

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

Notice

File No.: IT-13011(11)/1/2023-eoffice

Date: 16 JAN 2024

Subject – Launching of additional Forms on National Single Window System (NSWS) Portal- reg.

This is in continuation to this office notice dated 01.01.2024 whereby 3 Forms i.e. MD-01, MD-12 and MD-16 were made 'Live' on NSWS portal w.e.f. 01.01.2024.

Now following additional Forms have also been developed and will be made 'Live' on NSWS w.e.f. **16.01.2024:-**

1. Application for grant of permission to manufacture new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis- CT-10.
2. Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or bioavailability or bioequivalence study-CT-12.
3. 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-CT-13.
4. Application for grant of licence to import new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis -CT-16.

Further Form 12 i.e. 'Application for licence to import drugs for purpose of examination, test or analysis' will also be made 'Live' on **24.01.2024**.

In view of above, it is requested that all concerned stakeholders henceforth should submit application related to above said five activities through NSWS portal only and the existing SUGAM online portal for the said activities will be disabled w.e.f. **10.02.2024**.

The NSWS portal can be browsed through <https://www.nsws.gov.in> and a user guide is also attached herewith for guidance for ready reference.

This is for information of all concerned stakeholders.

Encl.: As above


(Dr. Rajeev Singh Raghuwanshi)
Drugs Controller General (India)

To:

1. All the concerned stakeholders
2. CDSCO Website



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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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 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**

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

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

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

Healthcare

Additional Information

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

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

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

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

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

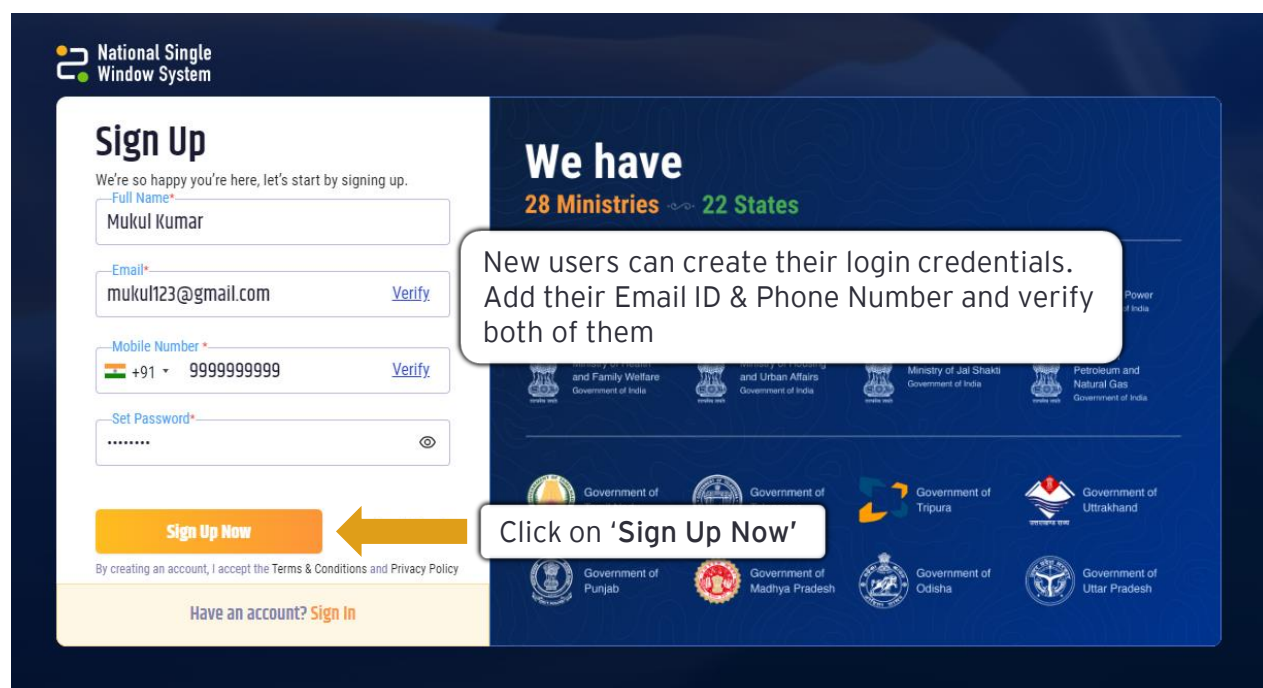
Existing users can 'Sign In' with their credentials

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

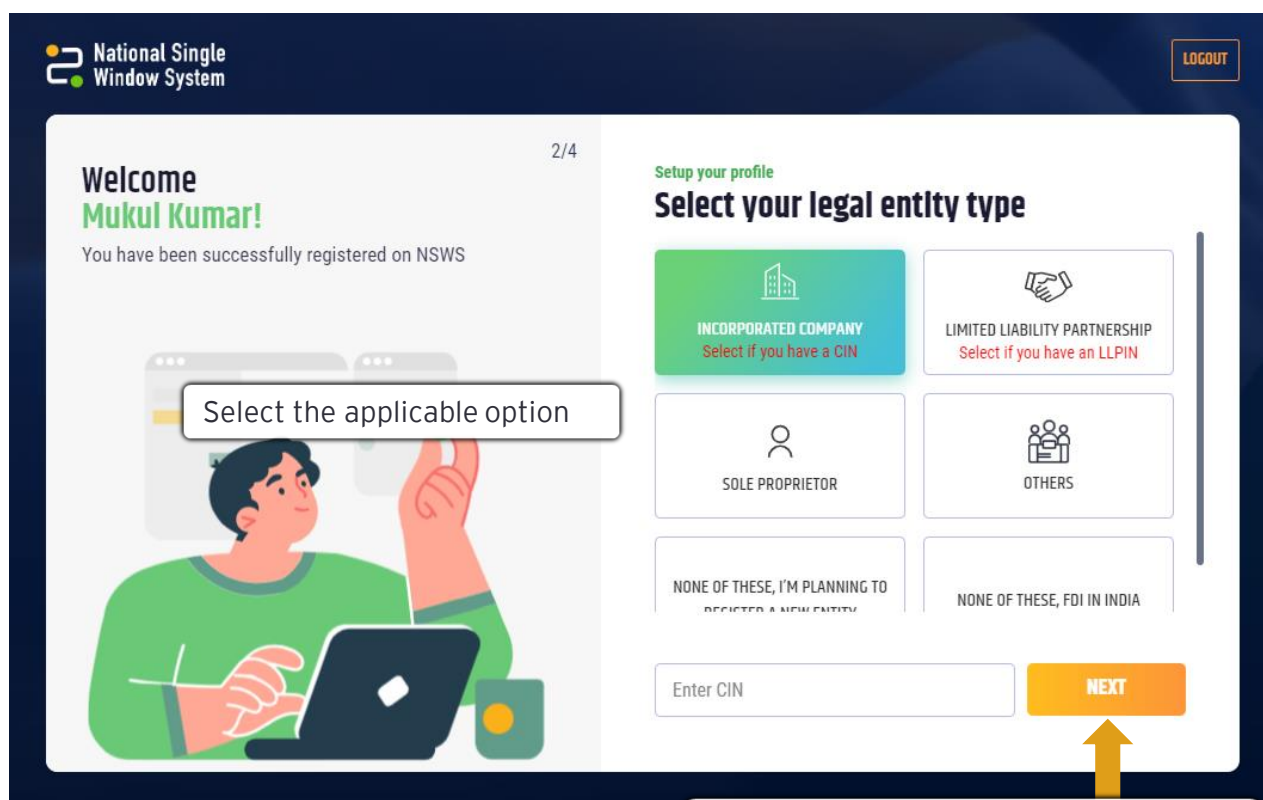
By creating an account, I accept the Terms & Conditions and Privacy Policy

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

Progress: **FILL FORM** | REVIEW FORM | MAKE PAYMENT

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

2


- 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) *

CDSCO 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 Purpose2 Depositor's Details3 Confirm Info4 Pay

Payment Made Online

Depositor's Details

Name	MUKUL KUMAR		
Address 1	DSSD	Address 2	
City	WEST DELHI	District	
State	DELHI	Country	INDIA
Pincodes/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)

← Go Back Save PDF Approval Details

MOH_Certi Download Digitally Signed Application Download Submitted Application

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

Applied on 26/06/2023 | 2:18 pm

App ID SW/MD/MD-1/2023/00000300
Directorate General of Health Services
Ministry of Health and Family Welfare

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 Name : Shaik Gajula

Date : 26/06/2023 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



**DEPARTMENT FOR PROMOTION OF
INDUSTRY AND INTERNAL TRADE**
MINISTRY OF COMMERCE & INDUSTRY,
GOVERNMENT OF INDIA

National Single Window System (NSWS)

CDSCO

Ministry User Guide



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1 About This Manual

1.1 Purpose of this Manual

The purpose of this manual is to provide guidance to the CDSCO Ministry/Department users concerning:

- ❖ Services and Functionalities provided by National Single Window System (NSWS) for approval application processing.
- ❖ Step-by-step guide on how to evaluate approvals applications received through NSWS.

1.2 Organization of This Manual

This manual has been organized into the following parts:

- ❖ Overview of NSWS
- ❖ NSWS Ministry/Department User Services

1.3 Acronyms, Abbreviations, Definitions

Term /Abbreviation	Definition / Full Form
Approval	Approvals, as used in this document, refer to any regulatory or legal clearance to be obtained from the government by any investors, entrepreneurs, businessperson, or business entity before commencing any business activity in India, including but not limited to Approvals, Registrations, Licenses, Permits, Clearances, Certifications etc.
ICC	Investment Clearance Cell
Investment Clearance Cell	Cell setup under Invest India, DPIIT, to facilitate investors. Responsible for developing and maintaining NSWS
KYA	Know Your Approval
National Single Window System (NSWS)	The digital portal serving as the national single window system under the Investment Clearance Cell

2 Introduction to NSWS

2.1 Objective of NSWS

The Hon'ble Minister of Finance, Government of India, during the budget speech on 1st February 2020, announced the setting up of an Investment Clearance Cell (ICC). The proposed ICC has been developed as an online portal, named NSWS, which will act as a National Single Window System (NSWS) for investors, entrepreneurs, and businesses.

NSWS enables investors to identify, apply, track and obtain approvals needed before starting any business operations in India. This eliminates the need for investors to visit multiple IT platforms and authorities to gather information and obtain approvals from different stakeholders.

NSWS aims to fulfill the following objective:

- ❖ Establish a single window mechanism to integrate the services provided by various central government ministries, departments, and select state governments related to starting and operating any business activity.
- ❖ Provide a single window interface for procuring approvals required to commence a business in India.
- ❖ Provide efficient, convenient, transparent, and integrated electronic services to investors.
- ❖ Provide a uniform and seamless experience to the investor through a unified interface.

2.2 Scope of NSWS

NSWS covers Central and State approvals required by any investor, both foreign or domestic, before starting any business operations or activities in India, including but not limited to registrations, licenses, permits, NOCs and approvals. It provides a platform for any investor to identify, apply track and obtain final decision on their applications. The final authority of approving or rejecting applications resides with the respective authorities.

2.3 Salient Features and Advantages of NSWS

NSWS has been designed keeping the investor at the centre, and boasts of the following features:

- ❖ Provides a single unified interface to investors to identify, apply, track and obtain approvals.
- ❖ Helps investors identify applicable approvals depending on the specific business activities being planned and other investor-specific context.
- ❖ Provides an 'Approval Repository' where the investor can select and apply for any approvals, as needed.
- ❖ Reduces the need to fill in same information at multiple places through intelligent auto-population.
- ❖ Provides ability to track status of an application and raise reminders to authorities, as per agreed process, if any.

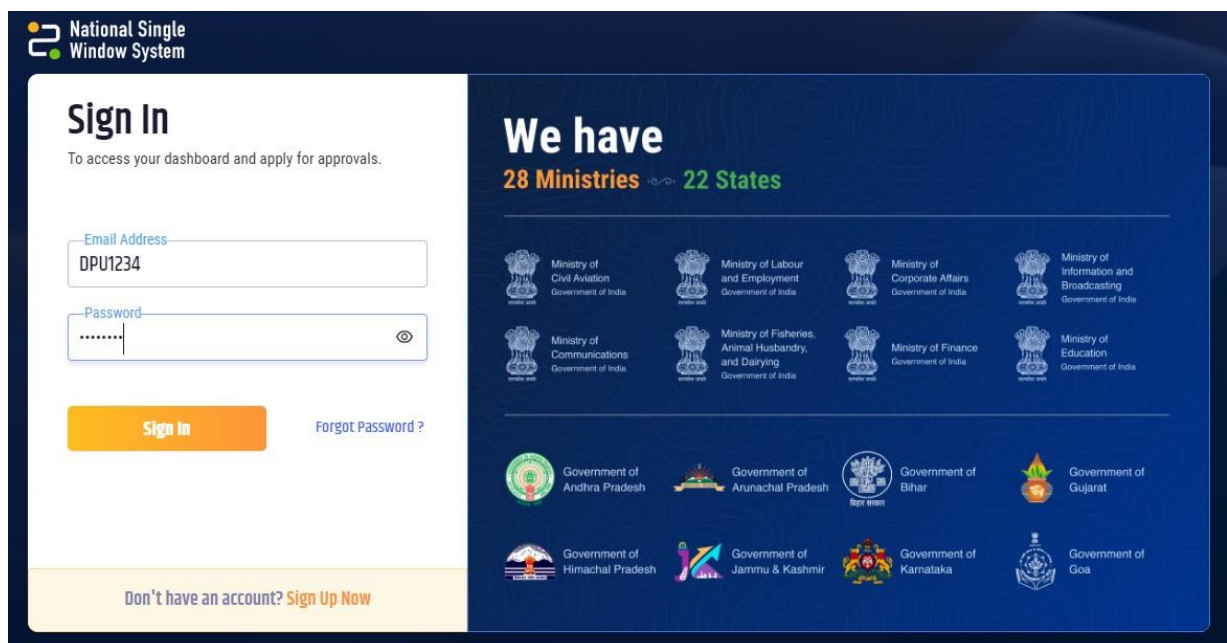
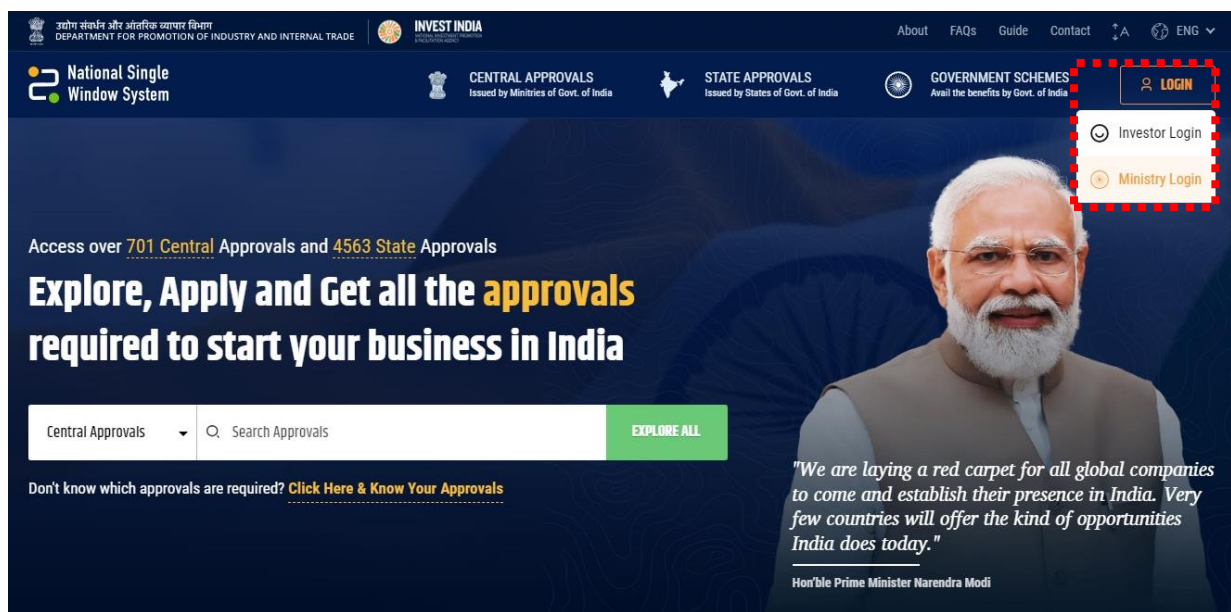
- ❖ Provides a unified document repository to where investors can upload and save their documents, and view and download documents issued to them by authorities.
- ❖ Provides an intuitive and easy to use communication module to respond to any clarifications or additional information requests raised by processing authority on submitted applications.
- ❖ Guides investor in situations where multiple forms or approvals need to be submitted in a specific sequence and timing.
- ❖ Provides a scheduler to arrange and conduct meetings online with concerned authorities, as per agreed process, if any.

3 Processing Applications on NSWS

3.1 Ministry Dashboard Overview

3.1.1 Ministry User Login

The authorised ministry officer can Login into the NSWS Ministry portal with the credentials available with them. The user can open the Ministry Login page from the Homepage of NSWS.



The Ministry Dashboard on Login: Upon logging-in the Ministry User will be redirected to the Dashboard. The Dashboard contains the count of Applications:

- ❖ **Assigned to me:** The applications that are pending for the specific logged in Ministry User to review.
- ❖ **New Application:** The fresh application that are applied by the investor and are yet to be reviewed.
- ❖ **Total Applications:** The total of the above stated Applications.

Ministry of Health and Family Welfare

Applications

Assigned to Me(1) **New Applications(5)** Total Applications(8)

Filters

New request X View All Clear All

Approval Name	App Id	Organisation Name	Date of Submission	Pending With	Application Status
FORM-12- APPLICATION TO IMPORT...	SW/BIO-BP/...	TO THE NEW PRIV...	13-06-2023	Mr. Sanj...	New Request
FORM-12- APPLICATION TO IMPORT...	SW/BIO-BP/...	pratheeksha	06-02-2023	Mr. Sanj...	New Request
FORM-12- APPLICATION TO IMPORT...	SW/BIO-BP/...	pratheeksha	03-02-2023	Mr. Sanj...	New Request
FORM-12- APPLICATION TO IMPORT...	SW/BIO-BP/...	FACEBOOK INDIA ...	01-02-2023	Mr. Sanj...	New Request
FORM-12- APPLICATION TO IMPORT...	SW/BIO-BP/...	sadasdasdad	01-02-2023	Mr. Sanj...	New Request

10/10 Page

3.1.2 Viewing Applications

Upon opening Application tab, the system shall display status for the applied licenses. A fresh application will appear on top of the “Total Application” tab, or they can be opened by clicking on the “New Application” tab which will show all the new applications submitted by the users.

To open an application for scrutinization the user should click on the name of the approval

Ministry of Health and Family Welfare

Applications

Assigned to Me(1) New Applications(5) **Total Applications(8)**

Filters

Approval Name	App Id	Organisation Name	Date of Submission	Pending With	Application Status
FORM-12- APPLICATION TO IMPORT...	SW/BIO-BP/...	TO THE NEW PRIV...	13-06-2023	Mr. Sanj...	New Request
FORM-12- APPLICATION TO IMPORT...	SW/BIO-BP/...	pratheeksha	06-02-2023	Mr. Sanj...	New Request
FORM-12- APPLICATION TO IMPORT...	SW/BIO-BP/...	pratheeksha	03-02-2023	Mr. Sanj...	New Request
FORM-12- APPLICATION TO IMPORT...	SW/BIO-BP/...	FACEBOOK INDIA ...	01-02-2023	Mr. Sanj...	New Request
FORM-12- APPLICATION TO IMPORT...	SW/BIO-BP/...	sadasdasdad	01-02-2023	Mr. Sanj...	New Request
Send to CT-13- APPLICATION FOR GRANT OF...	SW/SND/CT...	pratheeksha	23-12-2022	Mr. Sanj...	Pending
CT-10 APPLICATION FOR GRANT OF...	SW/FDC/CT...	-	25-07-2022	Dr. V. G...	Approved
CT-10 APPLICATION FOR GRANT OF...	SW/FDC/CT...	-	06-07-2022	Dr. V. G...	INPROCESS

10/10 Page

User can click on each section name to review the inputs filled by the investor

National Single Window System

Total Applications

Mr. Sanjeev Kumar

New Request

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

App ID: SW/BIO-BP/12/2023/0000011 SWS ID: SW4473066169 Applied on: 13-06-2023

Download

FORM-12-... Checklist-... Checklist-F12-... Checklist-... Document Communic... Payment Audit Log

Pre Registration Form

Applicant Address Details

Test or Analysis Site

Foreign Manufacturer details

Address Details

Product Details

BA/BE Study Details

I accept that I have reviewed the form carefully.

