File No. IMP/70/2024eoffice
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi-110002

Dated : 07/03/2025

Public Notice

Sub: New online Export NOC System on SUGAM Portal- Regarding

CDSCO to further enhance "ease of doing business" has streamlined the process of issuing export NOC for unapproved / approved new drugs 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, the Sugam checklist is revised and also a guidance document is attached herewith.

Application, for Export NOC shall be submitted through SUGAM Portal along with the prescribed checklist of documents.

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

(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

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

Introduction

A manufacturer holding valid license copy in Form -25, Form- 28 and Form 28D can obtain No Objection Certificate from Zonal offices of Central Drugs Standard Control Organization (CDSCO) for export purpose only for **Unapproved/Approved New drugs** in India.

Purpose

Requirement for the common submission format in online mode for issuance of No Objection Certificate for Manufacture for export of unapproved/approved new drugs/ drugs from India. This document made as per guidelines issued by Ministry of Health and Family Welfare for Export purpose and Rule 94 of the Drugs and Cosmetic Act, 1940.

Scope

This document is applicable for the manufacturer to obtain No Objection certificate for **Unapproved/Approved New drugs** from Zonal offices of Central Drugs Standard Control Organization (CDSCO) for export purpose.

Procedure

Requirement for Common Submission Format for issuance of No Objection Certificate for manufacture for export of unapproved / approved new drugs involve 2steps i.e. Registration at zonal office followed by procedure for release of consignments at port, except NDPS and drugs.

Step-I

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

1. Export NOC form
2. Legal undertaking in Annexure -I / Annexure -II
3. Copy of Manufacturing License
4. Reconciliation details
5. Approval status in Importing country.

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.

Undertaking in Annexure -I /II: Applicant /Manufacturer shall submit undertakings in the prescribed format from the manufacturer of API – Annexure -I and from Formulation Manufacturer as Annexure -II digitally signed by the Applicant (attached at the End of the page)

Copy of Manufacturing License: Valid License issued by the State Licensing Authority in Form -25, Form- 28 and Form 28D should be enclosed along with each application for the required location to manufacture the drug for export purpose. In case of Issue of Export NOC for the second time firm is required to submit quantity specific export License issued by SLA for the specific product

Reconciliation data: Applicant /Manufacturer is required to submit history of Reconciliation Data of previously issued NOC in 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

Approval Status: The firm need to submit approval status of the applied Drug (s) as issued by the NRA of Importing country. In case NRA approval is not applicable, then approval status of India may be submitted.

Step-II

Procedure for release of consignment at port office: In this step after getting Valid Export NOC from Zonal office, Applicant is required to submit following dynamic details at the time of release of consignment which will be verified by concerned port office.

During this Step, An applicant/Manufacturer is required to submit documents in online mode and requires submission of the following documents at the time of Export:

1. Valid Export NOC
2. Reconciliation details for the Quantity exported in the prescribed online module.
3. Test/ Batch Release Certificate
4. Purchase order (PO) /Export Invoice (EI) /Shipping Bill (SB)details(PO/EI/SB)

Valid Export NOC: Physical copy ofValid Export NOC issued by concerned Zonal office to be uploaded

Reconciliation details for the Quantity exported: Reconciliation data for each export at the time of release need to be filled by the applicant in the given online format and the same to be verified by concerned port office. Reconciliation module will be open throughout the validity of 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

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

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.

Accordingly, An applicant is required to first apply to concerned zonal office with all the requisite documents (staticdata) for issuance of Export NOC having 1-year validity at a single time for single/multiple products.

"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."

Key Points:

1. Qty specific/PO Specific NOC is being discontinued except for NDPS and drugs
2. Issuance of Export NOC with 1 year validity from date of Registration.
3. Allowance of usage of un-exported Quantity. for next export order within 60 % residual shelf life. If shelf life is below 60% the same shall be destructedin the presence of State Licensing Authority.
4. Timeline of 7 working days for Issuance of NOC and 2 level processing for timely disposal
5. "For the issuance of an Export NOC for NDPS drugs and drugs, a quantity-specific and PO-specific NOC will be issued for each order/Consignment for which the Existing system may be followed as per existing guideline documents.

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 utilisation of quantityissued through Export NOC etc., Manufacturer shall ensure physical destruction of stocks having shelf life less than 60 %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 utilisation 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

1.1 User Manual for

SUGAM- An e-Governance solution

Online Forms Submission

NOC (Zone)- Export NOC

by

Central Drugs Standard Control Organization (CDSCO)

1.1.1.1 Directorate General of Health Services
Ministry of Health &Family Welfare, Government of India

1.2 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

1.3 Contents

1.4 NOC (Zone)

All the Corporate users can submit online forms under NOC (Zone). Following are the steps involved in the same.

- When the Applicant logins using his credentials, he needs to switch his role to Corporate by selecting **Corporate** from the list of **Switch Role** dropdown present on his dashboard.

  For better understanding, here is the image.

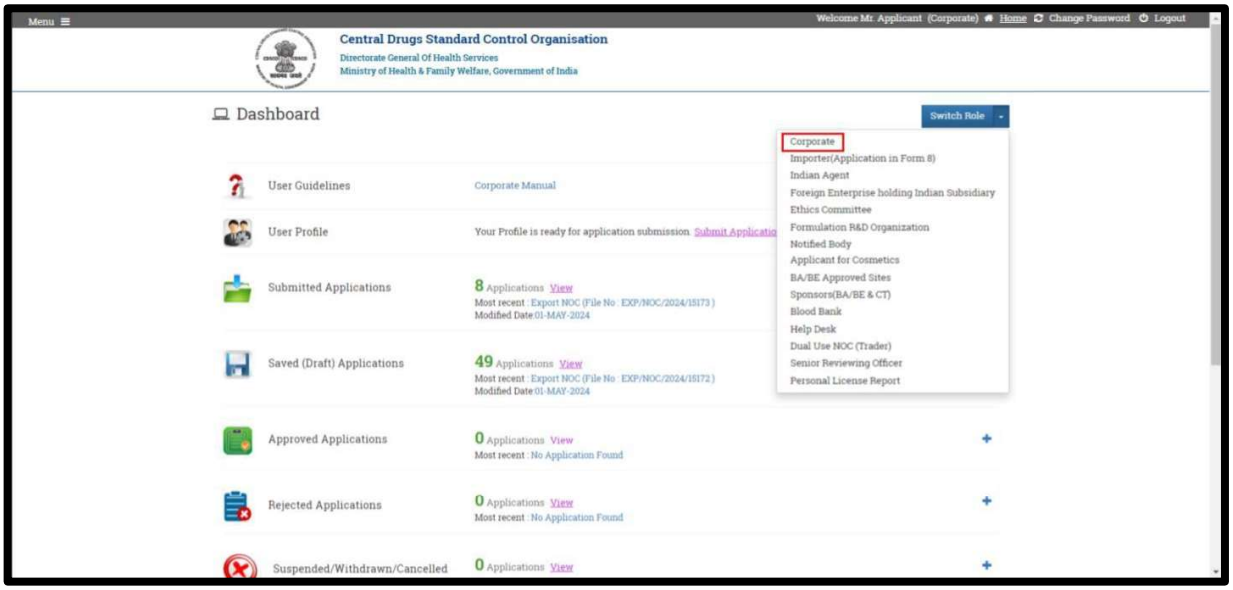

Figure 1: Applicant Dashboard

- After switching the role, the Applicant needs to click on the **Submit Application** hyperlink present on the dashboard. The following popup will appear as mentioned below.

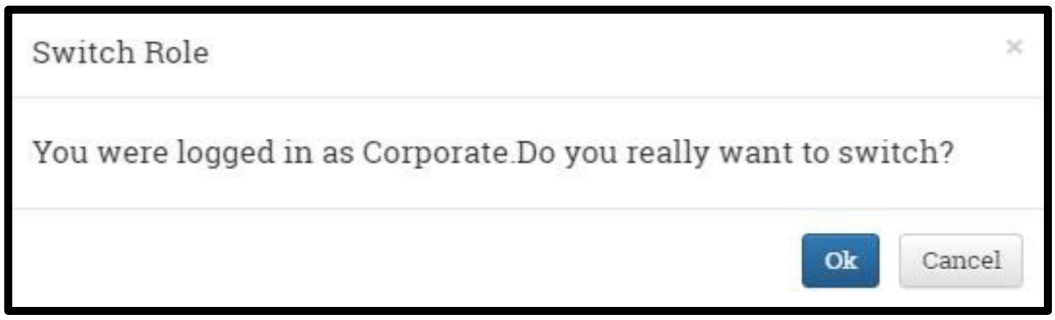

Figure 2: Switch Role

- Once the Applicant confirms to switch role by clicking **OK** in the above screen, the **Online Form Submission** page will open as shown below.

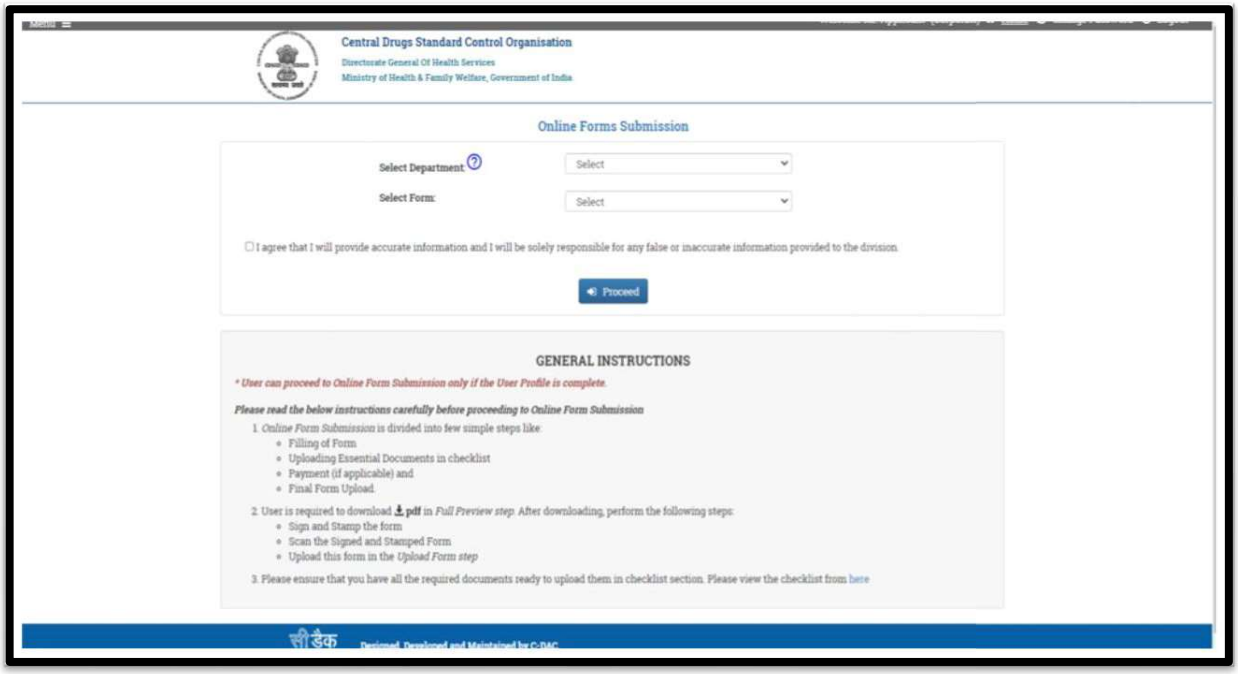

Figure 3: Online Form Submission

- There is a list of departments present in the **Select Department** dropdown. The Applicant needs to select **NOC (Zone)** form the list.

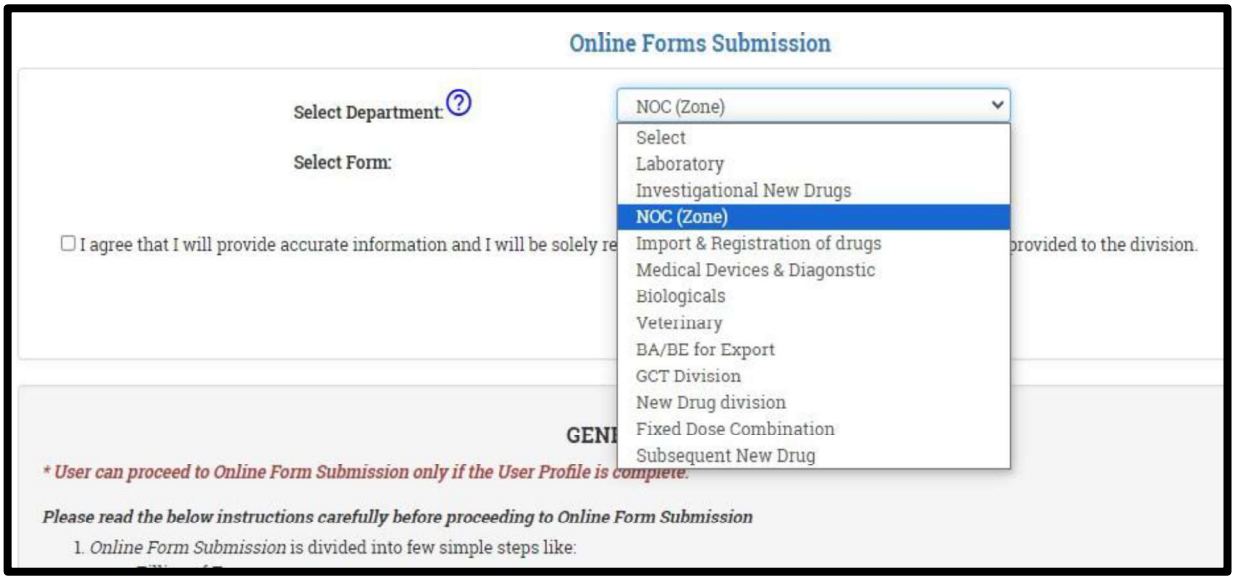

Figure 4: Select Department

- After selecting **NOC (Zone)** department, two options would be available for select Form: **Export NOC** and **Dual Use NOC**.

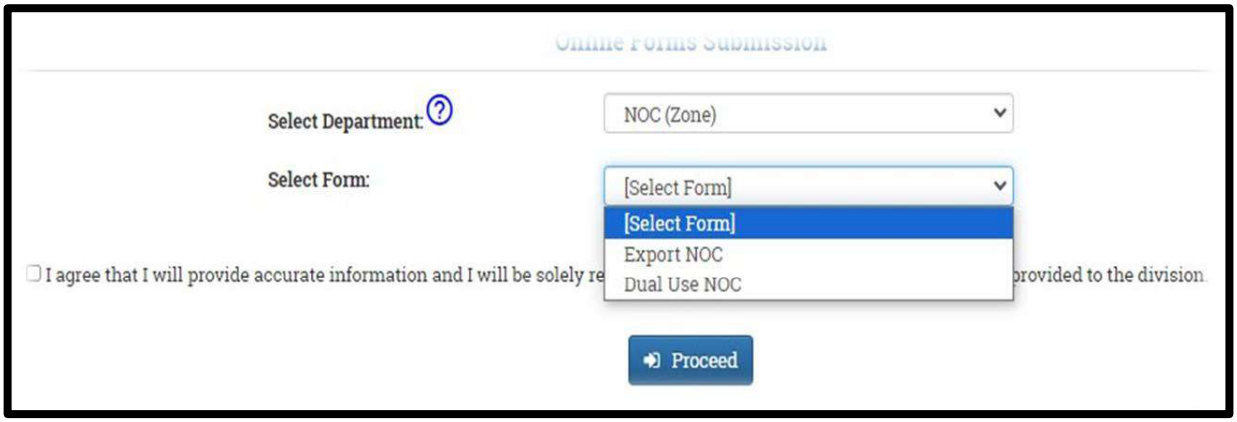

Figure 5: Select Form

1. Export NOC

- The Applicant selects **Export NOC** from the **Select Form** dropdown and clicking the checkbox, he can move further by clicking on **Proceed** button. The following screen will appear as shown below.

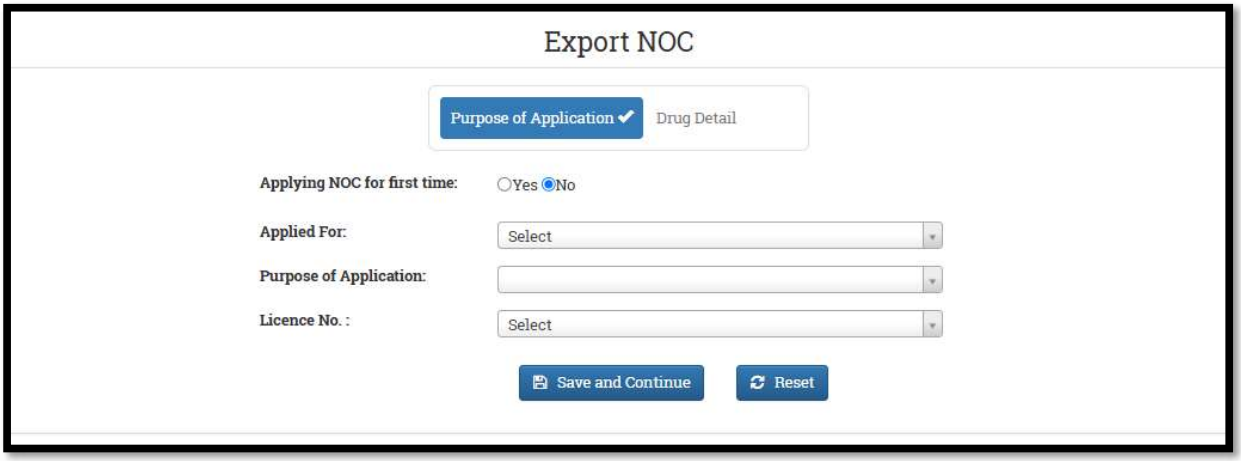

Figure 6: Export NOC

NOTE: All the License numbers present in the **License No.** dropdown are those licenses which have been added by the Applicant. The Applicant can add more license number by following the below steps.

The Applicant needs to click on the Menu button present at the left corner of the screen. Then he can go to User Profile --> Add Wholesale/ Manufacturing License Details. Here is the screenshot for better understanding.

