User Manual

for

SUGAM- An e-Governance solution

Online Forms Submission

NOC (Zone)- Export NOC

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)

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Contents

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.

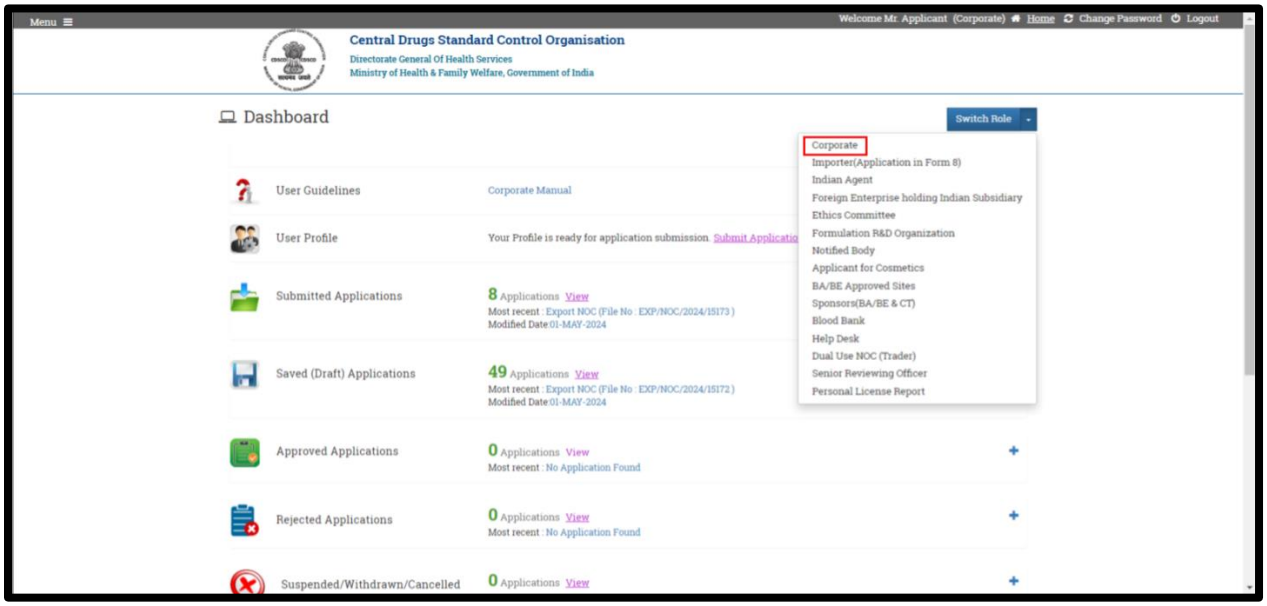


Figure 1: Applicant Dashboard

- 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.

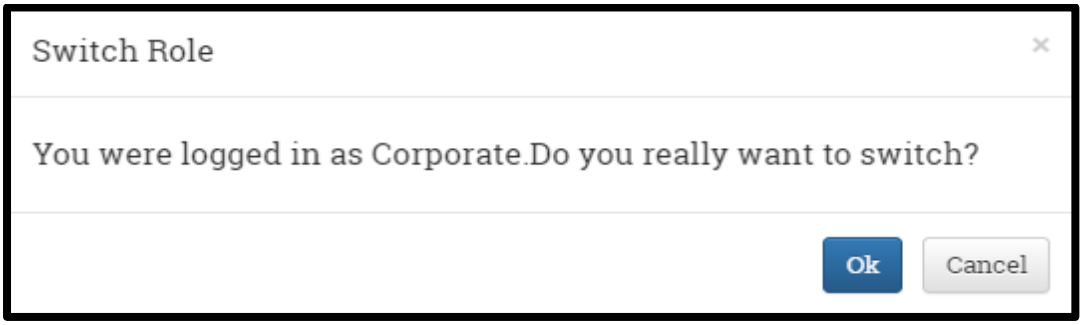


Figure 2: Switch Role

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

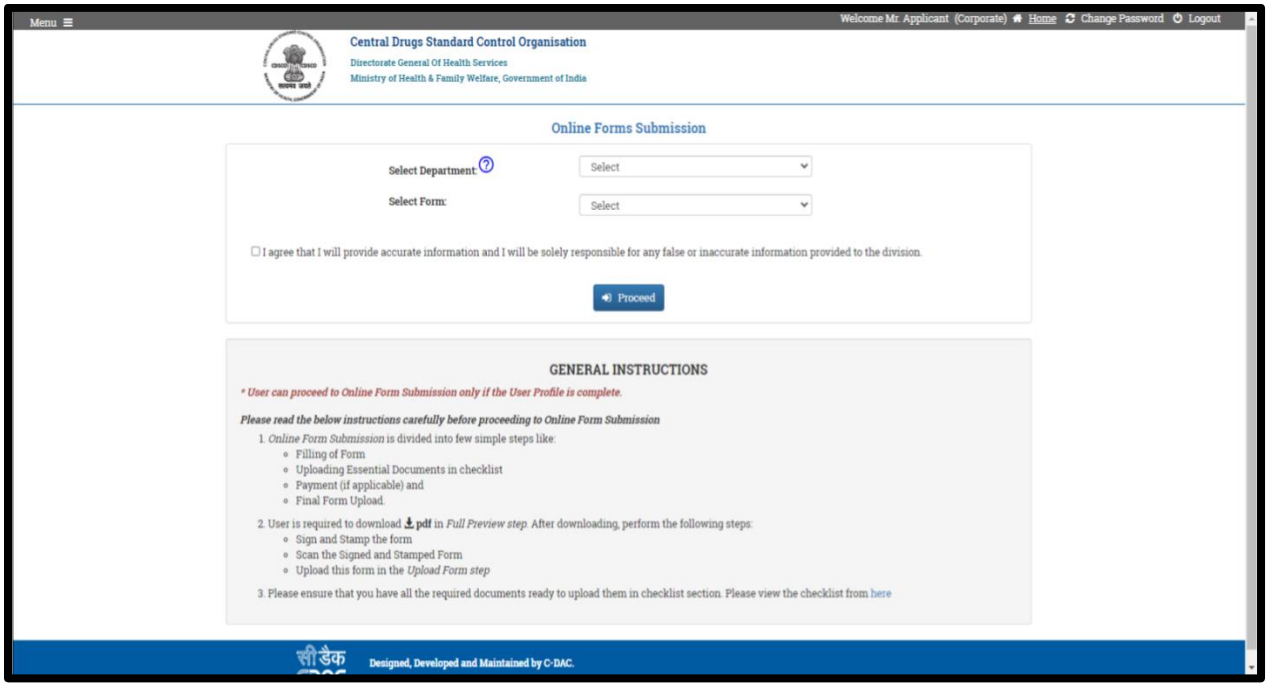


Figure 3: Online Form Submission

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

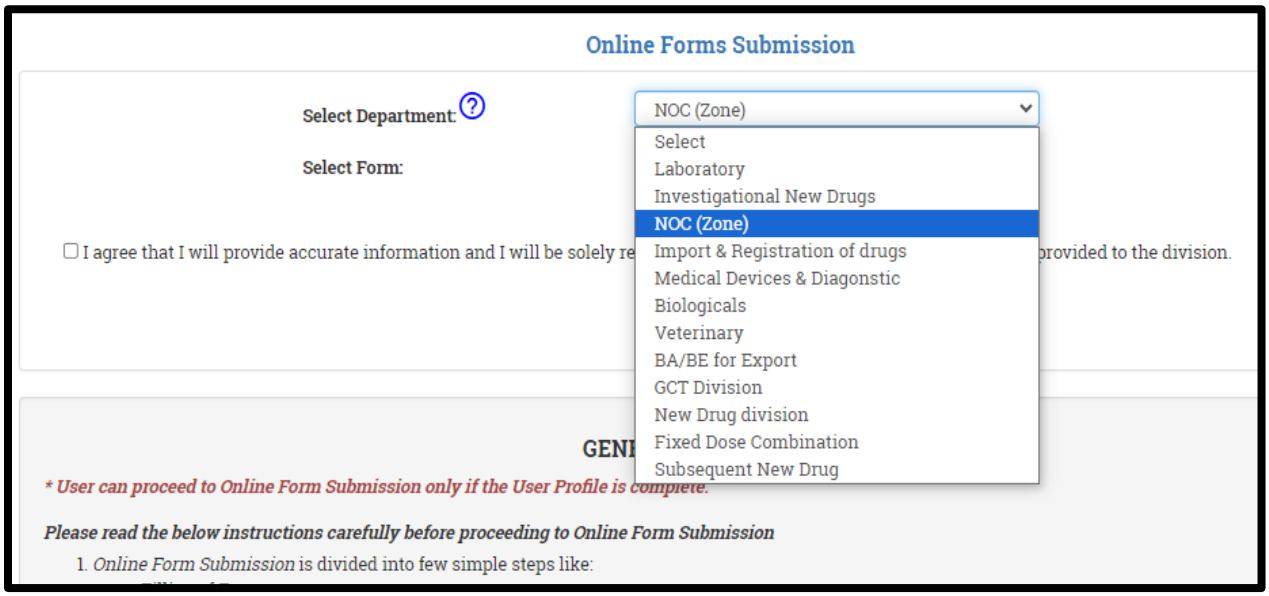


Figure 4: Select Department

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

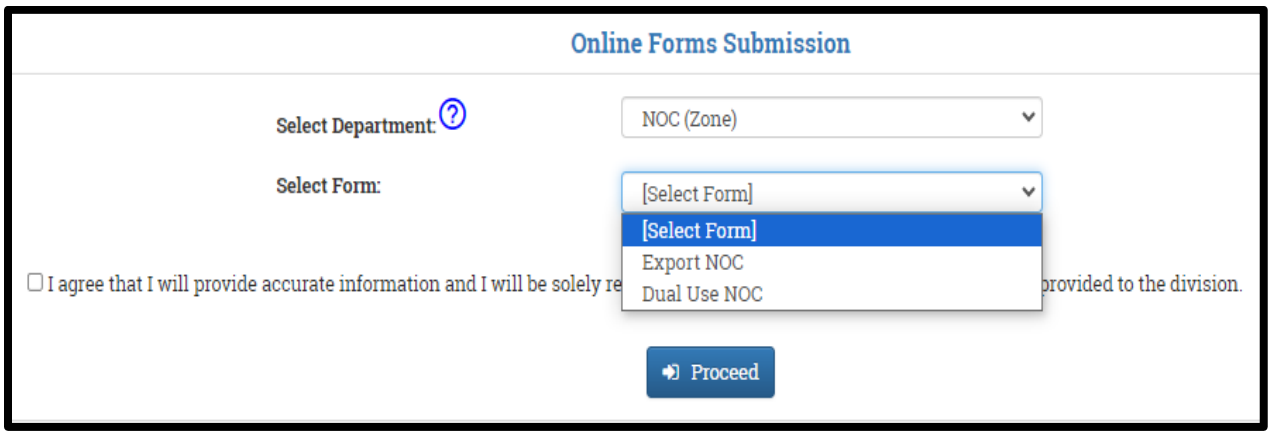


Figure 5: Select Form

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.

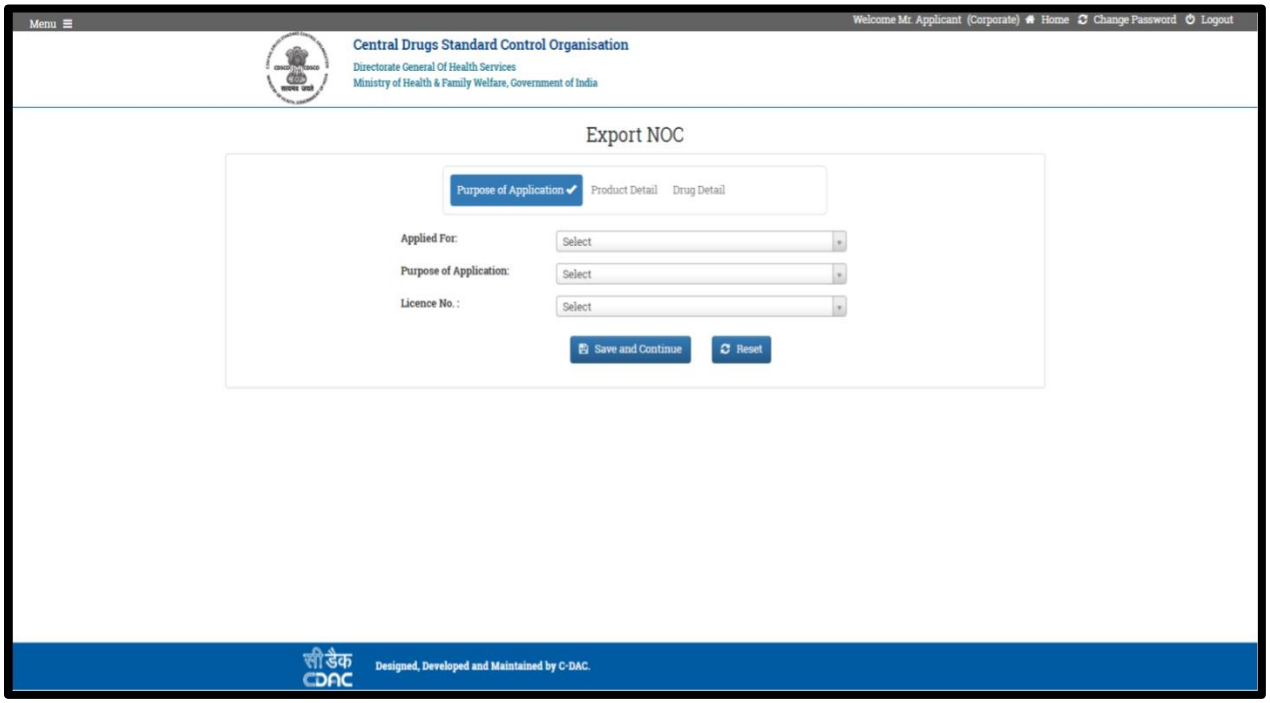


Figure 6: Export NOC

- On this page, there are following options available under **Applied For** dropdown. Below is the screenshot of the same.

Figure 7: Applied For dropdown

- After selecting the desired option from **Applied For** dropdown, the Applicant can see two options on the **Purpose of Application** dropdown: **Bulk Drug** and **Finished Formulation.** We will see these in detail in the further sections.

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.