Take Investor Action Take Internal Action

PROCESSING STATUS

Ministry User can navigate the through a single form vertically.

National Single Window System

App ID: SW/BIO-BP/12/2023/0000011 SWS ID: SW4473066169 Applied on: 13-06-2023

FORM-12-... Checklist-... Checklist-F12-... Checklist-... Document Communic... Payment Audit Log

Pre Registration Form

Select Department Biological - Blood Products

Purpose of Application For Examination, Test or Analysis

CDSCO Applicable zone/HQ CDSCO HQ

CDSCO Applicable zone

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

Test or Analysis Site

Foreign Manufacturer details

Address Details

PROCESSING STATUS

3.1.3 Unique Application ID

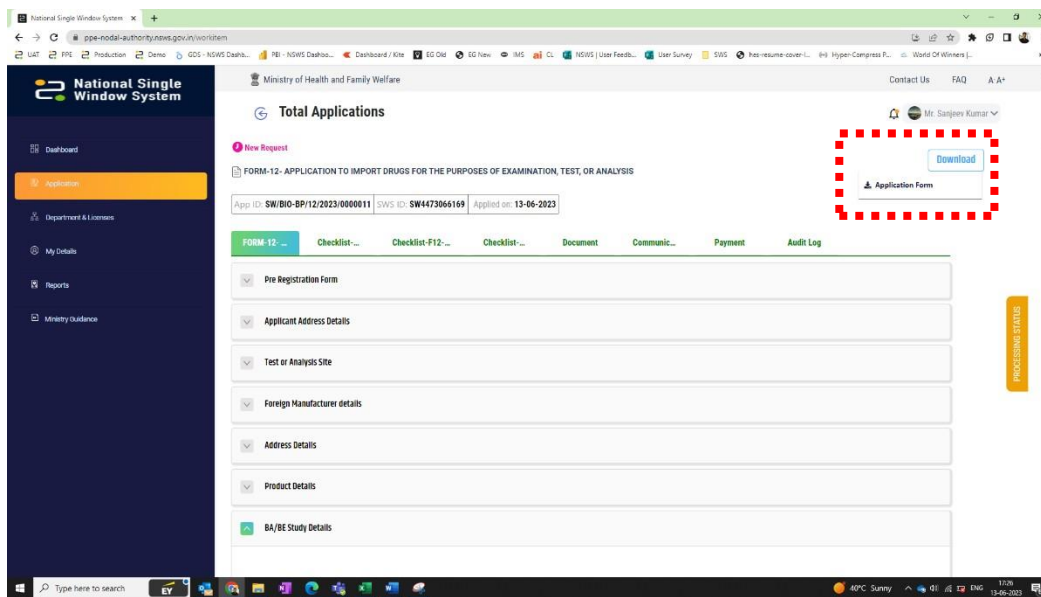
For each application there will be a Unique Application ID which will be displayed on Investor as well as the Ministry portal throughout the entire scrutinization journey.

New Request

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

App ID: SW/BIO-BP/12/2023/0000011 SWS ID: SW4473066169 Applied on: 13-06-2023

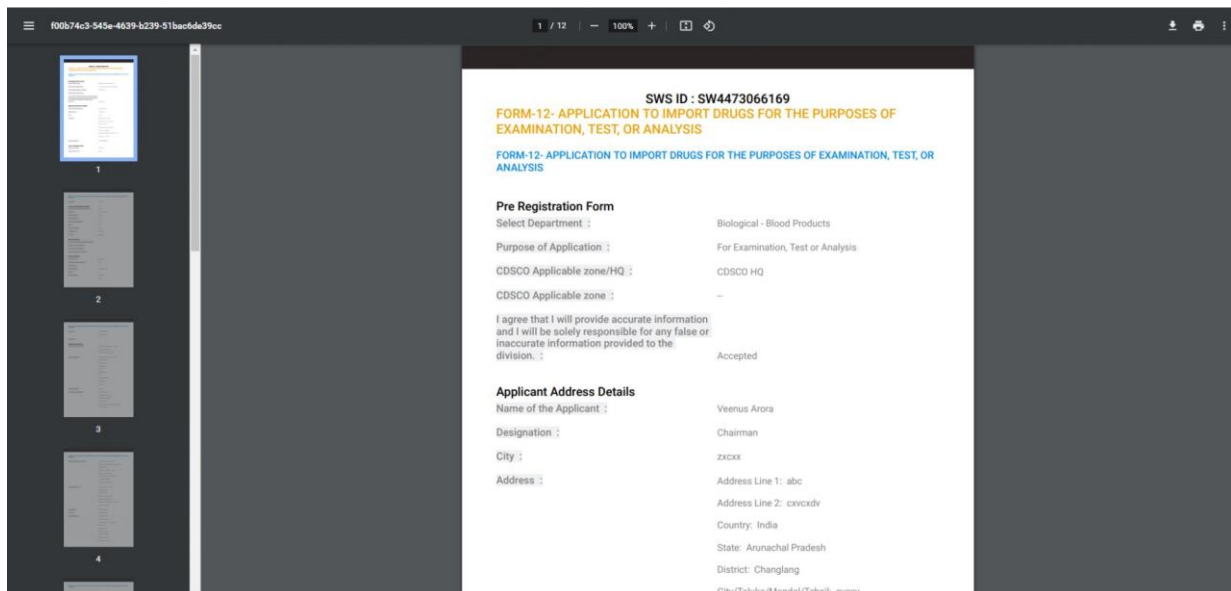
3.1.4 Download Application and Documents



An option to download the whole application submitted and the payment details is also provided to the Ministry User which will enable to easily visualize the Applicant's Input by the Ministry User. The button to preview the application is given on the top right corner as shown in the above image.

This Document will include application inputs by the investor and the Payment Receipt Details

On downloading it the application can be previewed as shown below, the same can be downloaded / printed.



3.1.5 Viewing Documents

To view the documents submitted by the Investor, the Ministry User can click on the field and click on the Attached button beside such field. The Ministry User can click on the "Attached" button on the right side of each field to download the corresponding documents.

National Single Window System

Ministry of Health and Family Welfare

Contact Us FAQ A A+

Total Applications

New Request

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

App ID: SW/BIO-BP/12/2023/0000011 SWS ID: SW4473066169 Applied on: 13-06-2023

FORM-12-... Checklist-... **Checklist-F12-...** Checklist-... Document Communic... Payment Audit Log

Checklist

1. Name of Applicant (Applicant Details)

Name of Applicant (Applicant Details) Attached

2. Drug Details

Drug Details Attached

3. Dosage Form and Composition

Dosage Form and Composition Attached

Download

PROCESSING STATUS

Upon clicking the attachment option, Ministry User will be presented with a split screen which will have two drop down lists having all the documents submitted by Investor in that particular Application in both of them. Thus, the Ministry user can view all the documents along with the option of comparing different documents.