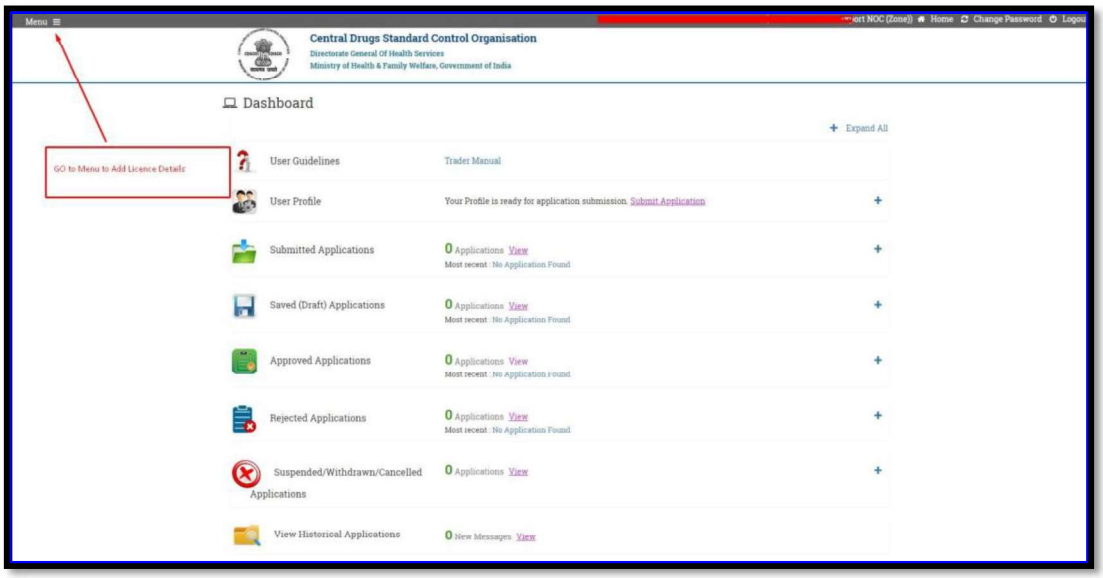

Figure 7: Add Wholesale/ Manufacturing License Details

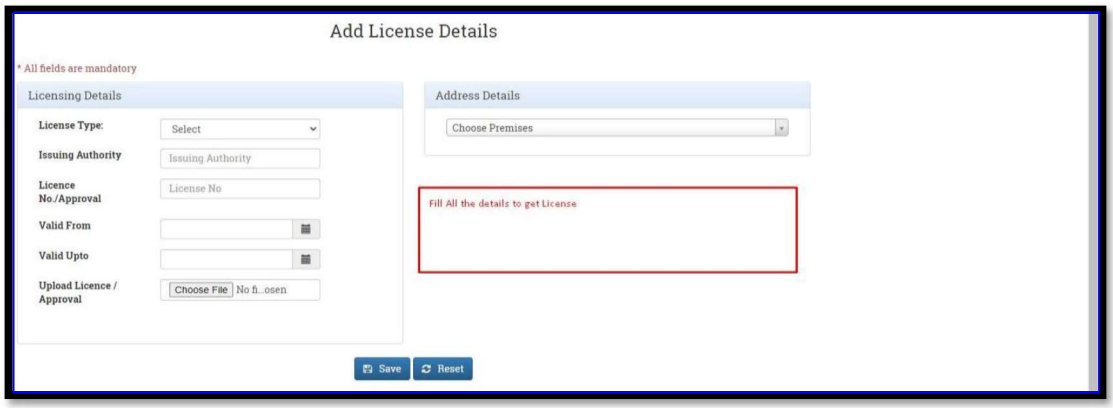

Figure 8: Add Wholesale/ Manufacturing License Details

On this page, there are following options available under **Applying for NOC first time** below is the screenshot of the same. There is a two option if user is applying **Yes or No.**

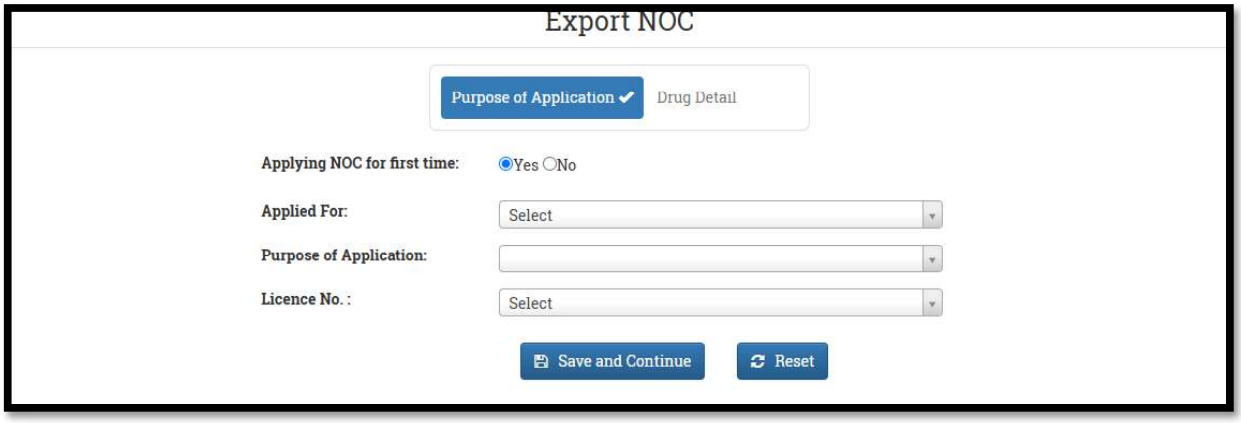

Figure 9: Applied For dropdown

1. After selecting the desired option from **Applying NOC for first time** dropdown, the Applicant can see two options on the **Applied for** option from the dropdown: Approved New Drug and **Banned new drug, Material transfer, Narcotics and Psychotropic Substances Drug (NDPS), Unapproved Drug.** We will see these in detail in the further sections.

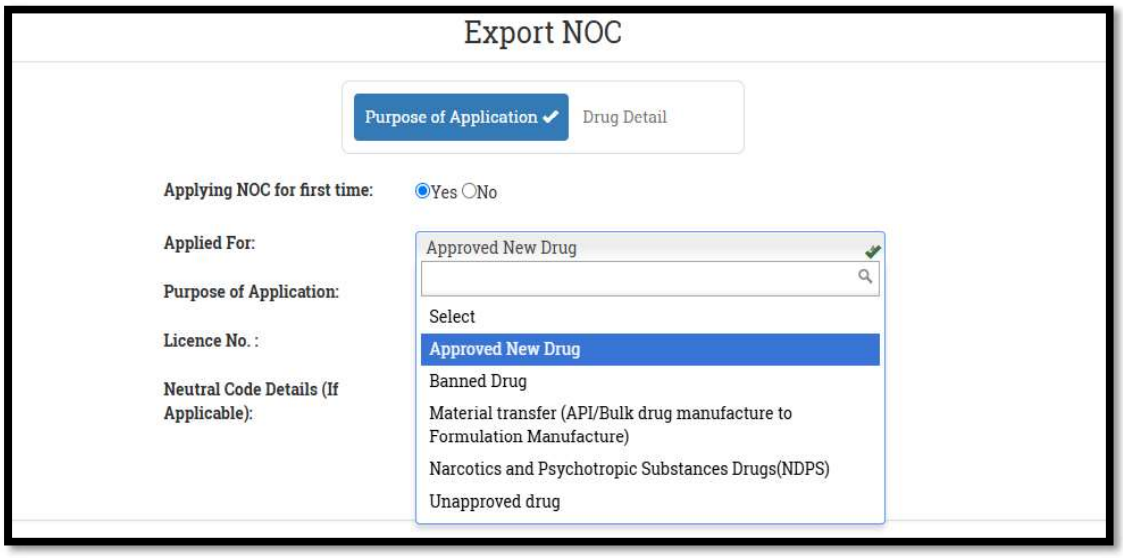

Figure 10: Approved New Drug

1.1 After selecting the Approved New Drug

User has to select Purpose of Application **Bulk Drug API, Finished Formulation, R&D for BD, and R&D for FF** as mention in below screen**.**

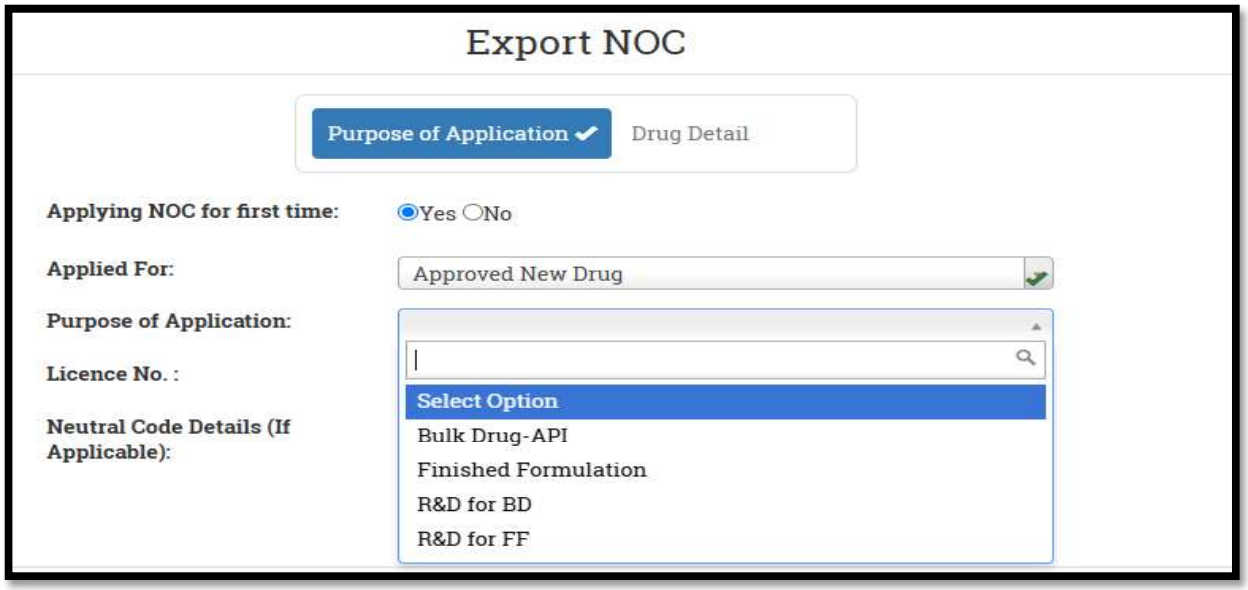

Figure 11: Purpose of Application

- After selecting Bulk Drug –API user have to select the License NO which was added in the drop-down by the User While clicking on the MENU button as screenshot added in the drop-down.
    - **Now user has to add a License No (**How to manufacturing license number please referee page No. 6).
-

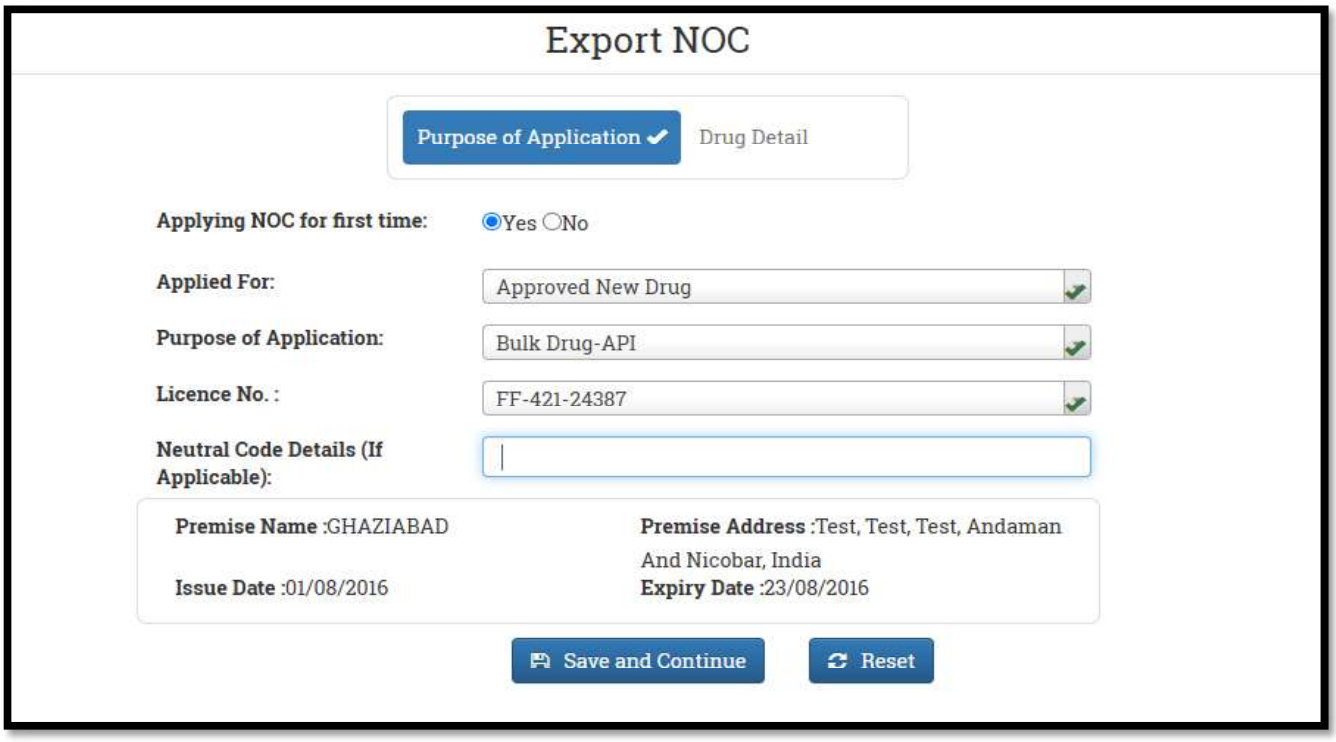

Figure 12: Purpose of Application with Bulk Drug

- After clicking Save and Continue Button by the user Page will be re-direct to the next page as per attached screenshots.
- Now the drug details page will be visible where users have to fill the drug details as per attached screenshots.

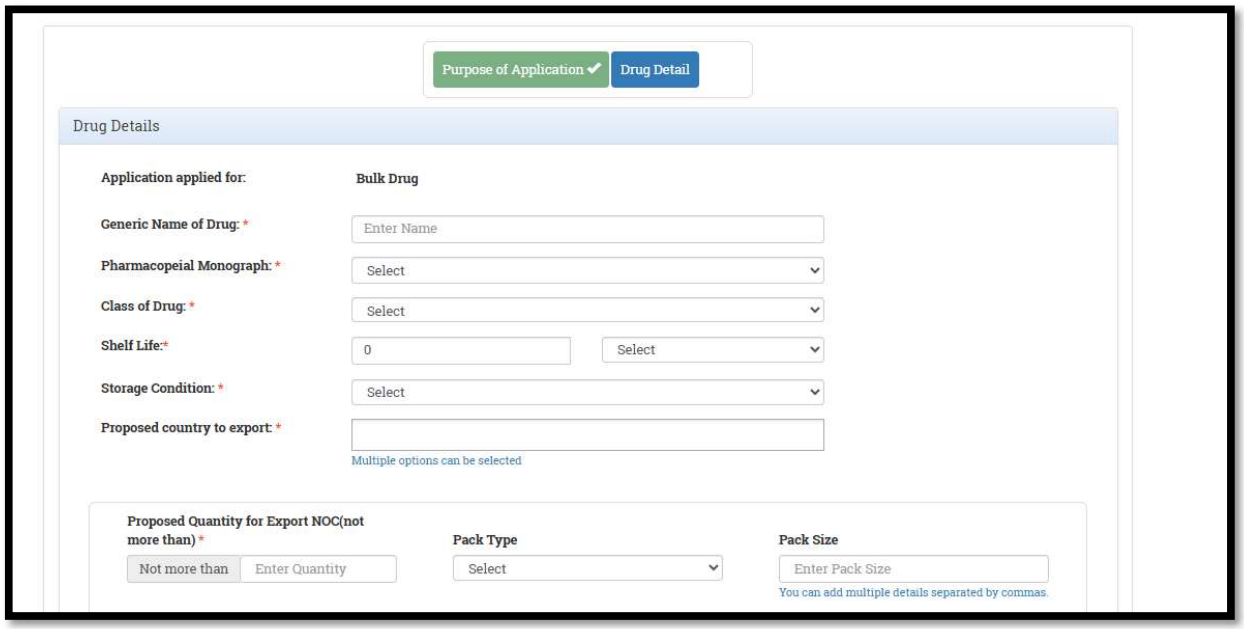

Figure 13: Bulk Drug Details

- Generic Name of drug (user have to entered correct drug name
- Pharmacopeia Monograph (can be select from the drop-down)
- Class of Drug (can be selected from the drop-down)
- Shelf life (in the filed user needs to entered the value in the number and they have to select shelf in Days, weeks, Month, year)
- Storage condition can be selected from the drop-down,
- Now user, have to select the country from the drop-down where he has to export the Products from * ***Multiple country can be selected from the drop-down.***

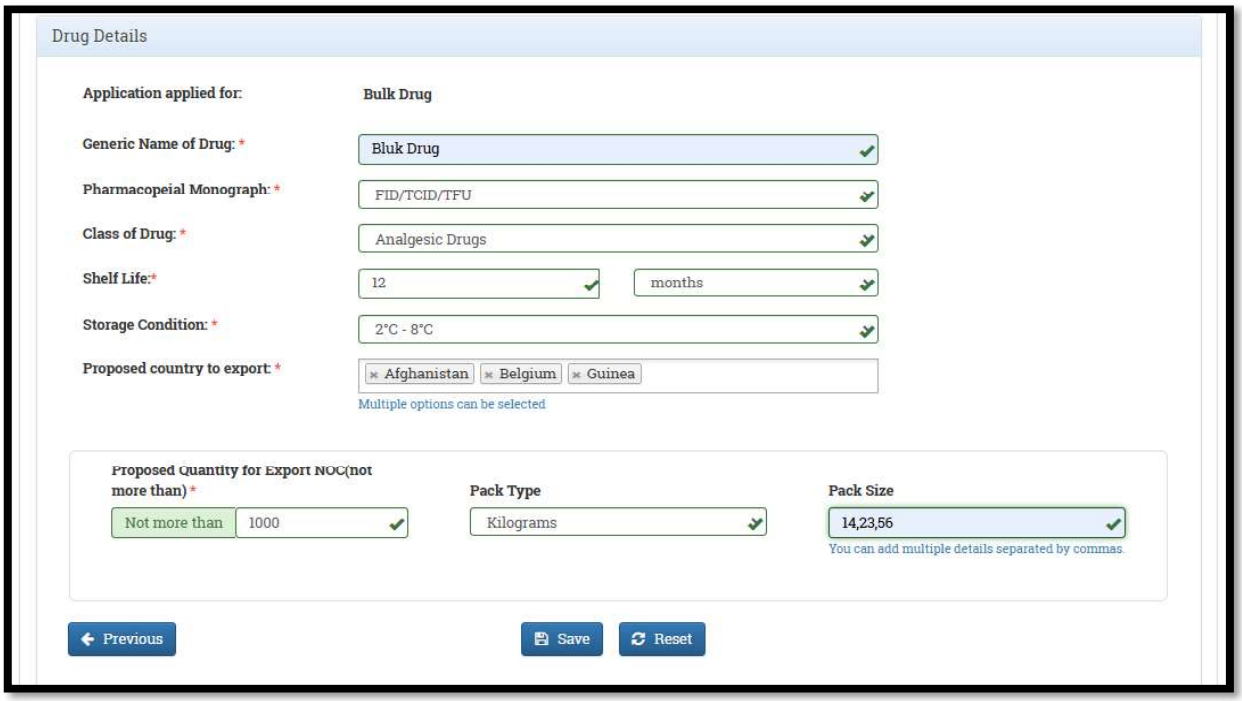

Figure 14: Bulk Drug Details with details

- After clicking on save button drug details will be added successfully (user can add multiple drug) as per attached screenshots.

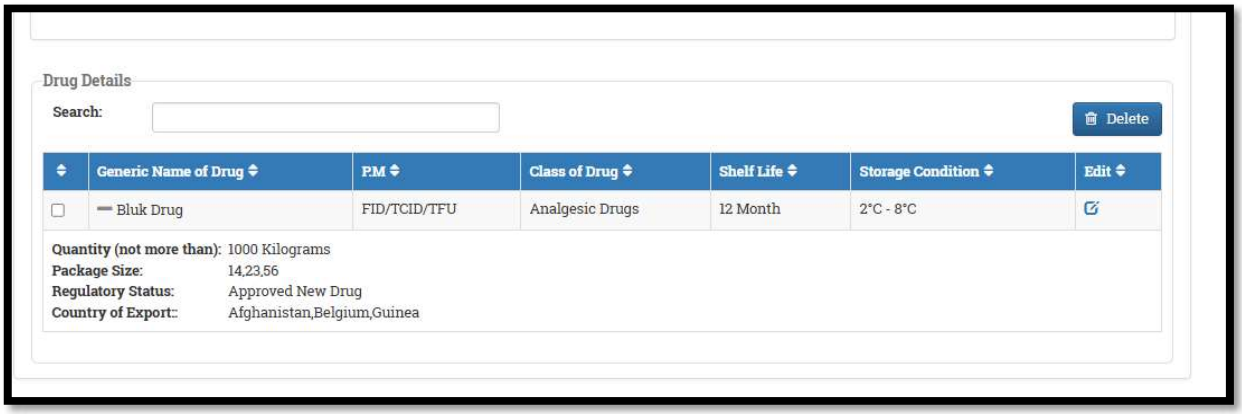

Figure 15: Bulk Drug Details added

1.2 After selecting the Ban Drug

- User has to select Purpose of Application **Bulk Drug API, Finished Formulation,** as mention in below screen.

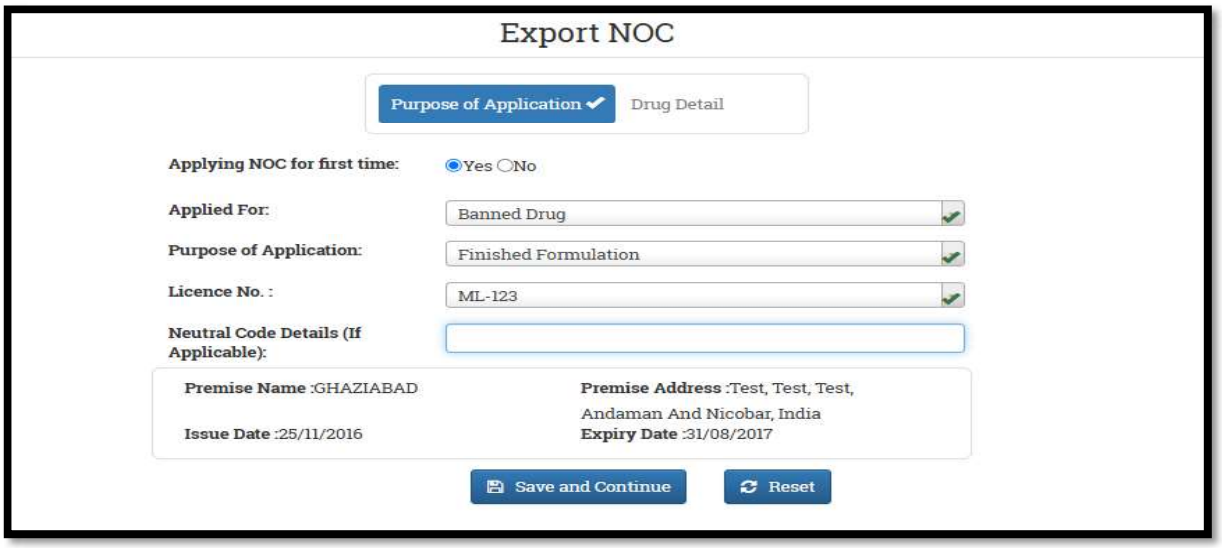

Figure 16: Ban Drug

- After selecting the Finished Formulation option and Licence No (**How to manufacturing license number please referee page No. 6)** from the drop-down user have to click on save and continue button for drug details entry as attached screenshots.
- Generic Name of drug (user have to entered correct drug name)
- Brand Name(this field is optional for user)
- Pharmacopeia Monograph (can be select from the drop-down)
- Class of Drug (can be selected from the drop-down)
- Shelf life (in the filed user needs to entered the value in the number and they have to select shelf in Days, weeks, Month, year)
- Storage condition can be selected from the drop-down.
- Quantity (can be entered in number value and volume can be selected from the drop-down)
- Now user, have to select the country from the drop-down where he has to export the Products from * ***Multiple country can be selected from the drop-down.***
- Dosage form (can be selected from the drop-down).
- Strength can be entered in numeric value, and volume of strength can be selected

from the drop-down.

- Composition can be selected from the drop-down.

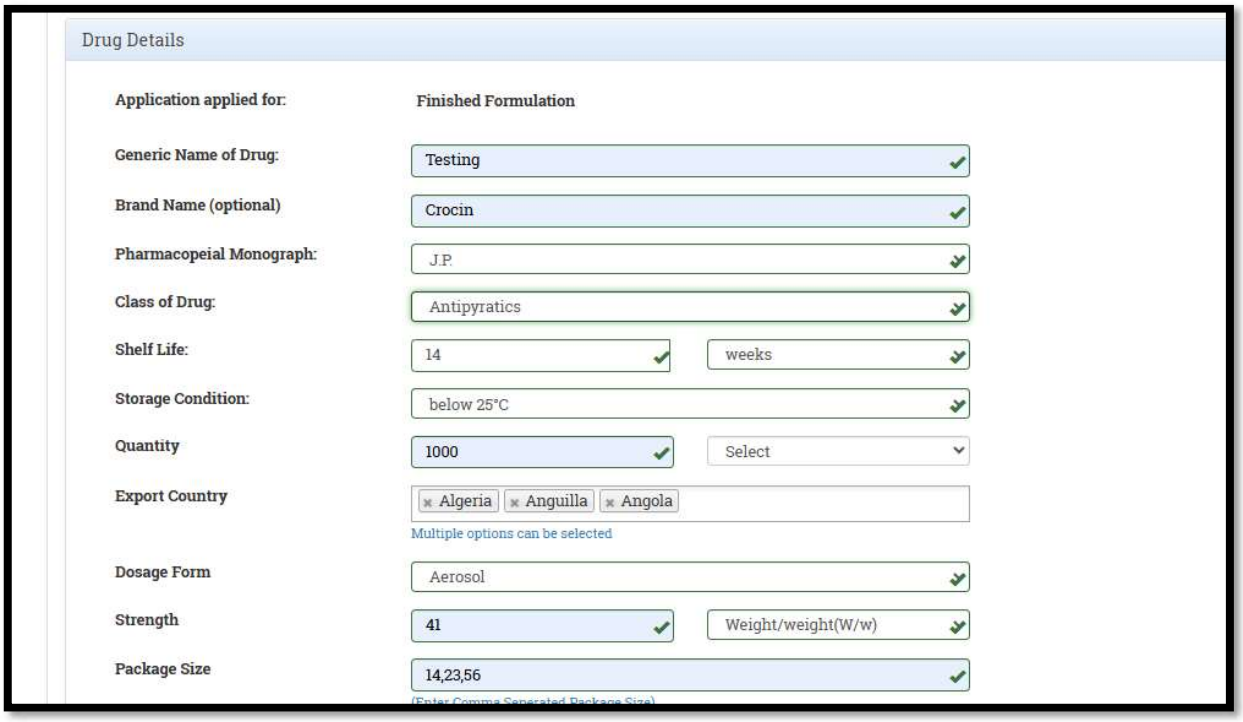

Figure 17: Ban Drug details

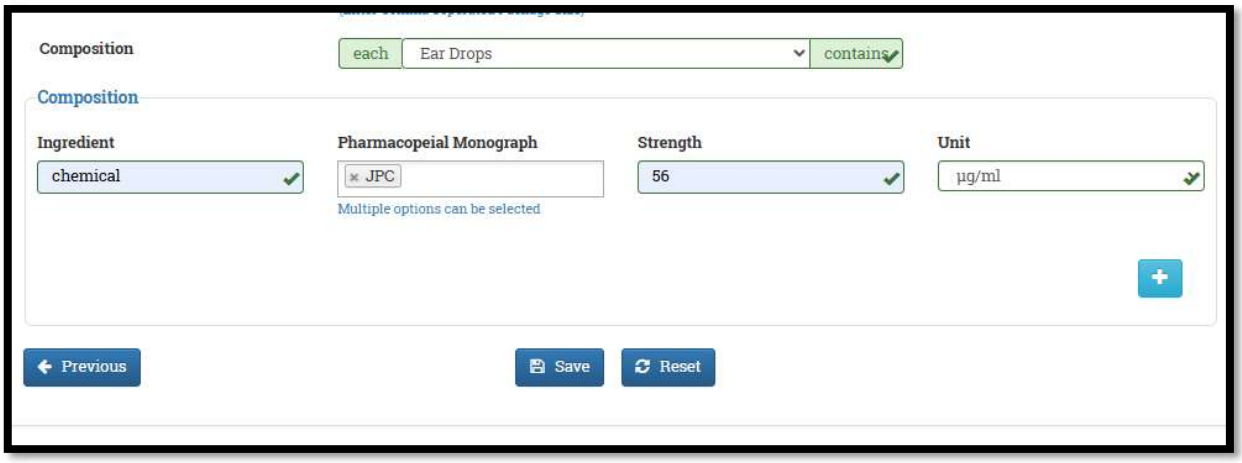

Figure 18: Ban Drug details

Note—to add drug details user need to click on save button to add a drug detail **(User can multiple drug details on same page after clicking on save button).**

1.3 After selecting the "Material Transfer from the drop-down"

- Purpose of application will be fixed to "Bulk Drug API".
- Now user have to add an Licence No (**How to manufacturing license number please referee page No. 6)** from the drop-down user have to click on save and continue button for drug details entry as attached screenshots.

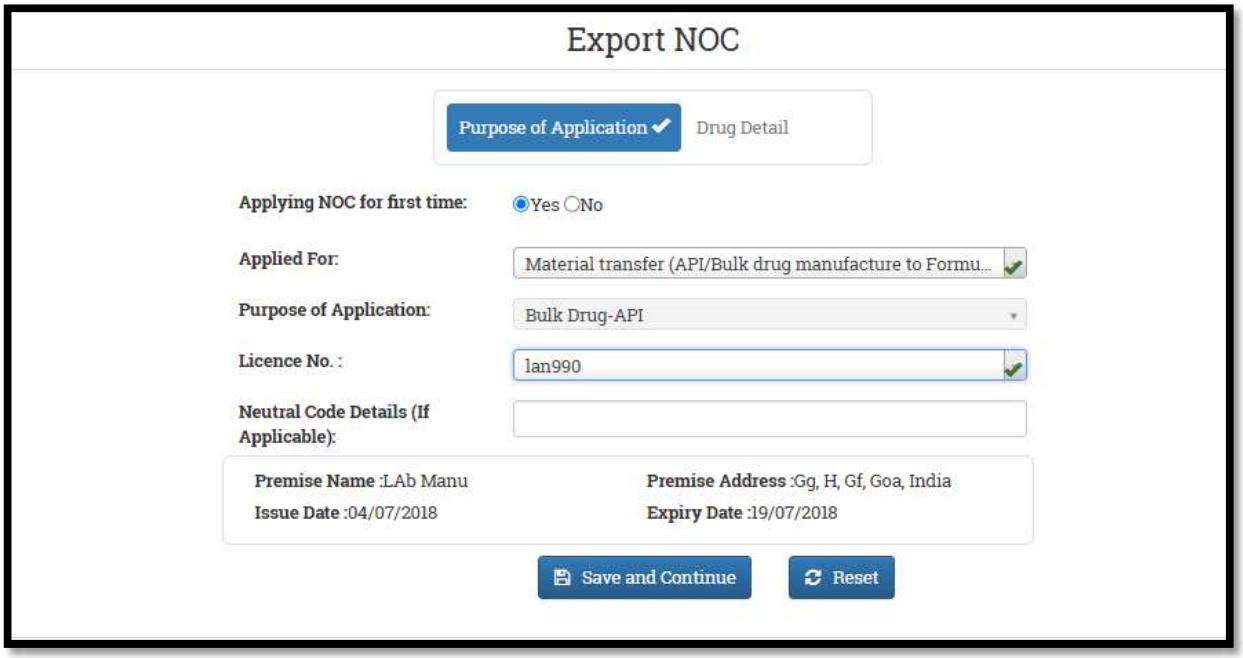

Figure 19: Ban Drug details

- Now User has to enter NOC no and have to select the zonal name from the drop-down as shown in attached screenshots below mention.

** Note—Details should be entered in NOC number should be correct and zonal name also.

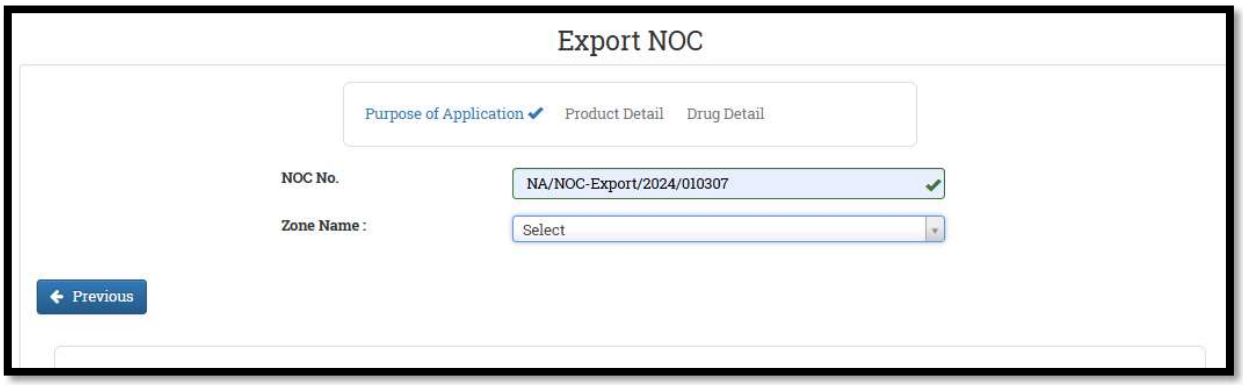

Figure 20: Ban Drug details NOC entry

- After entering the details user has to entered purchase order number, purchase order date, API name and Quantity as shown below.

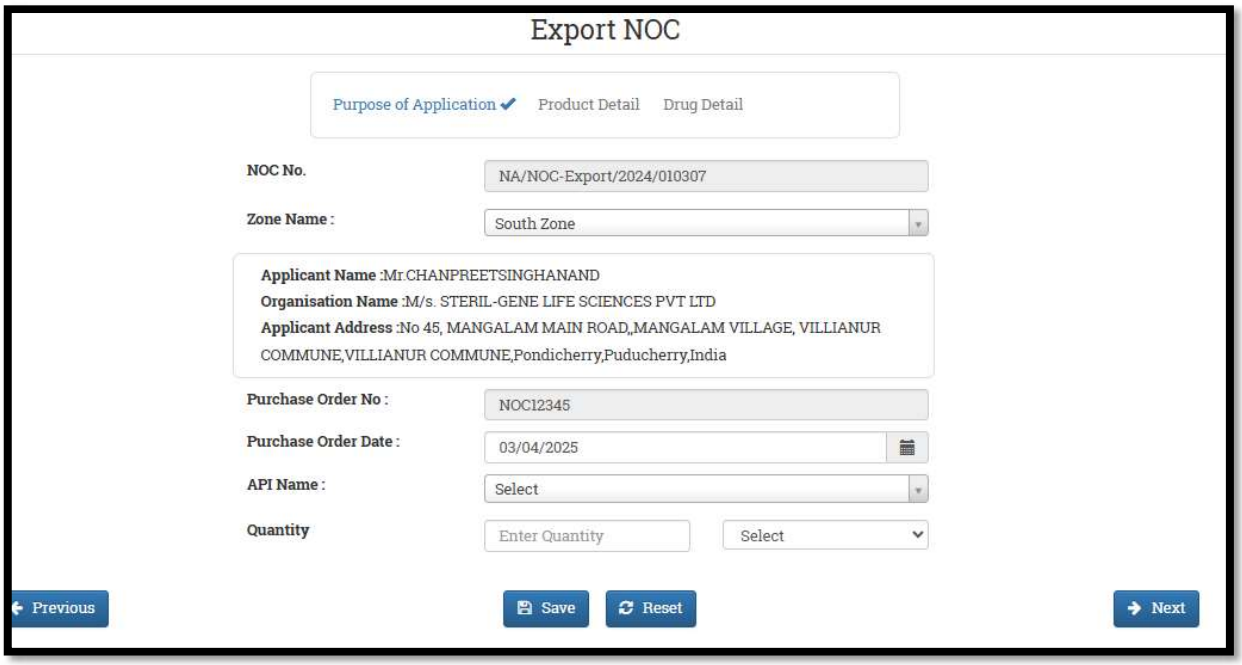

Figure 21: Ban Drug details NOC entry

1.4 After selecting the "NDPS"

- Purposed can be selected from the drop-down (Bulk drug API or Finished Formulation).

- Now user have to add an Licence No (**How to manufacturing license number please referee page No. 6)** from the drop-down.

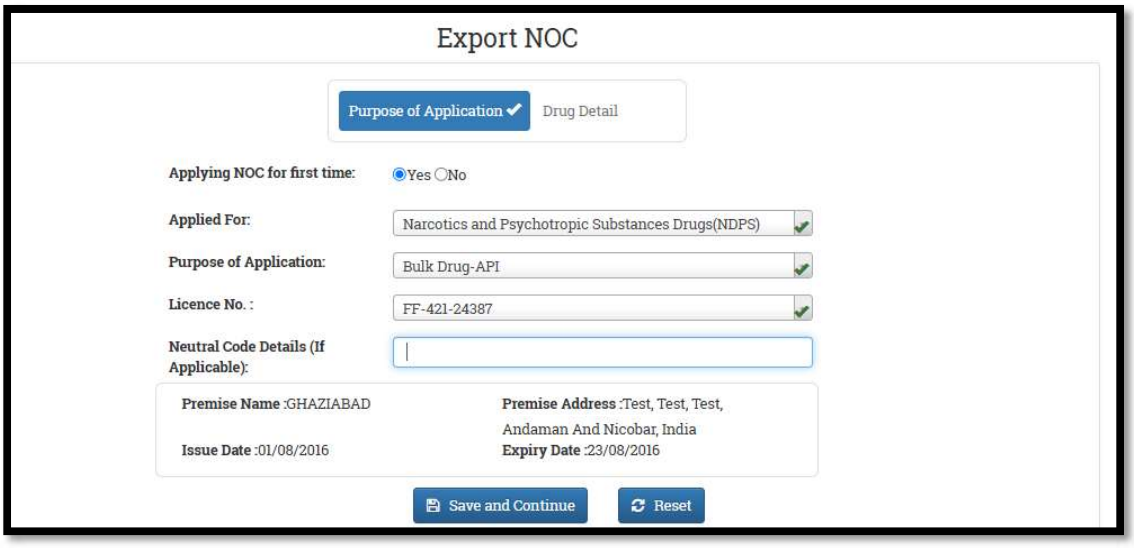

Figure 22: NDPS

- After clicking on save and continue button drug details page will be visible.

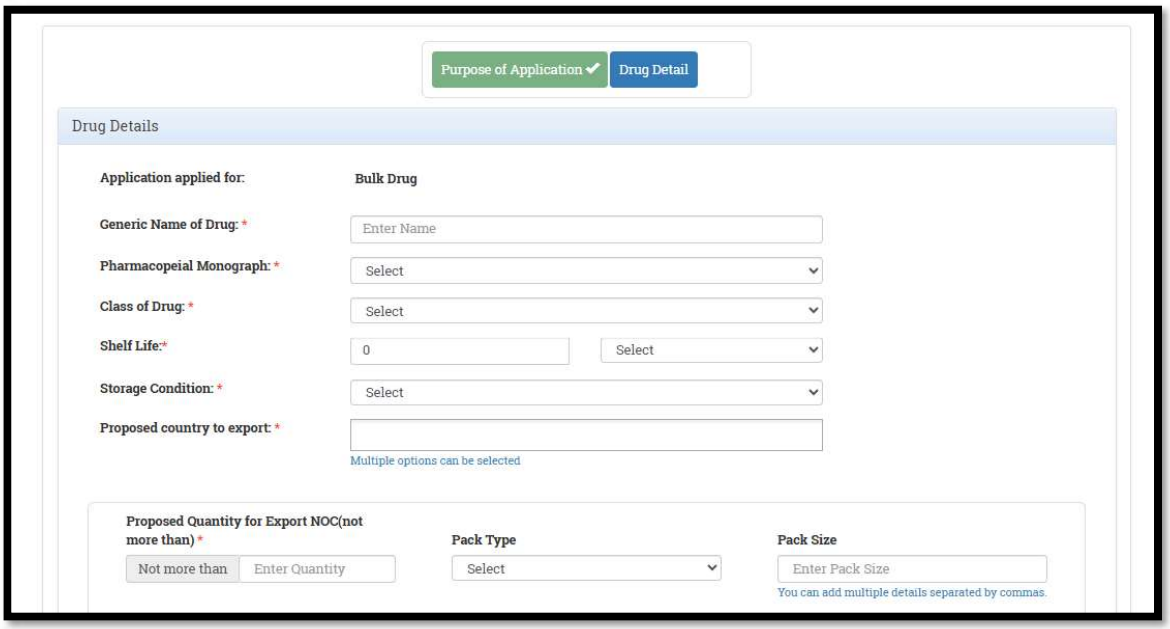

Figure 23: NDPS drug details

- Generic Name of drug (user have to entered correct drug name

- Pharmacopeia Monograph (can be select from the drop-down)
- Class of Drug (can be selected from the drop-down)
- Shelf life (in the filed user needs to entered the value in the number and they have to select shelf in Days, weeks, Month, year)
- Storage condition can be selected from the drop-down,
- Now user, have to select the country from the drop-down where he has to export the Products from * ***Multiple country can be selected from the drop-down.***

1.5 After selecting the "Unapproved Drug from the drop-down".

- User can select multiple options from the drop as shown in below mention figure.

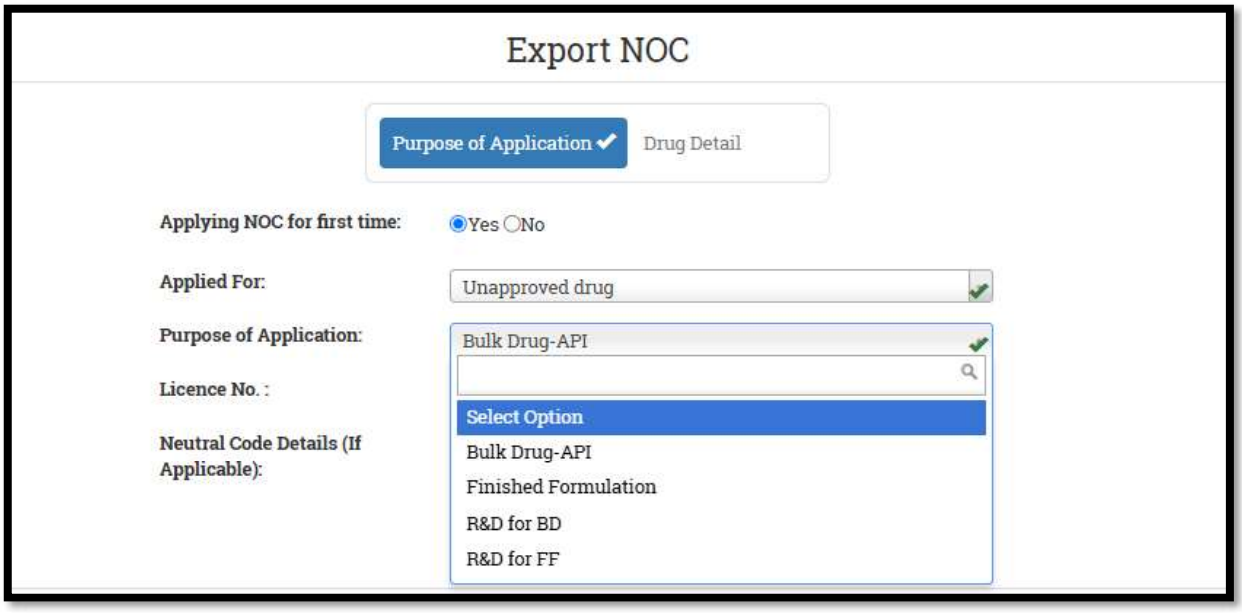

Figure 23: Unapproved drug from the drop-down

- **Now user has to add an Licence No (**How to manufacturing license number please referee page No. 6).