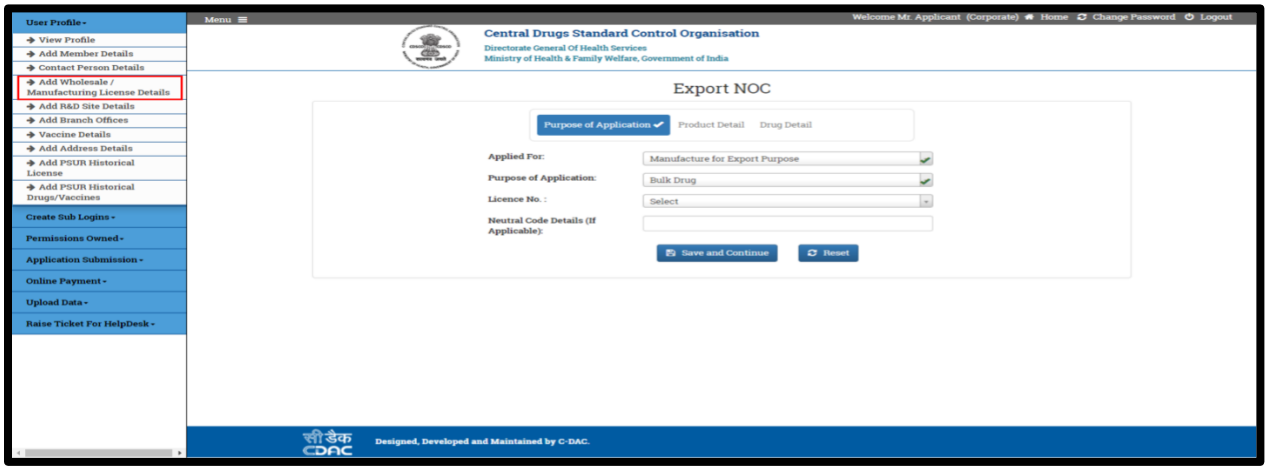


Figure 8: Add Wholesale/ Manufacturing License Details

Once the Applicant clicks on the **Add Wholesale/ Manufacturing License Details,** the following screen will appear as shown below.

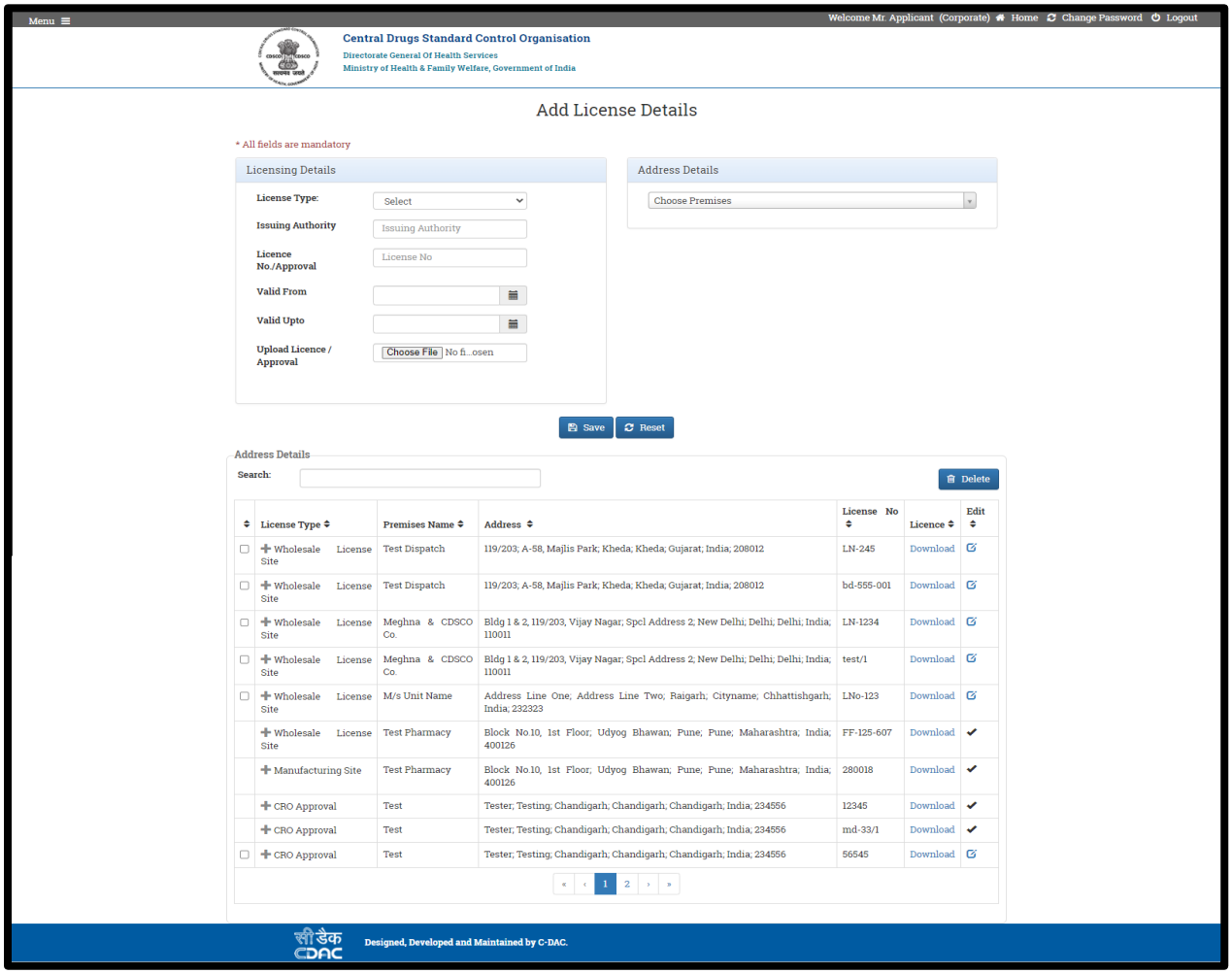


Figure 9: Add License Details

The Applicant can add the license details by filling the information asked in the **Licensing Details**. Now, this License Number will appear in **the License No.** dropdown.

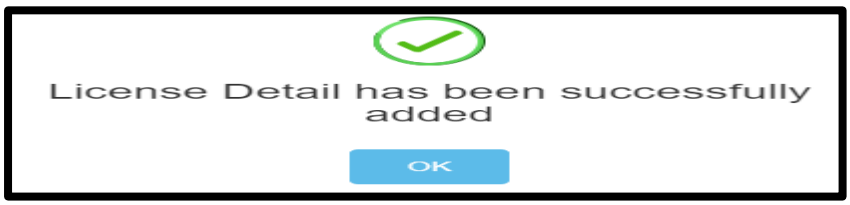


Figure 10: License Details added confirmation

1.1. Manufacture for Export Purpose with Bulk Drug as purpose of Application

- When the Applicant selects Manufacture for Export Purpose with Bulk Drug as purpose of Application, screen looks like as shown below in the image.

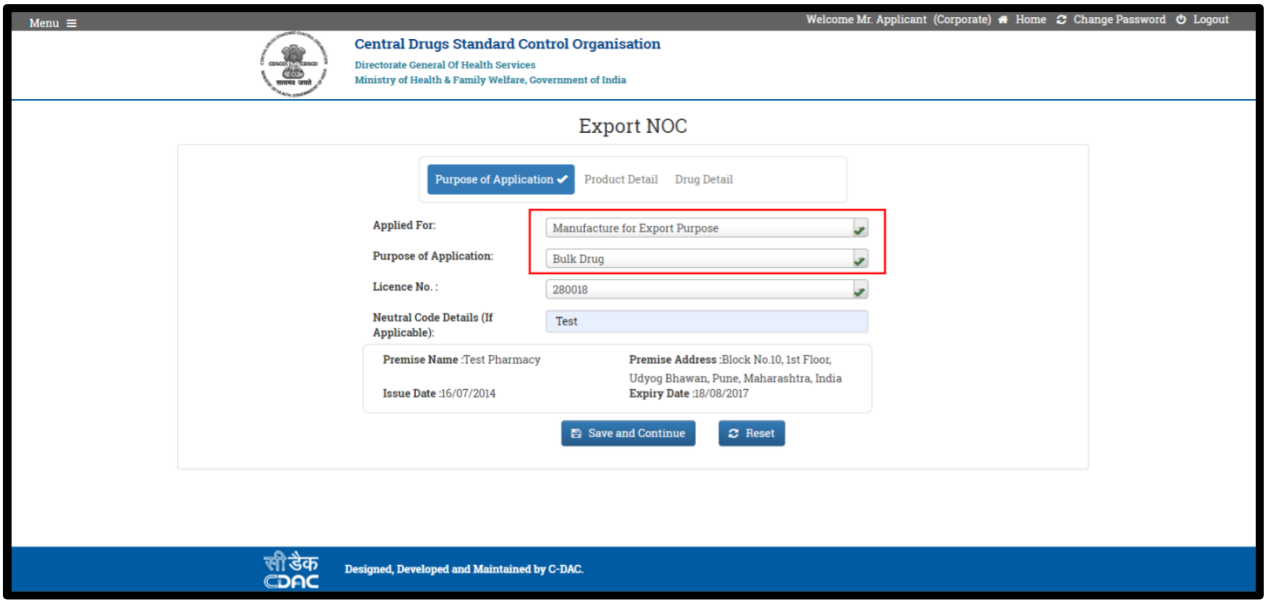


Figure 11: Manufacture for Export Purpose with Bulk Drug as purpose of Application

- The Applicant can edit his details by clicking on the **Reset** button present at the bottom of the page.
- After clicking on **Save and Continue button,** following page will appear**.**

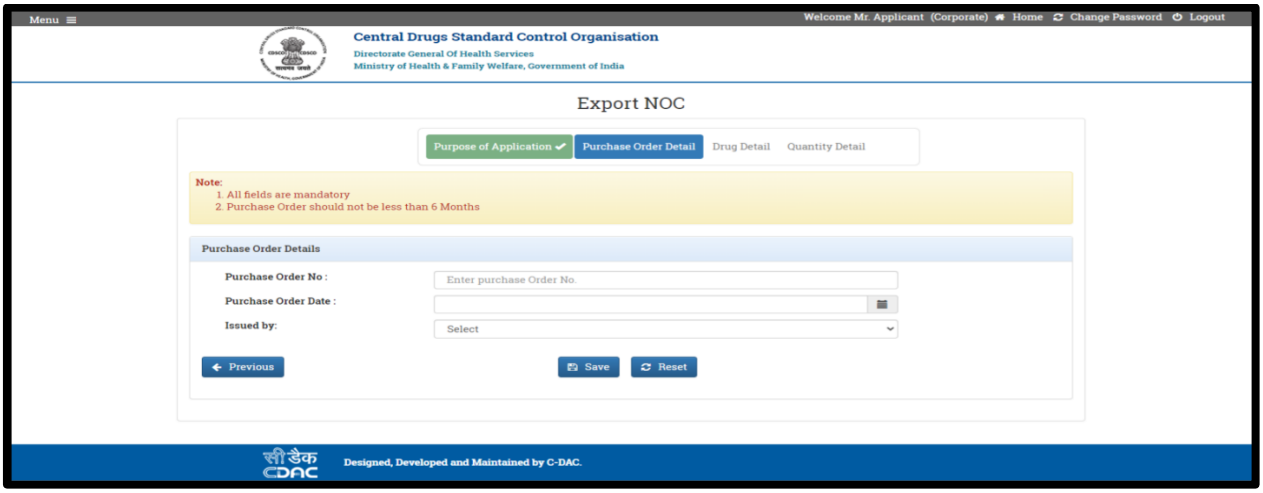


Figure 12: Purchase Order Detail

- Once the Applicant enters the details like **Purchase Order No., Purchase Order date**, he can then select the **Issued by** Buyer or Trader option form the list. This will open a Buyer or Trader Detail section, wherein the Applicant needs to enter all the mandatory details.

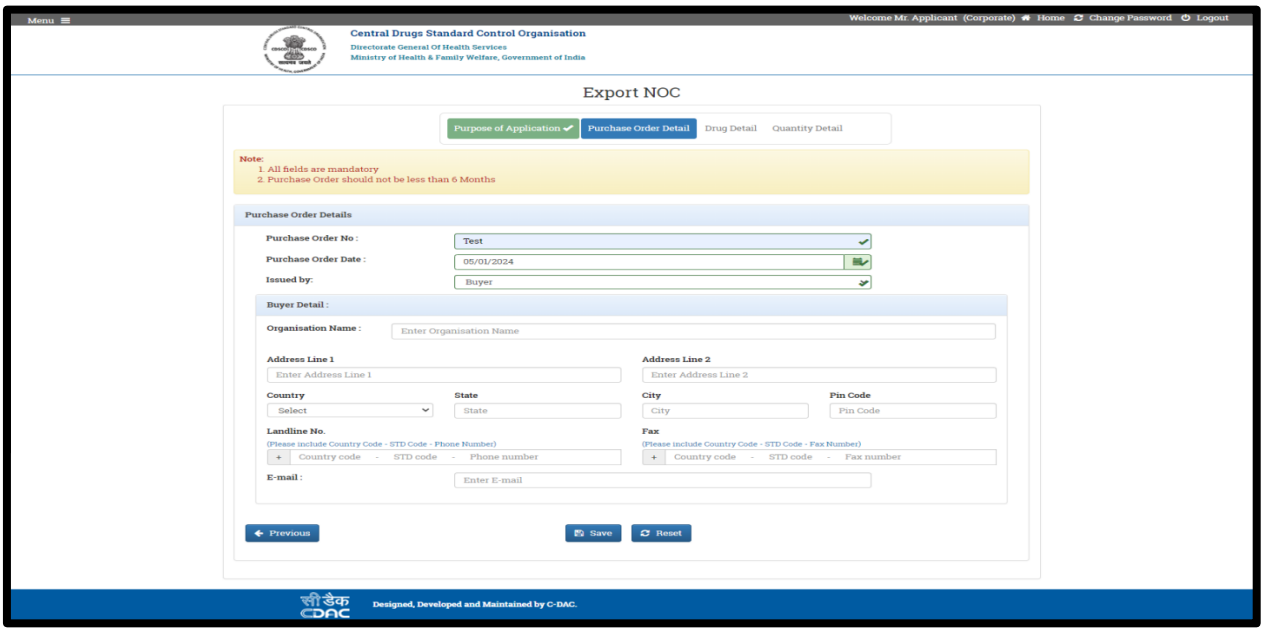


Figure 13: Buyer/ Trader details

- After entering all the Buyer/ trader details on this page, Applicant will save the information and then the saved details will be visible in a new line as shown below.

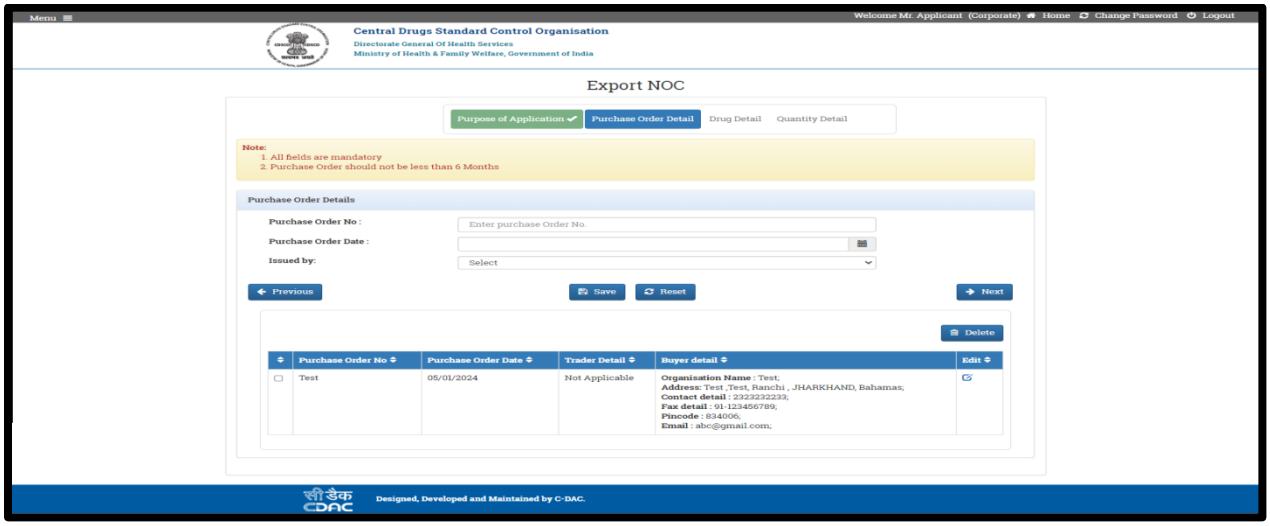


Figure 14: Buyer/ Trader details (continue)

- Now the Applicant can move to the next section by clicking on the **Next** button present on this page. The following screen will appear.

