GUIDANCE DOCUMENT FOR ISSUANCE OF NO OBJECTION CERTIFICATE FOR MANUFACTURE OF UNAPPROVED/APPROVED NEW DRUGS FOR EXPORT PURPOSE

Introduction

A manufacturer holding a valid license copy in Form -25/ Form-28/ Form 28 D and their respective loan licenses can obtain a No Objection Certificate from Zonal offices of the Central Drugs Standard Control Organisation (CDSCO) for export purpose only for **Unapproved / approved new drugs** in India.

Purpose

The Requirement of online submission of Application for issuance of a No Objection Certificate for Manufacture for export of unapproved/approved new drugs from India. This document was made as per guidelines issued by the Ministry of Health and Family Welfare for export purpose and Rule 94 of the Drugs and Cosmetics Act, 1940.

Scope

This document is applicable for the manufacturer to obtain No Objection Certificate for **unapproved/approved new drugs** from zonal offices of the Central Drugs Standard Control Organisation (CDSCO) for export purpose.

Procedure

The Requirement of online submission of Application for issuance of a No Objection Certificate for manufacture for export of unapproved / approved new drugs involves 2 steps i.e. Registration at zonal office followed by procedure for release of consignments at port.

This procedure is applicable to unapproved drugs and approved new drugs, except for NDPS (narcotic drugs and psychotropic substances) and banned drugs.

Accordingly, an applicant is required to first apply to the concerned zonal office with all the requisite documents for the issuance of an Export NOC having 1-year validity/ exhaustion of the sanctioned amount whichever is earlier.

"Thereafter, the applicant needs to fill out the reconciliation details in the prescribed format, along with the requisite documents, and obtain clearance for the consignments from the concerned port office for its release in Step -II."

Step-I

One-time Online registration process with zonal office: An Applicant is required to fill online Integrated Registration Form (IRF) one time before the grant of Export NOC which is valid for 1 year. IRF needs to be verified by the concerned zonal office & NOC may be issued with 1year validity for the applied products within 7 working days from the date of Application. For the same, applicant is required to submit documents as a part of the IRF with following documents:

1. Export NOC Form /Integrated Registration form (IRF): This is an automatically generated form that requires the applicant to submit relevant details when filing an online application.

2. Legal Undertaking in Annexure -I /II: The Applicant shall submit legal undertaking in the prescribed format from the manufacturer of API as Annexure -I and from Formulation Manufacturer as Annexure -II digitally signed by the Applicant (attached at the End of the page)

3. Copy of Manufacturing License: A valid license issued by the State Licensing Authority in Form 25/Form 28/Form 28-D and their respective loan license shall be enclosed along with each application for the required location to manufacture the drug for export purposes. In case of issuance of a subsequent Export NOC after the first one, the firm is required to submit a quantity-specific export license as issued by the concerned SLA for the specific product, being applied for.

4. Reconciliation Data: The applicant is required to submit history of reconciliation data of previously issued NOC in the online module in the following format.

NOC Qty	Batch Qty Manufactured	Packed and exported Qty	Left/ unpacked Qty	Country Exported	Customer Details	PO/EI/ SB Details	Upload documents

5. NRA Approval status of Importing Country: The applicant needs to submit a document of the applied drugs as issued by the NRA of the importing country.

In case NRA approval of the importing country is not available, the following documents may be submitted.

a) <u>Active Pharmaceutical Ingredient (API):</u>

- **Approved New Drugs in India:** The Approval status as issued by CDSCO may be submitted**.**
- **Unapproved API's in India:** The API / Bulk drug's Pharmacopeial status in IP/USP/BP/JP/EP may be submitted.
  Further, if formulation of the said API is approved in any SRA country (United states/ European Union Member States/ Canada/ Japan/Australia/Switzerland) & (or) Importing country & (or) India may be submitted**.**
- **Unapproved API of NDPS category in India & Banned API in India:** NRA approval of the importing country is mandatory to submit.

b) <u>Finished Formulation (FF):</u>

- **Approved New Drugs in India**: In case of Approved New Drugs (FF) approval status as issued by CDSCO may be submitted**.**
- **Unapproved Formulation in India:** Approval status in SRA Country (United States/ European Union Member States/ Canada/ Japan/Australia/Switzerland)/Importing country may be submitted.
- **Unapproved (fixed dose combination) FDC in India, Unapproved NDPS Drugs in India & Banned Drugs in India:** NRA approval of the importing country is mandatory to submit.

c) <u>R & D Batches:</u>

- **API:** The API / Bulk drug's Pharmacopeial status in IP/USP/BP/JP/EP may be submitted.

Further, if formulation of the said API is approved in SRA country (United States/ European Union Member States/ Canada/ Japan/Australia/Switzerland) &(or) Importing country &(or) India may be submitted**.**

- **Formulation:** Approval status of any SRA Country (United States/ European Union Member States/ Canada/ Japan/Australia/Switzerland) and (or) Importing country may be submitted.

d) <u>NCE Batches:</u>

- **NCE –Batches for Clinical trials, DMF/ANDA filings:** The firm is required to submit IUPAC name details, COA & STP.

In case of third country exports all the above requirements are applicable to destination country/end use country

In case the pharmaceutical product (API or formulation) has been registered and approved by the National Regulatory Authority (NRA) of the destination country for a specific firm, such approval may be considered applicable for other applicants.

Step-II

Procedure for release of consignment at port office: In this step after getting valid export NOC from the zonal office, the applicant is required to submit following details at the time of release of the consignment which will be verified by the concerned port office.

During this Step, an applicant is required to submit documents in online mode and require submission of following documents at the time of Export:

1. Valid Export NOC: The applicant must select the EXPORT NOC for the intended export through the Auto Fetch system.

2. Reconciliation details for the Quantity exported: Reconciliation data for each export at the time of release needs to be filled by the applicant in the given online format and the same to be verified by the concerned port office. The reconciliation module will be open throughout the validity of the NOC for a repetitive release of consignment.

NOC Qty	Batch Qty Manufactured	Packed and exported Qty	Left/ unpacked Qty	Country Exported	Customer details	PO/EI/ SB details	Upload documents

3. Test / Batch Release Certificate: Firm is required to upload physical document of COA (Certificate of Analysis).

4. Purchase order(PO) / Export Invoice (EI) / Shipping Bill (SB) details: The details of PO/EI/SB number date/customer name, country and quantity is to filled in the given format and the same needs to verified by concerned port office.

5. Label: Firm is required to submit original label for the applied product.

6. Export License copy from SLA: Firm is required to submit export license copy issued by SLA for the applied product.

Key Points:

1. Qty specific/PO Specific NOC is being discontinued except for NDPS And Banned drugs
2. Issuance of Export NOC with 1-year validity from date of Registration or exhaustion of the sanctioned amount, whichever is earlier.
3. In case of formulation, allowance of usage of un-exported quantity for next export order within 60 % residual shelf life. If the shelf life is below 60%, the same shall be destructed in the presence of the State Licensing Authority.
4. In case of API, allowance of usage of un-exported quantity for next export order within 3 months of residual shelf life. If the shelf life is below 3 months, the same shall be destructed in the presence of the State Licensing Authority.
5. Timeline of 7 days for Issuance of NOC (step – I - 5 working days & step – II - 2 working days).
6. "For the issuance of an Export NOC for NDPS drugs and banned drugs, a quantity-specific and PO-specific NOC will be issued for each order/Consignment.

ANNEXURE–I

LEGAL UNDERTAKING TO BE SUBMITTED BY THE BULK DRUG MANUFACTURER OF BANNED/ UNAPPROVED DRUGS/ APPROVED NEW DRUGS FOR EXPORT PURPOSE OR FOR SALE TO MANUFACTURING UNITS MANUFACTURING FORMULATIONS ONLY FOR EXPORT

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

I/We,_____S/o ___having premises at ____aged about ____do hereby solemnly affirm and undertake as under:

1. That Wehaving the manufacturing premises at_____and hold Manufacturing license no. ____in Form _____ for the manufacture of drugs.
2. That I undertake to maintain books and records of transaction of above said unapproved/ approved new drug/ banned drug for which NOC will be granted.
3. 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.
4. That the bags/containers of the said drug along with other requirements of labeling and packaging also mention ---"for further manufacturing".
5. That the above said quantity of the unapproved/ approved new drug/ banned drug shall not be diverted for sale in India/or used for any other purpose in India other than for export purpose only.
6. The batch to be exported shall undergo Quality Control testing as per specification of importing country and will comply with all the requirements of importing country including quality standards.
7. We undertake to submit details of export quantity as per online CDSCO reconciliation module for each and every consignment along with export quantity asper Step II requirement.
8. We undertake that in the event of submission of falsified document, the previously issued NOC shall be cancelled and will be barred from reapplying Export NOC for a period of one year for any product
9. I abide to undertake that I will submit label as per Rule 94 of Drugs and cosmetic Act 1940.
10. In the event of non-materialization of export due to cancellation of Export order /Non utilization of quantity issued through Export NOC etc., Manufacturer shall ensure physical destruction of stocks having shelf life less than 3months in the presence of State Licensing Authority.
11. We undertake to abide by the aforesaid information outlined in this annexure and to ensure compliance with all the conditions of Export NOC."

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)

I/We_____S/o ___, Authorized Signatory <Designation> of M/s _____having premises at_____ and age about_____yrs do hereby solemnly affirm and undertake as under:

1. That I/We undertake to use_____**kg/mg** (Quantity) of API (banned/unapproved/approved new) for the purpose of manufacturing **(name of formulation)** solely for export purpose.
2. That I undertake the entire quantity of the drug(s) manufactured on the basis of the above NOC shall be exported and no part of it will be diverted for domestic sale in India.
3. 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.
4. 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/Bulk Drug used for manufacturing of Formulation	Remaining API/Bulk Drug in hand

5. 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.
6. 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.
7. The batch to be exported shall undergo Quality Control testing as per specification of importing country and will comply with all the requirements of importing country including quality standards.
8. We undertake to submit details of export quantity as per online CDSCO reconciliation module for each and every consignment along with export quantity
9. We undertake that in the event of submission of falsified document, the previously issued NOC shall be cancelled and will be barred from reapplying Export NOC for a period of one year for any product
10. I abide to undertake that I will submit label as per Rule 94 of Drugs and cosmetic Act 1940
11. In the event of non-materialization of export due to cancellation of Export order /Non utilization of quantity issued through Export NOC etc., Manufacturer shall ensure physical destruction of stocks having shelf life less than 60 % in the presence of State Licensing Authority.
12. We undertake to abide by the aforesaid information outlined in this annexure and to ensure compliance with all the conditions of Export NOC."

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