



National Single Window System

User Guide:

How to apply for CDSCO Approval

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How to view, add approval from 'All Approvals'

उद्योग संवर्धन और आंतरिक व्यापार विभाग
DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE

INVEST INDIA

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LOGIN

All Approvals
PESO Approvals

Hover over 'Central Approvals' and click on 'All Approvals'

Access over **612** Central Approvals and **4197** State Approvals

Explore, Apply and Get all the approvals required to start your business in India

Central Approvals Search Approvals EXPLORE ALL

Don't know which approvals are required? [Click Here & Know Your Approvals](#)

"We are laying a red carpet for all global companies to come and establish their presence in India. Very few countries will offer the kind of opportunities India does today."

Hon'ble Prime Minister Narendra Modi

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LOGIN

58 Approvals

Filter by: Directorate General of Health Services Clear All

Ministries

Industry (143)

Ministry of Communications (47)

Ministry of Consumer Affairs, Food and Public Distribution (24)

Ministry of Corporate Affairs (9)

Ministry of Culture (8)

Ministry of Defence (1)

Ministry of Education (5)

Ministry of Environment, Forest and Climate Change (15)

Ministry of Finance (55)

Departments

Department of Water Resources (3)

☒ Directorate General of Health Services (58)

DPIIT (89)

Ministry of Civil Aviation (10)

Ministry of Health and Family Welfare
CT-16 Application for grant of license to import new drug or investigational new drug...

View details ADD TO DASHBOARD

Ministry of Health and Family Welfare
CT-13 Application for grant of permission to manufacture unapproved active pharmaceut...

Ministry of Health and Family Welfare
FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF

Ministry of Health and Family Welfare
Form B (See rule 24A) Application for License to Import Drugs(Excluding those specif...

Ministry of Health and Family Welfare
Form CT-10 Application for grant of permission to manufacture new drug or investigati...

Ministry of Health and Family Welfare
Form CT-12 - Application for grant of permission to manufacture formulation of unappr...

Ministry of Health and Family Welfare
MD-16 - APPLICATION TO IMPORT MEDICAL DEVICES FOR THE PURPOSES OF CLINICAL INVESTIGAT...

Select "Directorate General of Health Services" from the list of Departments

Click on "Add to Dashboard"



How to view, add approval through Central KYA

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Access over **612 Central Approvals** and **4197 State Approvals**

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Hon'ble Prime Minister Narendra Modi

Click on 'Know Your Approvals' on the NSWS homepage

National Single Window System

Begin your journey through KYA which helps generate a list of Centre and State approvals that may be required to start your business operations in India. This list of approvals is for guidance purposes only.

Which one would you like to go with first?

Central State

Continue with Central Back to Homepage

You understand that the 'Know Your Approval' feature is completely dependent on the information provided by You and is only indicative in nature to identify a list of Approvals and Registrations that may be required for Your business. This list does not constitute a legal opinion or advice and is not to be used as a substitute for independent professional advice. We recommend you to undertake your own independent analysis and your application falls under the respective Ministry/ Department's

Click on 'Continue with Central' to open the central KYA



How to view, add approval through Central KYA

Click on 'Business Activity Details'

STEP 1 Business Registration

STEP 2 Business Activity Details

STEP 3 Foreign Investment Details

STEP 4 Project Land Details

Additional Information

Would you like to provide any of the following services / establish facilities?

Which sector(s) best describes your project/ business activity?

Healthcare

Agriculture, Sericulture and Forestry

Aviation

Banking and Financial Services

Defence Manufacturing

Healthcare

Education and Skill Development

Food & Beverages, Catering, including Animal Husbandry and Fisheries

Infrastructure

Leather & Textiles

Select "Healthcare" and Answer the questionnaire and find applicability of different approvals to you

Click here to read more information

Know Your Approvals - Central

My Approvals (1)

STEP 1 Business Registration

STEP 2 Business Activity Details

STEP 3 Foreign Investment Details

STEP 4 Project Land Details

Will your business activity require dealing in chemicals? (Toxic, Hazardous, Petrochemicals, Chemicals & Fertilizers)

Yes No

Please select all products/services applicable to your business which you would additionally like to apply for:

Select

Submit to Know Your Approvals

Save as Draft

Reset Form

Click on 'My Approvals' tab to view the list of added approvals

Click "Submit to Know Your Approvals" to view the list of approvals

To save a draft of the KYA answers, users must be logged into NSWS

Click on "Reset form" to remove all previous responses to the questions



How to add identified approval to the Dashboard

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LOGIN

My Approvals(4) Edit KYA

Based on the Information provided by you in the previous step, below is the list of approvals Identified. This list of approvals is for guidance purposes only and does not constitute legal and/or official advice.