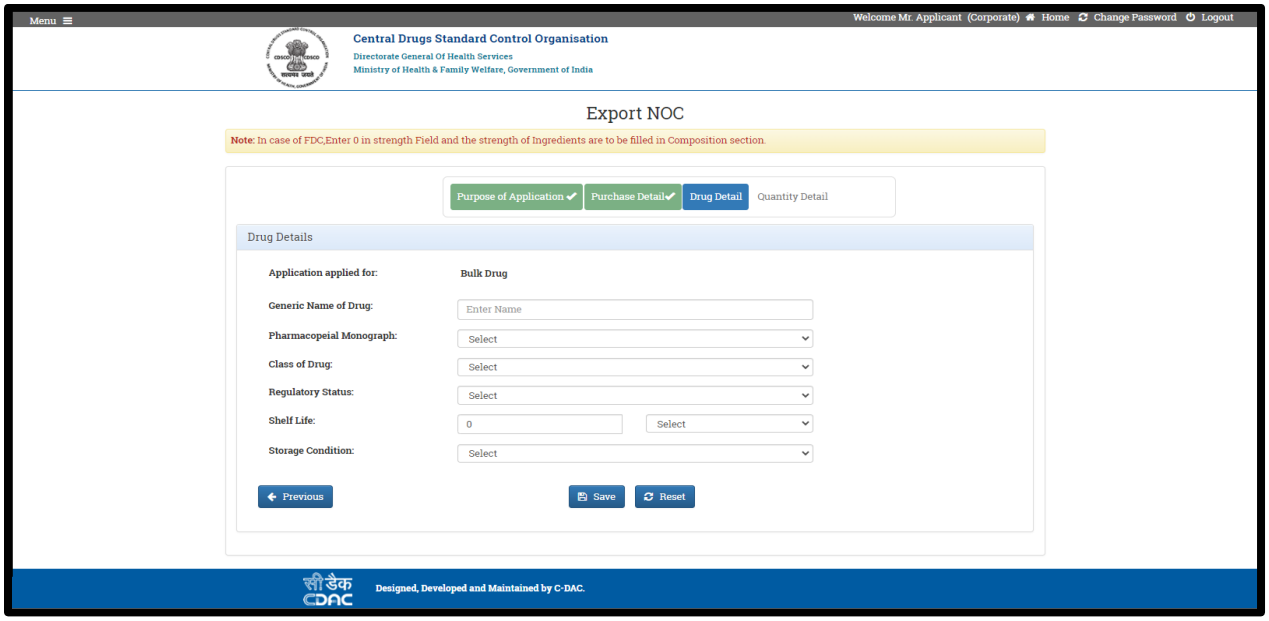


Figure 15: Drug Detail

- After filling all the details, a new line is generated and the screen looks like this.

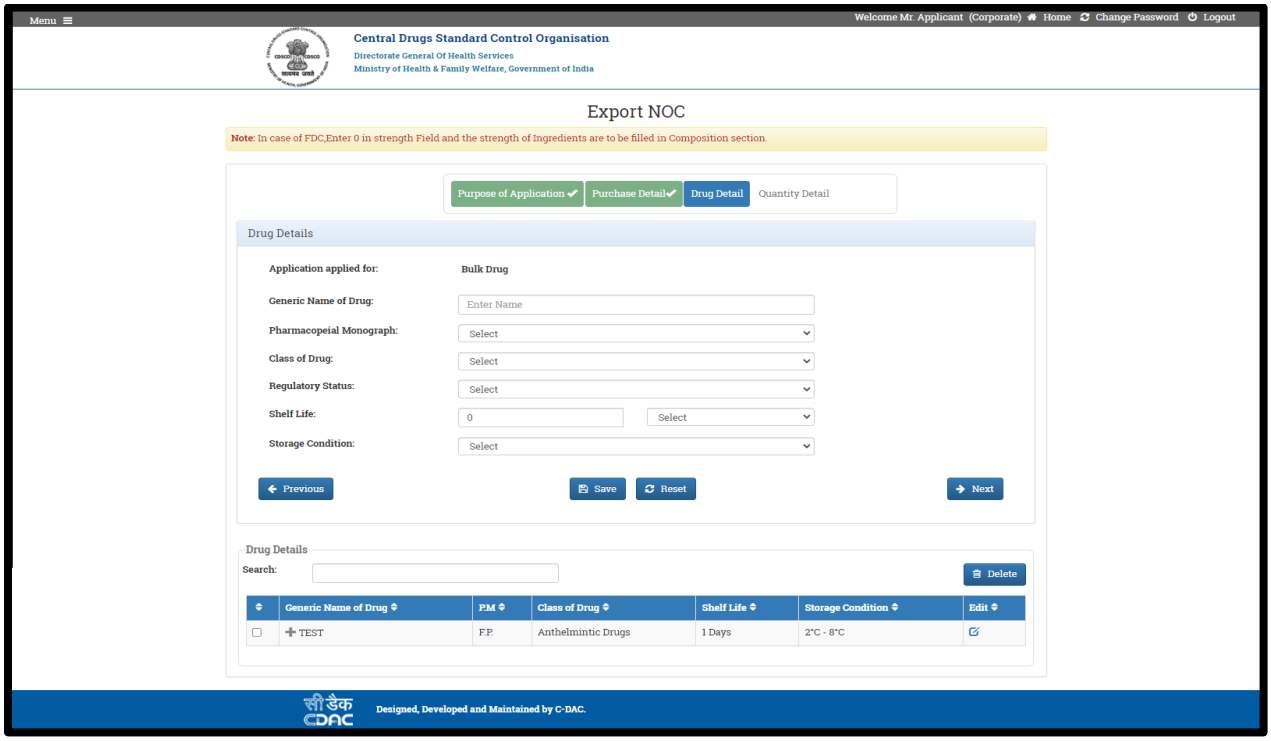


Figure 16: : Drug Detail (continued)

- Now the Applicant can move to the next section i.e. **Quantity Detail** by clicking on the **Next** button present on this page. The following screen will appear.

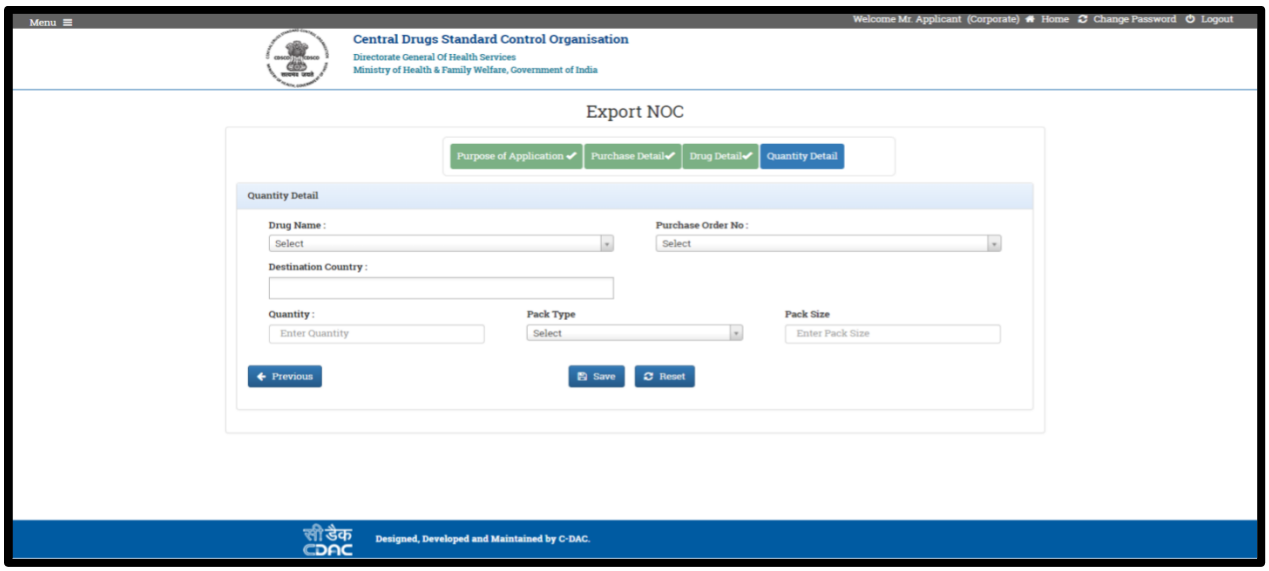


Figure 17: Quantity Detail

- After entering and saving all the details on this page, the Applicant can move to the next section by clicking on the **Next** button. The following screen will appear.

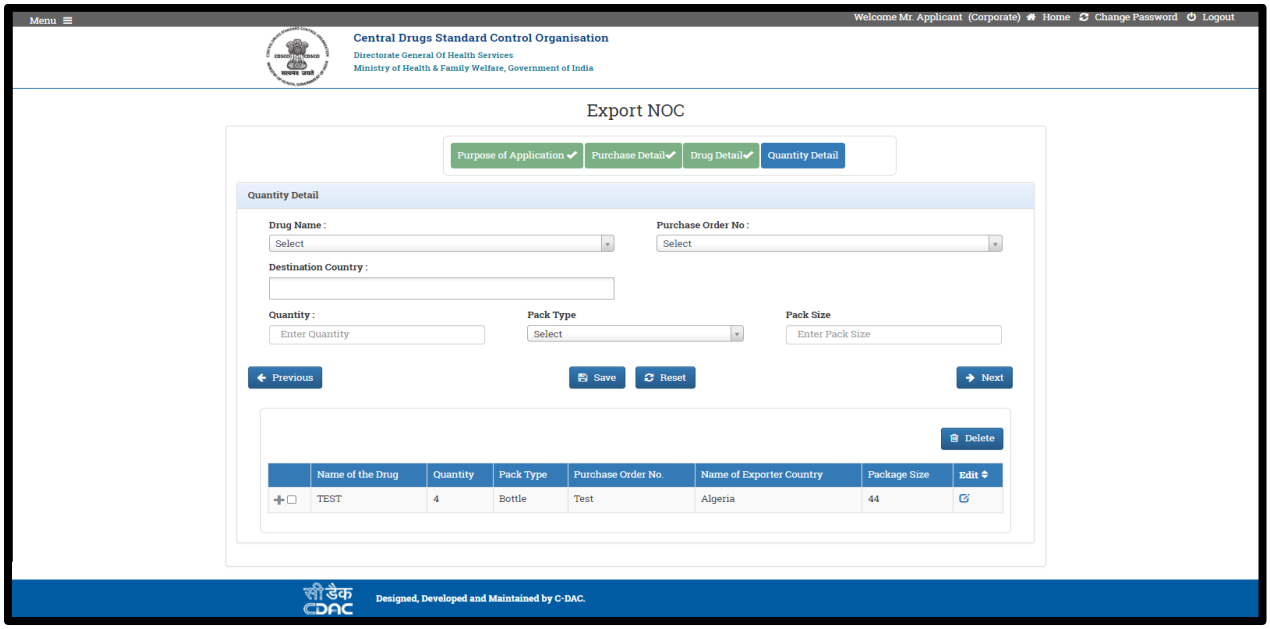
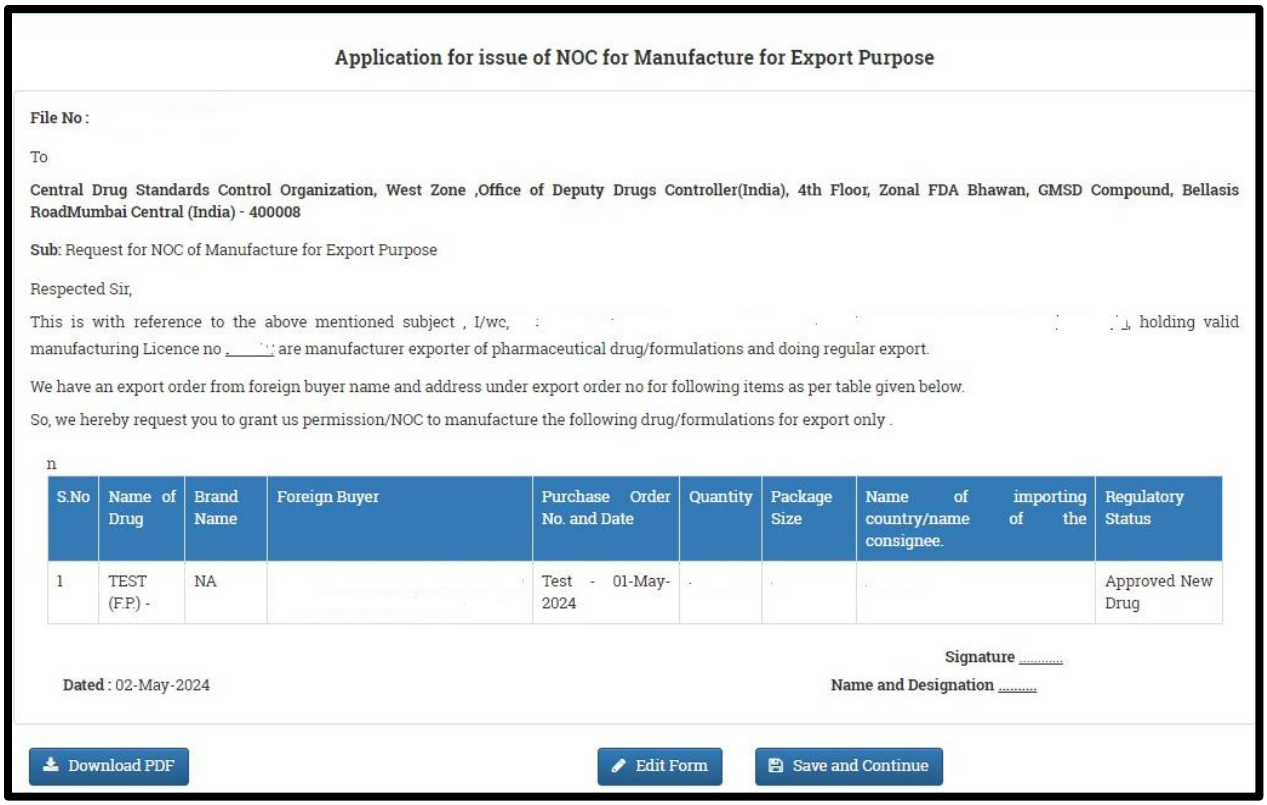


Figure 18: Quantity Detail (continued)

- The Application is now complete and the Applicant will get a File No. The Applicant can Download PDF or edit the form.



Application for issue of NOC for Manufacture for Export Purpose

File No :

To

Central Drug Standards Control Organization, West Zone ,Office of Deputy Drugs Controller(India), 4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis RoadMumbai Central (India) - 400008

Sub: Request for NOC of Manufacture for Export Purpose

Respected Sir,

This is with reference to the above mentioned subject , I/we, : , holding valid manufacturing Licence no _____: are manufacturer exporter of pharmaceutical drug/formulations and doing regular export.

We have an export order from foreign buyer name and address under export order no for following items as per table given below.

So, we hereby request you to grant us permission/NOC to manufacture the following drug/formulations for export only .

n

S.No	Name of Drug	Brand Name	Foreign Buyer	Purchase Order No. and Date	Quantity	Package Size	Name of importing country/name of the consignee.	Regulatory Status
1	TEST (F.P) -	NA		Test - 01-May-2024				Approved New Drug

Signature .....

Dated : 02-May-2024

Name and Designation .....

Download PDF | Edit Form | Save and Continue

Figure 19: Application for issue of NOC

- After checking all the details, the Applicant can move forward by clicking on **Save and Continue** button present at the bottom of the page. A window pop up will appear asking for the confirmation.

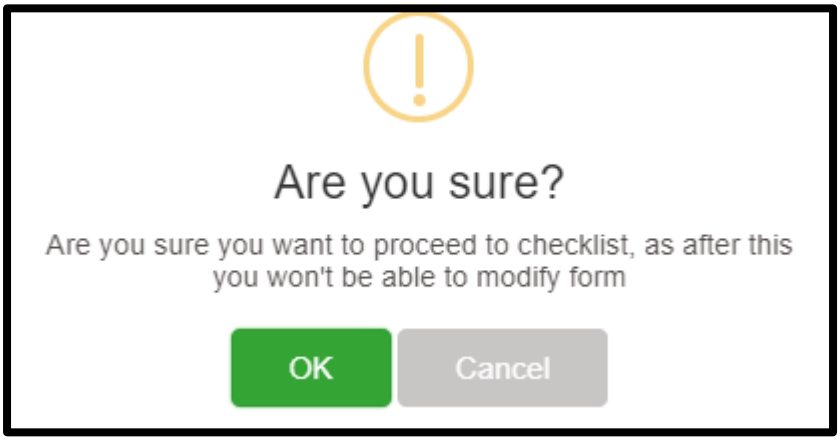


Figure 20: Confirmation window

- After confirming by clicking **OK** on the above screen, the Applicant will move to the checklist page as shown in the image below.

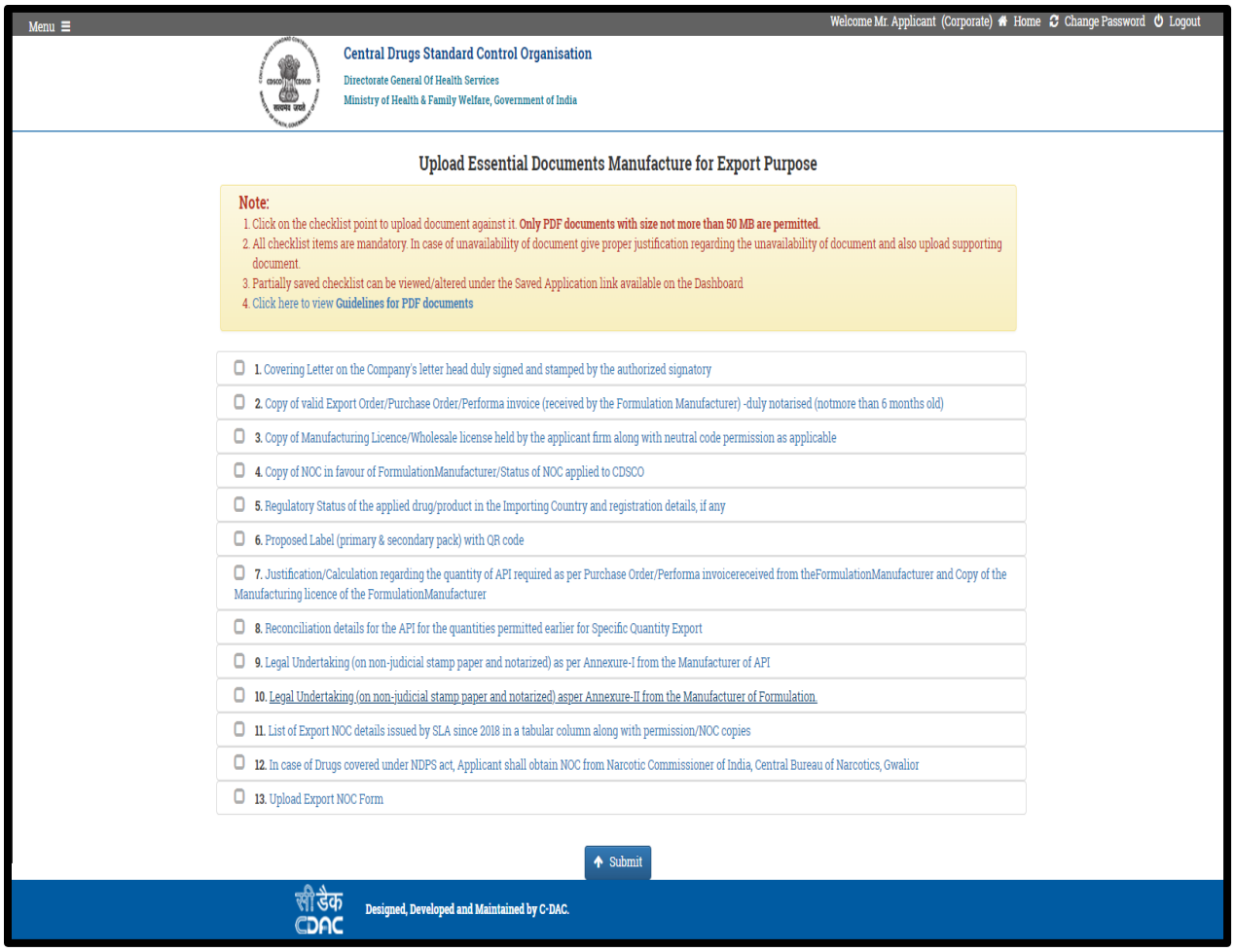


Figure 21: Upload document page

- After uploading all the documents, the Applicant clicks on Submit button. A file number is generated as shown below.

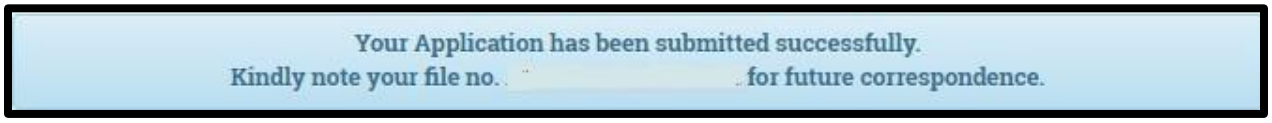


Figure 22: File Number Generated

1.2. Material Transfer (API Manufacture) with Bulk Drug as purpose of Application

- When the Applicant selects Material Transfer (API Manufacture) with Bulk Drug as purpose of Application, screen looks like as shown below in the image.

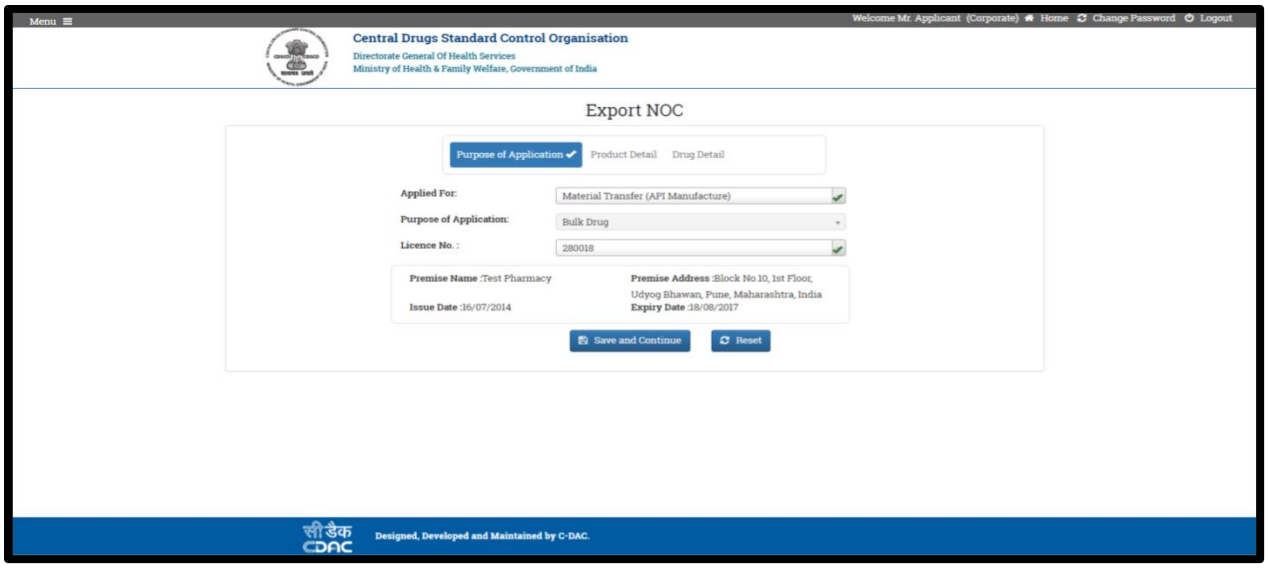


Figure 23: Material Transfer (API Manufacture) with Bulk Drug as purpose of Application

- After filling the details and clicking on Save and Continue, the Applicant will move to Product Detail page.

- After filling all the details and clicking on **Save** button, the information will get added in a new line and now the Applicant can move to the next section by clicking the **Next** button.

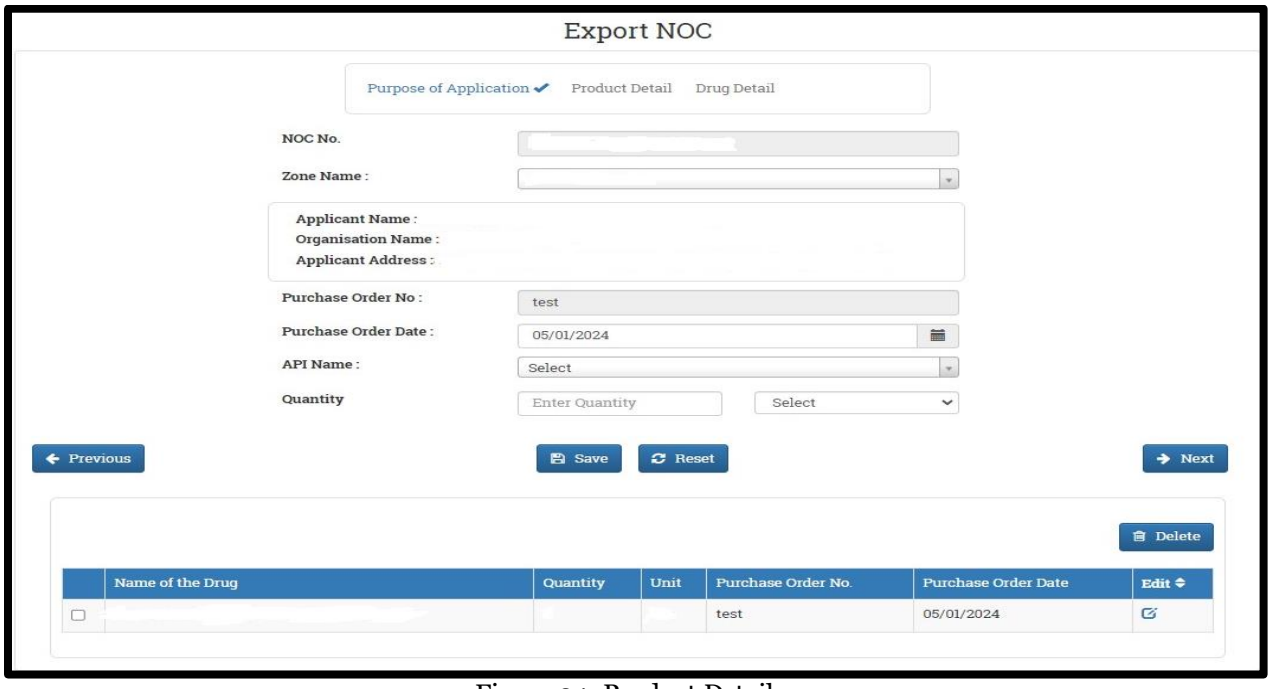


Figure 24: Product Detail

- After clicking on the Next button, following page will appear.

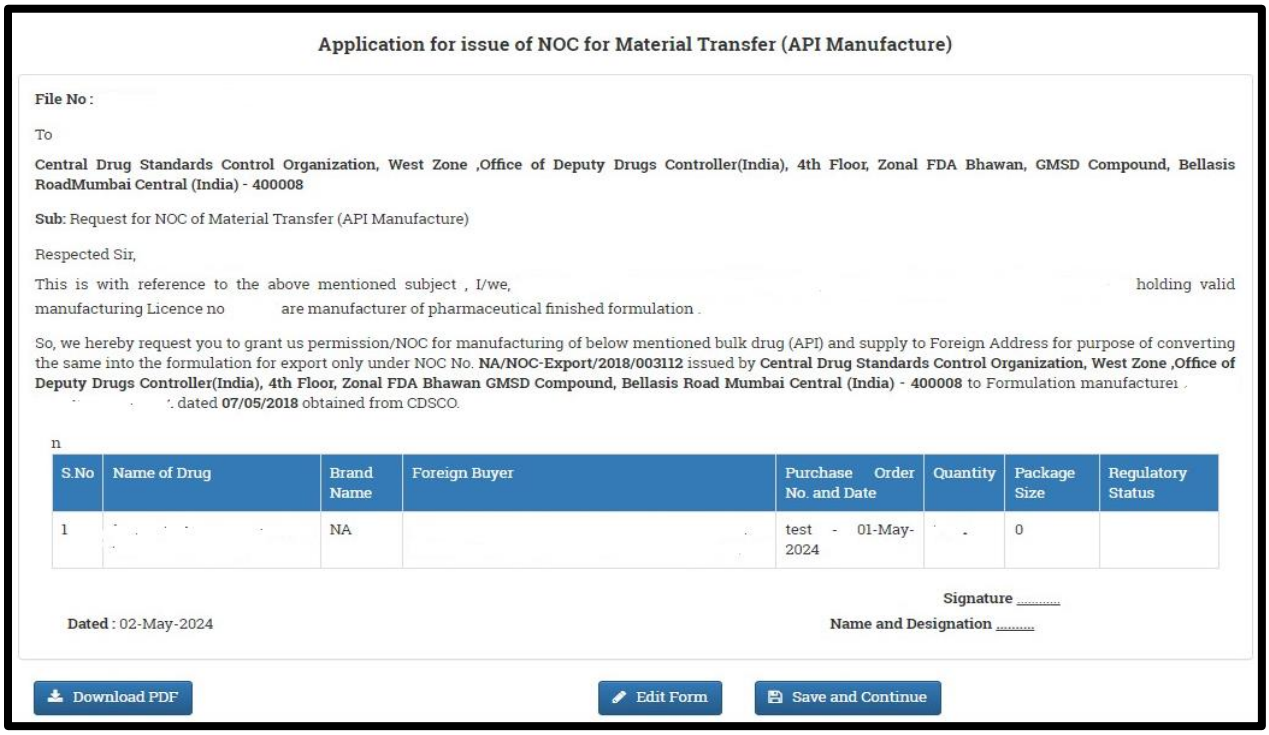


Figure 25: Application for NOC

- After checking all the details, the Applicant can move forward by clicking on **Save and Continue** button present at the bottom of the page. A window pop up will appear asking for the confirmation.

