

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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NOC (Zone)

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

- When the Applicant logs in 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.

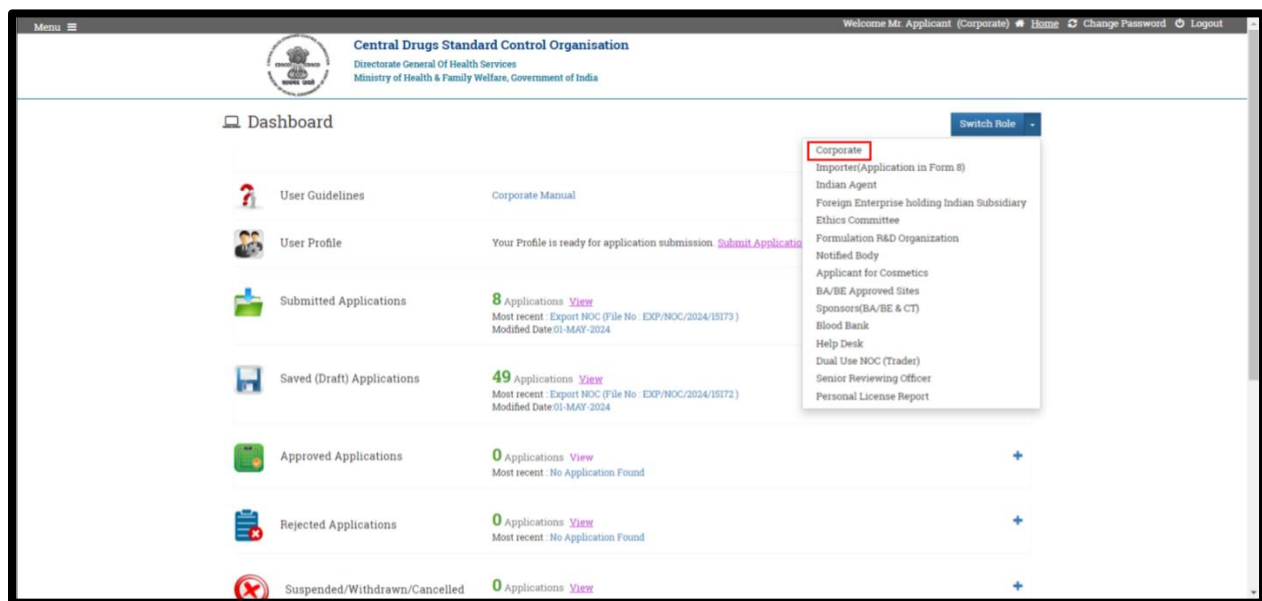


Figure 1: Applicant Dashboard

- 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.

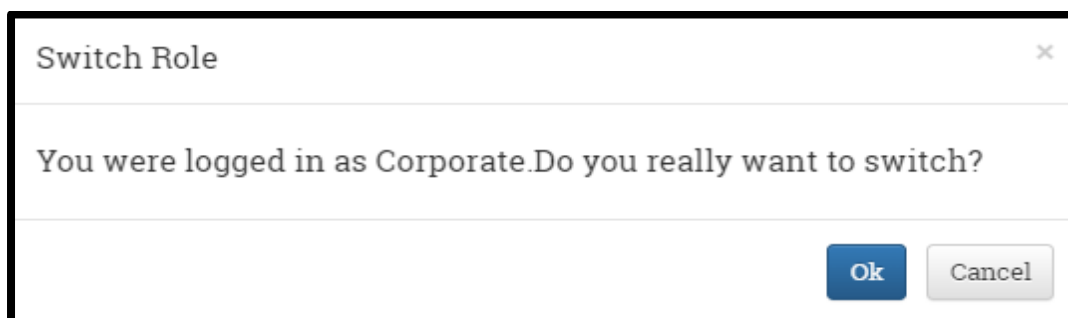


Figure 2: Switch Role

- 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**.

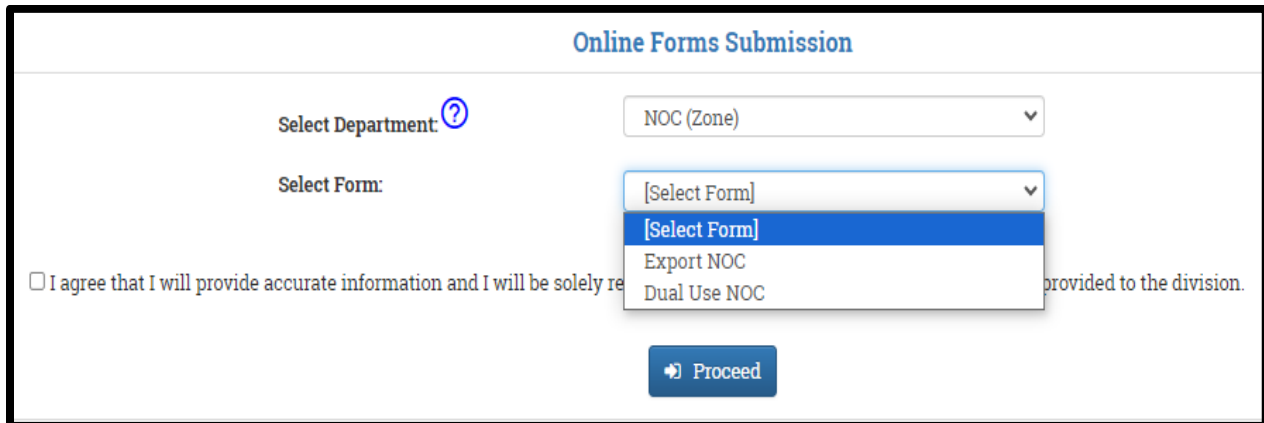


Figure 5: Select Form

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.

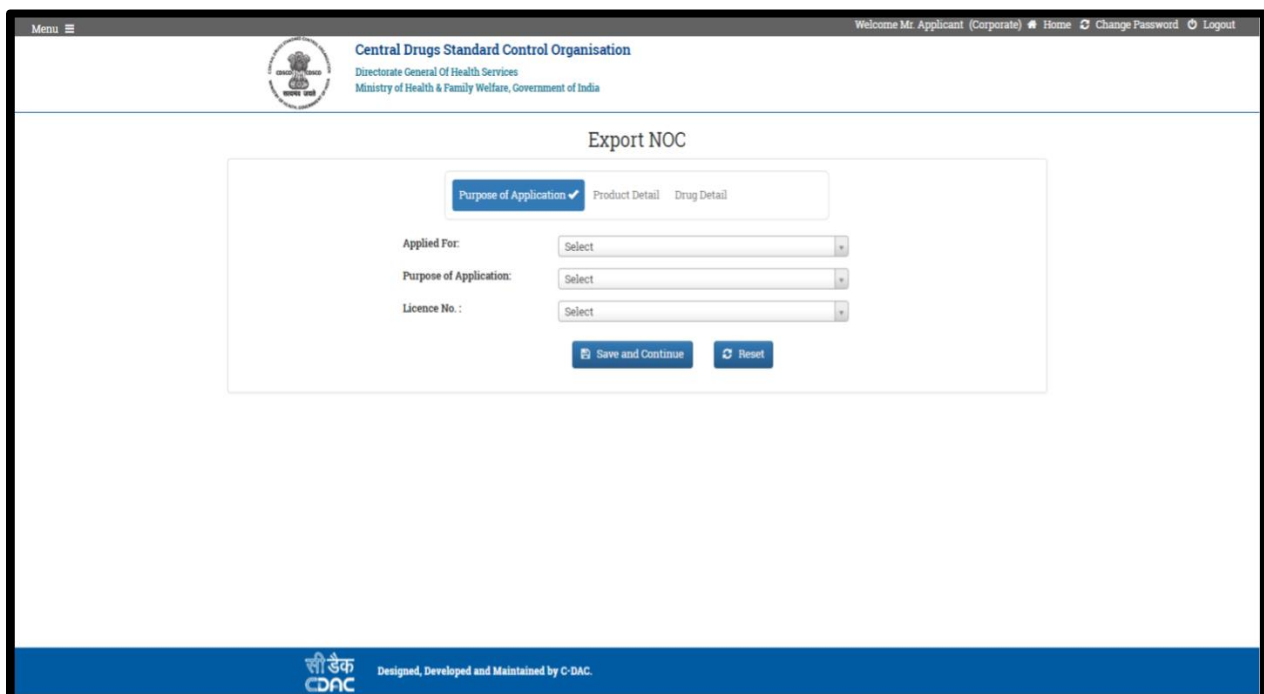



Figure 6: Export NOC

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



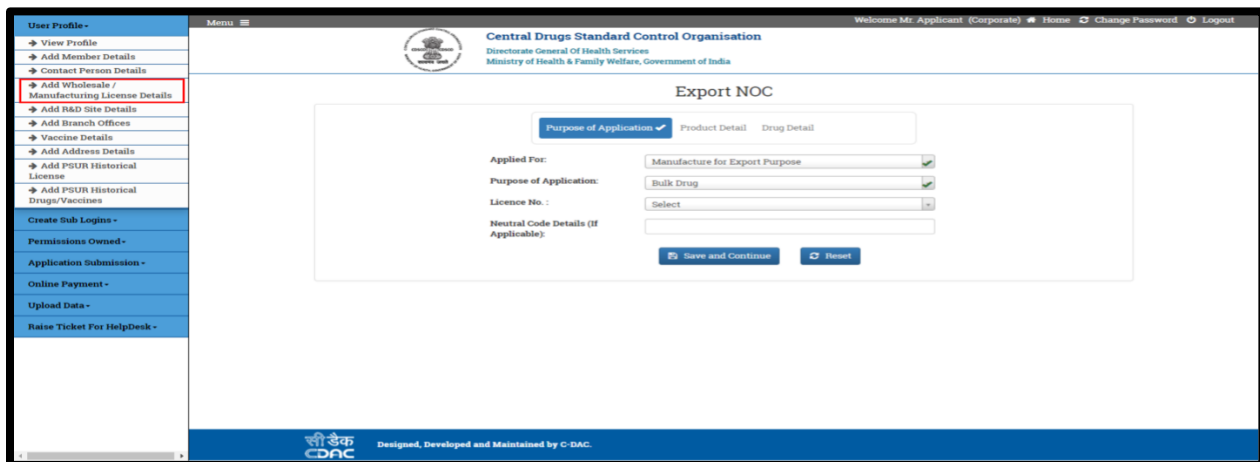
The screenshot shows the 'Export NOC' form. At the top, there are three tabs: 'Purpose of Application' (selected), 'Product Detail', and 'Drug Detail'. Below the tabs, there are three input fields: 'Applied For:', 'Purpose of Application:', and 'Licence No. :'. The 'Applied For:' dropdown menu is open, showing a search bar and the following options: 'Select', 'Manufacture for Export Purpose', 'Material Transfer (API Manufacture)', 'Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exhibit', and 'Batches for data of Export Purpose'.

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.



The screenshot shows the CDAC user profile menu. The 'Add Wholesale / Manufacturing License Details' option is highlighted in red. The main content area shows the 'Export NOC' form with the following fields: 'Applied For:' (Manufacture for Export Purpose), 'Purpose of Application:' (Bulk Drug), 'Licence No.:' (Select), and 'Neutral Code Details (If Applicable):'. There are 'Save and Continue' and 'Reset' buttons at the bottom of the form.

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.

License Type	Premises Name	Address	License No	Edit
Wholesale Site	Test Dispatch	119/203, A-58, Majlis Park, Kheda, Kheda, Gujarat, India, 208012	LN-245	Download
Wholesale Site	Test Dispatch	119/203, A-58, Majlis Park, Kheda, Kheda, Gujarat, India, 208012	bd-555-001	Download
Wholesale Site	Meghna & CDSCO Co.	Bldg 1 & 2, 119/203, Vijay Nagar, Spcl Address 2, New Delhi, Delhi, India, 110011	LN-1234	Download
Wholesale Site	Meghna & CDSCO Co.	Bldg 1 & 2, 119/203, Vijay Nagar, Spcl Address 2, New Delhi, Delhi, India, 110011	test/1	Download
Wholesale Site	M/s Unit Name	Address Line One, Address Line Two, Raigarh, Cityname, Chhattishgarh, India, 232323	LN-123	Download
Wholesale Site	Test Pharmacy	Block No.10, 1st Floor, Udyog Bhawan, Pune, Pune, Maharashtra, India, 400126	FF-125-607	Download
Manufacturing Site	Test Pharmacy	Block No.10, 1st Floor, Udyog Bhawan, Pune, Pune, Maharashtra, India, 400126	280018	Download
CRO Approval	Test	Tester, Testing, Chandigarh, Chandigarh, Chandigarh, India, 234556	12345	Download
CRO Approval	Test	Tester, Testing, Chandigarh, Chandigarh, Chandigarh, India, 234556	md-33/1	Download
CRO Approval	Test	Tester, Testing, Chandigarh, Chandigarh, Chandigarh, India, 234556	56545	Download

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.

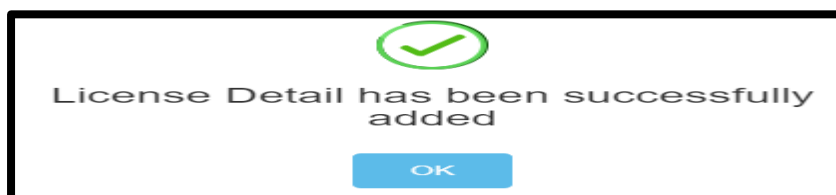


Figure 10: License Details added confirmation

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

Export NOC

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India

Buyer Detail:

Organisation Name:

Address Line 1: Address Line 2:

Country: State: City: Pin Code:

Landline No.: Fax:

E-mail:

Buttons: Previous, Save, Reset

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.

Export NOC

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India

Purchase Order No.	Purchase Order Date	Trader Detail	Buyer detail	Edit
<input type="checkbox"/> Test	06/01/2024	Not Applicable	Organisation Name : Test, Address: Test, Test, Ranchi , JHARKHAND, Bahamas, Contact detail : 2323232323, Fax detail : 91-123456789, Pincode : 934506, Email : abc@gmail.com,	<input type="button" value="Edit"/>

Buttons: Previous, Save, Reset, Next, Delete

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.

Central Drugs Standard Control Organisation
Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Welcome Mr. Applicant (Corporate) Home Change Password Logout

Export NOC

Note: In case of FDC, Enter 0 in strength Field and the strength of Ingredients are to be filled in Composition section.

Purpose of Application ✓ Purchase Detail ✓ **Drug Detail** Quantity Detail

Drug Details

Application applied for: Bulk Drug

Generic Name of Drug: Enter Name

Pharmacopeial Monograph: Select

Class of Drug: Select

Regulatory Status: Select

Shelf Life: 0 Select

Storage Condition: Select

Previous Save Reset

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Figure 15: Drug Detail

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

Central Drugs Standard Control Organisation
Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Welcome Mr. Applicant (Corporate) Home Change Password Logout

Export NOC

Note: In case of FDC, Enter 0 in strength Field and the strength of Ingredients are to be filled in Composition section.

Purpose of Application ✓ Purchase Detail ✓ **Drug Detail** Quantity Detail

Drug Details

Application applied for: Bulk Drug

Generic Name of Drug: Enter Name

Pharmacopeial Monograph: Select

Class of Drug: Select

Regulatory Status: Select

Shelf Life: 0 Select

Storage Condition: Select

Previous Save Reset Next

Drug Details

Search: Delete

Generic Name of Drug	PM	Class of Drug	Shelf Life	Storage Condition	Edit
+ TEST	FP	Anthelmintic Drugs	1 Days	2°C - 8°C	Edit

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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.

	Name of the Drug	Quantity	Pack Type	Purchase Order No.	Name of Exporter Country	Package Size	Edit
+ □	TEST	4	Bottle	Test	Algeria	44	⊗

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/wc, _____ 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 .

S.No	Name of Drug	Brand Name	Foreign Buyer	Purchase Order No. and Date	Quantity	Package Size	Name of country/name of 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.

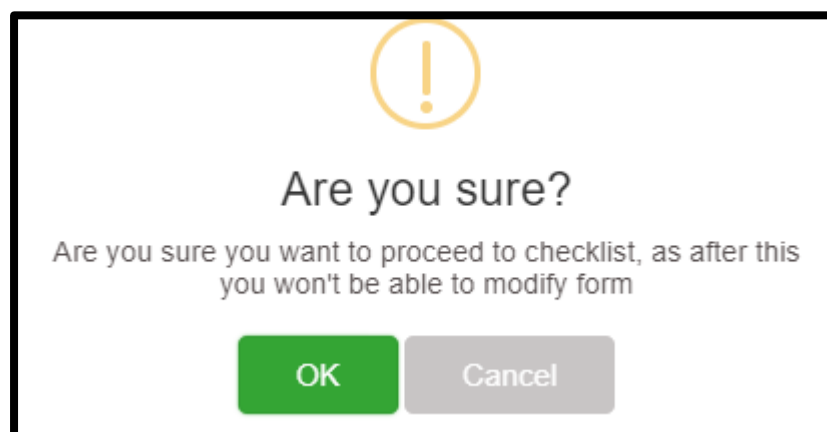


Figure 20: Confirmation window

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

Menu ☰ Welcome Mr. Applicant (Corporate) Home Change Password Logout

Central Drugs Standard Control Organisation
Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Upload Essential Documents Manufacture for Export Purpose

Note:

1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/alterd under the Saved Application link available on the Dashboard
4. Click here to view [Guidelines for PDF documents](#)

- 1. Covering Letter on the Company's letter head duly signed and stamped by the authorized signatory
- 2. Copy of valid Export Order/Purchase Order/Performa invoice (received by the Formulation Manufacturer) -duly notarised (notmore than 6 months old)
- 3. Copy of Manufacturing Licence/Wholesale license held by the applicant firm along with neutral code permission as applicable
- 4. Copy of NOC in favour of FormulationManufacturer/Status of NOC applied to CDSCO
- 5. Regulatory Status of the applied drug/product in the Importing Country and registration details, if any
- 6. Proposed Label (primary & secondary pack) with QR code
- 7. Justification/Calculation regarding the quantity of API required as per Purchase Order/Performa invoice received from the Formulation Manufacturer and Copy of the Manufacturing licence of the Formulation Manufacturer
- 8. Reconciliation details for the API for the quantities permitted earlier for Specific Quantity Export
- 9. Legal Undertaking (on non-judicial stamp paper and notarized) as per Annexure-I from the Manufacturer of API
- 10. Legal Undertaking (on non-judicial stamp paper and notarized) as per Annexure-II from the Manufacturer of Formulation
- 11. List of Export NOC details issued by SLA since 2018 in a tabular column along with permission/NOC copies
- 12. In case of Drugs covered under NDPS act, Applicant shall obtain NOC from Narcotic Commissioner of India, Central Bureau of Narcotics, Gwalior
- 13. Upload Export NOC Form

Submit

Designed, Developed and Maintained by C-DAC.

Figure 21: Upload document page

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

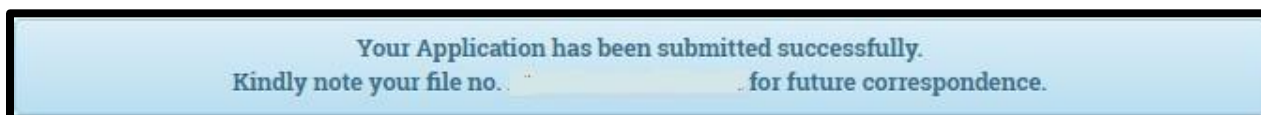


Figure 22: File Number Generated

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.

Name of the Drug	Quantity	Unit	Purchase Order No.	Purchase Order Date	Edit
<input type="checkbox"/>	<input type="text"/>		test	05/01/2024	<input type="text"/>

Figure 24: Product Detail

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

Application for issue of NOC for Material Transfer (API Manufacture)

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 Material Transfer (API Manufacture)

Respected Sir,

This is with reference to the above mentioned subject , I/we, _____ holding valid manufacturing Licence no _____ are manufacturer of pharmaceutical finished formulation .

So, we hereby request you to grant us permission/NOC for manufacturing of below mentioned bulk drug (API) and supply to Foreign Address for purpose of converting the same into the formulation for export only under NOC No. NA/NOC-Export/2018/003112 issued by Central Drug Standards Control Organization, West Zone ,Office of Deputy Drugs Controller(India), 4th Floor, Zonal FDA Bhawan GMSD Compound, Bellasis Road Mumbai Central (India) - 400008 to Formulation manufacturei .
 _____, dated 07/05/2018 obtained from CDSCO.

S.No	Name of Drug	Brand Name	Foreign Buyer	Purchase Order No. and Date	Quantity	Package Size	Regulatory Status
1		NA		test - 01-May-2024		0	

Dated : 02-May-2024

Signature _____
 Name and Designation _____

Download PDF
Edit Form
Save and Continue

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.

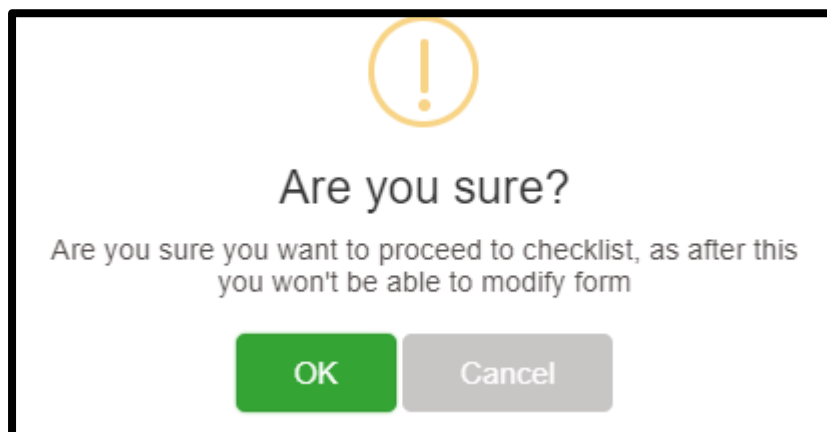


Figure 26: Confirmation window

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

Menu ☰ Welcome Mr. Applicant (Corporate) Home Change Password Logout

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India

Upload Essential Documents Material Transfer (API Manufacture)

Note:

1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/alterd under the Saved Application link available on the Dashboard
4. Click here to view [Guidelines for PDF documents](#)

- 1. Covering Letter on the Company's letter head duly signed and stamped by the authorized signatory
- 2. Copy of valid Export Order/Purchase Order/Performa invoice (received from the Formulation/Manufacturer) -duly notarised (notmore than 6 months old)
- 3. Copy of Manufacturing Licence/Wholesale license held by the applicant firm along with neutral code permission as applicable
- 4. Copy of NOC issued by CDSOO Zonal office in the name of Formulation manufacturer.
- 5. Regulatory Status of the applied drug/product in the Importing Country and registration details, if any
- 6. Proposed Label (primary & secondary pack) with QR code
- 7. Justification/Calculation regarding the quantity of API required as per Purchase Order/Performa invoice received from the Formulation/Manufacturer and Copy of the Manufacturing licence of the Formulation/Manufacturer
- 8. Reconciliation details for the API for the quantities permitted earlier for Specific Quantity Export
- 9. Legal Undertaking (on non-judicial stamp paper and notarized) as per Annexure-I from the Manufacturer of API
- 10. Legal Undertaking (on non-judicial stamp paper and notarized) as per Annexure-II from the Manufacturer of Formulation.
- 11. List of Export NOC details issued by SLA since 2018 in a tabular column along with permission/NOC copies
- 12. In case of Drugs covered under NDPS act, Applicant shall obtain NOC from Narcotic Commissioner of India, Central Bureau of Narcotics, Gwalior
- 13. Upload Export NOC Form.

Submit

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Figure 27: Upload document page

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

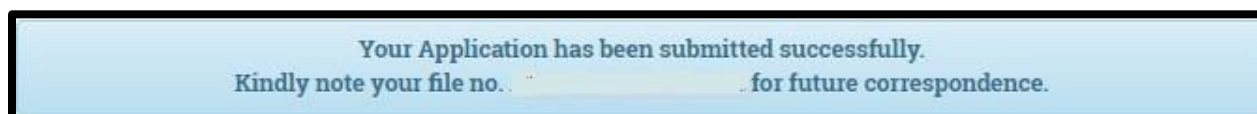


Figure 28: File Number Generated

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.

Application for issue of NOC for Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exhibit 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 Road Mumbai Central (India) - 400008

Sub: Request for NOC of Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exhibit 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.

S.No	Name of Drug	Brand Name	Quantity	Package Size	Name of importing country/name of the consignee.	Regulatory Status
1	TEST (Manufacturer:Specification)	NA		NA		Approved New Drug

Dated : 02-May-2024

Signature _____
Name and Designation _____

[Download PDF](#) [Edit Form](#) [Save and Continue](#)

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.

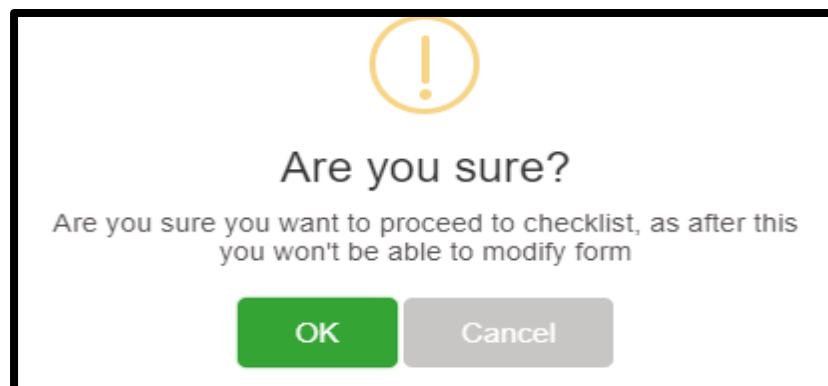
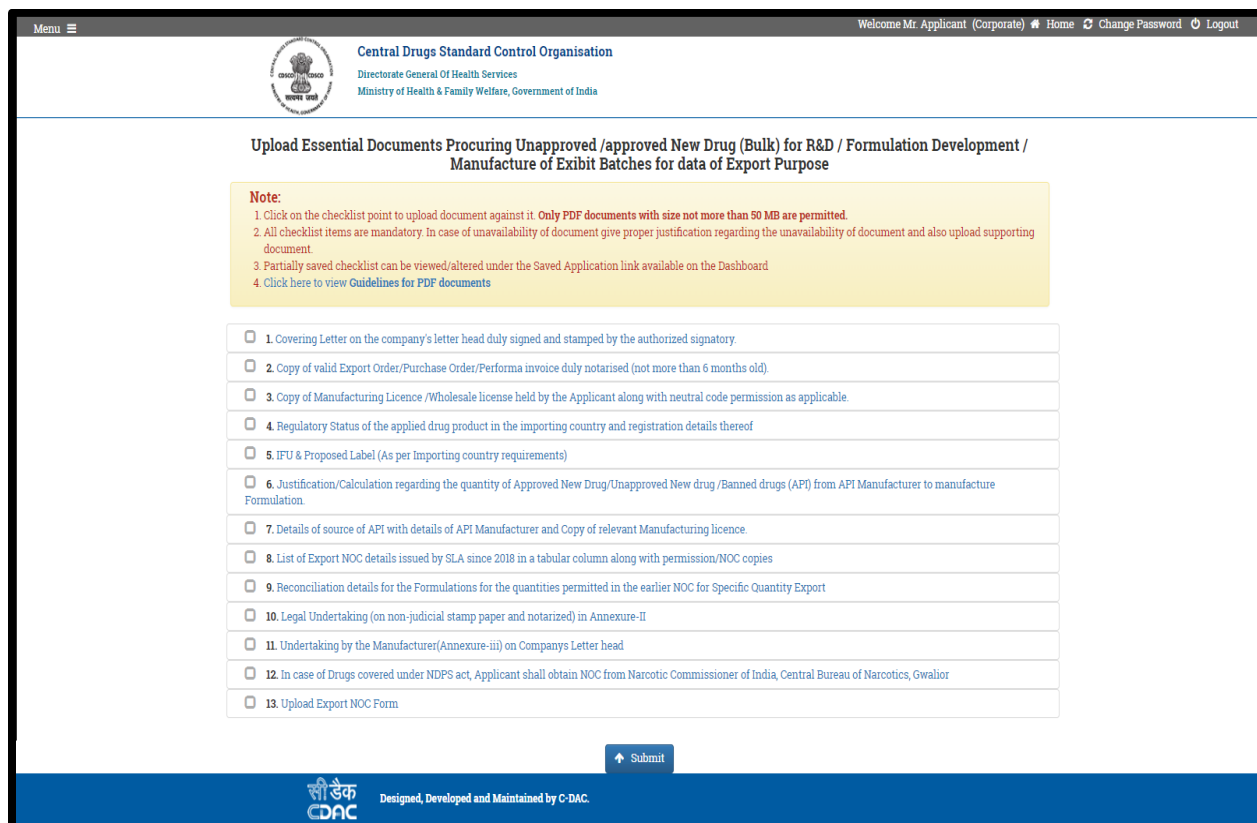


Figure 32: Confirmation window

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



Menu ☰ Welcome Mr. Applicant (Corporate) Home Change Password Logout

Central Drugs Standard Control Organisation
Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Upload Essential Documents Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exhibit Batches for data of Export Purpose

Note:

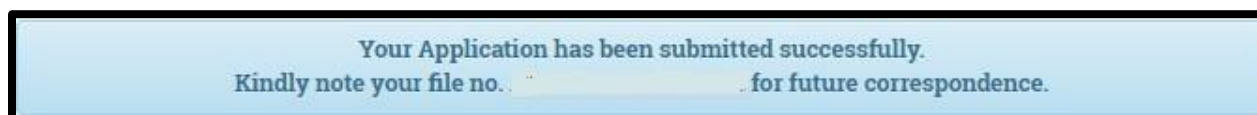
1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document
3. Partially saved checklist can be viewed/alterd under the Saved Application link available on the Dashboard
4. Click here to view [Guidelines for PDF documents](#)

- 1. Covering Letter on the company's letter head duly signed and stamped by the authorized signatory.
- 2. Copy of valid Export Order/Purchase Order/Performa invoice duly notarised (not more than 6 months old)
- 3. Copy of Manufacturing Licence /Wholesale license held by the Applicant along with neutral code permission as applicable
- 4. Regulatory Status of the applied drug product in the importing country and registration details thereof
- 5. IFU & Proposed Label (As per Importing country requirements)
- 6. Justification/Calculation regarding the quantity of Approved New Drug/Unapproved New drug /Banned drugs (API) from API Manufacturer to manufacture Formulation
- 7. Details of source of API with details of API Manufacturer and Copy of relevant Manufacturing licence.
- 8. List of Export NOC details issued by SLA since 2018 in a tabular column along with permission/NOC copies
- 9. Reconciliation details for the Formulations for the quantities permitted in the earlier NOC for Specific Quantity Export
- 10. Legal Undertaking (on non-judicial stamp paper and notarized) in Annexure-II
- 11. Undertaking by the Manufacturer(Annexure-iii) on Companys Letter head
- 12. In case of Drugs covered under NDPS act, Applicant shall obtain NOC from Narcotic Commissioner of India, Central Bureau of Narcotics, Gwalior
- 13. Upload Export NOC Form

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Figure 33: Document Checklist

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

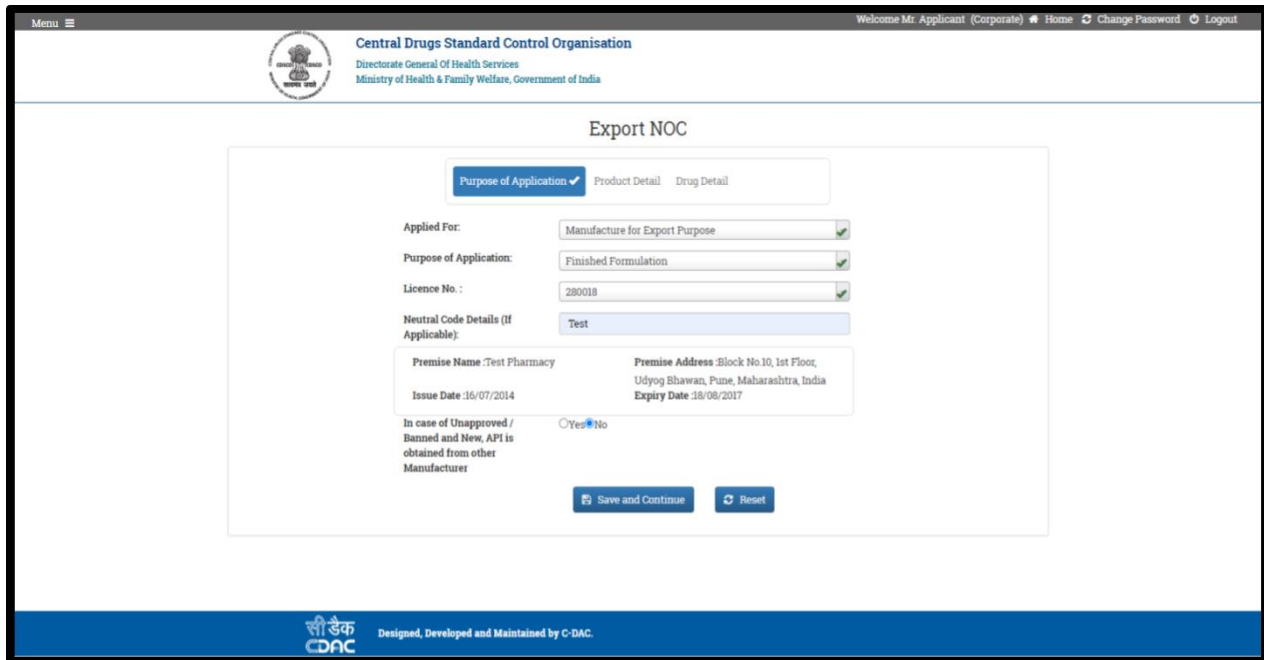


Your Application has been submitted successfully.
Kindly note your file no. [redacted] for future correspondence.

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.



Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India

Export NOC

Purpose of Application ✓ Product Detail Drug Detail

Applied For: Manufacture for Export Purpose ✓

Purpose of Application: Finished Formulation ✓

Licence No.: 280018 ✓

Neutral Code Details (If Applicable): Test

Premise Name :Test Pharmacy Premise Address :Block No 10, 1st Floor,
Udyog Bhawan, Pune, Maharashtra, India

Issue Date :16/07/2014 Expiry Date :18/08/2017

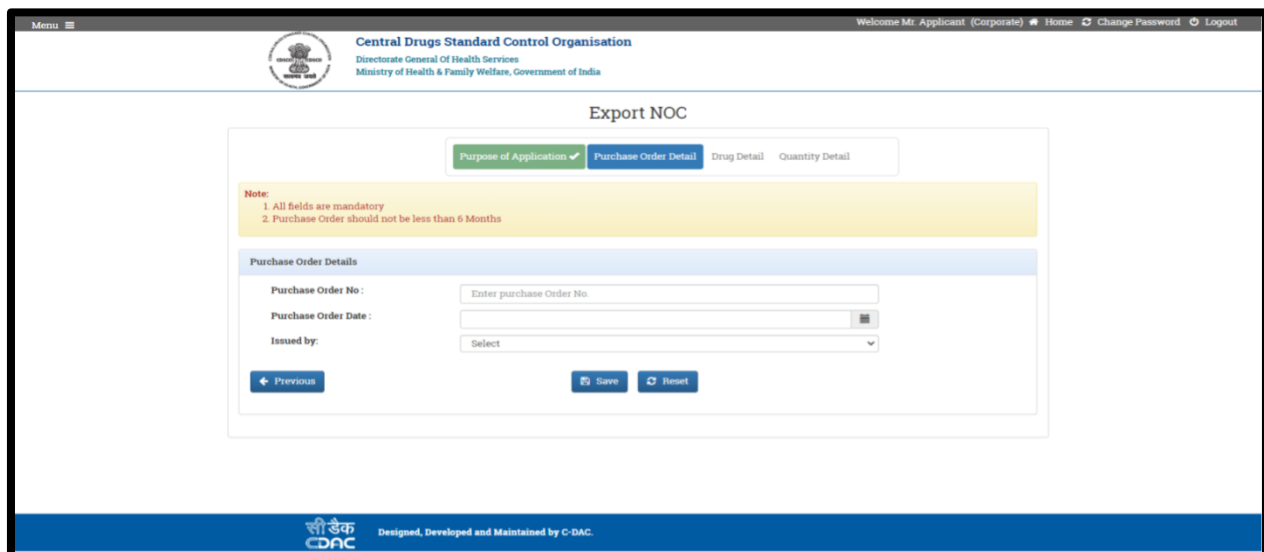
In case of Unapproved / Banned and New API is obtained from other Manufacturers: Yes No

Save and Continue Reset

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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.



Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India

Export NOC

Purpose of Application ✓ Purchase Order Detail Drug Detail Quantity Detail

Note:
1. All fields are mandatory
2. Purchase Order should not be less than 6 Months

Purchase Order Details

Purchase Order No: Enter purchase Order No.

Purchase Order Date: [Calendar Icon]

Issued by: Select

Previous Save Reset

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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.

Purchase Order No.	Purchase Order Date	Trader Detail	Buyer detail
<input type="checkbox"/> Test	05/01/2024	Not Applicable	Organisation Name : Test, Address : Test, Ranchi, JHARKHAND, Bahamas. Contact detail : 232322233, Fax detail : 91-123456789, Pincode : 9346006, Email : abc@gmail.com.

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.

Generic Name of Drug	FM	Class of Drug	Shelf Life	Storage Condition	Edit
TEST	Ph. Int.	Antihelmintic Drugs	2 Week	below 25°C	

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.

Central Drugs Standard Control Organisation
Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Export NOC

Purpose of Application ✓ Purchase Detail ✓ Drug Detail ✓ Quantity Detail

Quantity Detail

Drug Name : Purchase Order No :

Destination Country :

Quantity : Pack Type : Pack Size :

[← Previous](#) [Save](#) [Reset](#)

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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.

Central Drugs Standard Control Organisation
Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Export NOC

Purpose of Application ✓ Purchase Detail ✓ Drug Detail ✓ Quantity Detail

Quantity Detail

Drug Name : Purchase Order No :

Destination Country :

Quantity : Pack Type : Pack Size :

[← Previous](#) [Save](#) [Reset](#) [→ Next](#)

[Delete](#)

	Name of the Drug	Quantity	Pack Type	Purchase Order No.	Name of Exporter Country	Package Size	Edit
+ □	TEST	4	Bottle	Test	Algeria	44	✎

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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 .

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.

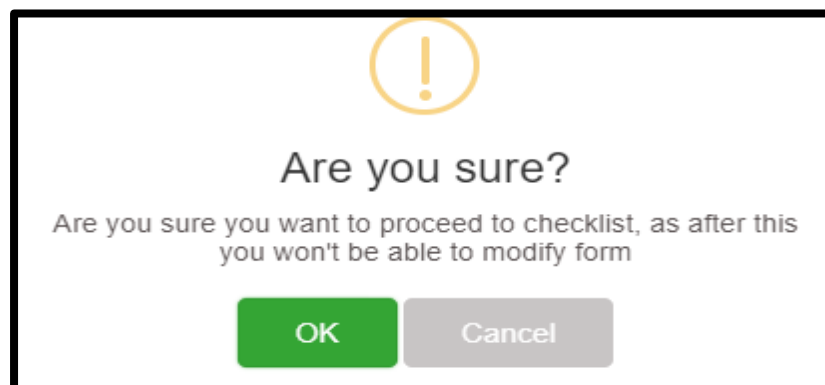
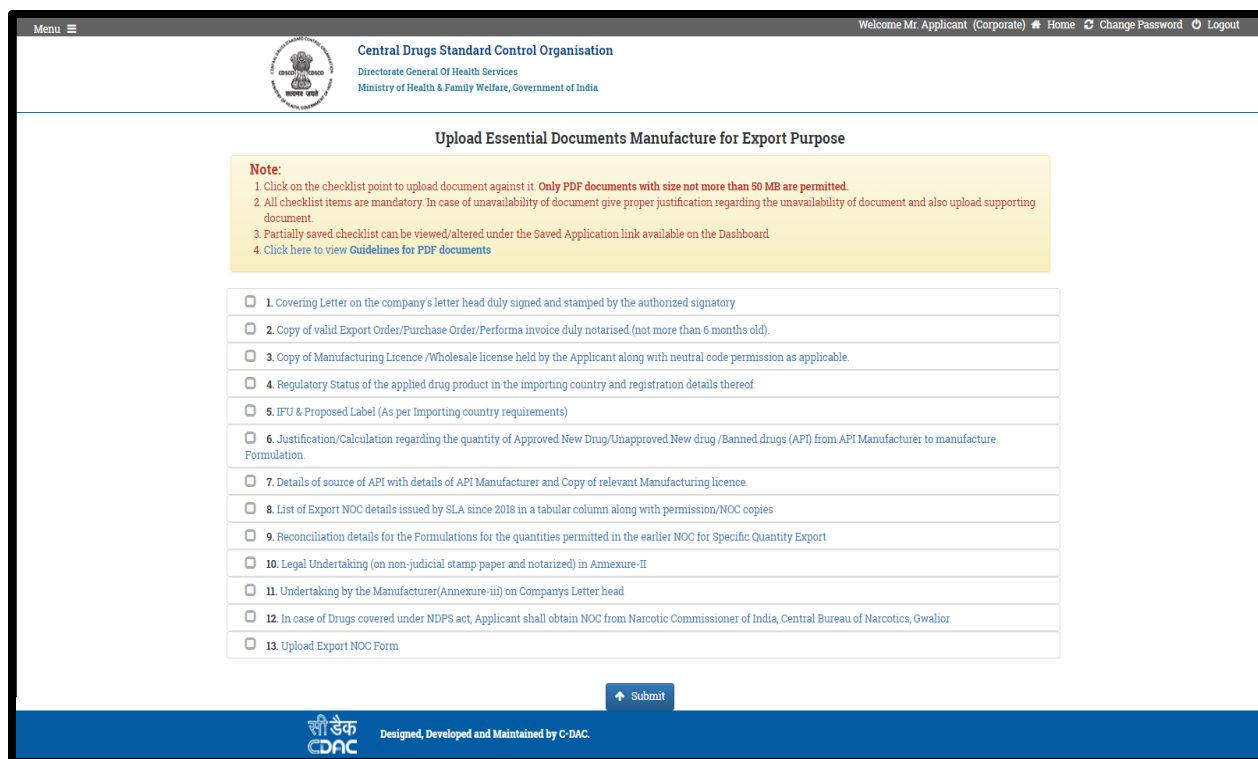


Figure 44: Confirmation window

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



Menu ☰ Welcome Mr. Applicant (Corporate) Home Change Password Logout

Central Drugs Standard Control Organisation
 Directorate General Of Health Services
 Ministry of Health & Family Welfare, Government of India

Upload Essential Documents Manufacture for Export Purpose

Note:
 1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
 2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
 3. Partially saved checklist can be viewed/alterd under the Saved Application link available on the Dashboard
 4. [Click here to view Guidelines for PDF documents](#)