CENTRAL APPROVALS (4)

- Form CT-10 Application for grant of permission for bioavailability or bioequivalence study or for examination, test and analysis**
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare
- CT-13 Application for grant of permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study**
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare
- MOH_Permission to manufacture new active pharmaceutical ingredient**
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare
- MOH_Licence to manufacture drugs for purposes of examination, test or analysis**
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare

To add the list of approvals on the Dashboard, log into NSWS

Add to Dashboard

Know State Approvals

Save PDF

Save the existing list of approvals in pdf format using 'Save PDF'

National Single Window System

Sign In
To access your dashboard and apply for approvals.

Email Address

Password

Sign In

Users will be redirected to the 'Sign In' Page

We have
28 Ministries 22 States

Ministry of Civil Aviation
Government of India

Ministry of Labour and Employment
Government of India

Ministry of Corporate Affairs
Government of India

Ministry of Information and Broadcasting
Government of India

Ministry of Communications
Government of India

Ministry of Fisheries, Animal Husbandry, and Dairying
Government of India

Ministry of Finance
Government of India

Ministry of Education
Government of India

Government of Andhra Pradesh

Government of Arunachal Pradesh

Government of Bihar

Government of Gujarat

Government of Karnataka

Government of Goa

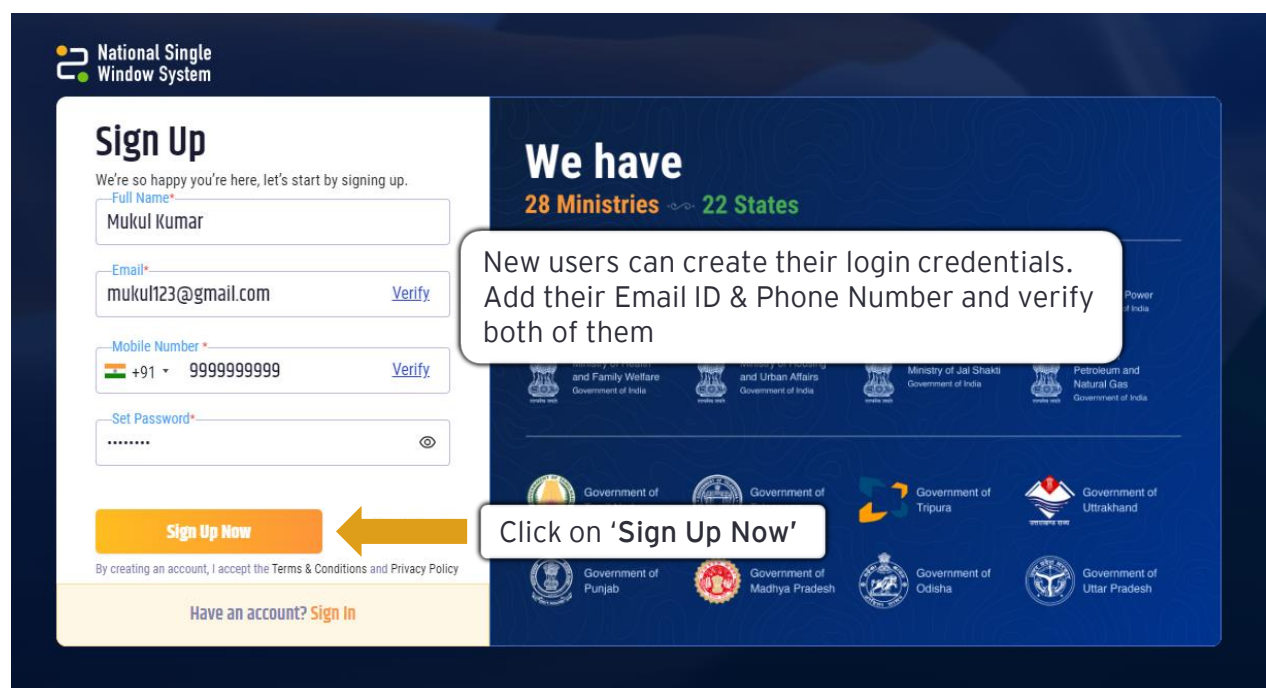
Existing users can 'Sign In' with their credentials

Don't have an account? Sign Up Now

New users can create an account using 'Sign Up Now'



How to login and apply for approval (New User)



National Single Window System

Sign Up

We're so happy you're here, let's start by signing up.