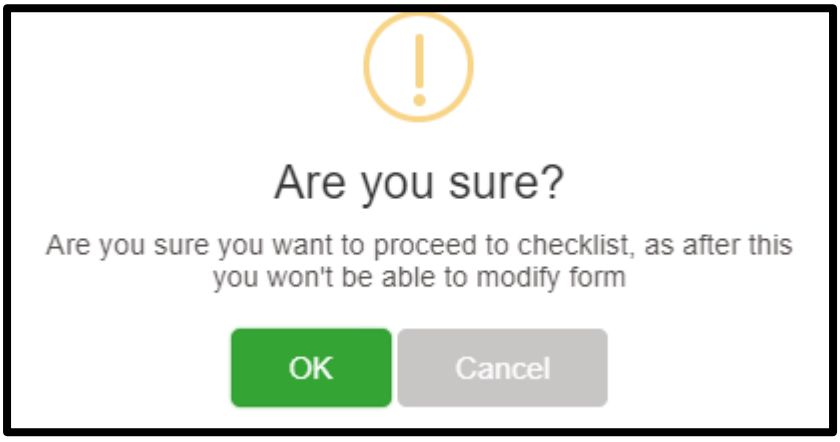


Figure 26: Confirmation window

- After confirming by clicking **OK** on the above screen, the Applicant will move to the checklist page as shown in the image below.

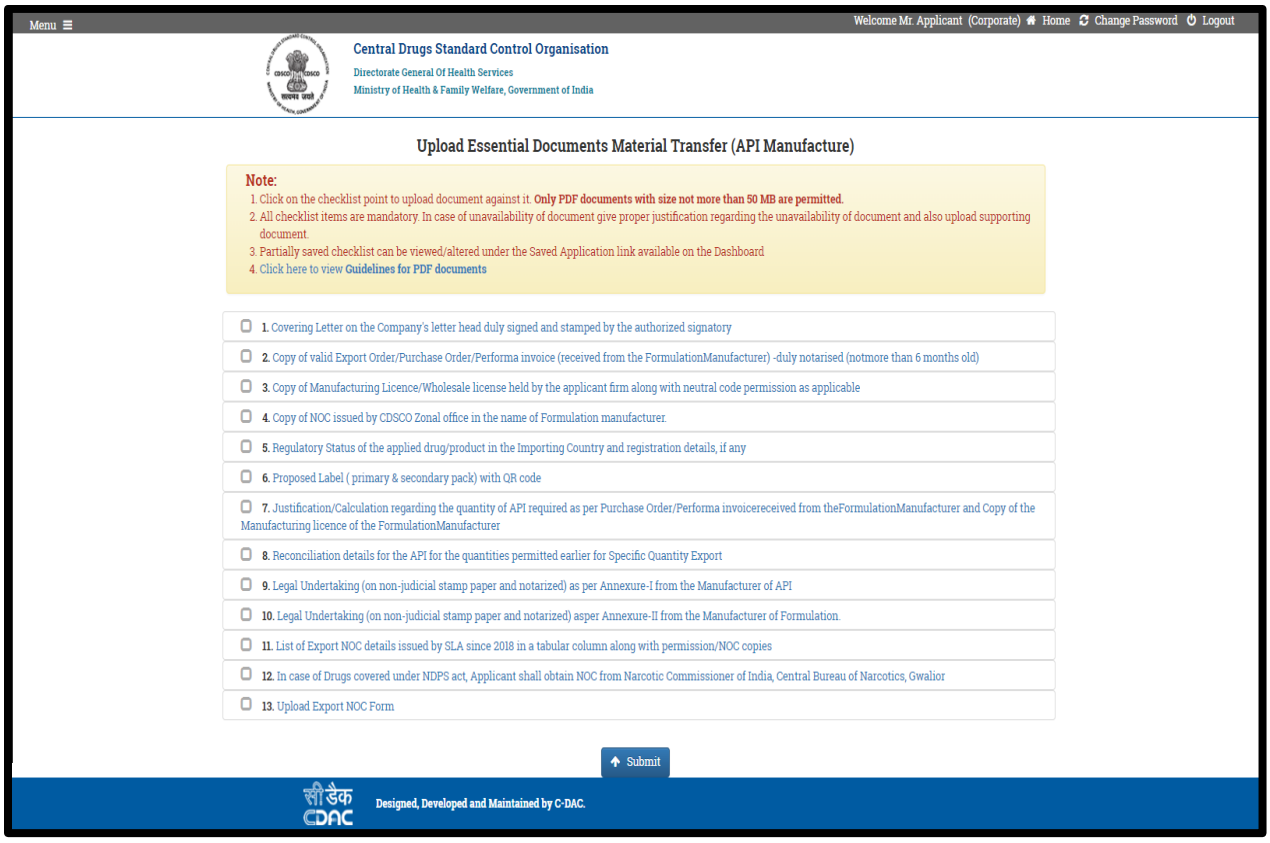


Figure 27: Upload document page

- After uploading all the documents, the Applicant clicks on Submit button. A file number is generated as shown below.

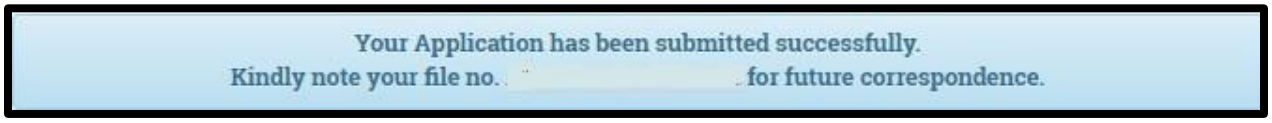


Figure 28: File Number Generated

1.3. Procuring Unapproved/ approved New Drug (Bulk) for R&D/ Formulation Development/ Manufacture of Exhibit Batches for data of Extract Purpose with Bulk Drug as purpose of Application

- When the Applicant selects Procuring Unapproved/ approved New Drug (Bulk) for R&D/ Formulation Development/ Manufacture of Exhibit Batches for data of

Extract Purpose with Bulk Drug as purpose of Application, screen looks like as shown below in the image.

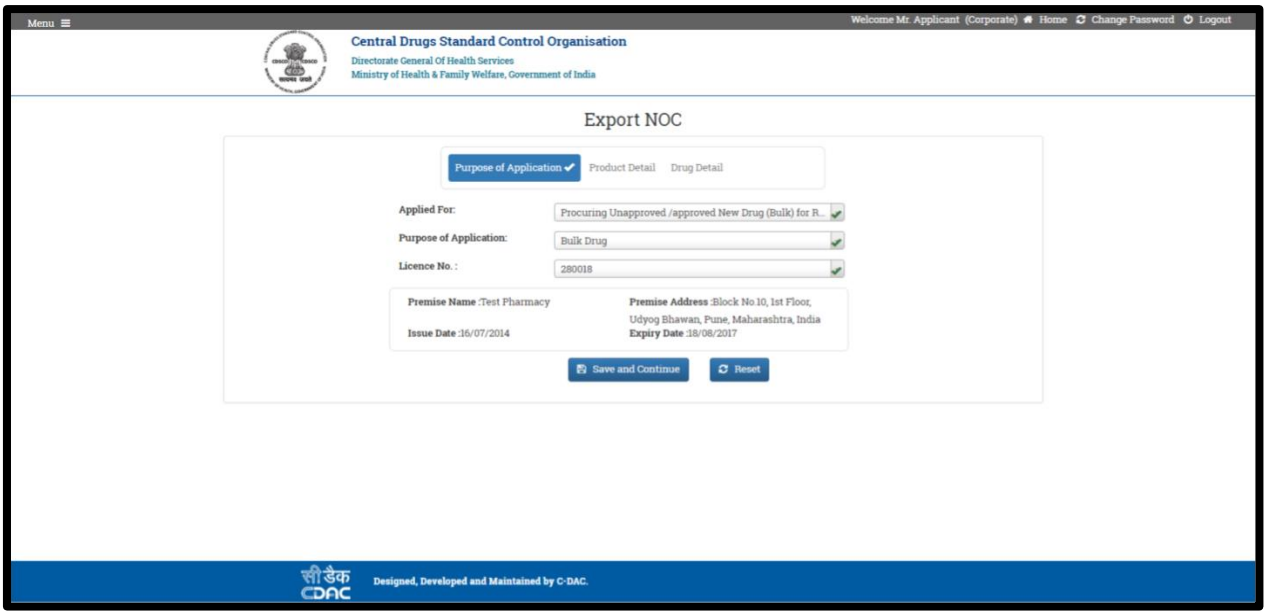


Figure 29: Procuring Unapproved/ approved New Drug (Bulk) for R&D/ Formulation Development/ Manufacture of Exhibit Batches for data of Extract Purpose with Bulk Drug as purpose of Application

- After filling the details and clicking on Save and Continue, the Applicant will move to Drug Detail page.

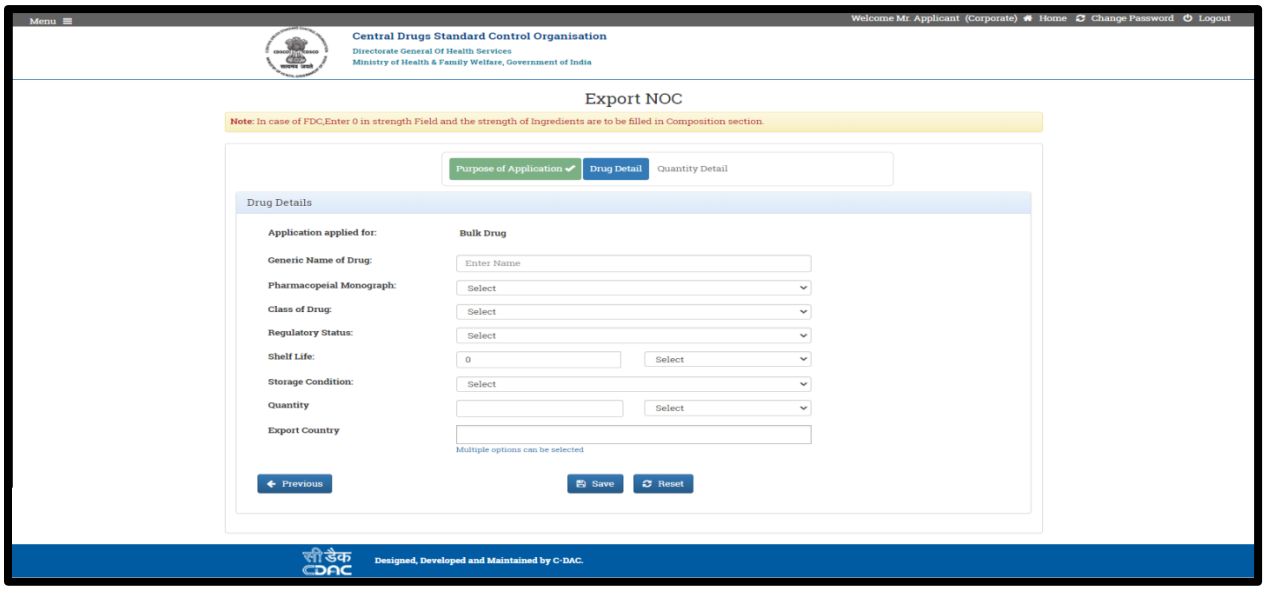


Figure 30: Drug Detail

- After filling all the details and clicking on **Save** button, the information will get added in a new line and now the Applicant can move to the next section by clicking the **Next** button.

Figure 31: Application for License of NOC

- After checking all the details, the Applicant can move forward by clicking on **Save and Continue** button present at the bottom of the page. A window pop up will appear asking for the confirmation.

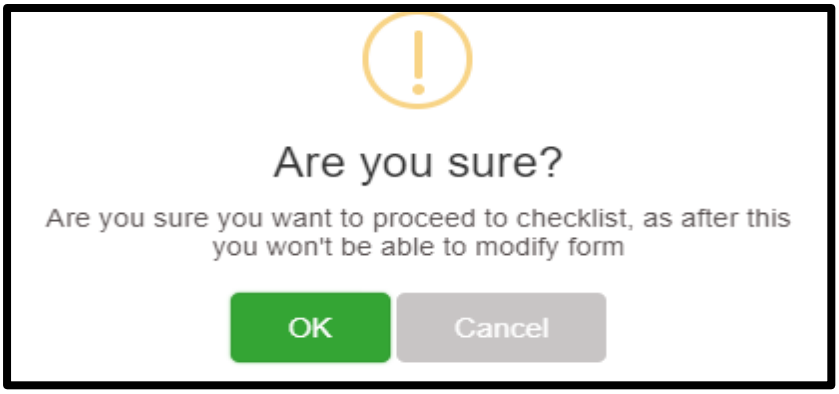


Figure 32: Confirmation window

- After confirming by clicking **OK** on the above screen, the Applicant will move to the checklist page as shown in the image below.

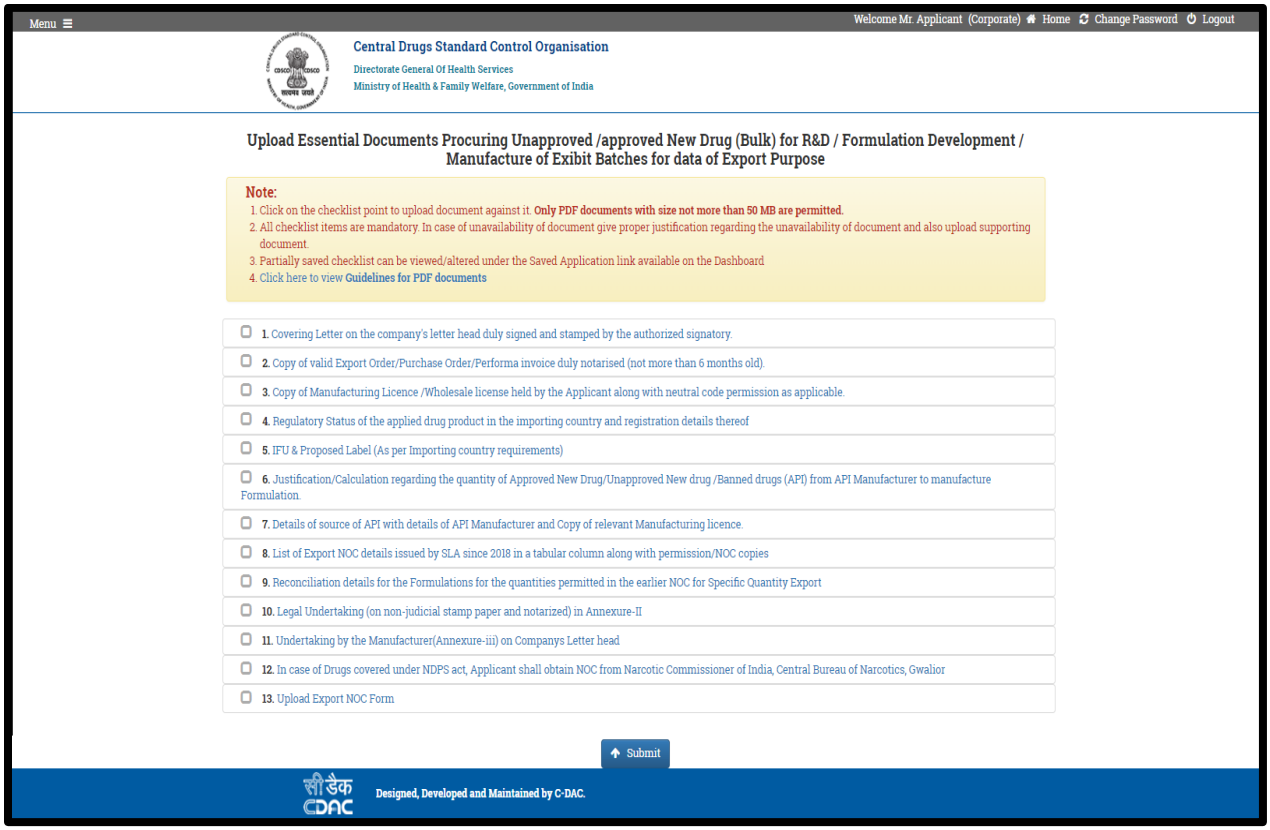


Figure 33: Document Checklist

- After uploading all the documents, the Applicant clicks on Submit button. A file number is generated as shown below.