National Single Window System

Ministry of Health and Family Welfare

Contact Us FAQ A A+

View Document

New Request

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

App ID: SW/BIO-BP/12/2023/0000011 SWS ID: SW4473066169 Applied on: 13-06-2023

Document Selected: Drug Details

Document to be Referred: Justification and Utilization breakup of the drug detail...

1 / 4


1 / 8

Download

3.1.6 Payment Status

User will be shown with the payment details of the submitted application by clicking on the Payment tab.

FORM-12- ...
Checklist-...
Checklist-F12-...
Checklist-...
Document
Communic...
Payment
Audit Log

5000 INR
Transaction ID
T1686645848691A53144L4194P19114
Transaction Date
Tue Jun 13 2023
Transaction Time
2:14:08 PM
Download Receipt



The download invoice button will download a PDF having the payment receipt as shown below

Payment Receipt

License	FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS
SWS ID	SW4473066169
Transaction ID	T1686645848691A53144L4194P19114
Payment Reference Number	T1686645848691A53144L4194P19114
Bank Reference Number	358800
CIN Number	20370013062300050333
Payment Amount	5000
Currency Code	INR
Payment Type	CREDIT CARD
Payment Status	SUCCESS
Payment Date and Time	13/06/2023 14:14:09

3.1.7 Communication

This tab will show all the Scrutiny and Query raised between the Ministry and Investor. The terms will be explained in the guide.



Dashboard
Applications
Department & Licenses
My Details
Reports
Ministry Guidance

Ministry of Health and Family Welfare
Contact Us
FAQ
A+

Total Applications
Approved
FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS
App ID: SW/BIO-BP/12/2023/0000011 | SWS ID: SW4473066169 | Applied on: 14-06-2023
Download

FORM-12- ...
Checklist-...
Checklist-F12-...
Checklist-...
Document
Communic...
Payment
Audit Log

Query History 01
Scrutiny History 01
Internal Communications
No Internal Communications made yet.

Processing Status

Privacy Policy
Terms of Use
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3.1.8 Audit Log

Audit log shows all the actions taken on the particular application taken the Ministry users and Investor

The screenshot shows the 'Audit Log' tab selected in the National Single Window System. The interface includes a sidebar with navigation options: Dashboard, Application, Department & Licenses, My Details, Reports, and Ministry Guidance. The main content area displays the application details for 'ABCD Ltd.' with fields for SWS ID, PAN, CONTACT, and EMAIL. Below this is a table with columns: Date, Action, Remark, Action Taken by, and Attachment. The table lists several actions taken on the application, including 'Investor files application', 'Send to', 'Forward', and 'verified, please review'. A 'Download' button is visible in the top right corner. A vertical orange bar on the right side of the screen indicates the 'PROCESSING STATUS'.

Date	Action	Remark	Action Taken by	Attachment
13-06-2023 14:14:08	Investor files application		Venus	-
14-06-2023 00:25:53	Send to	Sir, I have reviewed and it looks fine, sending it for your review and action	Mr. Sanjeev Kumar Gupta - Accountant	-
14-06-2023 10:54:34	Forward	File according to me. Please review	Mr. J. Suresh Kumar -Accountant	-
14-06-2023 12:04:19	Send to	Verified, please review	Mr. Sanjeev Kumar Gupta - Accountant	-
14-06-2023 12:14:21	Forward	verified, please review	Dr. Rubina Bose-Deputy Drugs Controller (India)	-

3.2 Process for Application Review

Ministry User will be provided with two tabs as shown below

The screenshot shows the 'Application Review' tab selected in the National Single Window System. The interface includes a sidebar with navigation options: Dashboard, Application, Department & Licenses, My Details, Reports, and Ministry Guidance. The main content area displays the application details for 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS'. Below this is a list of checkboxes for various details: Pre Registration Form, Applicant Address Details, Test or Analysis Site, Foreign Manufacturer details, Address Details, Product Details, and BA/BE Study Details. At the bottom, there is a checkbox for 'I accept that I have reviewed the form carefully.' and two buttons: 'Take Investor Action' and 'Take Internal Action'. A red dashed box highlights the 'Take Internal Action' button. A 'Download' button is visible in the top right corner. A vertical orange bar on the right side of the screen indicates the 'PROCESSING STATUS'.

3.2.1 Take Internal Action

A ministry user can use this option when they have to communication regarding the application within the ministry.

Click on checkbox for "I accept that I have reviewed the form carefully" and then click on "Take Internal Action"

A ministry user can perform the following Internal Actions:

3.2.1.1 Seek Info

In case the ministry user wants to ask some specific information from any other user from the workflow, the application still remains with the same officer.

3.2.1.2 Forward to next level

In case the user wants to forward application for review to his immediate superior officer.

3.2.1.3 Send to

In case a ministry user wants to assign or reassign this application to any level user in the workflow. This will transfer the application to the assignee on which they can act upon.

The screenshot shows the 'Internal Action' section with a 'Go Back' link. Below the title bar are buttons for 'Forward to Next Level', 'Seek Info', 'Send To' (highlighted), and 'Generate Draft Permission License'. A secondary row contains 'Notesheet' and 'Generate Draft Covering Letter'. The main area features a 'Select User' dropdown menu with a list of users: Mr. Sanjeev Kumar Gupta -Accountant-NO-Level:1, Mr. Sanjeev Kumar Gupta -Accountant-NO-Level:3, Mr. Sanjeev Kumar Gupta -Accountant-DDA-Level:4, Dr. Rubina Bose-Deputy Drugs Controller (India)-DA-Level:5, and Dr. Rubina Bose-Deputy Drugs Controller (India)-LA-Level:6. At the bottom, there is a note about supported file formats (PDF, JPEG, PNG, GIF) and a maximum file size of 100MB. To the right of the note are 'Attachment' and 'Send' buttons.

3.2.1.4 Pull Back and Reassign

If the application is with a particular officer and they may not be able to process it (for example a leave or any official engagement), then the higher-level user to such officer can use this function to pull back the license from such user and reassign it to another officer.

The screenshot shows the 'Internal Action' section with a 'Go Back' link. Below the title bar are buttons for 'Seek Info', 'Pull Back and Reassign' (highlighted), 'Send To', and 'Notesheet'. The main area features a 'Select User' dropdown menu with 'Mr. Sanjeev Kumar Gupta -Accountant-Level No:4-DDA' selected. Below this is a text box containing the text 'Pulling back and reassigning to D.D.A. (Deputy Deciding Authority)'. At the bottom right is a 'Reassign Request' button.

3.2.1.5 Review Checklist items

A ministry user has to review the checklist documents one by one in order to move the application to his higher-level officer. This process has to be done from Level 2 onwards till final level officer. There onwards, Each level officer has to complete this process.

User has to click on Checklist from the top vertical tab and open each item. Then click on the downward arrow beside each line item.

App ID: SW/BIO-BP/12/2023/0000011 | SWS ID: SW4473066169 | Applied on: 13-06-2023

FORM-12-... Checklist-... Checklist-F12-... Document Communic... Payment Audit Log

Checklist

- 1. Name of Applicant (Applicant Details)
 - Add Remarks
 - Name of Applicant (Applicant Details) Attached Pending
- 2. Drug Details
 - Drug Details Attached Pending
- 3. Dosage Form and Composition
 - Dosage Form and Composition Attached Pending
- 4. Upload Duly Signed Application in Form-12
- 5. Challan of Fees Paid
- 6. Justification and Utilization breakup of t...

PROCESSING STATUS

User can either raise query on the document which will be communicated to the investor, or they can provide their confirmation.

1. Name of Applicant (Applicant Details)

Name of Applicant (Applicant Details) Attached Pending

Veenus

Remarks

No remarks found

Mr. J. Suresh Kumar (Ministry)

Correct

Cancel Raise Query Document OK

3.2.1.6 Generate Notesheet

Once completed with the review of all items in the checklist, user has to generate Notesheet from the showed option in order to move forward with the application

National Single Window System

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

App ID: SW/BIO-BP/12/2023/0000011 | SWS ID: SW4473066169 | Applied on: 13-06-2023

Download

FORM-12-... Checklist-... Checklist-F12-... Checklist-... Document Communic... Payment Audit Log

Checklist

- 1. Name of Applicant (Applicant Details)
- 2. Drug Details
- 3. Dosage Form and Composition
- 4. Upload Duly Signed Application in Form-12
- 5. Challan of Fees Paid
- 6. Justification and Utilization breakup of t...
- Additional Documents

Review & Generate Notesheet

PROCESSING STATUS

Provide confirmation through the comments and Generate Notesheet

National Single Window System

Ministry of Health and Family Welfare

Assigned To Me

Pending

Item	Status	Action
5. Challan of Fees Paid	ok	Document OK
6. Justification and utilization breakup of the drug detailing the test parameters vis-a-vis quantities of the drugs, batch manufacturing plan	ok	Document OK

Reviewing Officer Comments

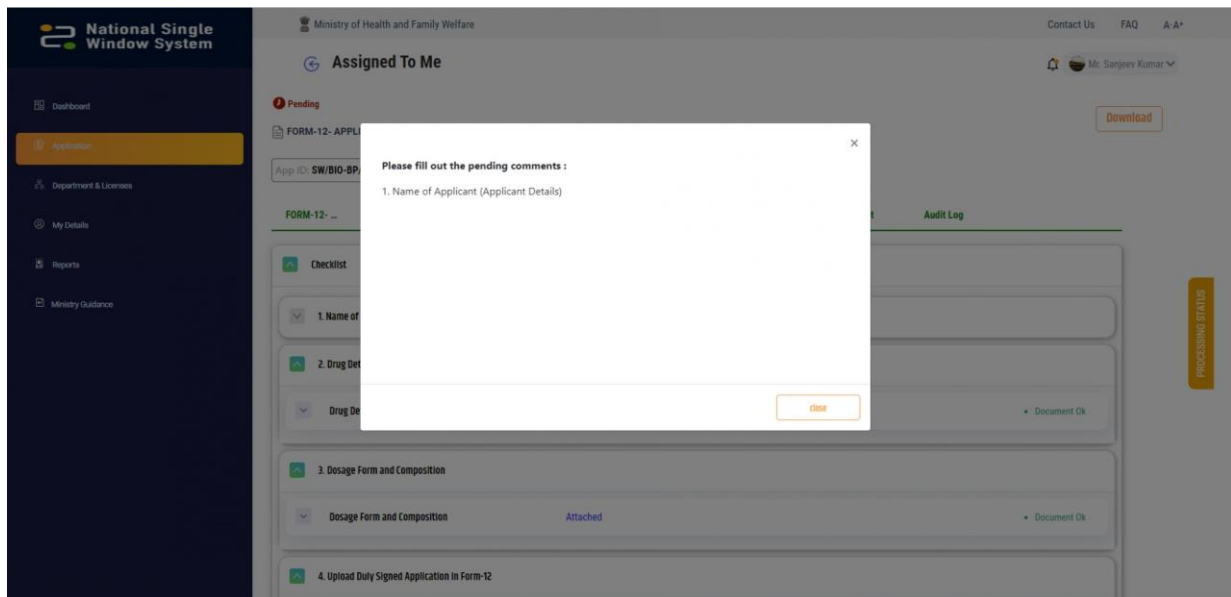
Checked and verified

Note: Maximum 2000 characters are allowed for remarks.1

Cancel Generate Notesheet

A Ministry user has to complete “Review Checklist Items” and “Generate Notesheet” action as shown in 3.2.1.5 and 3.2.1.6, respectively, to forward the application

In case the user has missed a checklist item to verify, the system will communicate the same by showing this screen



3.2.1.7 Send Back

In case the ministry user wants to send it back to the last user for reviewing it again

Internal Action

Go Back ✕

Forward to Next Level

Seek Info

Send Back

Send To

Generate Draft Permission License

Notesheet

Generate Draft Covering Letter

Dr. Rubina Bose-Deputy Drugs Controller (India)

Please review the address details section for site again.

Note Maximum 2000 characters are allowed for remarks.

Send ↗

3.2.1.8 View Notesheet

Internal Action

Go Back ✕

Seek Info

Send Back

Approve Application

Reject Application

Send To

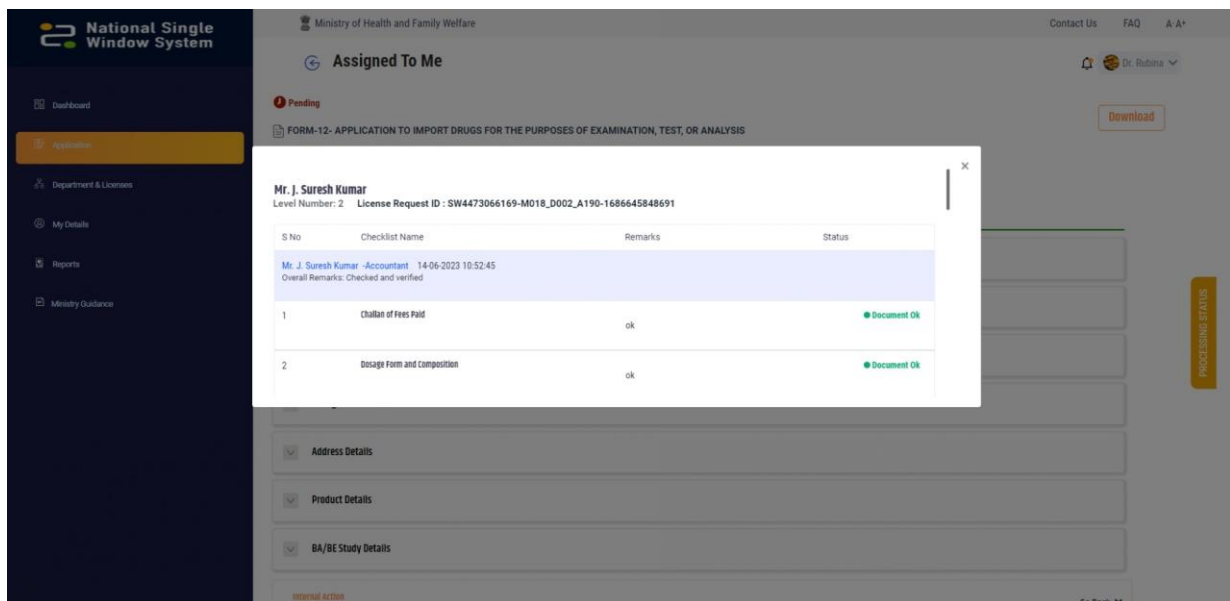
Generate Permission/License

Notesheet

Generate Covering Letter

View NoteSheet

Notesheet captures actions taken by ministry users on checklist documents



3.2.1.9 Draft Permission License

- ❖ Ministry user can generate draft license using this option. User can click on the button and update or edit the required details.

