

MANUFACTURING OF BULK-DRUGS (USER-MANUAL)

DEPARTMENT OF INDUSTRIES GOAP.

- To apply for Drug License the entrepreneur should apply through single desk portal.
- Go to Apply for approvals in the home page as shown below and login with credentials.

- After Successful login it will go to the entrepreneur dashboard then click on proceed to which ever industry you want to apply for Drug License as shown below.

ENTREPRENEUR DASHBOARD

Sl.No	Organisation Name	Location	Sector	Line of Activity	Total No. of Applications				--
					Required	Approved	Rejected	Pending with Department	
1	praveen infra	Visakhapatnam	IT	IT-Infra	6	0	0	0	Proceed
2	Madhava Workshop	Anantapur	Leather	Leather footwear and leather products (excluding tanning and hide processing) (except cottage scale)...	7	0	0	0	Proceed
3	herbal plant	Visakhapatnam	Bulk Drugs, Pharmaceuticals	CHEMICALS AND ALLIED SUBSTANCES AND PRODUCTS	9	0	0	0	Proceed
4	Abids				0	0	0	0	Proceed


- Then click on Pre Establishment Services and you will be redirected to below dashboard. To apply for bulk drugs manufacturing click on the highlighted link as shown in the below figure.

PRE-ESTABLISHMENT CLEARANCE DESK

You have proposed to invest Rs 5000 Lakhs (Plant and Machinery) for setting up of unit with line of activity: **Manufacturers of Bulk Drugs and API**. Your industry is categorized as **Large Enterprise Category**.

Click [here](#) to fill the **Common Application Form (CAF-I)**, which is required for all **Pre-Establishment clearances** and pay the **Processing Fee** to the Department of Industries.

List of Pre-Establishment clearances requiring only Common Application Form (CAF-I):

(Click on the pdf image to download the **Common Application Form**) 

(Click on the pdf image to download the **Department Acknowledgement form**) 

Sl. No.	Clearance Name	Application Filing Date	Department Received Date	Approval / Rejected Date	Status	File ID
1	Sanction of Estimate/Issuance of Service Connection for Power Supply for 11KV or 33KV	08-MAR-2019	-	-	Yet to Apply	
2	Factory Plan Approval	08-MAR-2019	-	-	Yet to Apply	
3	Water Connection and Approval for water supply sanction from Municipal Corporations	08-MAR-2019	-	-	Yet to Apply	
4	Permission to dig new wells	08-MAR-2019	-	-	Yet to Apply	

List of Pre-Establishment clearances requiring Department specific application along with Common Application Form (CAF-I):

(Click on the pdf image to download the **department specific application form**)

Sl. No.	Clearance Name	Application Filing Date	Department Received Date	Approval / Rejected Date	Status	File ID
5	Fire-No Objection Certificate 	-	-	-	Yet to Apply	
6	Consent for Establishment Red Category 	-	-	-	Yet to Apply	
7	License for manufacture of bulk drugs / formulations 	11-MAR-2019	-	-	Yet to Apply	
8	New Building plan Approval from APIIC-IALA 	-	-	-	Yet to Apply	AutoDCR file details

- The below form opens with 4 options as shown below and whichever form you want to apply click on it and proceed.

Form 24 Form 24-A Form 27 Form 27-A

- Then after selecting the required form we need to fill the application form and submit the form. For example, if you select 'form24' from the above list then the 'form 24' form is opened as shown below. You need to fill the details and submit it.
- Note: Payment is calculated based on number of drug products you give in this form.

FORM 24 (SEE RULE 67)

APPLICATION FOR GRANT OF A LICENCE TO MANUFACTURE FOR SALE [OR DISTRIBUTE OF DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULED X,C AND C(1)]

General Details

1. Name* 2. Organization* 3. Location of Drugs Manufacture*

List Of Organisation Staff

Name* Qualification* Type* Experience(In years)*

List Of Drugs Manufacturing

Drug Category* Purpose* Product/ Drug Name* Specification/ Pharma Specifications* Composition

After submitting the above form payment page is shown as below.

PAYMENT DETAILS

To obtain License for manufacture of bulk drugs / formulations From Department of Health, Medical & Family Welfare an Amount of Rs. 7500 to be paid through Challan
To make online challan payment please [Click here](#)

ONLINE ENCLOSURES

To Apply for License for manufacture of bulk drugs / formulations Clearance, The following enclosures need to be uploaded online. Please select the enclosure and then choose file to upload

Sl No.	Select	Enclosure Name	Attachment
1	<input type="checkbox"/>	Plan and layout of the premises showing the installation of Machinery and Equipment.	
2	<input type="checkbox"/>	Attested copies of documents relating to the ownership/rent/lease.	
3	<input type="checkbox"/>	Declaration of the proprietor/Partnership/Director etc, in Affidavit-I (enclosed with online form), attested copies of partnership Deed/Memorandum and Articles of Association.	
4	<input type="checkbox"/>	Attested copies of certificates of academic qualification, experience certificate from Ayurveda/Unani and declarations of Technical Staff in the prescribed proforma with photo duly attested.	
5	<input type="checkbox"/>	Affidavit-II (enclosed with online form) attested by Notary regarding the name, address and other details of the persons responsible to the day-to-day affairs of the company and for the conduct of business along with his photograph duly attested.	
6	<input type="checkbox"/>	Attested copy of Ration Card or Passport or Electoral Card in support of the residential address of the responsible person.	
7	<input type="checkbox"/>	Detailed list of Manufacturing and Analytical Equipment with copies of purchase bills.	
8	<input type="checkbox"/>	Clearance from Drugs Controller General (India), New Delhi in case of new drugs (Either Bulk Drug or Formulation) New drugs are defined under Rule 122 E of the Drugs and Cosmetic Rules 1945.	
9	<input type="checkbox"/>	Brief manufacturing procedure and Flow Chart along with consumption co-efficient of effluents generated and their treatment for the drug applied for along with the method and procedure of Test/Analysis.	
10	<input type="checkbox"/>	Consolidated list of formulations with packing particulars.	
11	<input type="checkbox"/>	Specimen labels.	
12	<input type="checkbox"/>	Labels of similar products in respect of non-pharmacopeia products.	
13	<input type="checkbox"/>	Method of test/analysis for the finished products and also for the ingredients which are not official in any pharmacopeia or any official compendia or Drug Standards.	
14	<input type="checkbox"/>	Copies of monographs of drugs, which are not included in I.P.	

No file chosen
Please upload .pdf/.jpg/.jpeg/.png file with size less than 10 MB.

- After completing the payment, we need to upload the required documents by selecting one-by-one. After uploading all the enclosures, you need to click on **SENT TO DEPT.**
- Then the application will forward to respective department.