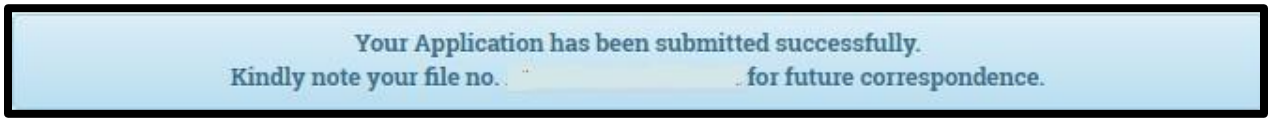


Figure 34: File Number Generated

1.4. Manufacture for Export Purpose with Finished Formulation as purpose of Application

- When the Applicant selects Manufacture for Export Purpose with Finished Formulation as purpose of Application, screen looks like as shown below in the image.

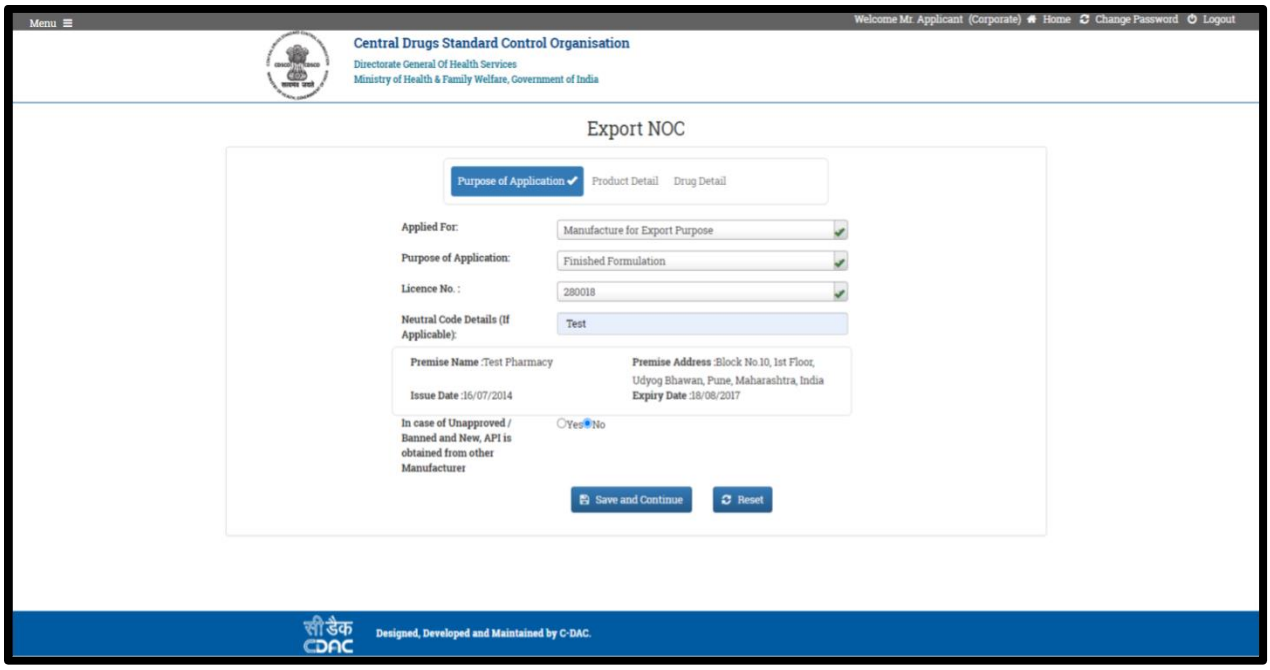


Figure 35: Manufacture for Export Purpose with Finished Formulation as purpose of Application

- After clicking on **Save and Continue button, Purchase Order Detail** page will appear as shown below**.**

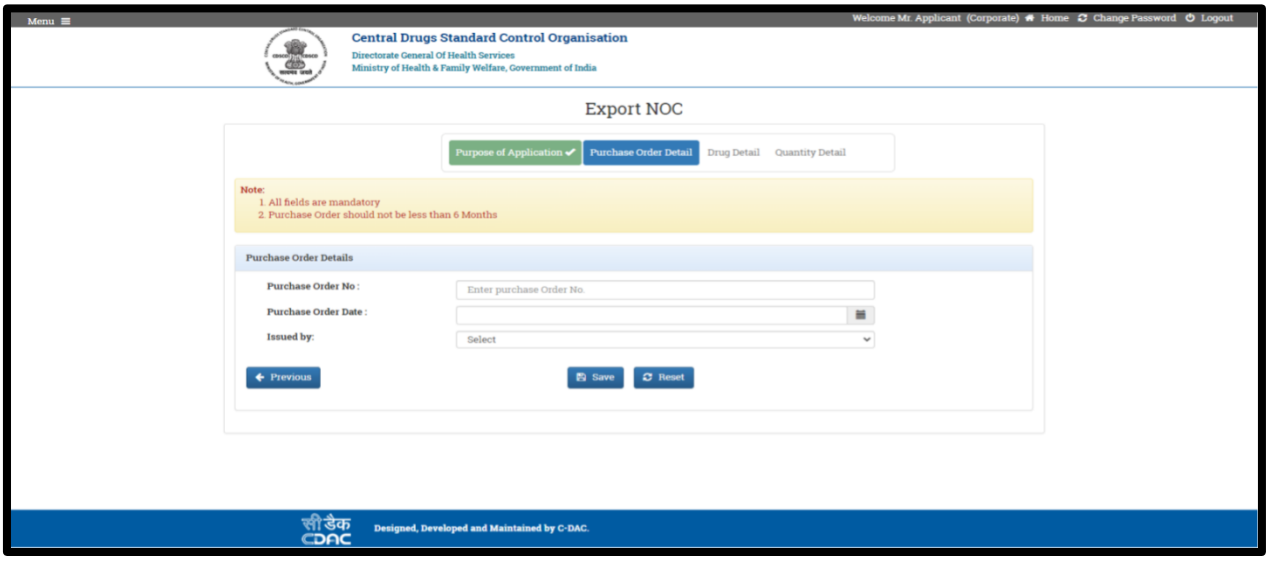


Figure 36: Purchase Order Detail

- Once the Applicant enters the details like **Purchase Order No., Purchase Order date**, he can then select the **Issued by** Buyer or Trader option form the list. This

will open a Buyer or Trader Detail section, wherein the Applicant needs to enter all the mandatory details.

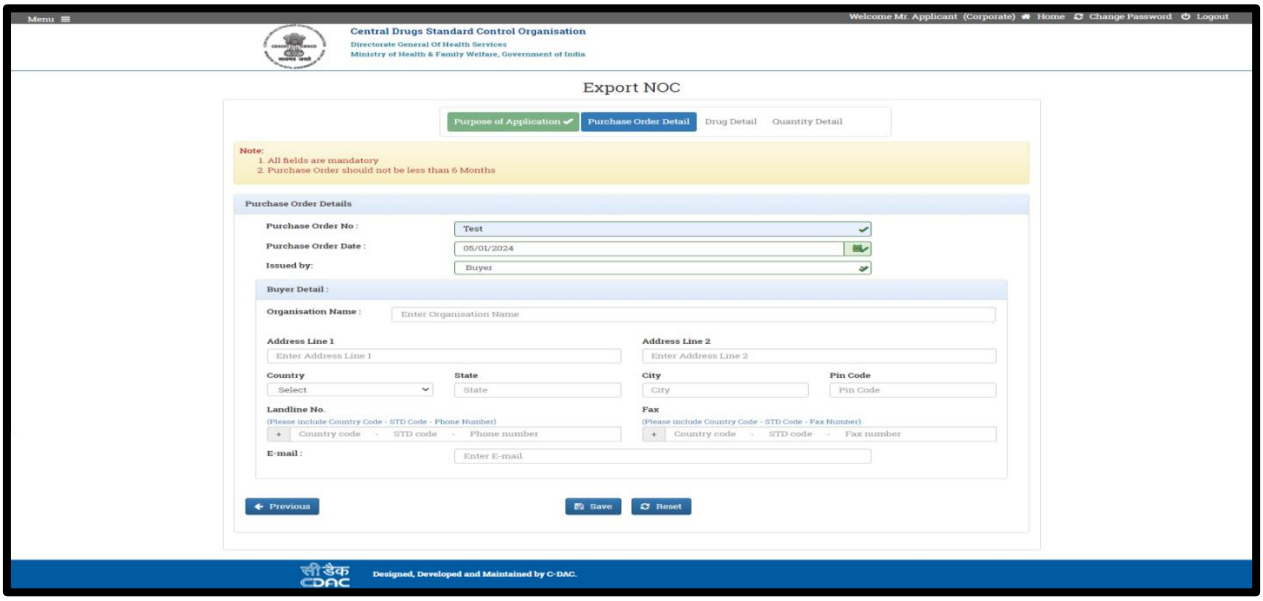


Figure 37: Buyer/ Trader details

- After entering all the Buyer/ trader details on this page, Applicant will save the information and then the saved details will be visible in a new line as shown below.

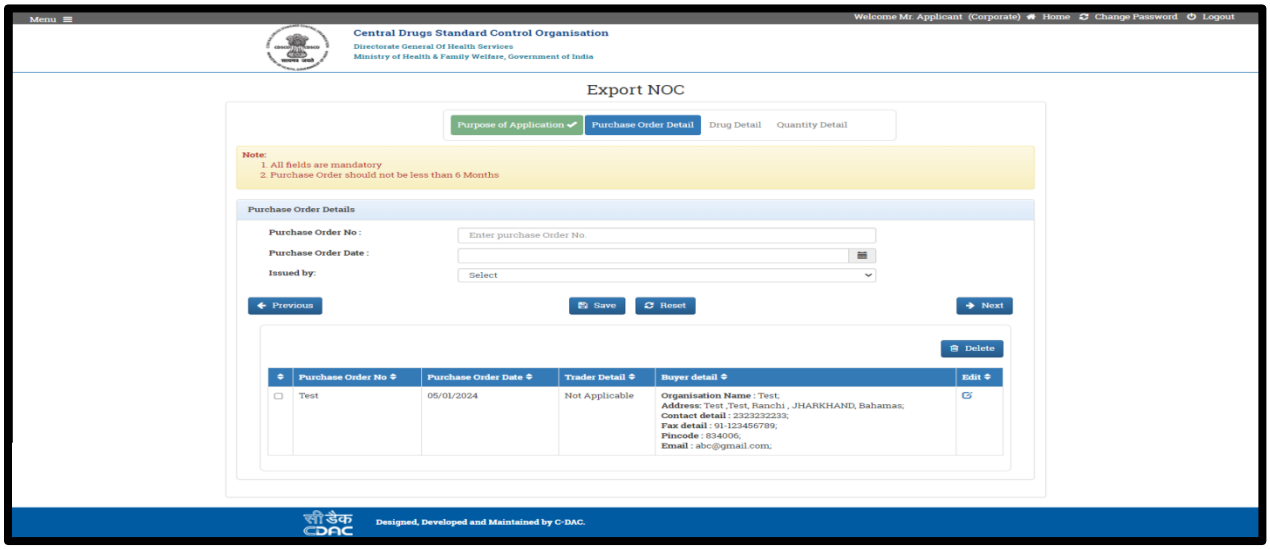


Figure 38: Buyer/ Trader details (continue)

- Now the Applicant can move to the next section by clicking on the **Next** button present on this page. The following screen will appear.

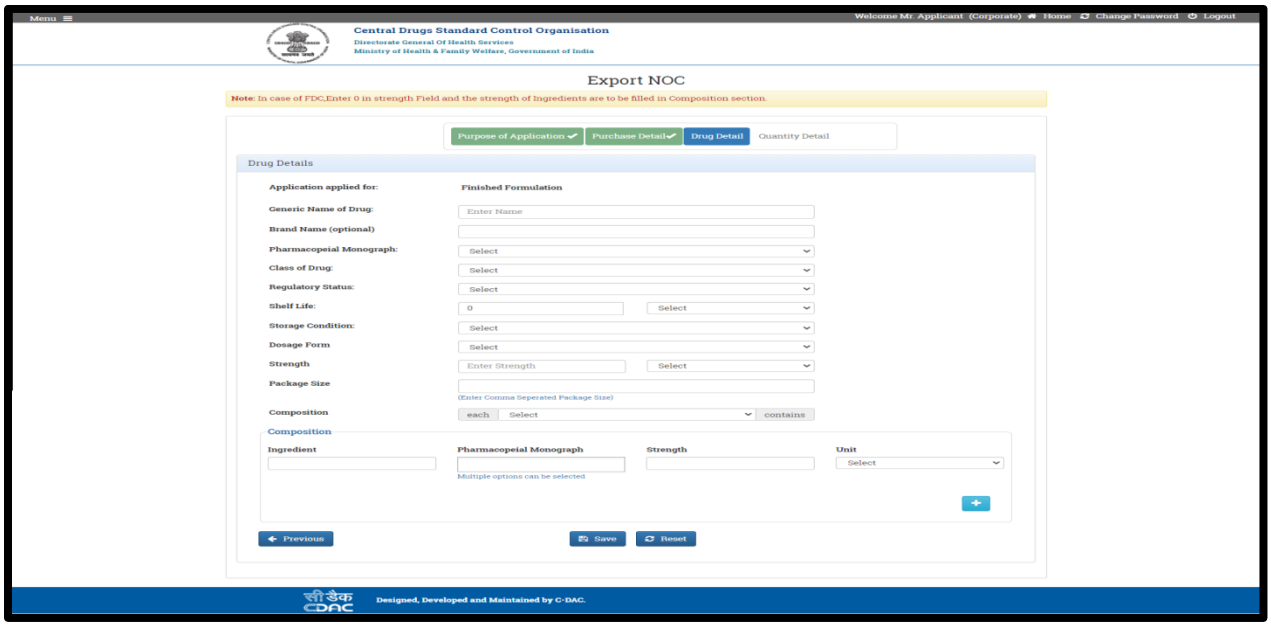


Figure 39: Drug Detail

- After filling all the details, a new line is generated and the screen looks like this.