- ❖ Click on Generate “Draft Permission License” as shown

National Single Window System

- Dashboard
- Application**
- Department & Licenses
- My Details
- Reports
- Ministry Guidance

INTERNAL ACTION

[Seek Info](#)
[Send Back](#)
[Send To](#)
[Generate Draft Permission License](#)

[Notesheet](#)
[Generate Draft Covering Letter](#)

[Go Back](#) ✕

Generate Draft Permission License

Registration/Number

draft

Designation

Chairman

Applicant address 2

cxvcxv

Applicant State

Arunachal Pradesh

Applicant City

cxvcxv

Name of the Foreign Manufacturer

cxvcxv

Address Line 2

Name of the Applicant

Veenus Arora

Applicant address 1

abc

Applicant Country

India

Applicant District

Changlang

Applicant Pincode

111222

Address Line 1

cxvcx

State/Province/Region

- ❖ Click on “Generate Certificate” on bottom of the page

Zip/Postal code

cxvxc

Fax No

344555

Address

xcvcx

Landline No

1222222

Name of the site

cxvcx

Select Department

Biological - Blood Products

Product Details

Name of Drug/Formulation	Brand Name	Class	Quantity	Unit
vbvb		Analgesic Drugs	34353	Aerosol

Cancel

Generate Certificate

- ❖ The Draft License will be generated

National Single Window System

Address Line 2: State/Province/Region:

City: Foreign Manufacturer Country:

Form 11
[See Rule 33]
LICENCE TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST OR ANALYSIS

Number of Licence: **draft**

1. Veerus Arora (Chairman), of abc, cvxcv, India, Arunachal Pradesh, Changlang, cvcxv-111222 is hereby licensed to import from cvcxv, cvxcv, xcv, xcvcx, xcv, American Samoa -cvcxc, 1222222-344555 the drugs specified below for the purposes of examination, test or analysis at cvxcv, xcvcx or in such other places as the licensing authority may from time to time authorize.

2. This licence is subject to the conditions prescribed in the Rules under the Drugs and Cosmetics Act, 1940.

3. This licence shall, unless previously suspended or revoked, be in force for a period of three year from the date specified below:

S N O	Name of drugs	Brand Name	Class Drug	Quantity which may be imported

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3.2.1.10 Generate Draft Covering Letter

Ministry User can generate Draft Covering Letter using this option. Click on the buttons shown and add remarks.

National Single Window System

Dashboard Application Department & Licenses My Details Reports Ministry Guidance

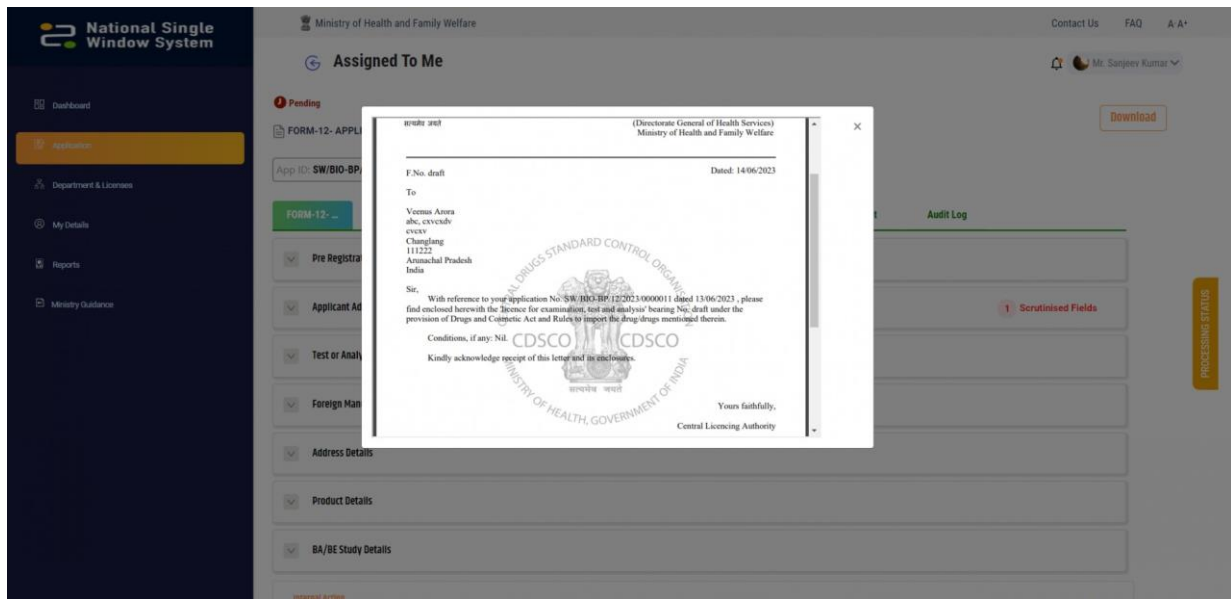
Address Details Product Details BA/BE Study Details

Internal Action:

