

**Standard Operating Procedure – Manufacturing Licence for Cosmetics**

<b>Name of Department</b>	<b>Drugs Control Department</b>
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**1. Standard Operating Procedure for Applicant**

<b>Application for</b>	Manufacturing Licence for Cosmetics
<b>Mandatory supporting documents required</b>	<ol style="list-style-type: none"> <li>1. Application in Form COS 5/COS 6</li> <li>2. Registration fee via online payment receipt of Rs. 10000/ for each category of cosmetics. Licence fee remitted is for approval of 10 products. For products beyond 10, additional fee of Rs.500 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. Approved Plan of the premises</li> <li>6. Declaration of technical staffs for manufacturing and testing/consent letter from Approved laboratories.</li> <li>7. Documents to prove their qualification and experience</li> <li>8. Details of products applied with their master formula records, SOPs, Specimen labels &amp; test reports.</li> <li>9. By remitting Rs. 10000/- as the licence fee along with application of Cosmetics (form COS 8,COS 9) a maximum of approval of 10 products under each category could be obtained. For products beyond 10 numbers additional fee of Rs. 500/- is to be remitted</li> </ol>
<b>Process description</b>	<ol style="list-style-type: none"> <li>1. Submission of entire application via ONDLS Portal</li> <li>2. Verification of the documents by the concerned staff in the Office of the Drugs Controller.</li> <li>3. If the application is in order as per the requirements stipulated in Rules, Manufacturing Licence for Cosmetics will be granted by the Drugs Controller within 45 days from the date of application.</li> <li>4. Post-licensing inspection within 30 days from the date of grant of licence by the Concerned Regional/Senior Drugs Inspector</li> </ol>
<b>Procedure for Fees payment</b>	Payment can be done through e-treasury
<b>List of Reference Documents</b>	Drugs & Cosmetics Act,1940 & Cosmetics Rules 2020
<b>Time line for completing the process</b>	45 days
<b>Checking of Application Status</b>	Online provision currently available
<b>Key Contact Person from department</b>	Drugs Controller

DRUGS CONTROL DEPARTMENT  
GOVERNMENT OF KERALA

**2. Standard Operating Procedure for Approver**

Application for	Grant or Retention of Licence for Manufacturing Cosmetics
Mandatory supporting documents required	<ol style="list-style-type: none"> <li>1. Application in Form COS 5/COS 6</li> <li>2. Registration fee via online payment receipt of Rs. 10000/ for each category of cosmetics. Licence fee remitted is for approval of 10 products. For products beyond 10, additional fee of Rs.500 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. Approved Plan of the premises</li> <li>6. Declaration of technical staffs for manufacturing and testing/consent letter from Approved laboratories.</li> <li>7. Documents to prove their qualification and experience</li> <li>8. Details of products applied with their master formula records, SOPs, Specimen labels &amp; test reports.</li> <li>9. By remitting Rs. 10000/- as the licence fee along with application of Cosmetics (form COS 8, COS 9) a maximum of approval of 10 products under each category could be obtained. For products beyond 10 numbers additional fee of Rs. 500/- is to be remitted</li> </ol>
List of Reference Documents	Drugs & Cosmetics Act, 1940 & Cosmetics Rules, 2020
Time line for completing the process	45 days
Departmental Work Flow	<ol style="list-style-type: none"> <li>1. Application submitted to Office of Drugs Controller and copy is forwarded to Assistant Drugs Controller Office.</li> <li>2. Verification of the documents by the concerned staff in the Office of the Drugs Controller.</li> <li>3. If the application is in order as per the requirements stipulated in Rules, Manufacturing Licence for Cosmetics will be granted by the Drugs Controller within 45 days from the date of application.</li> <li>4. Post-licensing inspection within 30 days from the date of grant of licence by the Concerned Regional/Senior Drugs Inspector</li> </ol>

**3. Verification/Inspection Procedure:**

Verification – Verification of application form and supporting documents

Inspection – Inspection of the premises by the concerned Drugs Inspector