GRANT OF DRUGS MANUFACTURING LICENSE

Process Description

Name of Process	Grant of Drug Manufacturing License
Name of a business process	Apply for the license to manufacture drugs
Related laws, rules, and regulations	Drug Regulatory Authority of Pakistan Act, 2012 Drugs Act, 1976 The Drugs (Licensing, Registration & Advertising) Rules, 1976
Process participant	Manufacturer DRAP
Input and criteria to enter/ begin the business process	Manufacturer is a registered company as per SECP regulations/Registrar of Firms/Sole Proprietor Manufacturing site area is minimum 2000 sq. yards.
Activities and associated documentary requirements	Initiate Process for Manufacturing License 1. The applicant files the application for site verification along with requisite documents as per checklist and fee. 2. The application and documents are received in DRAP and are scrutinized. 3. DRAP initiates the site inspection by a panel, if the application is complete. • If the application is in-complete, DRAP informs the applicant with observation note. 4. After recommendations by panel, Site approval letter issued with advice to submit building layout plan. • If not recommended, site rejection letter is issued to the applicant. 5. The applicant then files the application on letterhead for approval of layout plan along with requisite documents (site verification letter by DRAP etc.) and fee. 6. The application and documents are received in DRAP and are scrutinized/evaluated. 7. The case is presented before LOP Committee for approval, if the application is complete, layout plan approval letter is issued with the advice to start construction. • If the application is in-complete, DRAP informs the applicant with observation note. 8. Once construction is completed, Manufacturer files the application form (Form 1) for drug manufacturing license (DML) and attaches the documents as mentioned in form along with application for approval of technical staff. 9. Manufacturer submits the challan fee. 10. Manufacturer submits the complete application to DRAP. (Form 1) 11. DRAP receives the application form.

	12. DRAP scrutinize and evaluates the application form and supporting documents with the checklist. • If the application is in-complete, DRAP informs the applicant with observation note. 13. DRAP forms a panel to assess the case. 14. DRAP inspection team inspects and prepares the inspection report and submits to the DRAP. 15. DRAP Central Licensing Board review and finalize the case for granting the manufacturing license. 16. If Rejected, DRAP informs the manufacturer for application rejection. 17. If approved, DRAP issues Drug Manufacturing License (Form2) to the manufacturer. 18. Manufacturer collects the Form 2 from DRAP office. 19. In case of rejection of application by CLB, applicant has the right of appeal within 60 days before the Appellate Board.
Output criteria to exit the business process	Drug Manufacturing License (Form 2) from DRAP office. Form 2 Validity: 5 years Legal Reference: Drug Regulatory Authority of Pakistan Act, 2012
Time required to complete this business process	Minimum = 15 months Maximum = 18 months
Fee	The updated fee structure of regulatory functions can be accessed on https://www.dra.gov.pk/publications/regulatory-fees/.