CHECKLIST OF DOCUMENTS TO BE SUBMITTED FOR ISSUE OF MANUFACTURING LICENCE FOR MANUFACTURE OF UNAPPROVED/ APPROVED NEW DRUGS/ BANNED DRUGS – FORMULATIONS (with unapproved/approved "New Drug"/Banned drug API from domestic manufacturer) – SOLELY FOR EXPORT PURPOSE [Formulation manufacturer as applicant]

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. Dosage form(s)
   d. Composition and strength(s)
   e. Pack size(s)
   f. Place of manufacturing (Name & Address of the firm)
   g. Quantity/Quantities
   h. Export Order/ Purchase Order No. and date
   i. CDSCO NOC No. and date
   j. Name and address of the Foreign Buyer
   k. Name and address of the trader (if PO is in the name of domestic trader)
   l. Name and address of the Consignee *(Ship to)*
   m. Source of API-Name and address of the API domestic manufacturer
   n. Name of the API
   o. Quantity of API obtained from the domestic manufacturer

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
   - Dosage form(s)
   - Composition and strength(s)
   - 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. Justification/ Calculation regarding the quantity of *approved/ unapproved New Drug (API)* obtained from the domestic API manufacturer to manufacture the new formulation

7. Purchase Order issued by the formulation manufacturer to the API manufacturer and Copy of the site manufacturing licence of the API manufacturer

8. Registration Certificate from importing country in the name of the manufacturer along with composition and strength of the applied drug *in case of Banned Drugs*, translated into English and with an apostille by Indian Embassy in that country.

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

10. Reconciliation Data for the Formulations 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

11. Legal Undertaking (on non-judicial stamp paper and notarized) in ***Annexure-I*** **from the manufacturer of API and in** ***Annexure-II*** **from the manufacturer of formulation.**

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

13. 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.***

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

ANNEXURE – I

Legal undertaking to be submitted by the bulk drug manufacturer of the banned/ unapproved drugs/ approved new drugs for sale of drug to manufacturing units manufacturing formulations only for export

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

I/We,_____ S/o _____having premises at _____ aged about _____do hereby solemnly affirm and undertake as under:

1. That We _____having the manufacturing premises at_____ and hold manufacturing license no._____in Form____ for the manufacture of drugs.

2. That I undertake to manufacture and sell total Quantity _____of drug _____to **M/s.** _____having the manufacturing premises at_____for the purpose of manufacturing _____solely for export to _____**.**
3. That I undertake to maintain books and records of transaction of above said unapproved/ approved new drug/ banned drug for which Specific Quantity Export approval will be granted.

4. That I undertake to allow the inspection of the books and records as well as the actual usage of _____ **(Name of API)** by the inspector appointed under the Drugs and Cosmetics Act as and when required.

5. That the bags/containers of the said drug along with other requirements of labeling and packaging also mention ---"for further manufacturing".

6. That the above said quantity of the unapproved/ approved new drug/ banned drug shall not be diverted for sale into the country/or used for any other purpose.

7. In the event of non-materialization of export due to cancellation of export order etc. the same should be intimated to the concerned State Licensing Authorities and the manufacturer shall ensure physical destruction of such stocks in the presence of State Licensing Authority.

DEPONENT

VERIFICATION

Verified on this **_____day of _____**that the contents of my above undertaking are true and that no part it is false and that nothing material has been concealed here from.

DEPONENT

ANNEXURE– II

Legal undertaking to be submitted by the formulation manufacturer of the banned/ unapproved drugs/ approved new drugs for export

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

I/We_____ S/o _____having premises at _____ aged about _____do hereby solemnly affirm and undertake as under:

1. That I am the buyer of _____ (Name of the drug) as an API from M/s _____ (name of address of manufacturer) Quantity_____ in Kg/mg.

2. That I undertake to use_____ **kg/mg** (Quantity) of above said drug banned / unapproved drug/approved new drug for the purpose of manufacturing **_____ (name of formulation)** solely for export to **_____(country).**
3. That I undertake the entire quantity of the drug(s) manufactured on the basis of the above Specific Quantity Export approval shall be exported and no part of it be diverted for domestic sale in India.

4. That I undertake the stocks of the drugs manufactured solely for export shall invariably bear the inscription "For export only - Not for domestic consumption " on the labels affixed to their cartons/packaging.

5. That I undertake to submit a certificate in below mentioned format after completion of the formulation development.

S. No.	Quantity of the formulation manufactured	API Quantity in hand

6. That I undertake to maintain separate stock register for quantities of API purchased for manufacturing, drug formulation manufactured, and remaining stocks of the drugs and API which will be open for a periodic inspection by the Authorities.

7. That I undertake to allow the inspection of the books and records as well as the actual usage of **_____ (name of drug)** by the inspector appointed under the Drugs and Cosmetics Act as and when required.

8. In the event of cancellation of the relevant Export Order, I shall ensure the physical destruction of all unexported quantity of the drug(s)

DEPONENT

VERIFICATION

Verified on this **_____day of _____**that the contents of my above undertaking are true and that no part it is false and that nothing material has been concealed here from.

DEPONENT

ANNEXURE-III

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 purchased for manufacturing, drug formulations manufactured, consignments exported and remaining stocks of formulations and bulk drugs, 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: