File no. IMP-12018(19)/1/2025
Government of India
Ministry of Health and family Welfare
Directorate General of Health Service
Central Drugs Standard Control Organization
FDA Bhawan, KotlaRoad, New Delhi – 110002

Dated:01/08/2025

Circular

Sub: New online Dual Use System on SUGAM Portal- Regarding

CDSCO to further enhance "ease of doing Business" has streamlined the process of issuing Dual Use NOC for drugs imported in bulk for non-medicinal use through Sugam Portal. Further to reduce the compliance burden, CDSCO has initiated issue of 1 year NOC, subject to prescribed conditions for such drugs.

Accordingly Sugam Checklist and procedure is revised and also a guidance document is attached herewith.

Application, for Dual Use NOC shall be submitted through SUGAM online portal by fresh registration process along with the prescribed checklist of documents. The details of the documents required for registration is **annexed**.

This is modified system is now functional now on SUGAM Portal atwww.cdscoonline.gov.in

In view of these concerns and support industry interests, the new online Dual use system will be live from **31.08.2025**.

Yours faithfully

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Enclosure: **User Manual and Guidance Document**
Copy to

1. All the Stakeholders Through CDSCO Website
2. CDAC Team
3. All Zonal/Sub Zonal office

Annexure

The new registration process will start on 05.08.2025.

From 01.09.2025, only users registered and approved by CDSCO as Dual Use NOC Traders/Actual Manufacturers will be allowed to apply for Dual Use NOC on the new Sugam portal.

Documents Required for Registration for the Purpose of Dual Use NOC

To process the registration, the applicant must upload the following documents:

1. **Address Proof**
   A copy of the address proof of the firm issued by a government authority.
   Acceptable documents include:
   - Certificate of Incorporation
   - Form 18
   - GST Certificate
   - INC-22
   - Importer Exporter Code (IEC) Certificate
   - BSNL/MTNL Telephone Bills

   Note: The name and address of the organization on the document must exactly match the details provided in the undertaking and on the portal.

2. **Undertaking Form**
   A scanned copy of the duly filled, stamped, and signed undertaking form must be uploaded.
3. **ID Proof of Authorized Person**

   A valid ID proof of the authorized person, as specified in Point No. 5 of the undertaking form, must be submitted.

   Important Note 1: An applicant who have already been granted login credentials under any of the following user roles—Applicant for Cosmetics, Importer, Corporate, Indian Agent, BA/BE Approved Sites, Test License, CRO, Export NoC or BA/BE Clinical Trial, etc.—must **select "Switch Role" option** to add as " Dual Use NOC " role for submission of Dual use NOC application on New online Dual Use System on SUGAM Portal which will be effective from 01.09.2025.

   Important Note 2: Please note that if a firm is already registered on the SUGAM Portal, any attempt to register again using new credentials will result in rejection of the new application. The firms registered with the user role **Export NOC (Zone)** will not be having the "Switch Role" option. Therefore, "for applying a Dual Use NOC application on New online Dual Use System on SUGAM Portal" applicants must submit a fresh registration selecting the user role **Dual Use NOC**.

Guidance Document for grant of permission for Drugs imported in Bulk for Non Medicinal Use as per Rule 43 of Drugs and Cosmetics Rules 1945.

Introduction

This document provides guidance on obtaining permission for the import of drugs in bulk for non-medicinal use, as per Rule 43 of the Drugs and Cosmetics Rules, 1945. Its primary objective is to ensure consistent and uniform implementation of this rule by the Central Drugs Standard Control Organization (CDSCO). The document also outlines the specific requirements importers must fulfil to obtain such permissions and provides clarity on the regulatory process for dual-use drugs.

Scope

This guidance covers the identification and regulation of drugs imported in bulk for non-medicinal use. It applies to industries such as pharmaceuticals, food, and animal feed that use these substances for specific purposes or in lower strengths. Importers are expected to conduct due diligence and consider regulatory and technical factors before applying. Permissions are granted after a technical review by the Deputy Drugs Controller (India) of the respective zones.

Purpose

The purpose of this guidance is to provide the process for obtaining permission for importing drugs intended for non-medicinal use under Schedule D of the Drugs and Cosmetics Rules. It aims to ensure that substances imported for non-medicinal use are compliant with the necessary regulatory requirements, and that the importation process is streamlined and transparent. The document specifies the conditions under which these substances can be imported and outlines the required documentation and steps for obtaining approval from the relevant authorities.

Procedure

The Requirement of online submission of Application for issuance of a No Objection Certificate for importing drugs intended for non-medicinal use under Schedule D of the Drugs and Cosmetics Rules involves 2 steps i.e., 1) Registration on Sugam portal and application of NOC at zonal/Sub zonal office followed by 2) procedure for release of consignments at port office

To begin the process, the applicant must register on the Sugam Portal by selecting the user role as "Dual Use NoC" and filling out the required registration form.

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

"Thereafter, the applicant needs to fill the form of Step/Phase II along with the requisite documents, and obtain clearance for the consignments from the concerned port office for its release and fill out the details in Supply chain module at the time of release of consignment."

Phase-I/Step 1

Registration process on Sugam portal followed by verification with CDSCO HQ: An Applicant is required to fill online Integrated Registration Form (IRF). After submission, the registration details will be reviewed and verified by CDSCO Headquarters. For the registration to be processed, the applicant must upload the necessary documents, including an undertaking form, valid address proof of the firm (such as Certificate of Incorporation, Form 18, GST Certificate, INC-22, IEC Certificate, or BSNL/MTNL utility bills), and a valid ID proof of the authorized person.

During the registration process, applicant shall be mentioned the details like Corporate Identification Number (CIN) details, Custom House Agent (CHA) details, Importer/Importer representative details with their Authorized Person/CHA Person (depends on Case to Case) to avoid/minimizing the interfere of unauthorized/third party persons.

The grant of Dual use NOC which is valid for 1 year needs to be verified by the concerned zonal/ Sub zonal office & NOC may be issued with 1year validity for the applied products within 7 working days (5 days for zonal office and 2 days for port) from the date of Application. For the same, applicant is required to submit documents as a part of the IRF with following documents:

To import drugs meant for non-medicinal use, the following procedure must be followed:

1. Integrated Registration Form (IRF): This is an automatically generated form that applicants must complete when submitting an online application. The form must be duly signed and stamped by the Authorized Signatory.

2. Supporting Documents: Upload relevant documents supporting all applied countries, such as sales contracts, agreements, undertakings, **copy of High seas sales agreement** etc.,

3. Legal Undertaking: A legal undertaking must be submitted on a Rs. 100 stamp paper (notarized), following the format provided in Annexure-I. If the drug is imported by the actual user, a legal undertaking must be obtained from the trader, as per Annexure-II, who will retain it for regulatory inspections.

4. Specific Usage Details: In cases where the drug is used as an animal feed supplement, food supplement, converted from one drug to another (including a brief manufacturing process or manufacturing flowchart), cosmetic use, or use in any other industry, relevant details must be provided.

5. Permissions and Justifications: Submit the required permissions from the concerned authorities along with justification for dual use.

6. Quantity Justification and Technical Literature: Provide a justification for the quantity of the drug/material requested, along with supporting technical literature.

7. Reconciliation Data: Submit reconciliation data of previously submitted quantities through supply chain system.

8. Declaration by Applicant: The applicant must declare that they have not applied for this particular item to any other office of CDSCO. If an application has been submitted elsewhere, provide the details and current status.

In case of the drug registered for import with CDSCO, details shall be enclosed.

Phase-II/Step-2

Procedure for release of consignment at port office: In this step after getting valid Dual use NOC from the zonal/ Sub 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 import:

1. Covering letter: The applicant must the covering letter that clearly outlines purpose, name and quantity of drugs to be imported, name and address of the manufacturer.

2. Certificate of Analysis (CoA): Firm is required to upload document of COA (Certificate of Analysis).

3. Bill of entry details: The details of bill of entry number date/customer name, country and quantity is to filled in the given format and the same needs to verified by concerned port office.

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

5. **Invoice:** Firm must submit purchase invoice.

Supply chain module

The applicant needs to submit data for each import at the time of release needs 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.

Note: In order to submit another application for Phase II Dual Use NOC port 80% of utilisation needs to be submitted.

S.No.	Drug Name	Supply name	Supply purpose	Batch No.	Supply Quantity	Invoice no.	Supply invoice date	Supply Address	Supply invoice Document

Key Points

 A complete application must be submitted before approaching the authorities.

 Dual-use clearance should be applied for at least two months before import to avoid delays.

 Imported items must be clearly labeled with their intended use on all documents (Copy of label)

 Manufacturers must submit a Licensing Authority–attested Master Formula Record for drug imports.

 Imports for the purpose of purification or sterilization are not eligible under dual-use.

 Import permission for dual-use items is valid for one year and issued to actual users.

Similar like Export NOC portal, Step 1/Phase-I will be done by CDSCO Zonal/Sub Zonal office with validity of 1 year and, Step 2/Phase-II will be done by Port Office for release of consignment(s)

Reason:- Since, Port Office shall maintain the all Dual Use NoC records of all such approvals and the released consignments details under Dual Use NoC category. The approved applications data also reflected in the Online Sugam portal (after individual login) for verification the approval status of Dual Use NoC by the both Zone/Sub Zone/Port offices of CDSCO.

 Port Offices will keep records of all such import approvals.

 Jurisdiction of filing dual use NOCs application shall be relooked with respect to Actual Importer address and its authorized branches located in the varies places, but not to the CHAs offices addresses.

Annexure I

Legal Undertaking for the Import of Drugs as per provisions of Schedule D of Drugs and Cosmetic Rules 1945 to be submitted by the Actual Users to The Central Drugs Standard Control Organisation (CDSCO) Zonal/ sub zonal office.

I/We.....S/o..... having premises at .....aged about .....do hereby solemnly affirm state and undertake as under: 1. That I am the importer of..... (Name of the drug) from..... (Name and full address of the Manufacturer) of..... (Quantity) vide Bill of Entry No.....dated.....

2. That I undertake to use..... (Quantity) of above said drug for Non-Medicinal purpose/ as a pharma aid / as a drug intermediate to manufacture other drugs only. (delete whichever not applicable).

3. That I undertake to maintain books and records of transaction of above said drug for which NOC will be granted.

4. That I undertake to allow the Drug Inspectors from the CDSCO to inspect the books and records as well as the actual usage of (Name of the drug) as and when required.

5. I state that that consignment document like Certificate of Analysis, Bill of Entry, invoice etc. clearly mentions —Not for Medicinal Use or ("for use as pharma aid").

6. That the bags/containers carrying (Name of the drug) along with other requirements of labelling and packaging also mentions – "Not For Medicinal Use" or ("for use as pharma aid").

DEPONANT VERIFICATION

Verified on this .....day of..... (Month & Year) 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.

DEPONANT

Annexure II

Legal Undertaking for the import of Drugs as per provisions of Schedule D of Drugs and Cosmetic Rules 1945 to be submitted by the Importer/Trader to The Central Drugs Standard Control Organisation (CDSCO) Zonal/ Sub zonal Office.

I/We.....S/o..... having premises at .....aged about .....do hereby solemnly affirm state and undertake as under: 1. That I am the importer/trader of..... (Name of the drug) from..... (Name and full address of the Manufacturer) of..... (Quantity) vide Bill of Entry / Purchase order no.....dated.....

2. That I undertake to sell..... (quantity) of above said drug for Non-Medicinal purpose / as a phrama aid / as a drug intermediate to manufacture other drugs only (delete whichever not applicable).

3. That I undertake to maintain books and records of transaction of above said drug for which NOC will be granted.

4. That I undertake to allow the Drug Inspectors from the CDSCO to inspect the books and records as well as the actual usage of said drug as and when required.

5. That the bags/containers of the said drug along with other requirements of labelling and packaging also mention ―Not For Medicinal Use

6. That the data of my previous transaction is annexed with this undertaking (Optional in cases of subsequent transaction).

DEPONANT VERIFICATION

Verified on this .....day of..... (Month & Year) that the contents of my above undertaking are true and that no part it is false and that nothing material has been concealed .

User Manual

for

SUGAM- An e-Governance solution

Online Forms Submission

DUAL-NOC (Zone)- STEP-1

and STEP-2

by

Central Drugs Standard Control Organization (CDSCO)

Directorate General of Health Services

Ministry of Health &Family Welfare, Government of India

Centre for Development of Advanced Computing

(A Scientific Society of the Ministry of Electronics and Information Technology, Govt. of India)

Anusandhan Bhawan, C-56/1, Institutional Area Block-B, Sector-62, Noida-201309

Phone:91-120-2210800 Website:http://www.cdac.in

Table of Contents

1.Introduction

Instructions for Dual-NOC Module (Step-1):

1. As per the new module, **Dual-NOC** has been separated into **two parts**:
   - **Step-1**
   - **Step-2**
2. This current module is designed for the **First Step (Step-1)** of the NOC process.
3. After successfully **logging into the SUGAM portal**, click on the **"Submit Applications"** tile to begin your application.

Dual-NOC (Step-1)

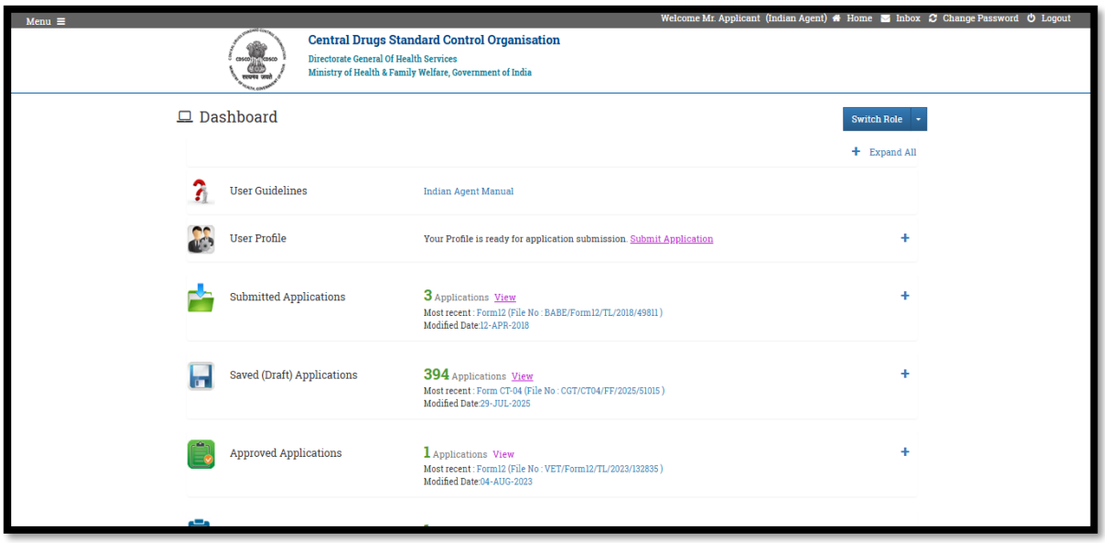

Figure: 1

- now, **select the department** as – **NOC (Zone)**
- then, **select the form** as – **Dual Use NOC**

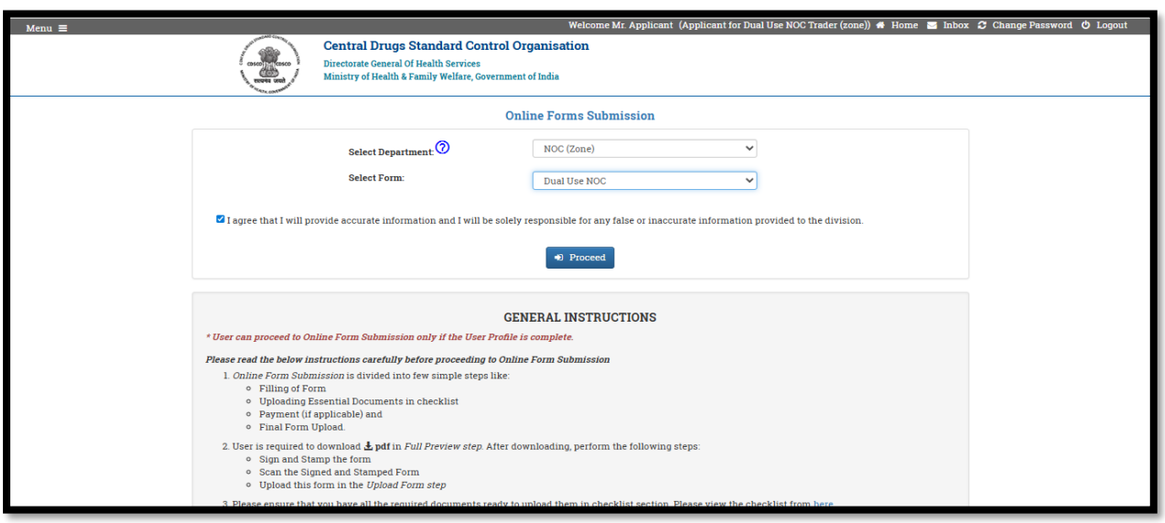

Figure: 2

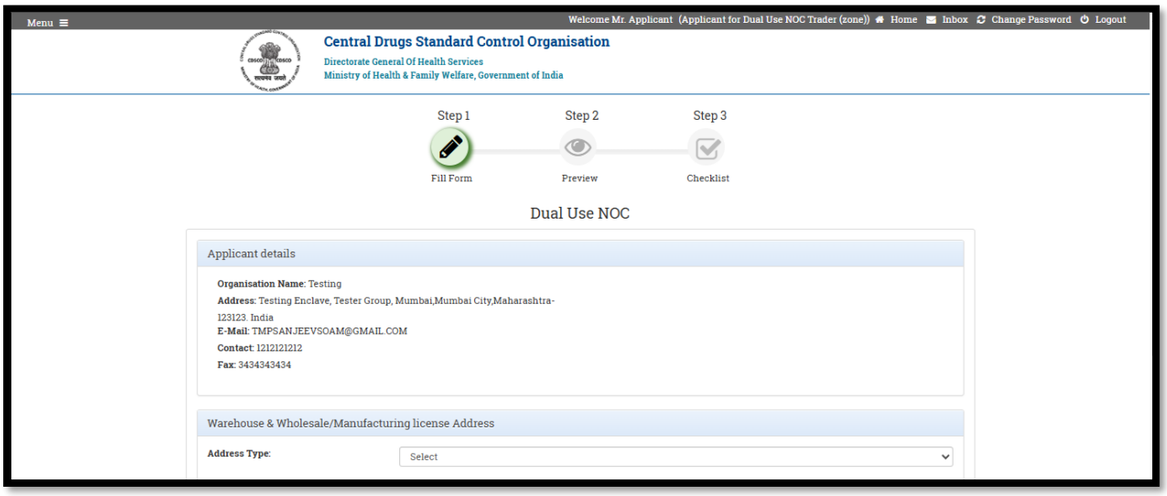

Figure: 3

2. Add -address Type from the Drop-down

In the attached figure, the **user has to select the Address Type** from the dropdown list. The available options are:

- **Wholesale Manufacturing License**
- **Warehouse**

How to Add Address for Wholesale Manufacturing License & Warehouse

A. To Add Address for Wholesale Manufacturing License:

1. Click on the **Menu**.
2. Then click on **User Profile**.
3. Next, click on **Add / Wholesale Manufacture License Details**.
4. Enter the required details and save.

B. To Add Warehouse Address:

1. Click on the **Menu**.
2. Go to **User Profile**.
3. Click on **Add Address Details**.
4. From the dropdown, select **Premises Type – Warehouse**.
5. Enter the required address information.
6. Click on the **Save** button.

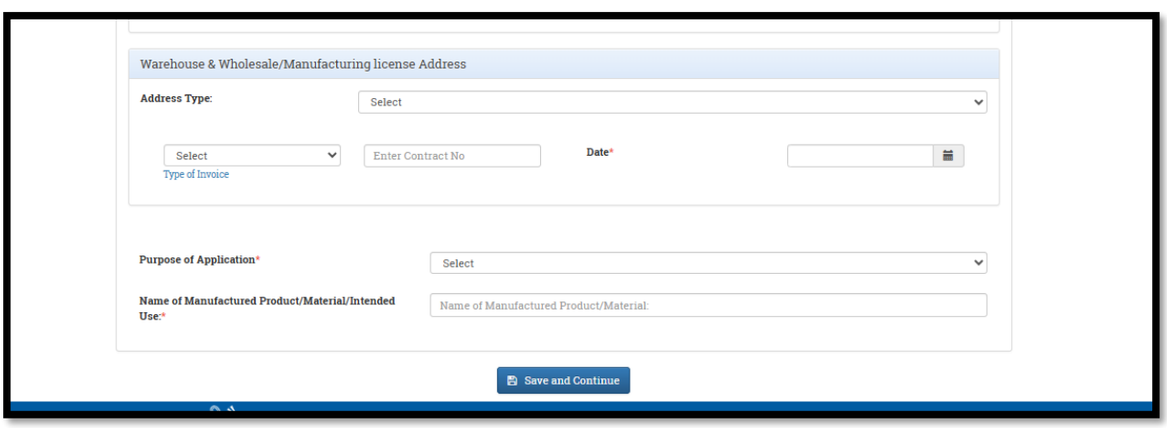

Figure: 4

3.Purpose of Application – Dropdown Options

In the case of **"Purpose of Application"**, the following options are available from the dropdown:

1. **Not For Medicinal Use**
2. **Excipients Use Only**
3. **Animal Feed & Not For Medicinal Use**
4. **Industrial Use & Not For Medicinal Use / Drugs Meant For Further Processing or Conversion To Other Drug**
5. **Others**
6. If your **category is not listed** in the mentioned dropdown, select the **"Others"** category.
7. After **filling in the drug details**, click on the **"Save and continue"** button (as shown in the figure below).

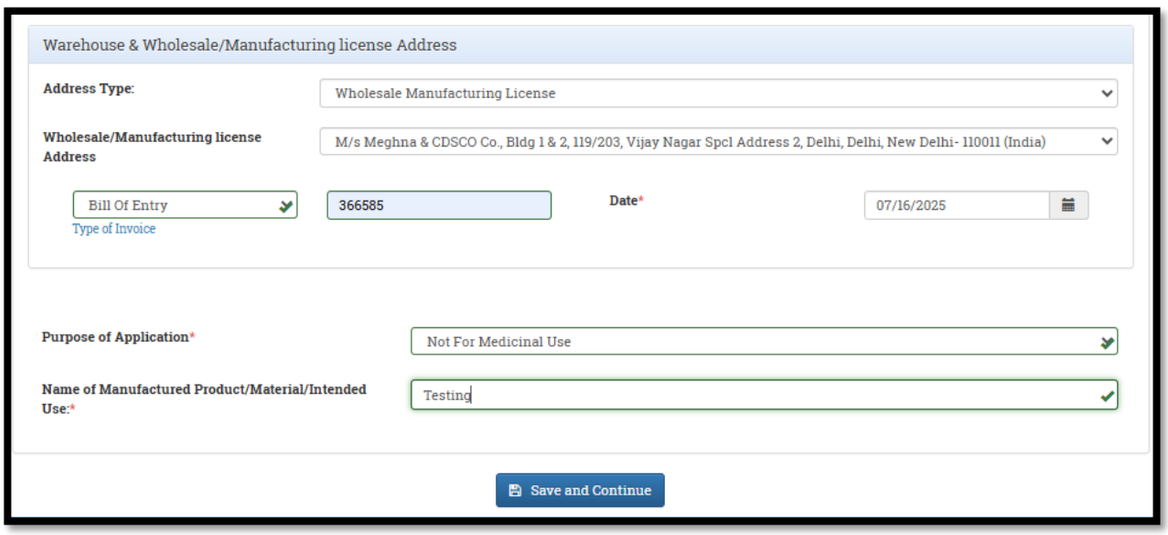

Figure: 5

4.Drug Page

- **Product/Material List**: User can select a **maximum of 5 products** at a time.
- **Material Use End**: User must select the intended end use from the **dropdown menu**.
- **Imported Material**: Choose the imported material type from the **dropdown**.
- **Brand Name**: Enter the **brand name** of the product.
- **Quantity**: Enter the **quantity** of the product.
- **Unit**: Select the appropriate **unit** of measurement.
- **Intended End Use**: Specify the **purpose** or end use of the product.
- **Foreign Country Selection**: User must select the **foreign country** from the dropdown.
    - **A maximum of** 10 countries per product **can be selected.**

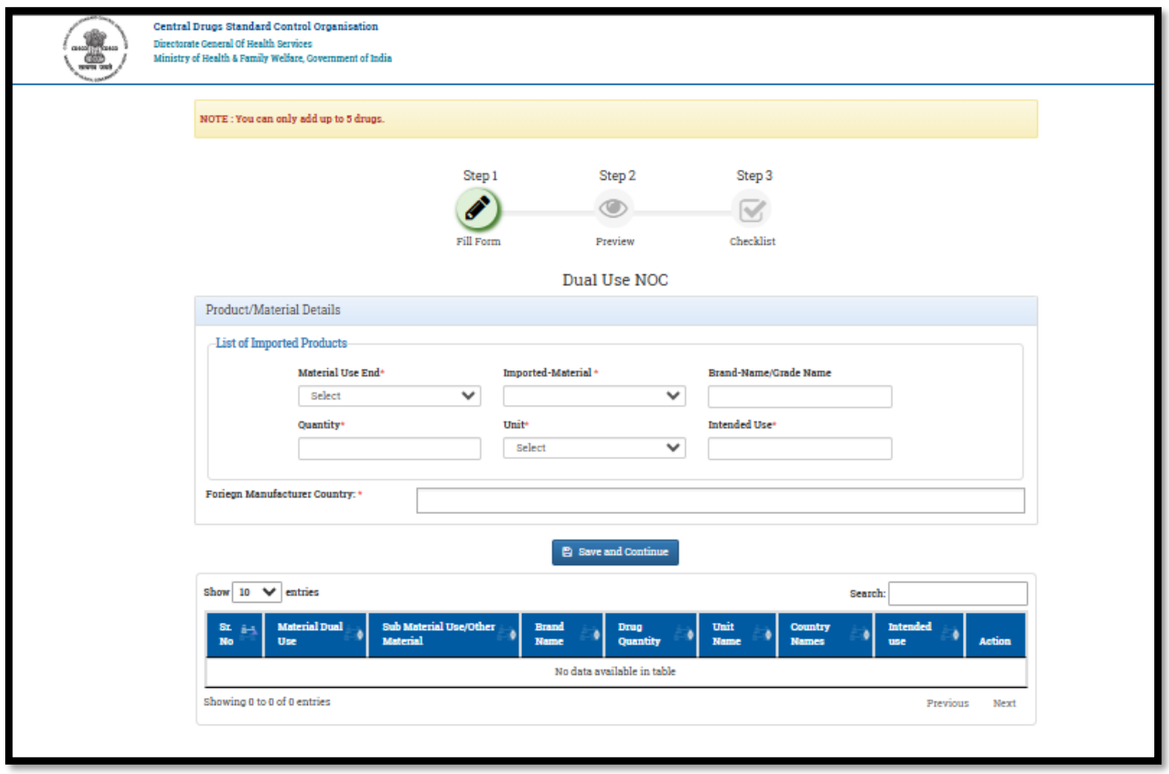

Figure: 6

- After Clicking on next button a preview page will be visible.

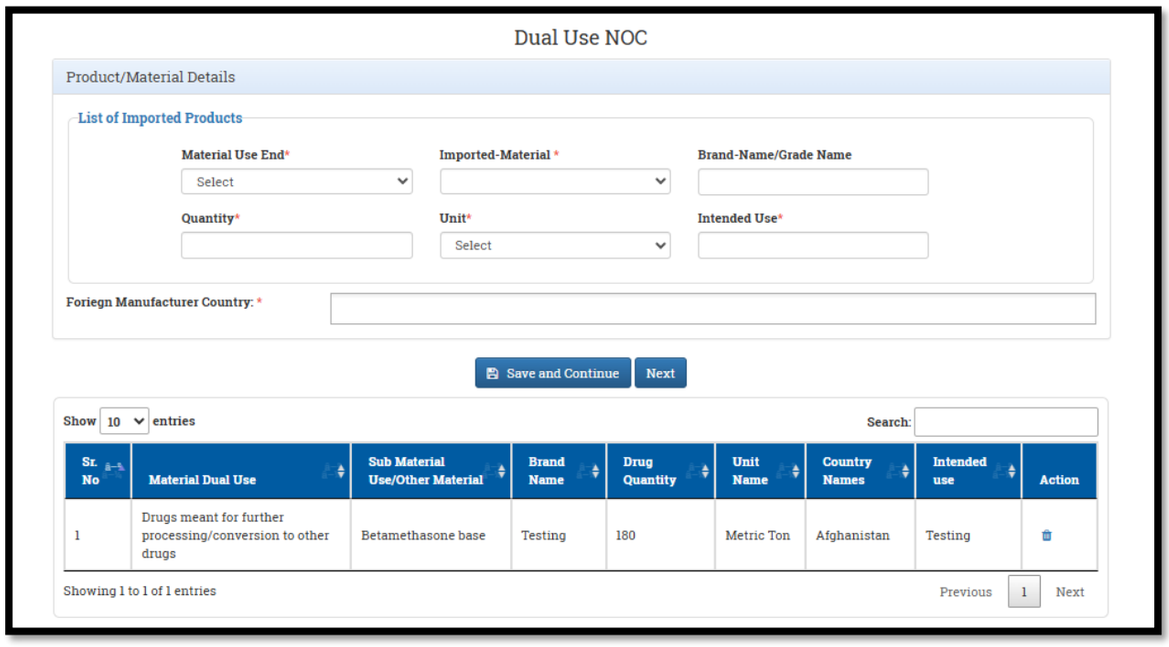

Figure: 7

- In the preview it is clearly mention that in which zonal office your NOC is landed in which zonal office.

5. Preview Page

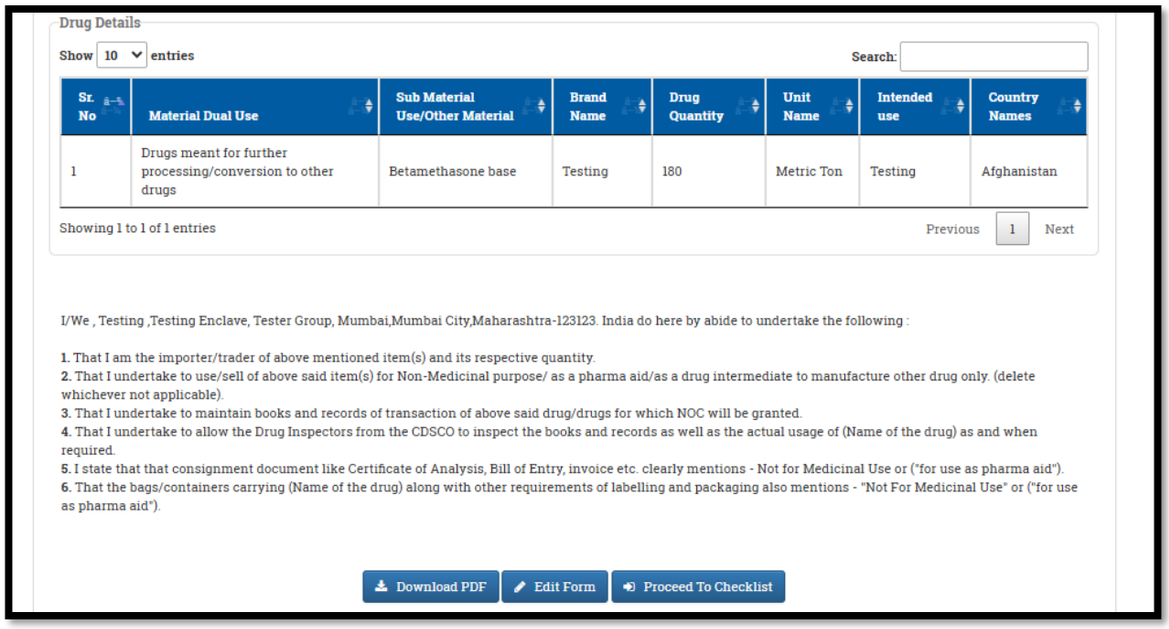

Figure: 8

- Here, you can either **Download the PDF** of the application or **Edit the form** if changes are required.
- After reviewing, click on **"Proceed to Checklist"** to move to the next step.

6. Checklist Page

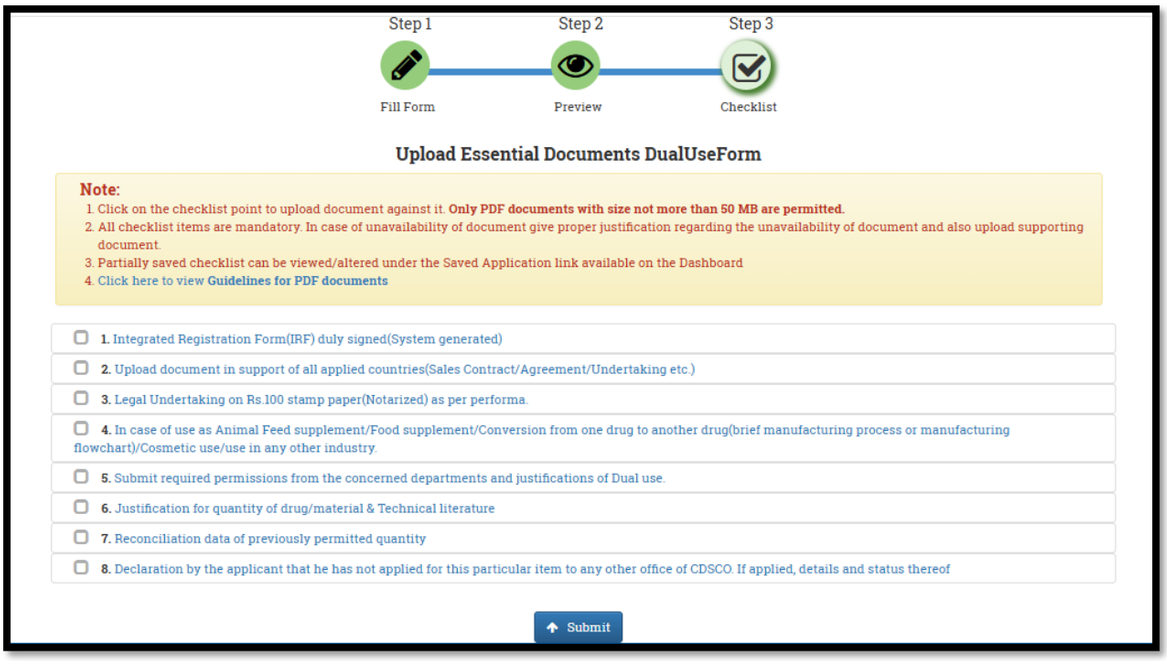

Figure: 9

- The **entire checklist is mandatory** — you must fill in **all checklist points** before proceeding.
- When you click on **Submit**, an **OTP is sent to your registered mobile number** for verification.

7.Submission of Application

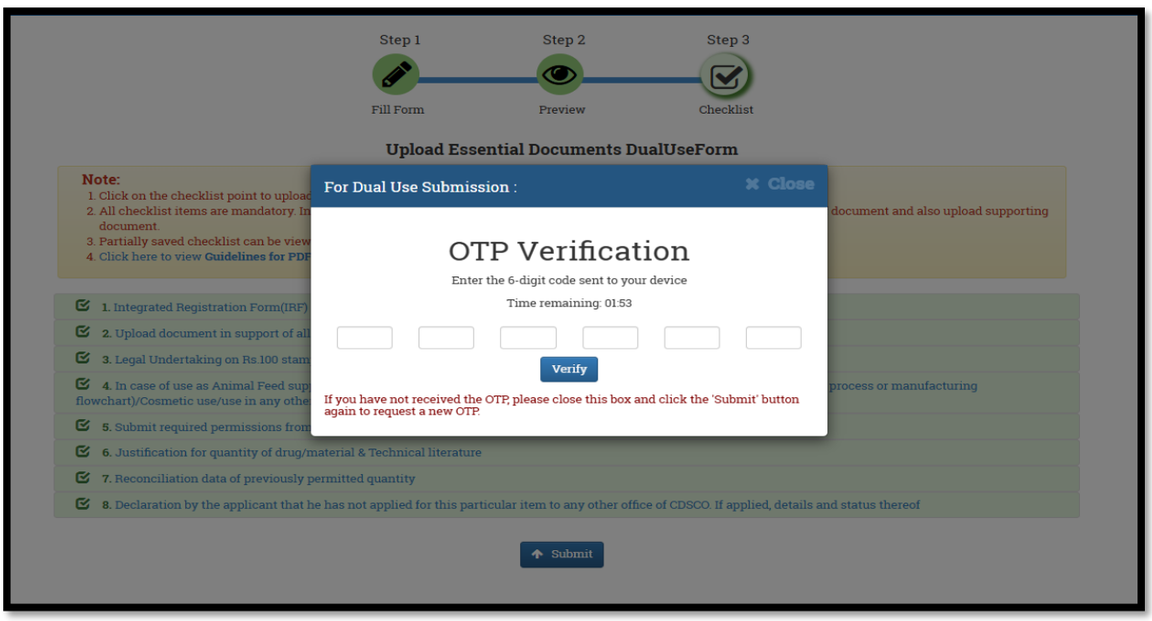

Figure: 10

After entering the **OTP**, the user must click on the **"Verify"** button to validate the entered OTP.

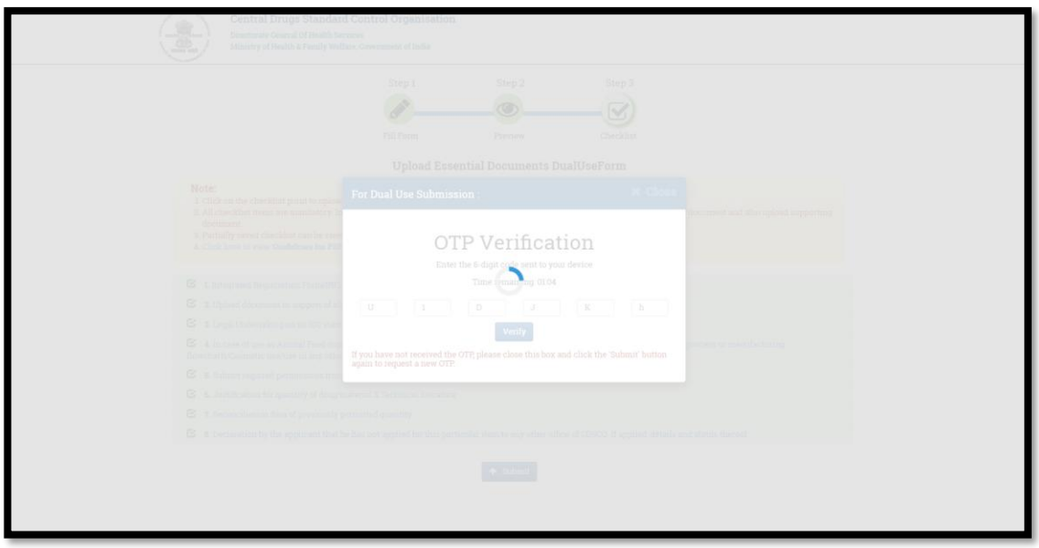

Figure: 11

- The **entire checklist is mandatory** — you must fill in **all checklist points** before proceeding.
- When you click on **Submit**, an **OTP** is sent to your **registered mobile number** for verification.

Figure: 12

Dual- Use NOC for Step-2

1.Online forms Submission

➢ After the successful approval of the Dual-Use NOC in Step-1, the user must apply for an NOC in Step-2.

Figure: 13

➢ From the drop-down menu, the user must select the Department as: ***NOC (Zone)***.
➢ Then, select the Form Type as: ***Dual Use NOC Step 2***

Figure: 14

2. Details from the approved license

➢ after clicking on the ***Proceed*** button, all the approved NOCs for the particular user will be displayed in the drop-down menu.
➢ the user must select one license number at a time from the drop-down and then click the ***Save*** button.

Figure: 15

➢ **The user must now select the Drug Name from the drop-down menu.**
(Only the drug name approved in NOC Step-1 will be visible.)

➢ **The user must select the Port Office from the drop-down where the shipment will be received.**

➢ **The Country for the Dual-Use NOC will be auto-populated.**
(It will reflect the country approved in NOC Step-1.)

➢ **The Brand Name will be displayed automatically.**

➢ **The actual Dual-Use NOC Quantity (as approved in NOC Step-1) will also be visible.**
The user must enter only the quantity they wish to import.

➢ ***Note:*** **The entered quantity must not exceed the actual approved quantity from Step-1.**

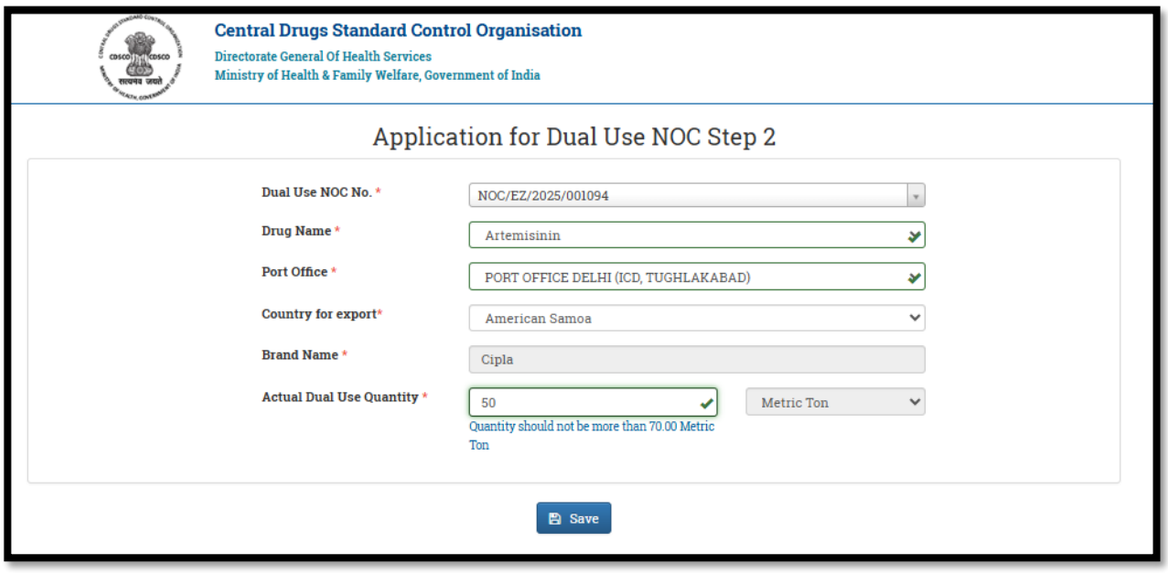

Figure: 16

➢ **After successfully adding all the details, the user must click on the *Save* button.**

➢ **The user can now either enter the same details for another drug, if needed, or click on the *Next* button to proceed.**

➢ **Upon clicking the *Next* button, the *Add Bill Details* section will become visible.**

3. Adding Bill details

Figure: 17

Add Bill Details

- The user must select the **Drug Name** from the drop-down menu.
- The user must select the **Quantity to be imported** from the drop-down and enter the quantity as per the **Bill of Entry**.