Full Name*
Mukul Kumar

Email*
mukul123@gmail.com [Verify](#)

Mobile Number*
+91 9999999999 [Verify](#)

Set Password*

Sign Up Now

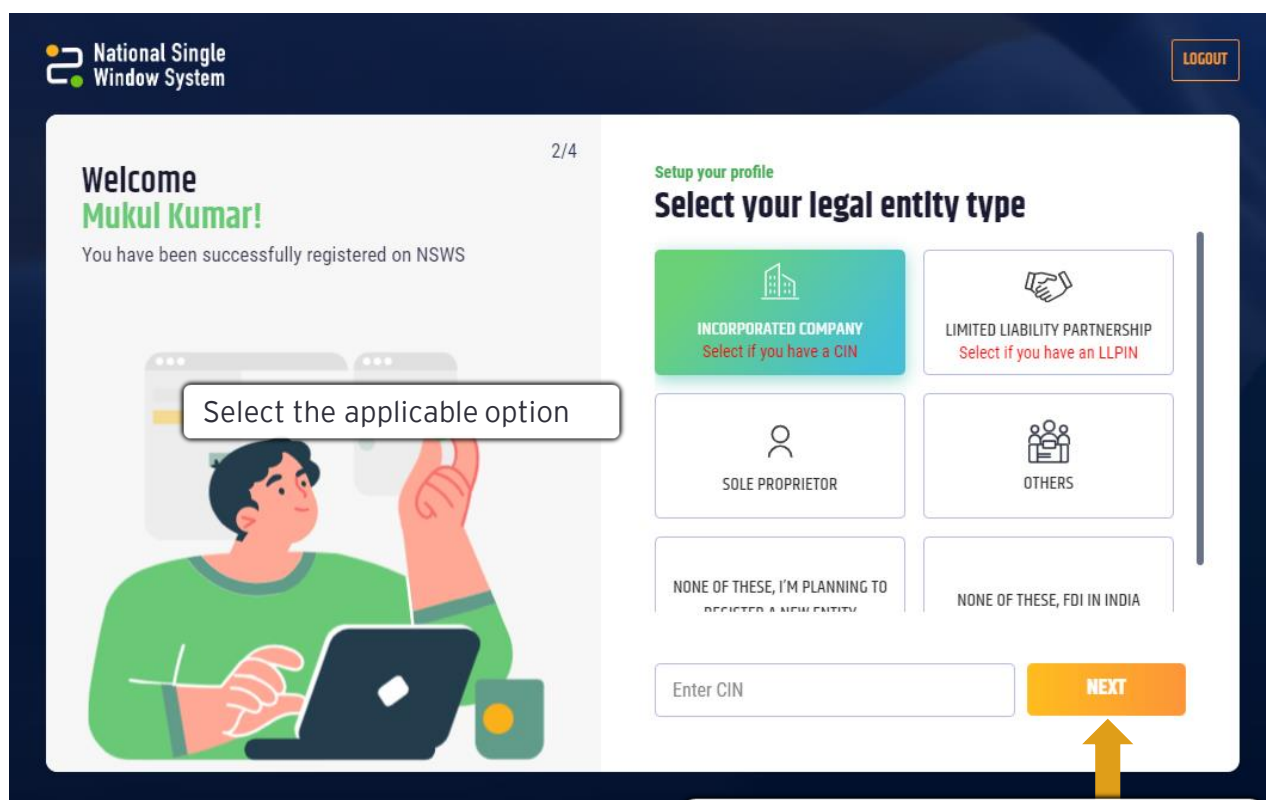
By creating an account, I accept the Terms & Conditions and Privacy Policy

Have an account? [Sign In](#)

We have
28 Ministries 22 States

New users can create their login credentials. Add their Email ID & Phone Number and verify both of them

Click on 'Sign Up Now'



National Single Window System [LOGOUT](#)

2/4

Welcome Mukul Kumar!

