

Drug Control Organisation
(Medical & Health Department)

Standard Operating Procedures



सत्यमेव जयते

Government of Rajasthan

Government of Rajasthan

Standard Operating Procedures of Medical & Health Department

Following are the Standard Operating Procedures (SoPs) for Grant / Renewal of Drug Manufacturing License:

Step No	Online Application and Approval Procedure
1	The applicant shall visit Rajasthan's Single Window Clearance System (SWCS) at swcs.rajasthan.gov.in and log into his / her account. (Please refer to http://bioscope.rajasthan.gov.in/EventDetails?id=72 for information on how to register on SWCS)
2	The applicant shall click on ' <i>I want to submit an application</i> ' and subsequently click on ' <i>I will select the service(s)</i> ' and select the required service under 'Medical and Health Department'
3	Upon clicking on the required service, an application form opens wherein the applicant is required to enter his / her personal details, establishment's details, Manufacturing Chemist/ Analytical Chemist/ QA Personnel details and details of premises of manufacturing
4	Following documents need to be uploaded on the portal for Grant / Renewal: <ol style="list-style-type: none">1. Site master file (duly signed)2. Section wise list of plant and machineries, AHU's, water system, analytical instruments, apparatus for quality control3. Registration from District Industries Centre4. Consent to establish & consent to operate from Rajasthan state pollution control board5. List of reference books and literature provided6. Document pertaining to ownership for the proposed site of the unit & documents in its support7. Memorandum of articles/ constitution8. Section wise blue print of location of plant and machineries & site plan9. Consent letter from government approved laboratory for sophisticated tests10. Ownership title deed
5	Upon filling in the required details and uploading all documents, the applicant shall click on 'Next' to proceed to the next step
6	The fees will be auto-calculated and applicant shall be required to make payment by clicking on 'Make Payment' button at the bottom of the page
7	The applicant shall choose a suitable online payment method from the list of options available to him / her and proceed to make payment

Standard Operating Procedures of Medical & Health Department

Step No	Online Application and Approval Procedure
8	On successful payment, the application shall be submitted to the Department
9	The application shall be received by the Drug Controller (DC) / Assistant Drug Controller (ADC) of the relevant district (for license on Form 25 for schedule F(II) Drugs), who shall review the application details and the attachments submitted by the applicant. He / She may seek clarification from the applicant if required. In case the application is found in order, the DC / ADC directs the ADC / Drug Control Officer (DCO) for conducting inspection
10	The ADC / DCO conducts inspection and submits the report to concerned DC/ ADC with his observations
11	The DC / ADC views the report and sends his observations, if any, to the applicant, for compliance. In that case, once the Applicant complies with all provisions / requirements, he / she intimates the DC / ADC regarding the same
12	The DC / ADC reviews the compliance report submitted by the applicant and forwards it to the ADC / DCO for compliance verification. Subsequently, the ADC / DCO reports his observations to the DC / ADC
13	If the compliance is verified, the DC sends the application to 'Formulation Screening Committee' (FSC) at the Headquarter and ADC to concerned DCO of the district, who may send report to DC / ADC, either objecting to products, rejecting products or approving them (or a combination of these)
14	The DC / ADC issues license for the products approved by FSC / DCO at the districts along with permission to manufacture them and sends objections, or information on rejection of products, if any, to the applicant as per report sent by FSC / DCO at the level of district (In case of renewal, Renewal certificate along with Product Renewal certificate is issued)
15	Once approved, digitally signed final certificate shall be generated in the system
16	The applicant shall receive an intimation from the Single Window System regarding the final approval, who shall then download the digitally signed certificate from his / her dashboard

Standard Operating Procedures of Medical & Health Department

Note

- The status of the application shall be updated on the applicant's dashboard (on Single Window System) at each stage of the application process. The same may be tracked without logging into the portal using the following URL: <http://swcs.rajasthan.gov.in/ApplicationTracker.aspx>
- The Department shall seek clarifications, if any, only once and within 7 working days of submission of application by the applicant
- The Department has mandated that all applications shall be accepted online only. The applicant is not required to visit Department for submitting application, documents, making payment, tracking status of application or collecting final signed certificate.
- The timelines for providing approval are 90 working days. The same has been mandated through the Rajasthan Guaranteed Delivery of Public Services Act, 2011