- Enter the **Bill of Entry** details accurately.
- The user can create **multiple entries** based on the quantity mentioned in each Bill of Entry.

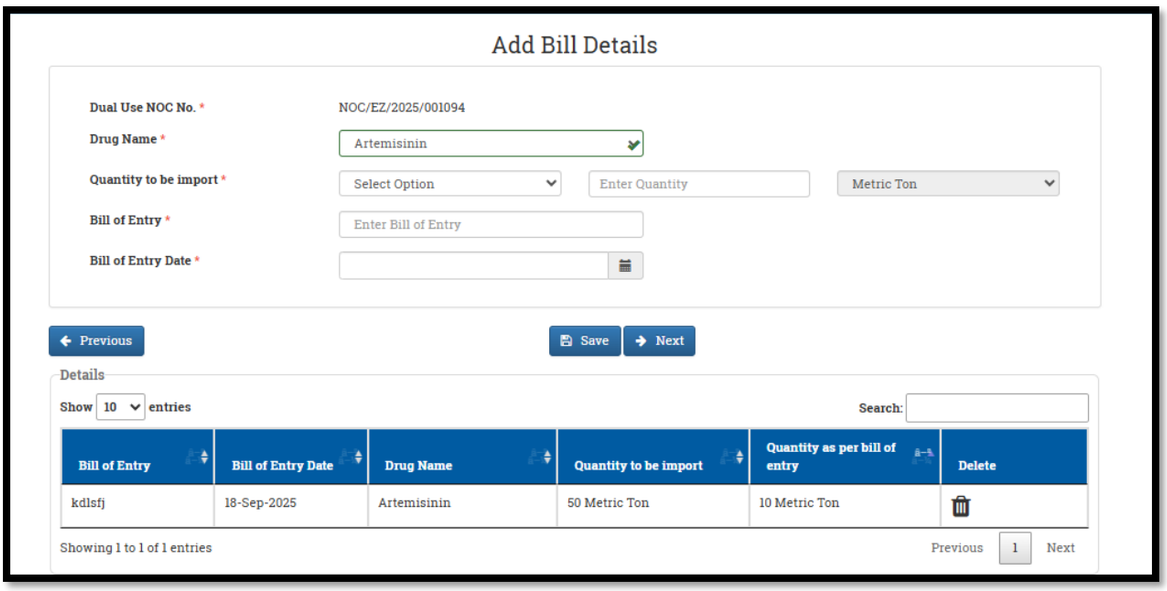

Figure: 18

4. Preview Page

➢ **After clicking the *Next* button, the *Preview* page will be displayed.**
Here, the user can:

- **Download** the form as a PDF
- **Edit** the form if any changes are required
- Or **Continue** to proceed with the submission

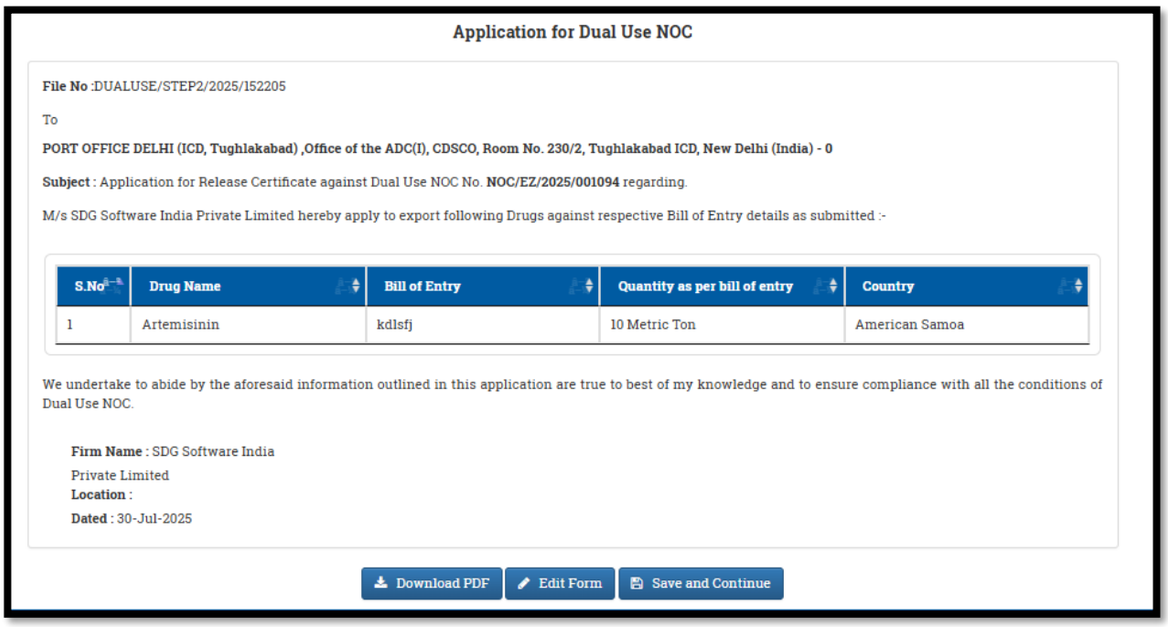

Figure: 19

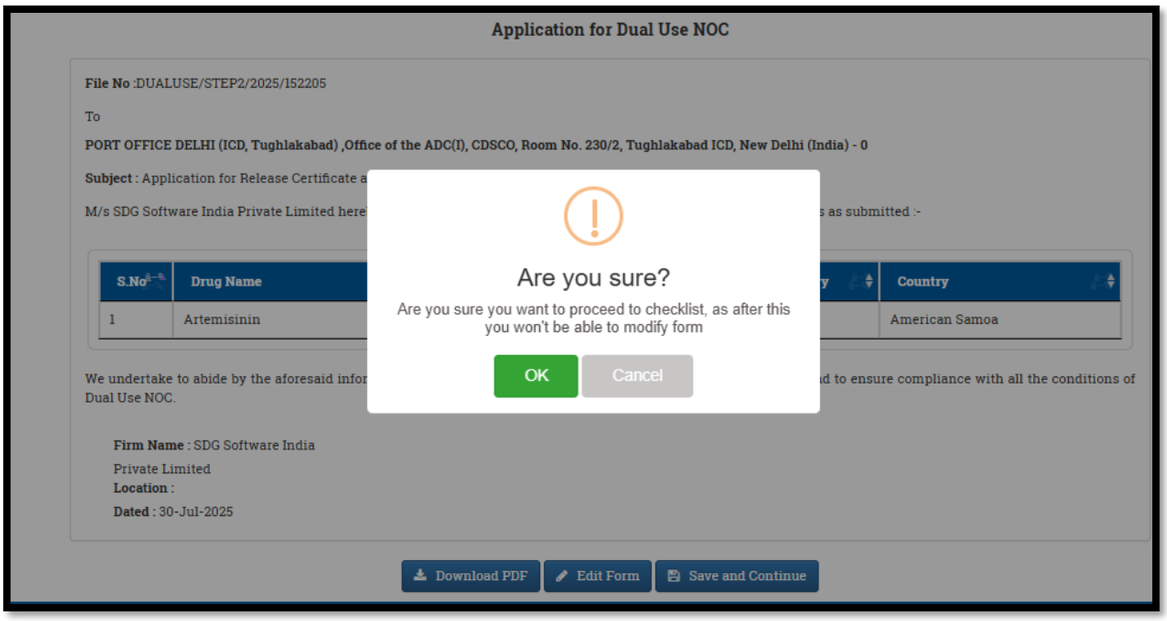

Figure: 20

5.Checklist and submission

➢ **The *Checklist* page will now be displayed, where the user must complete the entire checklist.**
Note: Filling out the checklist is **mandatory** before proceeding.

