation only. Licence fee remitted is for approval of 10 products. For products beyond 10, additional fee of Rs.50 is to be remitted for each product.</li> <li>3. Constitutional details of the firm (Proprietorship/Partnership including Limited Liability Partnership/ Private or Public company/ Society/Trust)</li> <li>4. Document from local authority to prove ownership of premises</li> <li>5. Plan of the premises</li> <li>6. Declaration of technical staffs for manufacturing and testing</li> <li>7. Documents to prove their qualification and experience</li> <li>8. Details of products applied with their master formula records, SOPs &amp; Specimen labels.</li> <li>9. For renewal of licences, fee of Rs. 250/- is to be remitted for manufacture of Homeopathic mother tincture &amp; potentised preparation, Rs. 250/- is to be remitted for renewal of licence for manufacture of potentised preparation only,</li> </ol>
Process description	<ol style="list-style-type: none"> <li>1. Submission of hard copy of entire application to the Drugs Controller Office, Thiruvananthapuram and copy of which is to be forwarded to concerned Assistant Drugs Controller office.</li> <li>2. Verification of the documents by the concerned Regional/Senior Drugs Inspector</li> <li>3. Pre-licensing inspection conducted by the Concerned Regional/Senior Drugs Inspector of Assistant Drugs Controller Office.</li> <li>4. Issue of Manufacturing Licence for Drugs by the State Drugs Controller</li> </ol>
Procedure for Fees payment	Payment can be done through e-treasury
List of Reference Documents	Drugs & Cosmetics Act,1940 & Rules,1945
Time line for completing the process	28 days
Checking of Application Status	Online provision currently not available
Key Contact Person from department	Drugs Controller