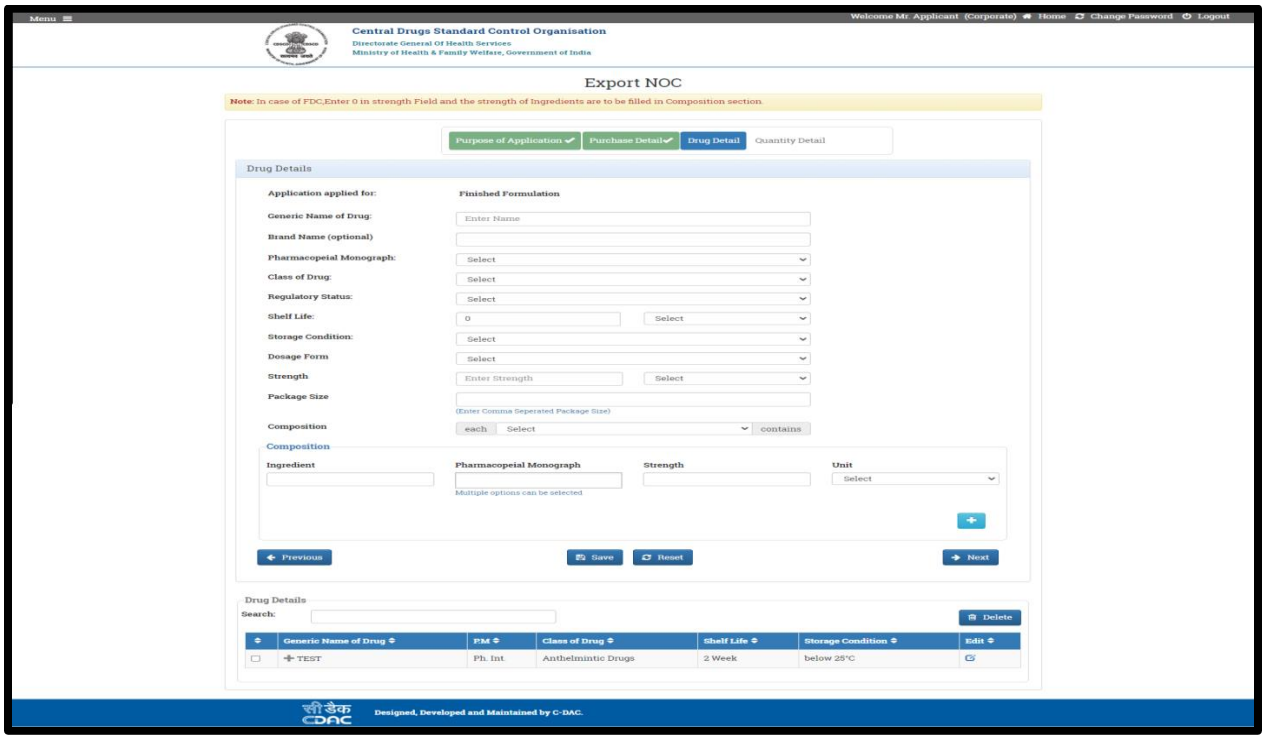


Figure 40: : Drug Detail (continued)

- Now the Applicant can move to the next section i.e. **Quantity Detail** by clicking on the **Next** button present on this page. The following screen will appear.

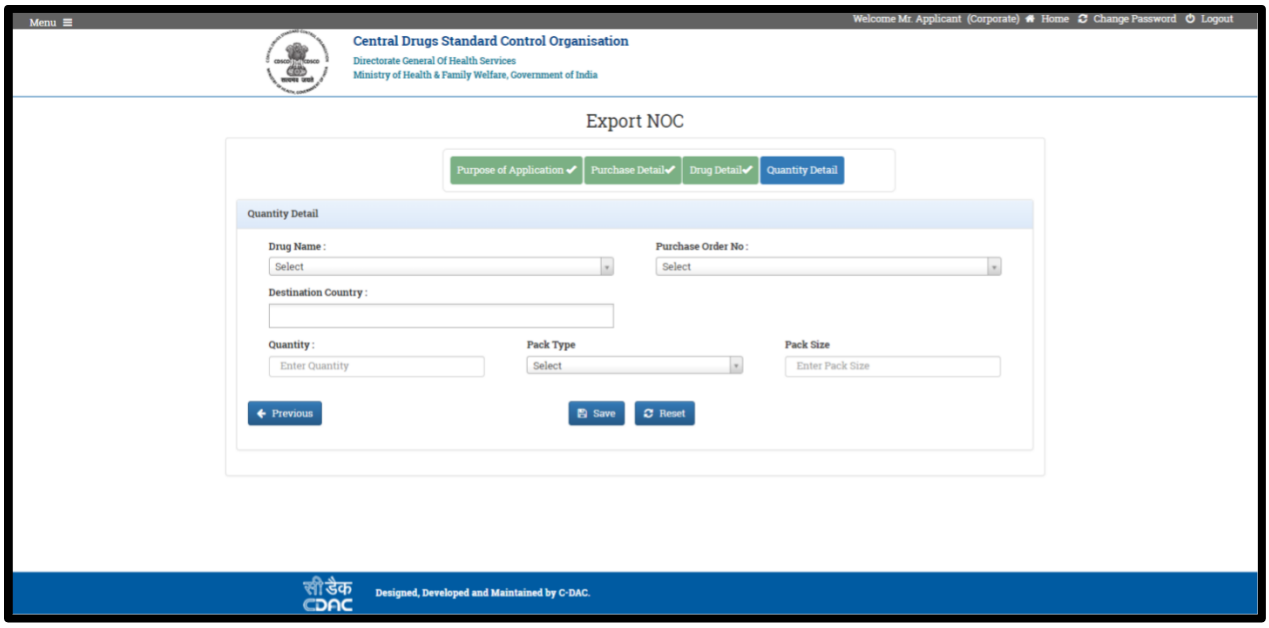


Figure 41: Quantity Detail

- After entering and saving all the details on this page, the Applicant can move to the next section by clicking on the **Next** button. The following screen will appear.

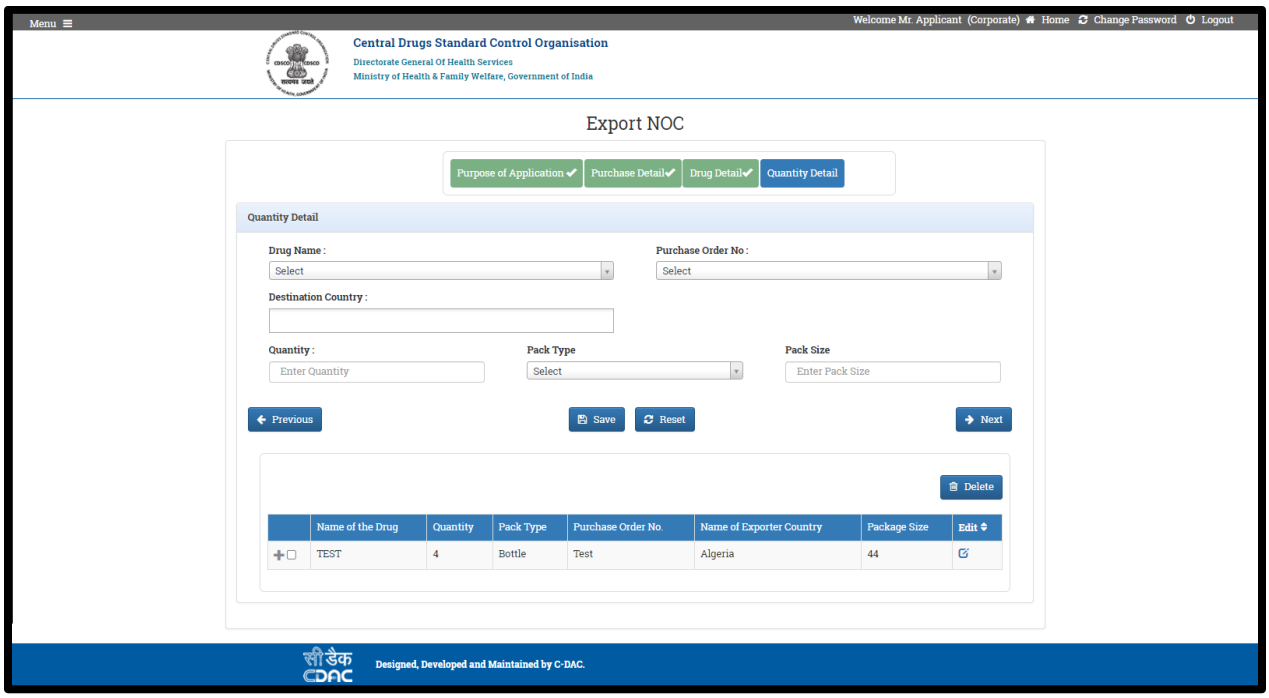
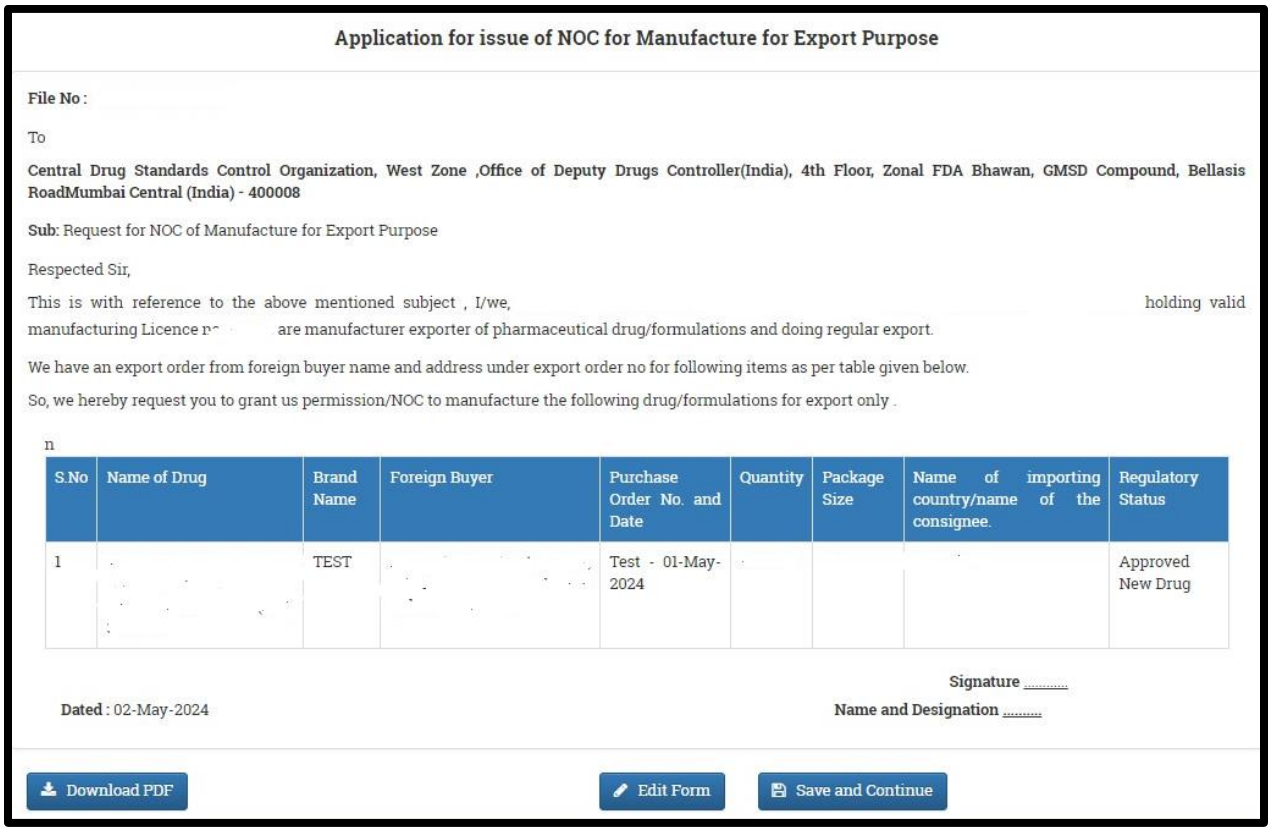


Figure 42: Quantity Detail (continued)

- The Application is now complete and the Applicant will get a File No. The Applicant can Download PDF or edit the form.



Application for issue of NOC for Manufacture for Export Purpose

File No :

To

Central Drug Standards Control Organization, West Zone ,Office of Deputy Drugs Controller(India), 4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis RoadMumbai Central (India) - 400008

Sub: Request for NOC of Manufacture for Export Purpose

Respected Sir,

This is with reference to the above mentioned subject , I/we, holding valid manufacturing Licence n are manufacturer exporter of pharmaceutical drug/formulations and doing regular export.

We have an export order from foreign buyer name and address under export order no for following items as per table given below.

So, we hereby request you to grant us permission/NOC to manufacture the following drug/formulations for export only .

n

S.No	Name of Drug	Brand Name	Foreign Buyer	Purchase Order No. and Date	Quantity	Package Size	Name of importing country/name of the consignee.	Regulatory Status
1		TEST		Test - 01-May-2024				Approved New Drug

Signature .....

Dated : 02-May-2024

Name and Designation .....

Download PDF | Edit Form | Save and Continue

Figure 43: Application for NOC

- After checking all the details, the Applicant can move forward by clicking on **Save and Continue** button present at the bottom of the page. A window pop up will appear asking for the confirmation.

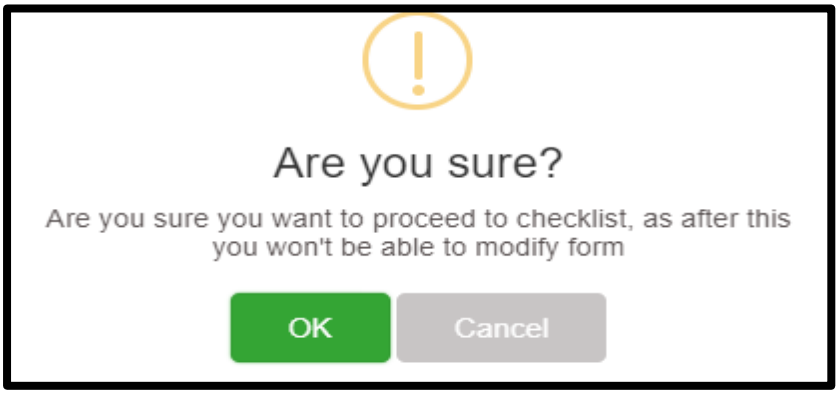


Figure 44: Confirmation window

- After confirming by clicking **OK** on the above screen, the Applicant will move to the checklist page as shown in the image below.