You have been successfully registered on NSWS

Select the applicable option

Setup your profile

Select your legal entity type

INCORPORATED COMPANY
Select if you have a CIN

LIMITED LIABILITY PARTNERSHIP
Select if you have an LLPIN

SOLE PROPRIETOR

OTHERS

NONE OF THESE, I'M PLANNING TO REGISTER A NEW ENTITY

NONE OF THESE, FDI IN INDIA

Enter CIN

NEXT

Enter the CIN / LLPIN / Business Name and click on 'Next'



How to fill the application form

ERNST AND YOUNG INDIA PRIVATE LIMITED
Incorporated on - 24/07/2002 CIN - U74140DL2002PTC116314

My Dashboard
Manage and track the status of your application

Central Approvals in List (2 approvals)

Approval Name	Applied on	Last Submitted By	Assigned to	Application Status	Application fees	Action
FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS + New Application	-	Mukul Kumar	Ministry of Health and Family Welfare	Not Applied	Subjective*	Apply Now
MDH_Permission to conduct clinical performance evaluation of new in vitro diagnostic medical device	-	Mukul Kumar	Ministry of Health and Family Welfare	Not Applied	₹ 25000	Apply Now

1 to / page

Callouts:

- Add the details in the Profile section
- Click on 'Apply Now' to proceed with the Application

Fill Application Form
Submit all the mandatory details(*) in the application form to apply

← Go Back

FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS

Part A
FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, ...

2

Sections to be filled:


- Pre Registration Form
- Applicant Address Details
- Test or Analysis Site
- Foreign Manufacturer details


Callouts:


- Click here to expand all section at once
- Navigate through different forms for the approval from here
- Click on the downward arrow against the section names to expand and fill the form






How to fill the application form





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Pre Registration Form

Select Department *

Biological - Blood Products

CDSO Applicable zone/HQ *

☐ I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division. *

The '*' indicates a mandatory field to be filled by the user

Applicant Address Details

Name of the Applicant *

Mukul

City *

Some Data will be pre-populated as filled up in the profile

Product Details

For each strength make new section application

Type of Drug *

☐ Bulk Drug ☐ Finished Formulation

Name of Drug/Formulation *

Class of Drug *

Select

Quantity

Quantity

Unit *

Select

+ Add Section

This button will create a duplicate section for the selected section

Product Details 2

For each strength make new section application

Type of Drug *

☐ Bulk Drug ☐ Finished Formulation

Name of Drug/Formulation *

Class of Drug *



How to fill the application form

BA/BE Study Details

Comparator Drug Details

Comparator Drug Name *

Name of Company

Name of Country *

Select ▼

+ Add Group

This button will create a duplicate group for the selected group

Comparator Drug Details 2

Comparator Drug Name *

Name of Company

Name of Country *

Foreign Manufacturer details

Name of the Foreign Manufacturer *

Country *

Select ▼

Address Line 1 *

Address Line 2 *

State/Province/Region *

City *

Please include Country Code - State Code - Landline Number

Zip/Postal code *

Landline No *

Fax No *

Click on '(i)' icon to read Additional Information



How to fill the application form

<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
An explanation about whom to contact for trial related queries, if any, to the Subject for participation in the trial	The anticipated prorated payment, if any, to the Subject for participation in the trial
<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Subject's responsibilities on participation in the trial	Statement that participation is voluntary, that the Subject can withdraw at any time
<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
PI's undertaking	International prescribing information
<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Justification i	
<input type="text"/>	

Next Form

Save as Draft

Use this button to save the progress of the filled up application

1

2

Part C

Checklist-F12-BIO-BP-FFBD

Move to the Checklist form for uploading the required documents



Checklist

1. Name of Applicant (Applicant Details)

Name of Applicant (Applicant Details) *

CDSO Checklist

Browse File

Select Document type and Click on 'Browse File' to add attachments

Supported files are PDF

Name of Applicant (Applicant Details) - Remarks *

2. Drug Details

Drug Details *

Select Document Type

Browse File

This button indicates that the user needs to Download a format, fill it up and upload the same on that particular field

Supported files are PDF

Drug Details - Remarks *



How to fill the application form

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An undertaking that the device in question conforms to the requirements of these rules, apart from aspects covered by evaluation and apart from those specifically itemised in the undertaking, and that every precaution has been taken to protect the health and safety of the patient, user and other persons *

Browse File

Supported files are PDF
dummy.pdf

Remarks *

Document

10. Performance evaluation report from a laboratory designated under sub-rule (1) of rule 19

Performance evaluation report from a laboratory designated under sub-rule (1) of rule 19 *

Browse File

Supported files are PDF
dummy.pdf

Remarks *

Uploaded

Review & Submit

Once filled, click on Review and Submit

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FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS

Part A

FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, ...

