CHECKLIST OF DOCUMENTS TO BE SUBMITTED FOR ISSUE OF MANUFACTURING LICENCE FOR MANUFACTURE OF UNAPPROVED/ APPROVED NEW DRUGS/ BANNED DRUGS – <u>ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)</u> – SOLELY FOR EXPORT PURPOSE

1. Covering Letter on the company's letter head duly signed and stamped by the authorized signatory (name & designation) indicating the following details clearly:
   a. Intent of application
   b. List of product(s) to be exported
   c. Pack size(s)
   d. Place of manufacturing (Name & Address of the firm)
   e. Quantity/Quantities
   f. Export Order/ Purchase Order No. and date
   g. CDSCO NOC No. and date
   h. Name and address of the Foreign Buyer
   i. Name and address of the trader (if PO is in the name of domestic trader)
   j. Name and address of the Consignee *(Ship to)*

2. **NOC obtained from CDSCO** for the Specific Quantity Export of the applied products.

3. Copy of valid Export Order/ Purchase Order.
   a. From foreign buyer in the name of manufacturer/ in the name of trader.
   b. If in the name of trader then a Letter from the trader addressed to the manufacturer (applicant) required to be submitted along with the application, signed by the competent person with valid Purchase Order No. along with the valid drug licence held by the trader.
   c. Notarized and recent dated not more than *6 months* prior to the application made by the firm.

   Export Order should indicate the following details clearly:
   - List of product(s) to be exported
   - Pack size(s)
   - Quantity/Quantities
   - Signed by the competent authority with specified destination point of the importing country

4. Copy of Manufacturing Licence held by the firm.

5. Status of the applied product (Approved New Drug/ Unapproved New drug/ Banned drugs)

6. Registration Certificate from importing country in the name of the manufacturer *in case of Banned Drugs*, translated into English and with an apostille by Indian Embassy in that country.

7. Manufacturing Licence *issued earlier* for Specific Quantity Export of the applied drug.

8. Reconciliation Data for the APIs for the quantities permitted earlier for Specific Quantity Export in the following format along with the copies of shipping bills and invoices.

Reconciliation Data

Mfg. Lic. No.:
Export NOC No. & issue date:
Quantity Permitted for Export:
Country permitted to Export:
Name & address of the firm to which the drug was exported:

Sl. No.	Name of the drug	Batch No.	Mfg. Date	Exp. Date	Batch Size	Qty . Manufactured	Qty. Exported	Invoice No. & Date	Importing Country	Shipping Bill No.	Remaining Stock available

9. Undertaking by the manufacturer on Company's Letter Head duly signed and stamped by the authorized signatory (with name & designation) as per ***Annexure-I.***

10. Affidavit (on non-judicial stamp paper and notarized) as per ***Annexure-II.***

11. Application (statutory) in Form-24/ 27/ 31/ 27D/24A/27A/27DA

    duly signed by the Proprietor / Managing Partner / Managing Director/ Person declared as responsible under Sec.34 / Person Authorized by the Board of Directors accompanied by Company Board Resolution. ***along with the documents as per Checklist for Additional Product.***

12. Challans regarding User Charges of Rs. 500/- and Act fees of Rs. 300/- per product.

ANNEXURE-I

UNDERTAKING SUBMITTED TO THE DRUGS CONTROL ADMINISTRATION, TELANGANA FOR EXPORT OF UNAPPROVED / APPROVED NEW DRUGS / BANNED DRUGS FROM INDIA.
(shall be submitted on Company's Letter Head)

a. The applied drugs (Name of the applied drugs) will be manufactured by us at (Name and address of the firm) **.**

b. The batch to be exported *shall undergo Quality Control testing at our site* **or** *shall be tested at the destined site.* ***(Delete whichever is not applicable).***

c. We shall ensure that the drug(s) manufactured on the basis of the permission granted is exported and that no part of it is diverted for domestic sale in India ***(a declaration in the form of an affidavit on Non-Judicial Stamp paper is submitted along with the application).***

d. We shall maintain a stock register for quantities of API manufactured, consignments exported and remaining stocks of APIs, which will be open for a periodic inspection.

e. We shall make available for inspection, on completion of the export order, information regarding each consignment dispatched, remaining stock of drug and related raw materials and intermediates in hand.

f. We shall ensure physical destruction of all un-exported quantity of drugs.

g. In the event of cancellation of the relevant Export Order, we shall ensure the physical destruction of all unexported quantity of the drug(s) ***(a declaration in the form of an affidavit on Non-Judicial Stamp paper is submitted along with the application).***

h. We shall ensure that the drug for which permission has been given shall cease to be manufactured or exported if the drug is prohibited in future in the country or in the importing country.
**The firm has to declare whether the applied drug is covered under NDPS Act.*

Date :

Authorized Signatory
Name:
Designation:

ANNEXURE-II

AFFIDAVIT

(on Rs. 100/- non-judicial stamp paper & Notarized)

We M/s. (Name and address of the firm), holding valid site manufacturing licence in Form-___ vide Licence No:_____ ,dated:_____, valid up to _____, received purchase order for the following drugs as per the below mentioned details.

Name of the Products	**Quantity**	**PO No. and Date PO received from**	**Export to/ Ship To (Name of the firm and address)**

We shall ensure that the drug(s) mentioned above and manufactured on the basis of the permission granted is exported and that no part of it is diverted for domestic sale in India

In the event of cancellation of the said Export Order, we shall ensure the physical destruction of all unexported quantity of the drug(s)

Date :

Authorized Signatory
Name:
Designation: