



# **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 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.

Menu =			Welcome Mr. Applicant (Corporate) # Home 3 Change Password 🙂 Logout
(	Central Drugs Standa Directorate General Of Health Ministry of Health & Family W	ard Control Organisation Services leffare, Government of India	
😐 Das	shboard		Switch Role · Corporate Importer(Application in Form 6)
2	User Guidelines	Corporate Manual	Indian Agent Foreign Enterprise holding Indian Subsidiary Ethics Committee
<b>8</b> 6	User Profile	Your Profile is ready for application submission. <u>Submit Applicatio</u>	Formulation R&D Organization Notified Body Ambient for Compaties
<b>*</b>	Submitted Applications	8 Applications <u>View</u> Most recent : Export NOC (Pile No : EXP/NOC/2024/15173 ) Modified Date 01-MAY-2024	Appendix the constant of the Appendix BA/BE Approved Sites Sponsors(BA/BE & CT) Blood Bank Help Desk
6	Saved (Draft) Applications	49 Applications View Most recent : Export NOC (Pile No : EXP/NOC/2024/15172) Modified Date 01-MAY-2024	Dual Use NOC (Trader) Senior Reviewing Officer Personal License Report
	Approved Applications	O Applications. View Most recent : No Application Found	
<b>i</b>	Rejected Applications	O Applications <u>View</u> Most recent : No Application Found	•
	Suspended/Withdrawn/Cancelled	O Applications View	+ .

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.

Menu =			Welcome Mr. Applicant (Corporate) 🖷 🛔	Home 3 Change Password 🛈 Logout 😭
	Central Drugs Standard Control Organis Directorate General Of Health Services Ministry of Health & Family Welfare, Government o	ation I India		
	0	nline Forms Submission		
	Select Department	Select 👻		
	Select Form:	Select 👻		
	□ I agree that I will provide accurate information and I will be sole	y responsible for any false or inaccurate information	provided to the division.	
		Proceed		
	G * User can proceed to Online Form Submission only if the User Profile Please read the below instructions carefully before proceeding to Onli 1. Online Form Submission is divided into few simple steps like: • Pline Sesential Documents in checklist • Payment (if applicable) and • Final Form Opload • Final Form Opload • Gan the Signed and Stamped Form • Opload this form in the Upload Form step • Opload this form in the Upload Form step • Dipload this form in the Upload Form step • Please ensure that you have all the required documents ready to	ENERAL INSTRUCTIONS * in complete. ine Form Submission lownloading, perform the following steps: o upload them in checklist section. Please view the ch	ecklist from here	
	ली डैक Designed, Developed and Maintained by C-D.	AC.		

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.

Onlin	ne Forms Submission						
Select Department	NOC (Zone)	)					
	Select	]					
Select Form:	Laboratory						
	Investigational New Drugs						
	NOC (Zone)						
□ I agree that I will provide accurate information and I will be solely re	Import & Registration of drugs	provided to the division.					
	Medical Devices & Diagonstic						
	Biologicals						
	Veterinary						
	BA/BE for Export						
	GCT Division						
	New Drug division						
GENI	Fixed Dose Combination						
t Hear ann proceed to Online Form Submission only if the Hear Profile is	Subsequent New Drug						
Submission only if the oser Flome is the	ompiete.						
Please read the below instructions carefully before proceeding to Online 1	Please read the below instructions carefully before proceeding to Online Form Submission						
1. Online Form Submission is divided into few simple steps like:							

Figure 4: Select Department





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

Onlin	e Forms Submission	
Select Department: ?	NOC (Zone)	•
Select Form:	[Select Form]	•
	[Select Form]	
□ I agree that I will provide accurate information and I will be solely re	Export NOC Dual Use NOC	provided to the division.
	Proceed	

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.

Menu E Central Drug Directorate Gener. Ministry of Health	gs Standard Control Organisation al Of Health Services à Family Welfare, Government of India	Welcome Mr. Applicant (Corporate) 🖷 Home 🧔 Change Passw	rord 🗢 Logout
	Purpose of Application  Product Detail Drug D	Detail	
Appli	ed For: Select	*	
Purpo	se of Application: Select	*	
Licen	ce No.: Select	¥.	
	😰 Save and Continue	€ Reset	
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Figure 6: Export NOC





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

Export NOC							
Purpose of Applic	ation 🗸 Product Detail Drug Detail						
Applied For:	Select						
Purpose of Application:	٩						
	Select						
Licence No. :	Manufacture for Export Purpose						
	Material Transfer (API Manufacture)						
	Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exibit 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.

User Profile -	Menu =			Welcome Mr. Applicant (Corporate) 🖷 Home 🏾 Change	Password 🔿 Logout
<ul> <li>View Profile</li> <li>Add Member Details</li> <li>Contact Person Details</li> </ul>		Central Drugs Standar Directorate General Of Health Se Ministry of Health & Family Well	d Control Organisation rvices fare, Government of India		
➔ Add Wholesale / Manufacturing License Details			Export NOC		
<ul> <li>Add R&amp;D Site Details</li> <li>Add Branch Offices</li> <li>Vaccine Details</li> </ul>		Purpose of Appli	cation 🖌 Product Detail Drug Detail		
<ul> <li>Add Address Details</li> <li>Add PSUR Historical License</li> <li>Add PSUR Historical</li> </ul>		Applied For: Purpose of Application:	Manufacture for Export Purpose Bulk Drug	3	
Drugs/Vaccines Create Sub Logins - Permissions Owned -		Licence No. : Neutral Code Details (If Applicable):	Select		
Application Submission -			Save and Continue 37 Re	rset	
Online Payment -					
Upload Data -					
Raise Ticket For HelpDesk -					
	सी डेक Designed Developed	and Maintained by C-DAC.			
4	CDAC	uno.			