Application Fee
₹5,000

Pre Registration Form

Select Department	Biological - Blood Products
Purpose of Application	For Examination, Test or Analysis
CDSO Applicable zone/HQ	CDSO HQ
I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division.	Accepted

Applicant Address Details

Review the application and click here for final submission

Pay & Submit

Back to edit details

Applicable fee will be visible here



How to fill the application form

Go Back

Review your application

Please carefully review the application before submission

FORM-12- APPLICATION

Part A

FORM-12- APPLICATION TO IMPORT DRUGS

Disclaimer

By proceeding with the payment, You acknowledge that the payment is being made directly to the concerned Ministry towards application fees (if applicable) or any other fees that may be charged by them. NSWS shall not be obligated to pay or refund any monies to You in any circumstance and is also not liable to facilitate refund of any payment made by You to the concerned Ministry. You may reach out directly to the concerned Ministry/ State in case of any discrepancies.

☒ I have read and accept.

Pay & Submit

Cancel

Click on the checkbox and then "Pay & Submit" button

training.pfms.gov.in/Bharatkosh/NTRPHome/Confirmation

Pay the amount using the Bharatkosh portal

Non-Tax Receipt Portal

1 Payment Purpose

2 Depositor's Details

3 Confirm Info

4 Pay

Payment Made Online

Depositor's Details

Name	MUKUL KUMAR		
Address 1	DSSD	Address 2	
City	WEST DELHI	District	
State	DELHI	Country	INDIA
Pincode/Zipcode	110063	Email	mukul682937@gmail.com
Mobile No. (+91)	7042517135		
TAN		TIN	

Purpose Details

Sl. No.	Ministry	P&O Name	DDO Name	Purpose and Payment Type	Payment Period / Frequency	Amount (in INR)
1	HEALTH and FAMILY WELFARE	PAO(DGHS), New Delhi(020946)	Section Officer, CDSCO (HQ), New Delhi(203700)	Import and Registration,	One Time	5000
				INR five thousand only		Total: 5000

Back

Confirm

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How to fill the application form

3 easy steps to add Digital Signature

- Step 1 Download and run emBridge Application. [Download](#)
- Step 2 Insert your crypto-token Pen Drive into system
- Step 3 Fill details here to add digital signature

After payment, user will be redirected to NSWS portal where the user has to Digitally Sign the application

Provider *
Microsoft Windows Store

Certificate *
Class 3 Individual Test

Token Password *

Document for sign
MOH_Certificate for Registration

Sign & Submit

This is the document containing the responses of the investor in the application with their DSC. Also known as Legal Form

Submitted Successfully

Your application for 'MOH_Certificate for Registration of Notified Body' has been submitted successfully to the respective Ministry. Please check the status from your dashboard.

Application ID: SW/MD/MD-1/2023/00000300

Application ID	SW/MD/MD-1/2023/00000300
Paid Amount	₹25000
Transaction ID	T1687768381684A53704L3335P22603
Date	26 Jun 2023 02:03 pm
Email	muskan3675@gmail.com

Done

This screen confirms the submission of application



How to fill the application form

My Dashboard
Manage and track the status of your application

Central Approvals In List (1 approvals)

0 Not Applied | 1 Submitted To Ministry | 0 Assigned To Me | 0 Approved | 0 Rejected

Search by Approval Name | Add More Approvals

Approval Name	Applied on	Last Submitted By	Assigned to	Application Status	Application fees	Action
MOH_Cert...				Submitted	₹ 25000	Upload Doc. ...

Once submitted, user can track the 'Application Status' from here

In case the user wants to submit any additional document. They can click here

5. Additional Documents :

Document Type *
1.2 Organization profile of notified body including organogram, busin...

Upload document *
Other | Browse File

Supported files are PDF

Remarks *

+ Add Section

< Review & Submit | Save as Draft

Upload the documents, add the information

Click on review and submit, and verify the application again using DSC as shown earlier



How to view the application form (Legal Form)

MOH_Certi Download Digitally Signed Application

In Case the user wishes to see the Legal form they can do so by clicking on this button

Form 1

Form 2

Document

Payment

Form 1 - MD-1 Application for grant of Certificate of Registration of a Notified Body

1. Form Type

Processing Details

26 Jun 2023, 02:23PM Submitted

upload Document

You have successfully uploaded the document.

by: Muskan...