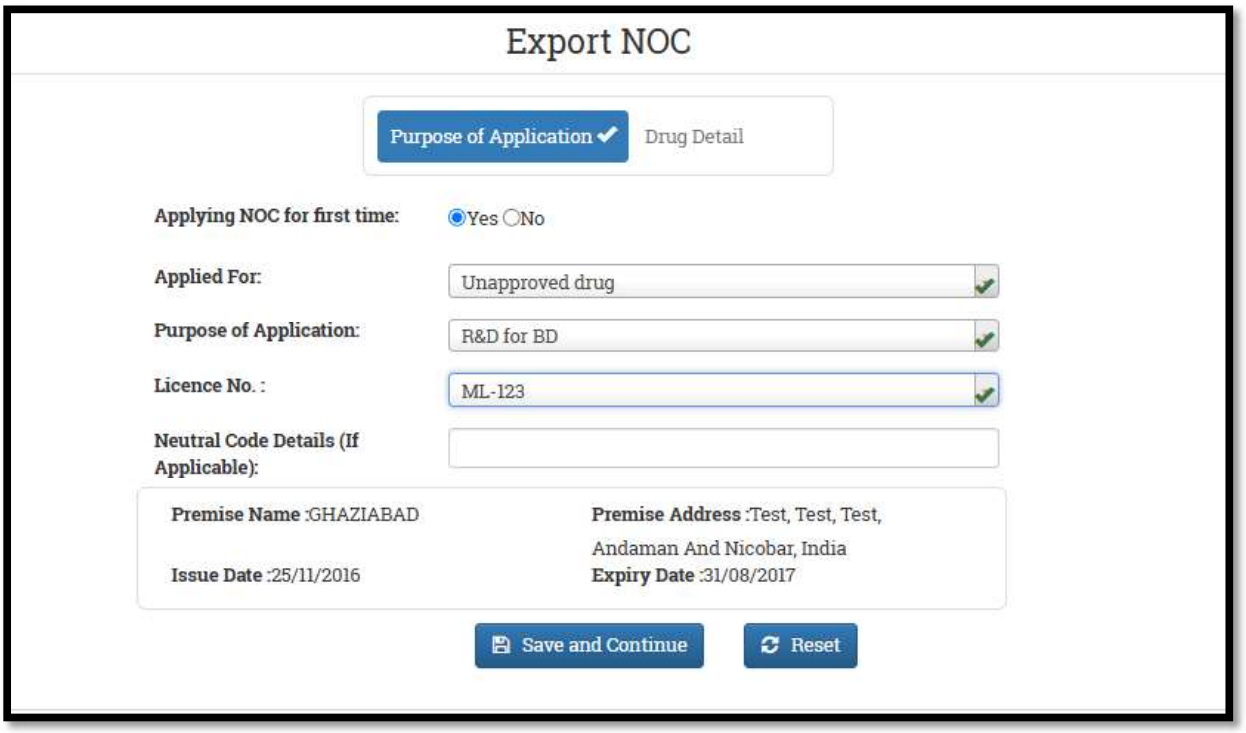

Figure 24: Unapproved drug for purpose

- While clicking on save and continue button drug details page will be visible.
- Where user has to fill the entire fill as mention below screenshots.

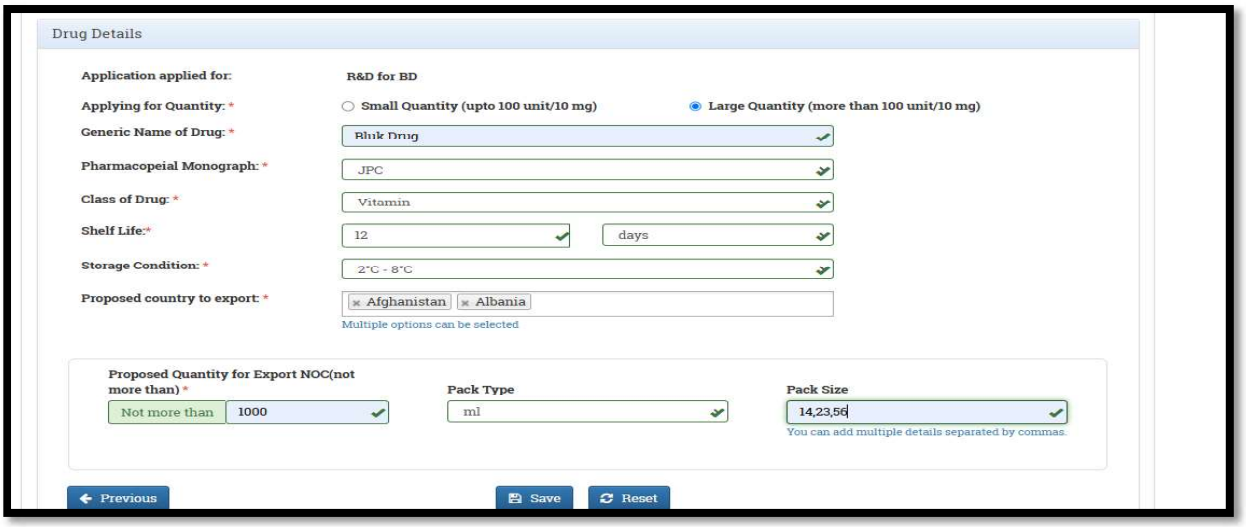

Figure 25: Unapproved drug details

- After clicking save button draft page will be visible.

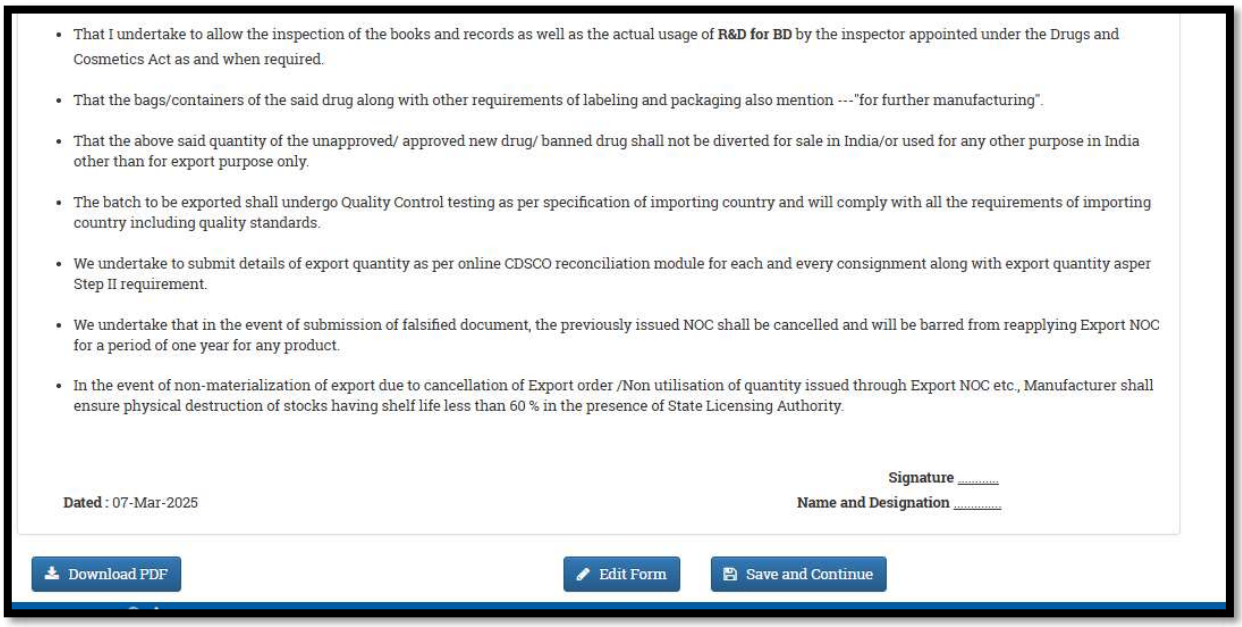

Figure 25: Draft field before the checklist

- After clicking Save and continue button checklist will be visible where user has to fill the entire checklist.

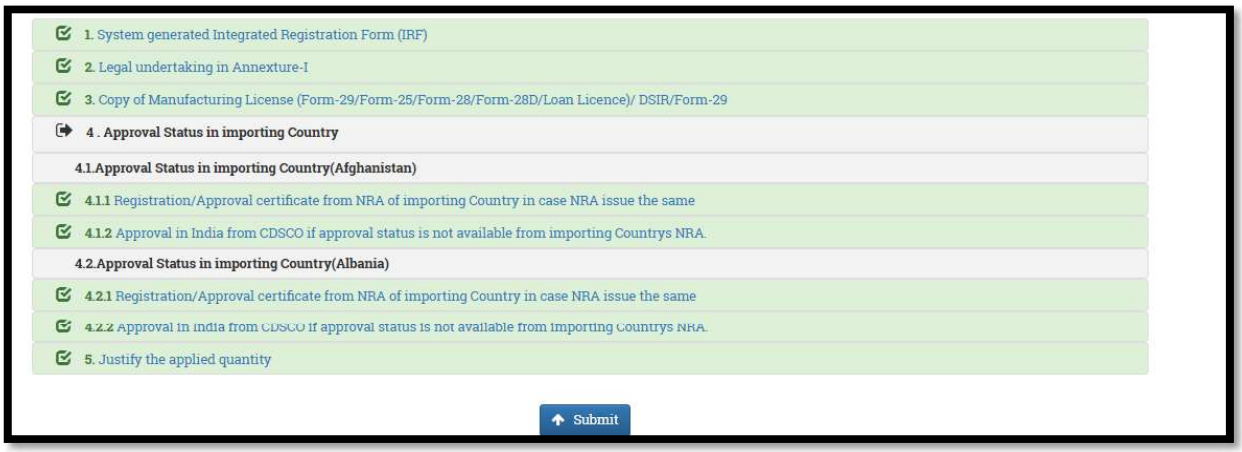

Figure 26: Checklist filed after the draft field

- After clicking on Submit button your file will be submitted successfully.