- 1. Covering Letter on the company's letter head duly signed and stamped by the authorized signatory
- 2. Copy of valid Export Order/Purchase Order/Performa invoice duly notarised (not more than 6 months old).
- 3. Copy of Manufacturing Licence /Wholesale license held by the Applicant along with neutral code permission as applicable.
- 4. Regulatory Status of the applied drug product in the importing country and registration details thereof.
- 5. IFU & Proposed Label (As per Importing country requirements)
- 6. Justification/Calculation regarding the quantity of Approved New Drug/Unapproved New drug /Banned drugs (API) from API Manufacturer to manufacture Formulation.
- 7. Details of source of API with details of API Manufacturer and Copy of relevant Manufacturing licence.
- 8. List of Export NOC details issued by SLA since 2018 in a tabular column along with permission/NOC copies
- 9. Reconciliation details for the Formulations for the quantities permitted in the earlier NOC for Specific Quantity Export
- 10. Legal Undertaking (on non-judicial stamp paper and notarized) in Annexure-II
- 11. Undertaking by the Manufacturer(Annexure-iii) on Company's Letter head
- 12. In case of Drugs covered under NDPS act, Applicant shall obtain NOC from Narcotic Commissioner of India, Central Bureau of Narcotics, Gwalior
- 13. Upload Export NOC Form

Submit

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Figure 45: Document Checklist

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

Your Application has been submitted successfully.
 Kindly note your file no. for future correspondence.

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.

The screenshot shows the 'Export NOC' form interface. At the top, there's a navigation bar with 'Menu' and user information. The main header identifies the 'Central Drugs Standard Control Organisation'. The form has three tabs: 'Purpose of Application' (selected), 'Product Detail', and 'Drug Detail'. Under 'Purpose of Application', there are three dropdown menus: 'Applied For:' (Procuring Unapproved /approved New Drug (Bulk) for R...), 'Purpose of Application:' (Finished Formulation), and 'Licence No.:' (280018). Below these are fields for 'Premise Name: Test Pharmacy', 'Issue Date: 16/07/2014', and 'Premise Address: Block No 10, 1st Floor, Udyog Bhawan, Pune, Maharashtra, India' with an 'Expiry Date: 18/08/2017'. A radio button group for 'In case of Unapproved / Banned and New, API is obtained from other Manufactures' is set to 'No'. At the bottom are 'Save and Continue' and 'Reset' buttons.

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.

The screenshot shows the 'Drug Detail' form. A yellow note at the top states: 'Note: In case of FDC, Enter D in strength field and the strength of ingredients are to be filled in Composition section.' The form has three tabs: 'Purpose of Application' (selected), 'Drug Detail', and 'Country Detail'. The 'Drug Details' section is divided into two columns. The left column contains labels for 'Application applied for:', 'Generic Name of Drug:', 'Brand Name (optional):', 'Pharmaceutical Monograph:', 'Class of Drug:', 'Regulatory Status:', 'Shelf Life:', 'Storage Condition:', 'Quantity:', 'Export Country:', 'Dosage Form:', 'Strength:', and 'Package Size:'. The right column contains corresponding input fields, many of which are dropdown menus. At the bottom, there are 'Previous', 'Save', and 'Reset' buttons.

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 Exhibit 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 Exhibit 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 .

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

Dated : 02-May-2024

Signature _____
Name and Designation _____

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.

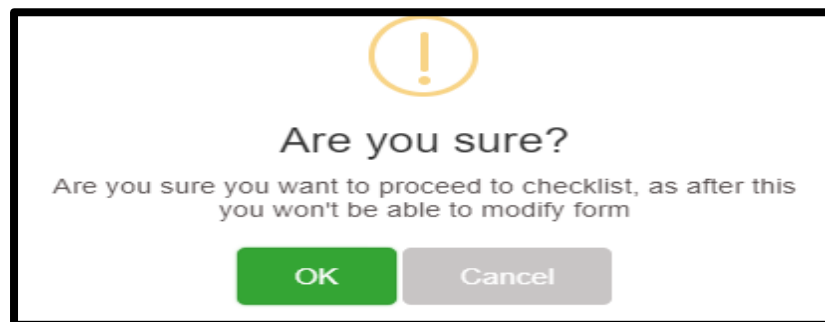


Figure 50: Confirmation window

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

Menu Welcome Mr. Applicant (Corporate) Home Change Password Logout

Central Drugs Standard Control Organisation
Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Upload Essential Documents Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exhibit Batches for data of Export Purpose

Note:

1. Click on the checklist point to upload document against it **Only PDF documents with size not more than 50 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/alterd under the Saved Application link available on the Dashboard
4. Click here to view [Guidelines for PDF documents](#)

<input type="checkbox"/>	1. Covering Letter on the company's letter head duly signed and stamped by the authorized signatory.
<input type="checkbox"/>	2. Copy of valid Export Order/Purchase Order/Performa invoice duly notarised (not more than 6 months old).
<input type="checkbox"/>	3. Copy of Manufacturing Licence /Wholesale license held by the Applicant along with neutral code permission as applicable.
<input type="checkbox"/>	4. Regulatory Status of the applied drug product in the importing country and registration details thereof.
<input type="checkbox"/>	5. IFU & Proposed Label (As per Importing country requirements)
<input type="checkbox"/>	6. Justification/Calculation regarding the quantity of Approved New Drug/Unapproved New drug /Banned drugs (API) from API Manufacturer to manufacture Formulation
<input type="checkbox"/>	7. Details of source of API with details of API Manufacturer and Copy of relevant Manufacturing licence.
<input type="checkbox"/>	8. List of Export NOC details issued by SLA since 2018 in a tabular column along with permission/NOC copies
<input type="checkbox"/>	9. Reconciliation details for the Formulations for the quantities permitted in the earlier NOC for Specific Quantity Export
<input type="checkbox"/>	10. Legal Undertaking (on non-judicial stamp paper and notarized) in Annexure-II
<input type="checkbox"/>	11. Undertaking by the Manufacturer(Annexure-iii) on Companys Letter head
<input type="checkbox"/>	12. In case of Drugs covered under NDPS act, Applicant shall obtain NOC from Narcotic Commissioner of India, Central Bureau of Narcotics, Gwalior
<input type="checkbox"/>	13. Upload Export NOC Form

[Submit](#)

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Figure 51: Document Checklist

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

Your Application has been submitted successfully.
Kindly note your file no. for future correspondence.

Figure 52: File Number Generated

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