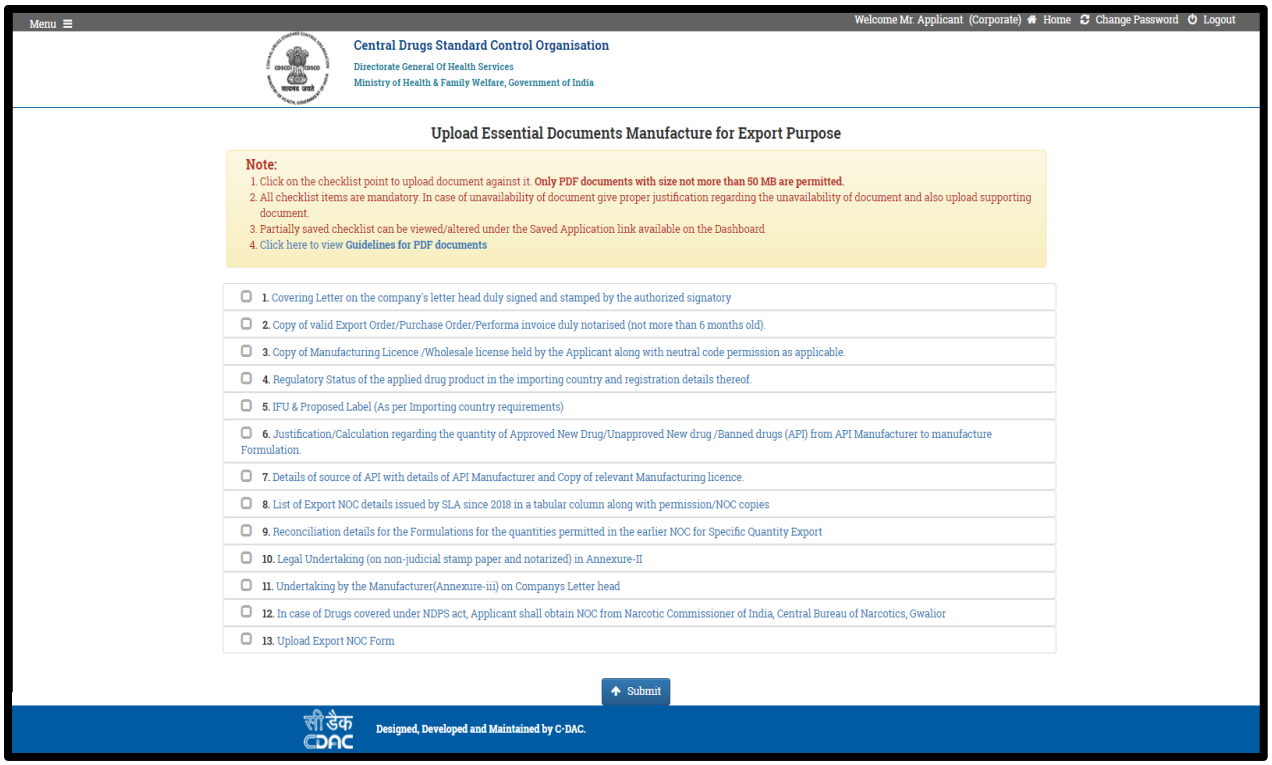


Figure 45: Document Checklist

- After uploading all the documents, the Applicant clicks on Submit button. A file number is generated as shown below.

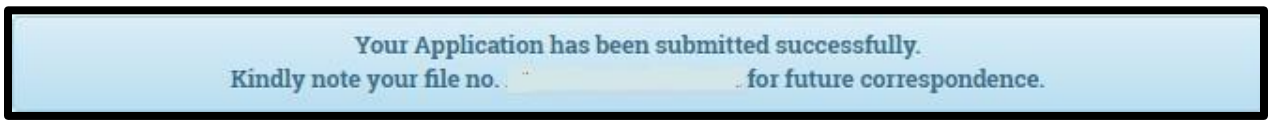


Figure 46: File Number Generated

1.5. Procuring Unapproved/ approved New Drug (Bulk) for R&D/ Formulation Development/ Manufacture of Exhibit Batches for data of Extract Purpose with Finished Formulation as purpose of Application

- When the Applicant selects Procuring Unapproved/ approved New Drug (Bulk) for R&D/ Formulation Development/ Manufacture of Exhibit Batches for data of

Extract Purpose with Finished Formulation as purpose of Application, screen looks like as shown below in the image.

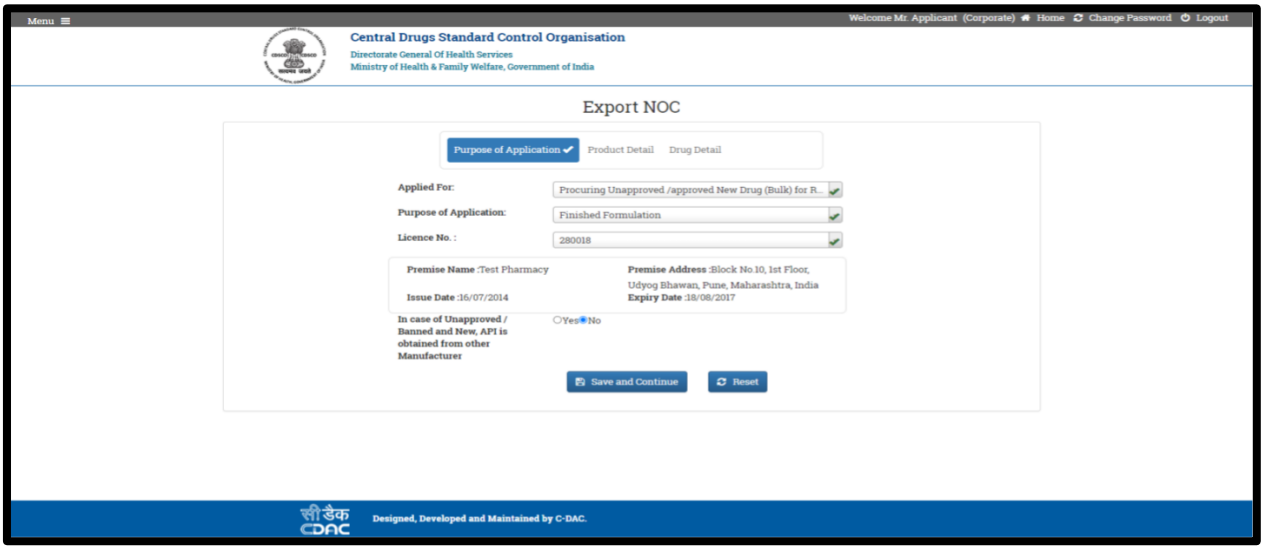


Figure 47: Procuring Unapproved/ approved New Drug (Bulk) for R&D/ Formulation Development/ Manufacture of Exhibit Batches for data of Extract Purpose with Finished Formulation as purpose of Application

- After clicking on **Save and Continue button, Purchase Order Detail** page will appear as shown below**.**

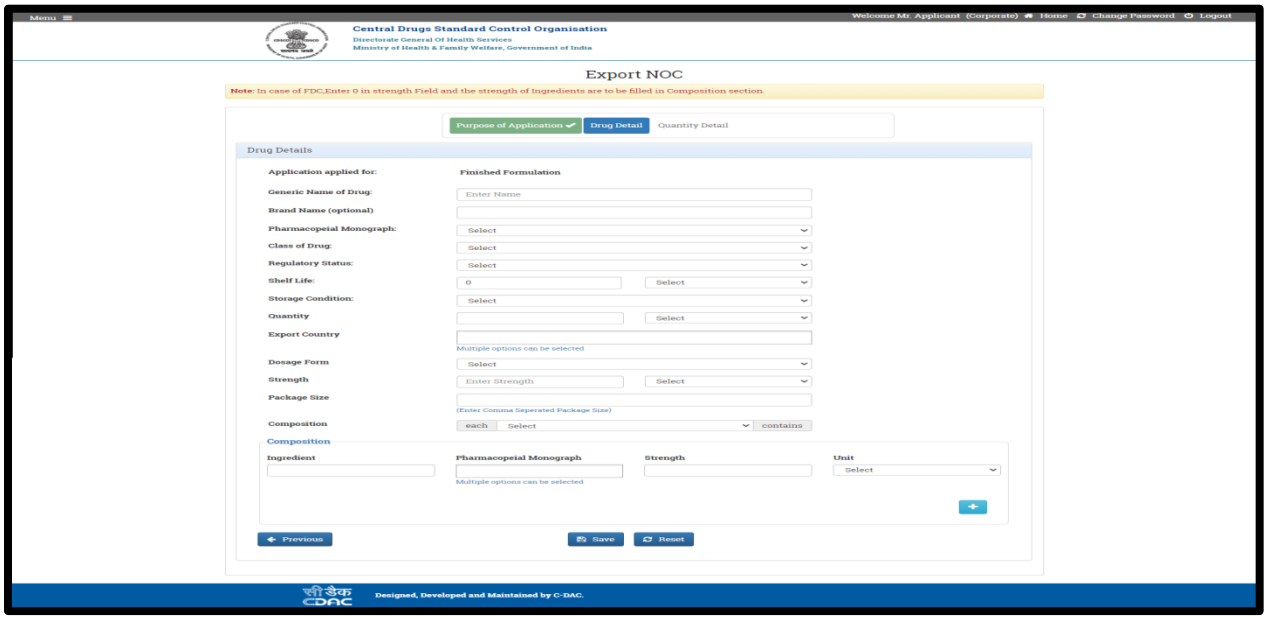


Figure 48: Drug Detail

- After entering and saving all the details on this page, the Applicant can move to the next section by clicking on the **Next** button.

- The Application is now complete and the Applicant will get a File No. The Applicant can Download PDF or edit the form.

Application for issue of NOC for Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exibit Batches for data of Export Purpose

File No :

To

Central Drug Standards Control Organization, West Zone ,Office of Deputy Drugs Controller(India), 4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis RoadMumbai Central (India) - 400008

Sub: Request for NOC of Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exibit Batches for data of Export Purpose

Respected Sir,

This is with reference to the above mentioned subject , I/we, holding valid manufacturing Licence no are manufacture exporter of following formulation for R&D/ Formulation Development/manufacture of exhibit batches for export purpose only.

So, we hereby request you to grant us permission/NOC to manufacture the following formulations for for R&D/ Formulation Development/manufacture of exhibit batches for export purpose only .

n

S.No	Name of Drug	Brand Name	Quantity	Package Size	Name of importing country/name of the consignee.	Regulatory Status
1		test		test		UnApproved Drug

Signature .....

Dated : 02-May-2024

Name and Designation .....

Download PDF | Edit Form | Save and Continue

Figure 49: Application for NOC

- After checking all the details, the Applicant can move forward by clicking on **Save and Continue** button present at the bottom of the page. A window pop up will appear asking for the confirmation.

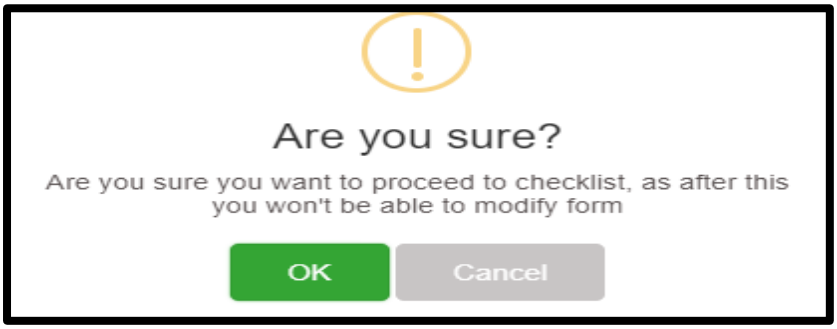


Figure 50: Confirmation window

- After confirming by clicking **OK** on the above screen, the Applicant will move to the checklist page as shown in the image below.

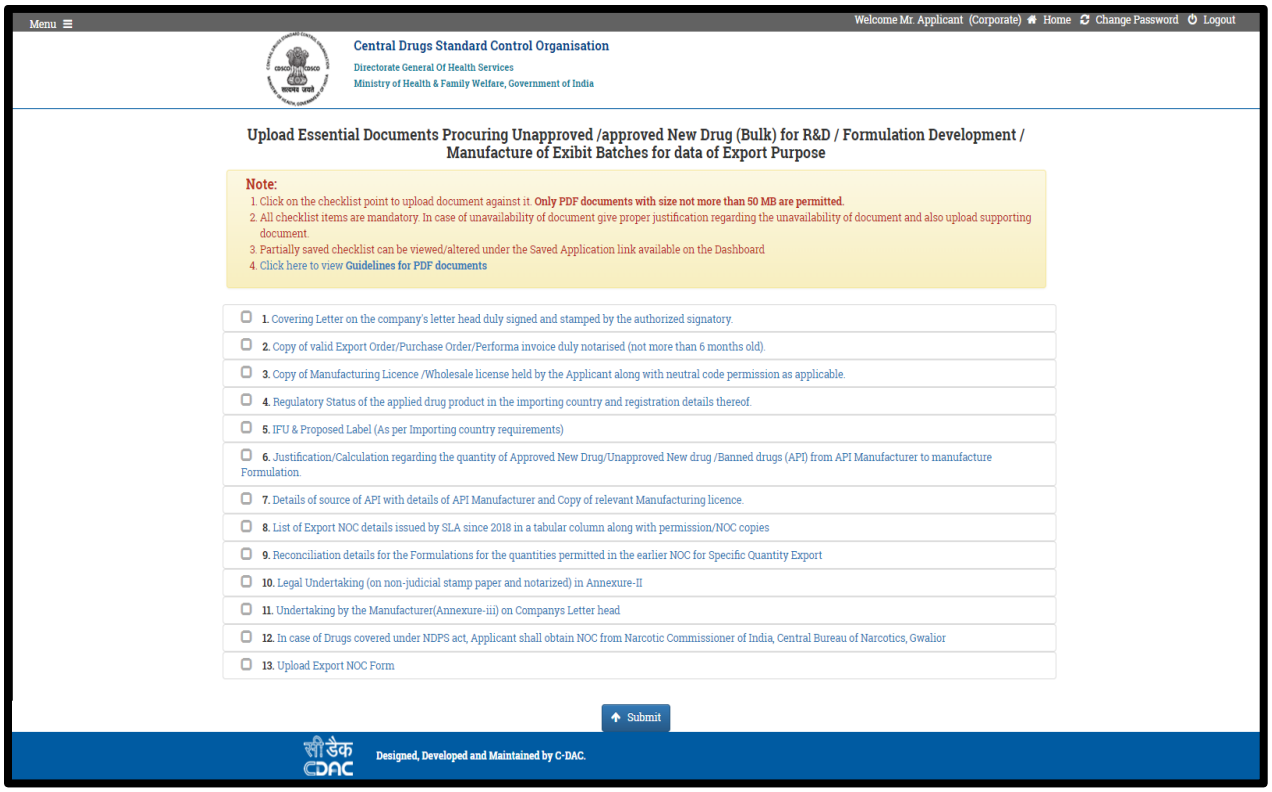


Figure 51: Document Checklist

- After uploading all the documents, the Applicant clicks on Submit button. A file number is generated as shown below.

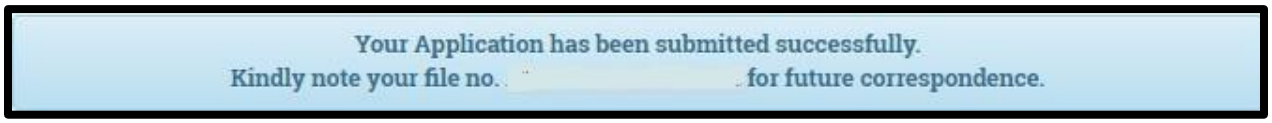


Figure 52: File Number Generated

END

Table of Figures