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.

Menu =					W	elcome Mr. Ap	plicant (Cor	rporate) 🕋	Home 🤁 Change Password 🖕 Logout
	Central Druge Standard Control Organisation Discontact General Of Health Services Ministry of Health S Family Welfare, Government of India								
				Add Lice	nse Details				
	* All fields are mandatory								
	Licensing Detail	5			Address Details				
	License Type:		Select	~	Choose Premises			¥	
	Issuing Authorit	y [	Issuing Authority						
	Licence No./Approval		License No						
	Valid From			<b></b>					
	Valid Upto			=					
	Upload Licence /		Choose File No fios	sen					
	Арргочаг								
				🖹 Save	2 Reset				
	Address Details						_		
	SearCIL						Ê	Delete	
	License Type		Premises Name 🗘	Address 🗢		License No \$	Licence 🗢	Edit \$	
	HWholesale     Site	License	Test Dispatch	119/203; A-58, Majlis Park; K	heda; Kheda; Gujarat; India; 208012	LN-245	Download	G	
	H Wholesale     Site	License	Test Dispatch	119/203; A-58, Majlis Park; K	heda; Kheda; Gujarat; India; 208012	bd-555-001	Download	Ø	
	H Wholesale     Site	License	Meghna & CDSCO Co.	Bldg 1 & 2, 119/203, Vijay Nag 110011	gar; Spcl Address 2; New Delhi; Delhi; Delhi; India;	LN-1234	Download	G	
	H Wholesale     Site	License	Meghna & CDSCO Co.	Bldg 1 & 2, 119/203, Vijay Nag 110011	gar; Spcl Address 2; New Delhi; Delhi; Delhi; India;	test/1	Download	Ø	
	H Wholesale     Site	License	M/s Unit Name	Address Line One; Addres India; 232323	s Line Two; Raigarh; Cityname; Chhattishgarh;	LNo-123	Download	G	
	+ Wholesale Site	License	Test Pharmacy	Block No.10, 1st Floor; Ud 400126	yog Bhawan; Pune; Pune; Maharashtra; India;	FF-125-607	Download	•	
	🕂 Manufacturi	ng Site	Test Pharmacy	Block No.10, 1st Floor; Ud 400126	lyog Bhawan; Pune; Pune; Maharashtra; India;	280018	Download	•	
	+ CRO Approva	d	Test	Tester; Testing; Chandigarh;	Chandigarh; Chandigarh; India; 234556	12345	Download	-	
	+ CRO Approva	d	Test	Tester; Testing; Chandigarh;	Chandigarh; Chandigarh; India; 234556	md-33/1	Download	•	
	CRO Approva	1	Test	Tester; Testing; Chandigarh;	Chandigarh; Chandigarh; India; 234556	56545	Download	Ø	
				к с <b>1</b>	2 > >				
	सी डेव CDA	ति Desi	igned, Developed and M	faintained by C-DAC.					
		_							

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.









# 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.

Menu =	Central Drugs Standard Co Directorate General Of Health Services Ministry of Health & Family Welfare, G	Welcom pontrol Organisation s overnment of India	ee Mr. Applicant (Corporate) # Home 🏾 Change Password 🕲 Logout					
Export NOC								
	Purpose of Applica	tion 🖌 Product Detail Drug Detail						
	Applied For:	Manufacture for Export Purpose	×					
	Purpose of Application:	Bulk Drug	<b>v</b>					
	Licence No. :	280018	>					
	Neutral Code Details (If Applicable):	Test						
	Premise Name :Test Pharmac	y Premise Address :Block No.10, 1st Floor,						
	Issue Date :16/07/2014	Udyog Bnawan, Pune, Manarashtra, India Expiry Date :18/08/2017						
		🗈 Save and Continue  🕫 Reset						
सी डेक ⊄DAC	Designed, Developed and Maintained	by C-DAC.						

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.

Menu =		Welcome Mr. Applican	t (Corporate) 希 Home 🏾 Change Password 🖕 Logout
á	Central Dr Directorate Gen Ministry of Hea	ugs Standard Control Organisation seral of Health Services lith & Family Welfare, Government of India	
		Export NOC	
		Purpose of Application 🖌 Purchase Order Detail Drug Detail Quantity Detail	
Note: 1. All field 2. Purcha	ds are mandatory ase Order should not be less thar	a 6 Months	
Purchase O	rder Details		
Purcha	se Order No :	Enter purchase Order No.	
Issued	by:	Select ~	
← Previo	aus	🔁 Save 🖉 🕫 Reset	
	सी डेक Designed, Devel CDAC	oped and Maintained by C-DAC.	

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.

Menu =	Standard Control Organisation 1 Of Health Services & Family Welfare, Government of India		Welcome Mr. Applicant (Corporate) 🕷 Home 🤁 Change Password 🙂 Logout
	Expo	ort NOC	
	Purpose of Application 🗸	se 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 :	Test		~
Purchase Order Date :	05/01/2024		
Issued by:	Buyer		¥
Buyer Detail : Organisation Name : Ente	Organisation Name		
Address Line 1		Address Line 2	
Enter Address Line 1		Enter Address Line 2	
Country	State	City	Pin Code
Landline No. (Please include Country Code - STD Cod	- Phone Number)	Fax (Please include Country Code - STD Code - F	ax Rumber)
+ Country code - SrD co E-mail:	Enter E-mail	+ Country code - STD code	- red Humber
	😰 Save	3 Reset	
सी डेक Designed, D ⊂DAC	eveloped and Maintained by C-DAC.		

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.

Menu 🔳					Welcome Mr.	Applicant (Corporate) 🖷	Home 😂 Change Password 🔿 Logout
	9	Central Dru Directorate Gen Ministry of Her	eral Of Health Services lith & Family Welfare, Governmen	<b>janisation</b>			
				Export	NOC		
			Purpose of Applicati	on 🖌 🛛 Purchase Or	der Detail Drug Detail Quantity Detail		
Ne	ote: 1. All fi 2. Purcl	elds are mandatory hase Order should not be le	es than 6 Months				
P	Purchase	Order Details					
	Purcl	hase Order No : hase Order Date :	Enter purchase Or	der No.			
	Issue	rd by:	Select		~		
	🗲 Prev	rious		🖺 Save 🕻	₹ Reset	➔ Next	
	_					🖻 Delete	
	÷	Purchase Order No 🗢	Purchase Order Date ≑	Trader Detail ≑	Buyer detail 🗢	Edit 🗢	
		Test	05/01/2024	Not Applicable	Crganusation Name : rest, Address : rest, Test, Ranchi, JHARKHAND, Bahamas; Contact detail : 2322322223; Fax detail : 01-123465789, Pincode : 834006, Email : abc@gmail.com;	6	
		सीडेक CDAC	, Developed and Maintained by	C-DAC.			

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.

Menu =			Welcome Mr. Applicant (Corporate) 🚸 Home 🏾 Change Password 🙂 Logout
	Central Drugs S Directorate General O Ministry of Health & J	tandard Control Organisation Health Services 'amily Welfare, Government of India	
		Export NOC	
	Note: In case of FDC,Enter 0 in strength Field a	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 V	
	Storage Condition:	Select	
	Previous	별 Save 37 Reset	
	सी डेक Designed, Deve CDAC	loped and Maintained by C-DAC.	

Figure 15: Drug Detail

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

Menu =					Welcome	e Mr. Applicant (Corporate) 希 🛙	Home 🏾 Change Password 🖕 Logout
l'as	Central Drugs Sta	andard Contro Health Services	ol Organisation				
( ) (	Ministry of Health & Fa	umily Welfare, Gov	ernment of India				
			Export	NOC			
Note: In cas	se of FDC,Enter 0 in strength Field ar	nd the strength o	of Ingredients are to be fille	d in Composition section.			
		Purpose of Ap	plication 🖌 🛛 Purchase De	tail / Drug Detail Quar	ntity Detail		
Drug D	letails						
Ap	plication applied for:	Bulk Drug					
Ger	neric Name of Drug:	Enter Name					
Pha	armacopeial Monograph:	Select			~		
Cla	iss of Drug:	Select			~		
Re	gulatory Status:	Select			~		
She	elf Life:	0		Select	~		
Sto	orage Condition:	Select			~		
<b>*</b>	Previous		🖺 Save	7 Reset		→ Next	
-Drug De	etails						
Search:						🔒 Delete	
\$	Generic Name of Drug 🗢	Р.М \$	Class of Drug 🗢	Shelf Life ≑	Storage Condition	► Edit Φ	
	+ TEST	F.P.	Anthelmintic Drugs	1 Days	2*C - 8*C	G	
	सीडेक Designed Develo	oped and Maintai	ned by C-DAC				
	CDAC	ped and Maintai	net by o bno.				

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.

Menu =			Welcome Mr. Applicant (Corporate) 🖷 Home 🏾 Change Password 🔿 Logout
	Central Drugs Standar Directorate General Of Health Se Ministry of Health & Pamily Well	d Control Organisation rvices fare, Government of India	
		Export NOC	
	Purpos	se of Application ✔	tail
	Quantity Detail		
	Drug Name : Select	Purchase Order No : Select	
	Destination Country :		
	Quantity :	Pack Type Pack Siz	28 Dark Gina
	amor quantity		A MININ VOINN
	<ul> <li>Previous</li> </ul>	🖺 Save 🎜 Reset	
	सी डैक Designed, Developed and	Maintained by C-DAC.	

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.

Menu 🗮							I	Welcome Mr. Applie	cant (Corporate) f	🖡 Home 🛭 😂 Change Pass	word 😃 Logout
(		Central Drug Directorate Genera Ministry of Health	s Standard al Of Health Sen a & Family Well	Control Orga rvices fare, Government o	nisation of India						
					Export NO	C					
					-						
			Purpos	e of Application	Purchase Detail	Drug Detail 🗸 🛛 Q	uantity Detail				
Quant	tity Detail										
D	rug Name :				Pu	chase Order No :					
	Select				* Se	ect			Ŧ		
D	esunation Cour	ury:									
Q	uantity :			Pack Ty	rpe		Pack Size				
	Enter Quantity			Select		Ŧ	Enter Pack S	ize			
<b>€</b> 8	Previous				🖹 Save 😂 Re	et			→ Next		
						_					
								1	🖻 Delete		
	Neme	of the Drug	Quantity	Dook Time	Durchase Order No.	Nome of Depart	er Country	Daalyaaa Cina	<b>T</b> .314 <b>A</b>		
	+ TEST	or the Drug	4	Bottle	Test	Algeria	er country -	44	Ci Ci		
	-										
		-									
	%ा डय <b>©DAC</b>	Designed, D	eveloped and	Maintained by C	-DAC.						

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.





No:									
itral I dMun	Drug Standa nbai Central	ards Conti l (India) - 4	ol Organization, West Zone ,Office 00008	e of Deputy Drugs Co	ontroller(In	dia), 4th Flo	oor, Zonal FDA Bh	awan, GMSD (	Compound, Bellasi
: Requ	uest for NOC	of Manufa	acture for Export Purpose						
pecte	d Sir,								
	turing Licen	ice no	' ' are manufacturer exporter of pha	armaceutical drug/form	nulations au	nd doing reg	ular export		
huract have a we he S.No	an export or reby reques Name of	rder from fo it you to gra Brand	oreign buyer name and address unde ant us permission/NOC to manufact	er export order no for f ure the following drug, Purchase Order	ollowing ite /formulation Quantity	ems as per ta ns for export Package	ble given below. only . Name of	importing	Regulatory
have a we he S.No	an export or rreby reques Name of Drug	rder from fo t you to gra Brand Name	preign buyer name and address under ant us permission/NOC to manufact Foreign Buyer	er export order no for f ure the following drug, Purchase Order No. and Date	ollowing ite /formulatio: Quantity	ems as per ta ns for export Package Size	ble given below. only . Name of country/name consignee.	importing of the	Regulator <b>y</b> Status
have a we he S.No 1	an export or reby reques Name of Drug TEST (F.P.) -	rder from fo it you to gra Brand Name NA	reign buyer name and address und ant us permission/NOC to manufact	er export order no for f ure the following drug, Purchase Order No. and Date Test - 01-May- 2024	ollowing ite /formulatio: Quantity	ems as per ta ns for export Package Size	ble given below. conly . Name of country/name consignee.	importing of the	Regulatory Status Approved New Drug
have a we he S.No	an export or preby reques Name of Drug TEST (F.P.) -	ider from fo t you to gra Brand Name NA	reign buyer name and address und ant us permission/NOC to manufact	er export order no for f ure the following drug, Purchase Order No. and Date Test - 01-May- 2024	ollowing ite /formulation Quantity	Package Size	ble given below. conly . Name of country/name consignee. Signat	importing of the	Regulatory Status Approved New Drug

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 👌 Logo
	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/altered 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
	<b>5</b> . Regulatory Status of the applied drug/product in the Importing Country and registration details, if any
	<b>6</b> . Proposed Label (primary & secondary pack) with QR code
	7. Justification/Calculation regarding the quantity of API required as per Purchase Order/Performa invoicereceived from theFormulationManufacturer and Copy of the Manufacturing licence of the FormulationManufacturer
	<b>8</b> . 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
	0 10. Legal Undertaking (on non-judicial stamp paper and notarized) asper Annexure-II from the Manufacturer of Formulation.
	D 11. List of Export NOC details issued by SLA since 2018 in a tabular column along with permission/NOC copies
	2 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 21: Upload document page

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 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.



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- 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.

		Expo	rt NO	C		
	Purpose of Appl	ication 🖌 Product	Detail I	Drug Detail		
	NOC No.					
	Zone Name :				*	
	Applicant Name : Organisation Name : Applicant Address :					
	Purchase Order No :	test				
	Purchase Order Date :	05/01/2024				
	API Name :	Select			¥	
	Quantity	Enter Quantit	у	Select	~	
Previous		🛱 Save	C Res	et		→ Ne
			į.			🔒 Delete
Name of the I	Drug	Quantity	Unit	Purchase Order No.	Purchase Order Date	Edit 🗢
				test	05/01/2024	CX.

Figure 24: Product Detail





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

e No :								
ntral Drug Standards adMumbai Central (Inc	Control Orga ia) - 400008	nization, V	West Zone ,Office of Deputy	Drugs Controller(Indi	a), 4th Floor, Zonal	FDA Bhaw	an, GMSD (	Compound, Bellas
b: Request for NOC of N	laterial Trans	fer <mark>(</mark> API Ma	nufacture)					
spected Sir,								
			subject L/we					holding va
is is with reference	o the above	mentionec	i subject, i/we,					monung vu.
is is with reference nufacturing Licence n we hereby request you same into the formul puty Drugs Controller	o the above o aren a to grant us p ation for expo India), 4th Flo	mentioned nanufactur ermission/ rt only und or, Zonal F	er of pharmaceutical finished f /NOC for manufacturing of belo ler NOC No. NA/NOC-Export/20 7DA Bhawan GMSD Compound	formulation . ow mentioned bulk dro 018/003112 issued by C I, Bellasis Road Mumb	ug (API) and supply to entral Drug Standard eai Central (India) - 40	Foreign Ad s Control O 00008 to Fo	ldress for pu g <b>anization,</b> rmulation m	urpose of converti West Zone ,Office lanufacture
is is with reference nufacturing Licence n we hereby request you same into the formul puty Drugs Controller dated N S.No Name of Drug	o the above o are n i to grant us p ation for expo India), 4th Flo 07/05/2018 ob	mentioned nanufactur ermission/ rt only und <b>oor, Zonal F</b> otained fror Brand	Foreign Buyer	ormulation . ow mentioned bulk dri 118/003112 issued by C I, Bellasis Road Mumb	ug (API) and supply to entral Drug Standard ai Central (India) - 44 Purchase Order	P Foreign A( s Control O 00008 to Fo Quantity	ldress for pu ganization, rmulation m Package	ripose of converti West Zone ,Office Ianufacture1 ,
is is with reference mufacturing Licence n we hereby request you same into the formul puty Drugs Controller dated Mame of Drug	o the above o are n a to grant us p ation for expo India), 4th Flo 07/05/2018 of	mentioned nanufactur ermission/ rt only und <b>por, Zonal F</b> otained fror Brand Name	r subject , if we, er of pharmaceutical finished f NOC for manufacturing of bele ler NOC No, <b>NA/NOC-Export/20</b> <b>PDA Bhawan GMSD Compound</b> m CDSCO. Foreign Buyer	iormulation . ow mentioned bulk dri 118/003112 issued by C I, Bellasis Road Mumb	ug (API) and supply to entral Drug Standard ai Central (India) - 44 Purchase Order No. and Date	o Foreign Ad s Control O D0008 to Fo Quantity	ldress for pu ganization, rmulation m Package Size	Regulatory Status
is is with reference nufacturing Licence n we hereby request you same into the formul puty Drugs Controller dated M S.No Name of Drug 1	o the above o are n a to grant us p ation for expo India), 4th Fle 07/05/2018 ob	mentioned nanufactur ermission/ rt only und oor, Zonal F otained fror Brand Name NA	For the second s	ormulation . ow mentioned bulk dr 018/003112 issued by C , Bellasis Road Mumb	ag (API) and supply to entral Drug Standard ai Central (India) - 40 Purchase Order No. and Date test - 01-May- 2024	P Foreign A s Control O 00008 to Fo Quantity	ldress for pu rganization, rmulation m Package Size 0	Regulatory Status
is is with reference nufacturing Licence n we hereby request you same into the formul puty Drugs Controller 	o the above o are n it o grant us p ation for expo mindia), 4th Fle 07/05/2018 of	mentionec nanufactur ermission/ rt only und por, Zonal F tained fror Brand Name NA	r subject , if we, er of pharmaceutical finished f /NOC for manufacturing of belo ier NOC No. NA/NOC-Export/20 PDA Bhawan GMSD Compound m CDSCO.	ormulation . ow mentioned bulk dri 018/003112 issued by C 4, Bellasis Road Mumb	ag (API) and supply to entral Drug Standard ai Central (India) - 44 Purchase Order No. and Date test - 01-May- 2024	Proreign Ad s Control O 00008 to Fo Quantity Signatur	ldress for pu ganization, rmulation m Package Size 0	Regulatory Status

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.





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





Army = Welcome Mr. Applicant (Corporate) # Hon	me 🕃 Cì
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)	
<ul> <li>Note:</li> <li>1 Click on the checklist point to upload document against it. Only PDF documents with size not more than 50 MB are permitted.</li> <li>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.</li> <li>3 Partially saved checklist can be viewed/altered under the Saved Application link available on the Dashboard</li> <li>4. Click here to view Guidelines for PDF documents</li> </ul>	
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 FormulationManufacturer) -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 CDSCO Zonal office in the name of Formulation manufacturer.	
<b>5</b> . 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 invoicereceived from theFormulationManufacturer and Copy of the Manufacturing licence of the FormulationManufacturer	
<b>8</b> . 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	
0 10. Legal Undertaking (on non-judicial stamp paper and notarized) asper 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	
ली डेक Designed, Developed and Maintained by C-DAC. €DAC	

#### Figure 27: Upload document page

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 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.

Menu =			Welcome Mr. Applicant (Corporate) 🖷 Home 🗘 Change Password 👌 Logout
	Central Drugs Standard Control O Directorate General Of Health Services Ministry of Health & Family Welfare, Governme	Organisation mt of India	
		Export NOC	
	Purpose of Applicatio Applied For: Purpose of Application: Licence No. : Premise Name :Test Pharmacy Issue Date :16/07/2014	Product Detail Drug Detail Procuring Unapproved /approved New Drug (Bulk) for R. Bulk Drug 280018 Premise Address filock No 10, 1st Floor, Udyog Bhawan, Pune, Maharashtra, India Expiry Date 18/08/2017 Save and Continue C Reset	
च्यी के	F		
CDA	C Designed, Developed and Maintained by	TC-DAC.	

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.

Menu =				Welcome Mr. Applicant (Corporate) 🗰	Home 🏾 Change Password 🖕 Logout
	Central Drugs Sta Directorate General Off Ministry of Health & Fe	andard Control Organisation Health Services mily Welfare, Government of India			
		Export	NOC		
No	ote: In case of FDC,Enter 0 in strength Field as	nd the strength of Ingredients are to be fill	led in Composition section.		
		Purpose of Application 🗸 Drug Detai	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		~	
	Quantity		Select	~	
	Export Country	Multiple options can be selected			
	Previous	🛱 Save	🕱 Reset		
	स्ती डैक Designed, Develo CDAC	oped and Maintained by C-DAC.			

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.

No '										
tral D dMun	Drug Standards Control Organization nbai Central (India) - 400008	n, West Zon	e ,Office of D	eputy Drugs	Controller(Indi	a), 4th Floo	r, Zonal FDA B	hawan, GN	ASD Compour	nd, <mark>Bell</mark>
: Requ pose	uest for NOC of Procuring Unapprove	ed /approved	l New Drug (Bu	llk) for R&D /	Formulation D	evelopment	/ Manufacture	of Exibit B	atches for dat	a of Exj
pecter	d Sir,									
s is v nufact pose o	with reference to the above mention turing Licence no are manufa only.	ned subject cture export	, I/we, <u> </u>	formulation	for R&D/ Form	ulation Deve	lopment/manuf	acture of e	, ho xhibit batches	lding v s for exj
s is v nufact pose o we he ches fo S.No	with reference to the above mention turing Licence no are manufa only. ereby request you to grant us permis or export purpose only . Name of Drug	ned subject cture export ssion/NOC to Brand	, I/we, ter of following o manufacture Quantity	formulation the following Package	for R&D/ Form formulations Name of	lation Deve for for R&D/ importing	lopment/manuf Formulation D country/name	acture of e evelopmen of the		Iding v s for exj e of exh Status
s is v nufact pose o we he ches fo S.No	with reference to the above mention turing Licence no are manufa only. ereby request you to grant us permis or export purpose only . Name of Drug	ned subject cture export ssion/NOC to Brand Name	, I/we, ter of following o manufacture Quantity	formulation the following Package Size	 for R&D/ Form formulations Name of consignee.	ulation Deve for for R&D/ importing	lopment/manuf Formulation D country/name	acture of e evelopmen of the	ho xhibit batches t/manufacture Regulatory \$	lding v s for ex e of exh Status
s is v nufact pose c we he ches fo S.No 1	with reference to the above mention turing Licence no are manufa only. ereby request you to grant us permis or export purpose only . Name of Drug TEST (ManufacturerSpecification)	ned subject cture export ssion/NOC to Brand Name NA	, I/we, ter of following o manufacture Quantity	formulation the following Package Size NA	 for R&D/ Form formulations Name of consignee.	Ilation Deve for for R&D/ importing	opment/manuf Formulation D country/name	acture of e evelopmen of the	ho xhibit batches t/manufacture Regulatory s Approved Drug	lding v s for ex e of exh Status New

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.







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) 🕷 Ho	me 🤁 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 Exibit 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/altered 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 6. Justification/Calculation regarding the quantity of Approved New Drug/Unapproved New drug/Banned drugs (API) from API Manufacture to manufacture Formulation.	
	O 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	
	0 10. Legal Undertaking (on non-judicial stamp paper and notarized) in Annexure-II	
	🔲 11. Undertaking by the Manufacturer(Annexure-iii) on Companys Letter head	
	212. 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	
	स्ती उँक Designed, Developed and Maintained by C-DAC.	

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.





Menu =			Welcome Mr. Applicant (Corporate) 🕷 Home 🕃 Change Password 🖕 Logout
	entral Drugs Standard Contro irectorate General Of Health Services finistry of Health & Family Welfare, Govern	ol Organisation ument of India	
		Export NOC	
	Purpose of Applic	ation 🗸 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 Pharma Issue Date :16/07/2014	Acy Premise Address :Block No.10, 1st Flo Udyog Bhawan, Pune, Maharashtra, 1 Expiry Date :18/08/2017	or, ndia
	In case of Unapproved / Banned and New, API is obtained from other Manufacturer	OYes®No	
		Save and Continue	
सी डेक CDAC	Designed, Developed and Maintaine	il by C-DAC.	

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.

Memu =	Central Drugs St Directorate General Of P Ministry of Health & Fra	andard Control Organisation lealth Services mily Welfare, Government of India	Welcome Mr. Applicant (Corporate)
		Export NOC	
		Purpose of Application 🖌 Purchase Order Detail Drug Detail Quantity D	betail
	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 : Issued by:	Select	× v
	♣ Previous	🔁 Save 🛛 🗯 Reset	
	सी डैक Designed, Develo CDAC	ped and Maintained by C-DAC.	

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.

Menu =	Central Drugs Sta Directorate General Of Ministry of Health & F	ndard Control Organisation Health Services amily Welfare, Government of India		Welcome Mr. Applicant (Corporate) 🏘 Home 🧔 Change Password 🕲 Logout
		Expo	ort NOC	
		Purpose of Application 🖌 🏼 Purcha	se Order Detail Drug Detail Quantity	Detail
1. All fields are 2. Purchase Or	mandatory der should not be less tha	n 6 Months		
Purchase Order I	Details			
Purchase Or	der No :	Test		~
Purchase Or	der Date :	05/01/2024		
Issued by:		Buyer		8
Organisation	a Name : Enter Or	ganisation Name		
Address Line	e 1		Address Line 2	
Enter Add	ress Line I		Enter Address Line 2	
Country		State	City	Pin Code
Select	~	State	City	Pin Code
Landline No	Country Code - STD C P	hone Memberl	Fax	an Mirmharl
+ Court	try code - STD code - P	- Phone number	+ Country code - STD code -	- Fax number
E-mail :		Enter E-mail		
<ul> <li>Previous</li> </ul>		🖏 Save	2 Reset	
ন্দ্	डैक Designed, Devel	oped and Maintained by C-DAC.		

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.

Menu =					Welcome Mr. A	Applicant (Corporate) 🚓	Home 😂 Change Password 🙂 Logou
		Central Dru Directorate Gen Ministry of Hee	igs Standard Control Org eral Of Health Services lith & Family Welfare, Governmer	<b>janisation</b> at of India			
				Export	NOC		
			Purpose of Application	on ✔ Purchase Or	der Detail Drug Detail Quantity Detail		
	Note: 1. All : 2. Pur	fields are mandatory chase Order should not be le	ss than 6 Months				
	Purchas	e Order Details					
	Pur	chase Order No : chase Order Date :	Enter purchase Or	der No.			
	Issu	ed by:	Select		-		
	🔶 Pre	vious		🖺 Save	3 Reset	➔ Next	
						🔋 Delete	
	٠	Purchase Order No 🗢	Purchase Order Date 🗢	Trader Detail 🗢	Buyer detail 🗢	Edit 🗢	
		Test	05/01/2024	Not Applicable	Organisation Name: Test: Address: Test, Test, Ranchi, JHARKHAND, Bahamas; Contact detail: 23223222323; Fax detail: 91-123465799; Pincode: 834006; Email: abc@gmail.com;	G	
		लीडैक ©DAC	, Developed and Maintained by	C-DAC.			

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.





Welcome	e Mr. Applicant (Corporate) 🐗
Central Drugs Standard Control Organisation Diselectuated consult of Health Services Ministry of Health & Family Welfare, Government of India	
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 OUantity Detail	
Drug Details	
Application applied for: Finished Formulation	
Generic Name of Drug: Enter Name	
Brand Name (optional)	
Pharmacopsial Monograph: Select 🗸	
Class of Drug: Select 🗸	
Regulatory Status: Select	
theif Life: 0 Select 🗸	
Storage Condition: Select ~	
Dosage Form Select	
Strength Enter Strength Select ~	
Package Size (Enter Comma Seperatel Package Size)	
Composition each Select 🗸 contains	
Composition	
Ingredient Pharmacopeial Monograph Strength Unit Select	~
Multiple options can be selected	
	-
<ul> <li>← Previous</li> <li>Ø Save</li> <li>Ø Reset</li> </ul>	
র্লী উফ Designed, Developed and Maintained by C-DAC.	

#### Figure 39: Drug Detail

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

Menu E	Drugs Standard Control le General Of Health Services of Health & Family Welfate, Gover	Organisation		Welcome Mr. /	Applicant (Corporate) 🔿	Home 🏾 Change Password 🗢 Logout
		Export N	DC			
Note: In case of FDC,Enter 0 in stree	ngth Field and the strength of	Ingredients are to be filled ir	Composition section.			
	Purpose of Apple	ication 🖌 📔 Purchase Detail	Drug Detail Quan	atity Detail		
Drug Details						
Application applied for:	Finished Formu	ilation				
Generic Name of Drug:	Enter Name					
Brand Name (optional)						
Pharmacopeial Monograph	Select			~		
Class of Drug:	Select			~		
Regulatory Status:	Select			~		
Storage Condition	0	S	elect	•		
Dosage Form	Select			~		
Strength	Enter Strength	1 S	plect	~		
Package Size						
Composition	(Enter Comma Sepe	erated Package Size)	×	taina		
Composition	each Selec	a	Con	ttains		
Ingredient	Pharmacopeial 1	Monograph Stre	ngth	Unit		
	Multiple options ca	in be selected		Select	~	
+ Previous		🛤 Save 😂 I	eset		→ Next	
Drug Details						
Search:					🛱 Delete	
Generic Name of Drug	PM ≎	Class of Drug +	Shelf Life 🗢	Storage Condition +	Edit ¢	
- + TEST	Ph. Int	Antheimmüc Drugs	z week	below 25°C	6	
सी डेक CDAC	igned, Developed and Maintaine	d by C-DAC.				

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.





Menu =		Welcome Mr. Applicant (Corporate) 🖷 Home 🏾 Change Password 🖄 Logout
	Central Drugs Standard Control Organisation Directorate Consent Of Health Services Ministry of Health & Family Welfare, Covernment of India	
	Export NOC	
	Purpose of Application 🖌 Purchase Detail 🖌 Drug Detail 🖌 Quantity D	Detail
	Quantity Detail	
	Drug Name : Purchase Order No : Select # Select	v
	Destination Country :	
	Quantity:         Pack Type         Pack t           Enter Quantity         Select         Enter	Size er Pack Size
	♥ Previous ♥ Save ♥ Reset	
	सी डैक Designed, Developed and Maintained by C-DAC.	

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.

Menu =					Welcome Mr. Applicant	t (Corporate) 希 Home 🤁 Change Password 也 Logout
	Central Drue Directorate Gene Ministry of Heal	gs Standard Control eral Of Health Services Ith & Family Welfare, Govern	Organisation			
			Export NC	OC		
		Purpose of Applie	ation 🖌 🛛 Purchase Details	✔ Drug Detail✔ Quantity Detail		
Quantity I	Detail					
Drug	Name :		Pu	rchase Order No :		
Desti	ination Country :		* 5	elect		×
Quan	<b>itity</b> : iter Quantity	Pa	<b>ck Type</b> elect	Pack Size     Enter Pack	Size	
← Prev.	vious		🖺 Save 🖉 R	eset		→ Next
					<b>a</b>	Delete
	Marrie a Cultor Prove		Durchase Online Wa	New of Personal Second		
+0	TEST	4 Bottle	Test	Algeria	44 (	
	सीडेक Designed,	Developed and Maintained	by C-DAC.			

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.





		App	lication for issue of NOC	for Manufact	ure for E	kport Purj	pose		
File No :									
То									
Central D RoadMum	rug Standards Control Org bai Central (India) - 400008	anization	, West Zone ,Office of Deputy	y Drugs Controlle	er(India), 4	th Floor, Zo	onal FDA Bhawan,	GMSD C	ompound, Bellasis
Sub: Requ	est for NOC of Manufacture i	for Export	Purpose						
Respected	l Sir,								
This is w	ith reference to the above	mention	ed subject , I/we,						holding valid
manufactu	uring Licence r^ are	manufact	urer exporter of pharmaceutica	al drug/formulatio	ns and doir	ng regular ex	port.		
We have a	n export order from foreign	buyer nan	ne and address under export or	der no for followir	ng items as	per table giv	ven below.		
So, we her	eby request you to grant us j	permissio	n/NOC to manufacture the follo	owing drug/formul	lations for e	export only .			
n									
S.No	Name of Drug	Brand Name	Foreign Buyer	Purchase Order No. and Date	Quantity	Package Size	Name of in country/name of consignee.	nporting of the	Regulatory Status
1		TEST		Test - 01-May- 2024	u		64-		Approved New Drug
Dated	: 02-May-2024					Name an	Signature d Designation		
🛓 Down	nload PDF			🖋 Edit Form	🖺 Sa	ave and Cont	inue		

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.





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 🙂 Loge
	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/altered 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 Manufacture to manufacture Formulation.
	O 7. Details of source of API with details of API Manufacturer and Copy of relevant Manufacturing licence.
	<b>8</b> . 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
	0 10. Legal Undertaking (on non-judicial stamp paper and notarized) in Annexure-II
	11. Undertaking by the Manufacturer(Annexure-iii) on Companys Letter head
	2 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
	ন্ধী উক Designed, Developed and Maintained by C-DAC.

#### 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.

Menu =				Welcome Mr. Applicant (Corporate) 🏶 Home 🤁 Change Password 🗴 Logout
		Central Drugs Standard Control ( Directorate General Of Health Services Ministry of Health & Family Welfare, Governme		
			Export NOC	
		Purpose of Applicati	on 🖌 Product Detail Drug Detail	
		Applied For:	Procuring Unapproved /approved New Drug (Bulk) for R_	*
		Purpose of Application:	Finished Formulation	•
		Licence No. :	280018	s
		Premise Name :Test Pharmacy Issue Date :16/07/2014	Premise Address :Block No.10, 1st Floor, Udyog Bhawan, Pune, Maharashtra, India Expiry Date :18/08/2017	
		In case of Unapproved / Banned and New, API is obtained from other Manufacturer	⊖Yes●No	
			😫 Save and Continue 🤤 🕄 Reset	
	सीडेक ⊂⊃ค⊂	Designed, Developed and Maintained by	y C-DAC.	

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.

Menu =				w	felcome Mr. Applicant (Corporate	e) 🕷 Home 😂 Change Password 😊 Logout
	Central Drugs Sta	ndard Control Organisation				
	Ministry of Health & Far	nily Welfare, Government of India				
		Expo	rt NOC			
Note: In case of FDC.	Enter 0 in strength Field an	d the strength of Ingredients are to be	filled in Composition section.			
		Purpose of Application 🖌 Drug De	ail Quantity Detail			
			_			
Drug Details						
Application	applied for:	Finished Formulation				
Generic Nam	e of Drug:	Enter Name				
Brand Name	(optional)					
Pharmacope	ial Monograph:	Select		~		
Class of Dru	r.	Select		~		
Regulatory 5	tatus:	Select		~		
Shelf Life:		0	Select	~		
Storage Cone	lition:	Select		~		
Quantity			Select	~		
Export Coun	try					
		Multiple options can be selected				
Dosage Form		Select		~		
Strength		Enter Strength	Select	~		
Package Size		(Enter Comma Seperated Package Size)				
Composition		each Select	✓ con	tains		
Composition	1					
Ingredient		Pharmacopeial Monograph	Strength	Unit		
		Multiple options can be selected		Sele	ect 👻	
					_	
					+	
🔶 Previous		P Save	C Reset			
	•					
খ্য	डेक Designed Develor	and and Maintained by C-DAC				
ĊĎ	AC	contraction of the second s				

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.

le No :						
D						
entral I oadMur	Drug Standards Control Organization, West : mbai Central (India) - 400008	Zone ,Office	of Deputy D	rugs Control	ler(India), 4th Floor, Zonal FDA Bhawan, G	MSD Compound, Bella
ub: Requ	uest for NOC of Procuring Unapproved /appro	ved New Dri	ug (Bulk) for I	R&D / Formul	lation Development / Manufacture of Exibit E	latches for data of Exp
urpose						
especte	ed Sir,					
		oct I/wo				holding va
his is v	with reference to the above mentioned subj	ect, 1/ we,				
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his is v anufact urpose c o, we he atches f n S.No 1	with reference to the above mentioned subj turing Licence no are manufacture exp only. ereby request you to grant us permission/NO for export purpose only.	Brand Name test	Quantity	ation for R&D owing formu Package Size test	V Formulation Development/manufacture of e lations for for R&D/ Formulation Developmen Name of importing country/name of t consignee.	exhibit batches for expent nt/manufacture of exhi he Regulatory Status UnApproved Drug
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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
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 Exibit Batches for data of Export Purpose
<ul> <li>Note:</li> <li>1. Click on the checklist point to upload document against it. Only PDF documents with size not more than 50 MB are permitted.</li> <li>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.</li> <li>3. Partially saved checklist can be viewed/altered under the Saved Application link available on the Dashboard</li> <li>4. Click here to view Guidelines for PDF documents</li> </ul>
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).
C 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.
<b>5</b> . 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 Manufacture to manufacture Formulation.
<b>7</b> . 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
2. 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
श्ती डेंक Designed, Developed and Maintained by C-DAC.

#### 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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