26 Jun 2023, 02:21PM Submitted

Form MD-1

1 / 1 - 80% +

The legal form can be previewed/downloaded

Form MD-1

(See sub-rule (5) of rule 13)

APPLICATION FOR ISSUE OF CERTIFICATE OF REGISTRATION OF NOTIFIED BODY

1. Name Of Applicant : -

2. Nature and Constitution of Body : Proprietorship

3. Corporate/Registered Office Address : KRISHNA NAGAR , North Delhi, Delhi, 110051 (India). -, 5756765

4. Details of accreditation :

Issued by : NABCB

Issued On : 06/01/2023

Valid Upto : 06/28/2023

5. Standard for which notified body has been accredited under rule 13 : ISO 13485

6. Payment Fees Details : Refer details in Payment Receipt.

7. Documents enclosed as specified in the Part 1 of the Third Schedule of the Medical Devices Rules, 2017, duly signed by me.

I/We undertake to comply with the provisions of the Drug and Cosmetic Act, 1940(23 of 1940) and the Medical Device Rules, 2017 and other terms and conditions for working as a Notified Body as may be specified from time to time

Place : delhi

Date : 26/06/2023

Name: Shaik Gajula

Designation: owner

Signature of designated person in India :



Checklist Activation

← Go Back

Fill Application Form

User will be presented with multiple tabs containing different checklists. Only one Checklist will be enabled for the investor to fill up, based on their Responses in the Pre Registration Form

Form CT-12 - Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or...

Form 1
Form CT-12 - Application for grant of permission to manufacture formulation of un...

2 3 4 5

Pre Registration form

Select Department *
Select

Purpose of the application: *
Select

Location for processing of application *
Select

☐ I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division. *

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FILL FORM REVIEW FORM MAKE PAYMENT

Expand All

Form CT-12 - Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or...

Form 1
Form CT-12 - Application for grant of permission to manufacture formulation of un...

2 3 4 5

Pre Registration form

Select Department *
Biological (r-DNA incl Re combinant Blood Product)

Purpose of the application: *
Clinical Trial

Location for processing of application *
CDSCO Head Quarter

Applicable HQ *
HQ - Biological (r-DNA incl Re combinant Blood Product)

☒ I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division. *

Application Details

Fill up the details on Pre registration Form. Click on the checkbox. Post this, Once the user clicks on Next Form at the bottom of the page, user will be presented with the checklist they have to fill.



Checklist Activation

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FILL FORM REVIEW FORM MAKE PAYMENT

Form CT-12 - Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or...

6 7 8 **Form 9** 10

CT12-BIO-rDNA-FFBD-Clinical Trial-Checklist

Checklist

1. Covering Letter

1. Covering Letter *

CDSO Checklist Browse File

Supported files are PDF
dummy.pdf CDSO Checklist

1 Remarks *

NA

2. Justification of Quantity

2. Justification of Quantity *

Select Document Type Browse File

Supported files are PDF

User will land on checklist enabled for them to fill up

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FILL FORM REVIEW FORM MAKE PAYMENT

Form CT-12 - Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or...

1 **Form 2** 3 4 5

CT12-ND-FFBD-Test & Analysis-Checklist

Checklist

1. Covering Letter of the firm *

Select Document Type Browse File

Supported files are PDF

1. Covering Letter of the firm - Remarks *

2. Self attested by Head of the institution proprietor or director of the company or firm (with authority letter)/Copy of manufacturing licenses in form -25/28/28D or loan license issued by SLA or DSIR approval in case of R6D.

Select Document Type Browse File

Supported files are PDF

2. Self attested by Head of the institution proprietor or director of the company or firm (with authority letter)/Copy of manufacturing licenses in form -25/28/28D or loan license issued by SLA or DSIR approval in case of R6D - Remarks *

The checklists which are disabled for the user to fill in will appear as shown here. The user do not need to fill these up in order to submit their application



What are the technical Requirements for NSWS

System Requirements for National Single Window Portal

- Windows OS (XP or higher)
- MAC OS (X 10.9 or higher with latest updates)
- **View/ Download Pdf:** Download the pdf reader to view and download the pdf files from the link: <https://get.adobe.com/reader/>
- Platform requires a minimum screen size of 976px wide , but using 1024px or higher is recommended
- **Digital Signature Certificate (DSC):** Latest version of emBridge software need to be installed in the system which acts a connecting link/driver between the NSWS and DSC

Web browsers best suited for National Single Window System

- Google Chrome
- Mozilla Firefox
- Apple Safari

Have any further questions?

Please submit your queries and feedback on:

<https://www.nsws.gov.in/contact-us>

Email: contactus-nsws@investindia.org.in

Ph: 1800 102 5841

(Monday - Saturday, 9am - 6pm)

Last Updated on 14 March 2023