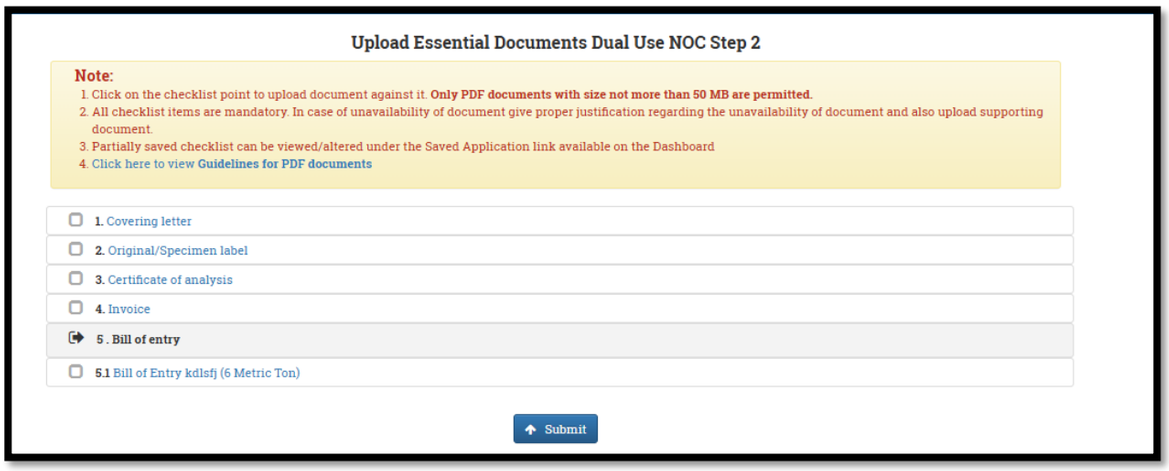

Figure: 21

➢ **after completing the checklist, the user must click on the *Submit* button.**
An **OTP** will be sent to the user's **registered mobile number**.
After verifying the OTP, the application will be made visible to the **concerned Port Office of the CDSCO**.

Supply Chain Module

➢ after approval of Step-2, the user must apply for the Supply Chain Module by visiting the approved application tile.

➢ Open the approved application tile and click on the Action button to apply for the Supply Chain Module, as shown below.

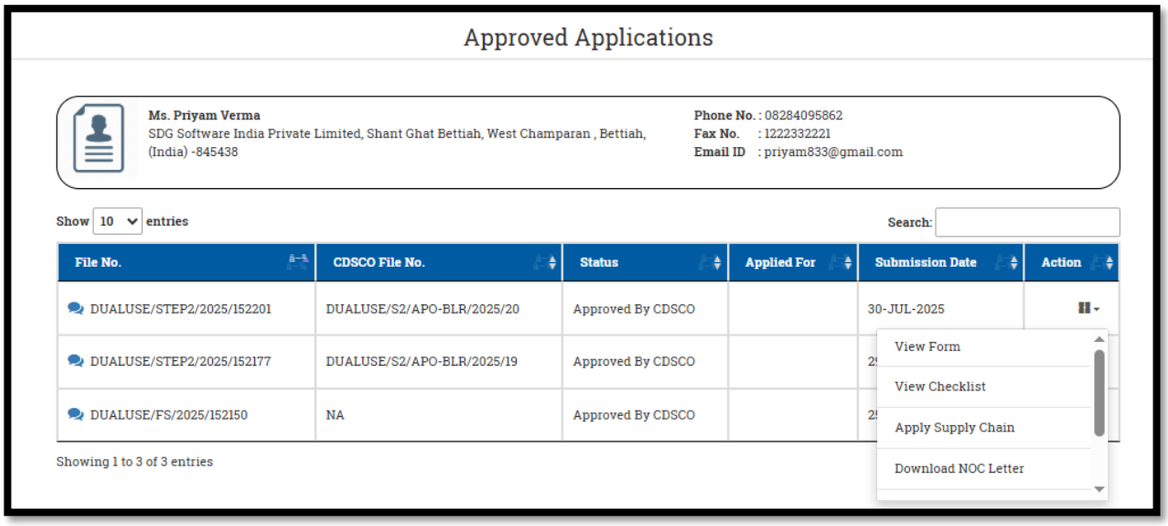

Figure: 22

After click on Apply Supply Chain Module the next page will be visible as attached below:

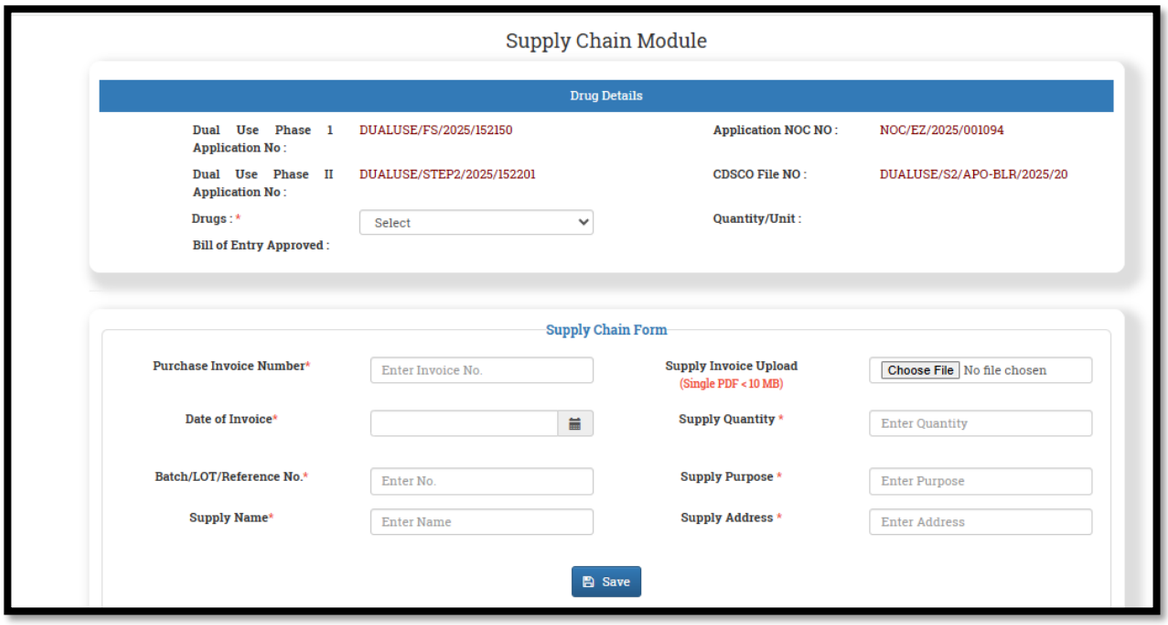

Figure: 23

- The Applicant has to select the drug from the drop-down and subsequently fill the as column as per the format provided.
- After entering all the details user has to click on Save Button (this details will be official end also).