

Grant of license to export drugs (other than finished drugs/raw materials)

Process Description

Name of Process	Grant of license to export drugs (other than finished drugs)
Name of a business process	Apply for Grant of license to export drugs (other than finished drugs/raw materials)
Related laws, rules, and regulations	The Drug Regulatory Authority of Pakistan Act, 2012 The Drugs Act, 1976 The Drugs (Import & Export) Rules, 1976
Process participant	Drug Manufacturer DRAP
Input and criteria to enter/ begin the business process	DML (By way of Basic/Semi basic manufacturing) Product Approval Certificate
Activities and associated documentary requirements	Process for Grant of license to export drugs (other than finished drugs/raw materials) 1. Applicant fills the application Form 10 for drug export license (other than finished drugs/raw materials). Applicant attaches supporting documents required as per the checklist . 2. Applicant submits fee through bank challan. 3. Applicant submits application form to DRAP office. 4. DRAP officer receives the application form, challan copy and supporting documents. 5. DRAP verifies the application form and supporting documents. <ul style="list-style-type: none"> • If application not compliant, DRAP informs the Applicant with observation notes. 6. If request is rejected, DRAP informs the applicant. 7. If request is accepted, DRAP approves the application. 8. DRAP issues Drug Export License - Form 9 . 9. Exporter receives the Drug(s) Export License (Form 9) from DRAP office.
Output criteria to exit the business process	License to export drugs (other than finished drugs)/Raw Materials. Validity: 2 years Legal Reference: Drug Regulatory Authority of Pakistan Act, 2012 , The Drugs Act, 1976 & The Drugs (Import & Export) Rules, 1976
Time required to complete this business process	Minimum = 1 day Maximum = 3 days
Fee	PKR 5000