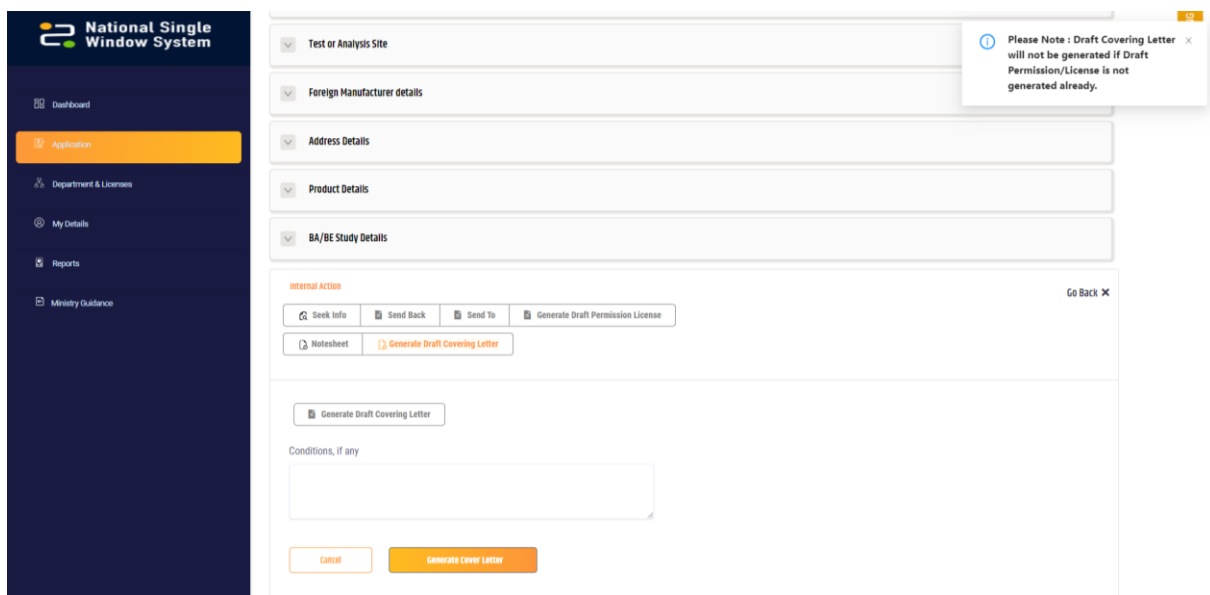
Conditions, if any

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The document will be generated



Condition: In case the user wants to “Generate Draft Covering Letter” , the ministry user has to first generate the “Draft Permission License” first. Otherwise, user will be provided with such a message



3.2.1.11 Approve Application

In case final level Ministry User finds the Application correct they would provide Final Approval using this option attaching the License Certificate.

User has to first generate the “Generate Permission/License” for such Approval

Internal Action Go Back ✕

[Seek Info](#)
[Send Back](#)
[Approve Application](#)
[Reject Application](#)

[Send To](#)
[Notesheet](#)
[Generate Covering Letter](#)

[License Certificate.pdf](#)

[B](#)
[I](#)
[U](#)

Approving the license

Note Maximum 2000 characters are allowed for remarks.

[Approve Application](#)

3.2.1.12 Reject Application

In case the ministry user is the final approver they would provide Final Rejection using the “Reject Application” option.

National Single Window System

[Dashboard](#)
[Application](#)
[Department & Licenses](#)
[My Details](#)
[Reports](#)
[Ministry Guidance](#)

☒ Test or Analysis Site
 ☒ Foreign Manufacturer details
 ☒ Address Details
 ☒ Product Details
 ☒ BA/BE Study Details

Internal Action Go Back ✕

[Seek Info](#)
[Send Back](#)
[Approve Application](#)
[Reject Application](#)

[Send To](#)
[Generate Permission/License](#)
[Notesheet](#)
[Generate Covering Letter](#)

[B](#)
[I](#)
[U](#)

Your application does not fit our final criteria, Rejecting the application

Note Supported files - PDF, JPEG, PNG, GIF.
Maximum file size should be up to 100MB
Maximum 2000 characters are allowed for remarks.

[Attachment](#)
[Reject Application](#)

3.2.1.13 Generate Permission/License

- ❖ Ministry user can generate final license using this option. User can click on the button and update or edit the required details.

National Single Window System

- Dashboard
- Application**
- Department & Licenses
- My Details
- Reports
- Ministry Guidance

Internal Action

[Seek Info](#)
[Send Back](#)
[Approve Application](#)
[Reject Application](#)

[Send To](#)
[Generate Permission/License](#)
[Notesheet](#)
[Generate Covering Letter](#)

[Generate Draft Permission License](#)
[Generate Final Permission License](#)

RegistrationNumber

SW/BIO-BP/11/2023/000002

Name of the Applicant

Venus Arora

Designation

Chairman

Applicant address 1

abc

Applicant address 2

cxvcdv

Applicant Country

India

Applicant State

Arunachal Pradesh

Applicant District

Changlang

Applicant City

cxvxy

Applicant Pincode

111222

Name of the Foreign Manufacturer

cxvxy

Address Line 1

cxvxc

Address Line 2

xcv

State/Province/Region

xcvxc

❖ Click on “Generate Final Permission License” as shown

National Single Window System

- Dashboard
- Application**
- Department & Licenses
- My Details
- Reports
- Ministry Guidance

Internal Action

[Seek Info](#)
[Send Back](#)
[Approve Application](#)
[Reject Application](#)

[Send To](#)
[Generate Permission/License](#)
[Notesheet](#)
[Generate Covering Letter](#)

[Generate Draft Permission License](#)
[Generate Final Permission License](#)

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Arunachal Pradesh

Applicant District

Changlang

Applicant City

cxvxy

Applicant Pincode

111222

Name of the Foreign Manufacturer

cxvxy

Address Line 1

cxvxc

Address Line 2

xcv

State/Province/Region

xcvxc

City

Foreign Manufacturer Country

❖ Click on “Generate Certificate” on bottom of the page

City xcv	Foriegn Manufacturer Country American Samoa
Zip/Postal code cxvxc	Landline No 1222222
Fax No 344555	Name of the site cxvcx
Address xcvcx	Select Department Biological - Blood Products

Product Details				
Name of Drug/Formulation	Brand Name	Class	Quantity	Unit
vbvb		Analgesic Drugs	34353	Aerosol

[Cancel](#)
[Generate Final Permission License](#)

❖ The Final License will be generated

Form 11
[See Rule 33]
LICENCE TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST OR ANALYSIS

Number of Licence: **SW/BIO-BP/11/2023/000002**

I, Veenus Arora (Chairman), of abc, cxvxc, India, Arunachal Pradesh, Changlang, cxvxc-111222 is hereby licensed to import from cxvxc, cxvxc, xcv, cxvxc, xcv, American Samoa -cxvxc, 1222222, 344555 the drugs specified below for the purposes of examination, test or analysis at cxvxc, cxvxc or in such other places as the licensing authority may from time to time authorize.


2. This licence is subject to the conditions prescribed in the Rules under the Drugs and Cosmetics Act, 1940.

3. This licence shall, unless previously suspended or revoked, be in force for a period of three year from the date specified below:

S	Name of drugs	Brand Name	Class of Drug	Quantity which may be imported
N				
O				
.				

3.2.1.14 Generate Covering Letter

Ministry User can generate Final Covering Letter using this option.



[Dashboard](#)
[Application](#)
[Department & Licenses](#)
[My Details](#)
[Reports](#)
[Ministry Guidance](#)

Applicant Address Details

1 Scrutinised Fields

Test or Analysis Site

Foreign Manufacturer details

Address Details

Product Details

BA/BE Study Details

Internal Action

Go Back ✕

Seek Info

Send Back

Approve Application

Reject Application


Send To

Notesheet

Generate Covering Letter

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[Terms of Use](#)
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Click on the buttons shown and add remarks.



[Dashboard](#)
[Application](#)
[Department & Licenses](#)
[My Details](#)
[Reports](#)
[Ministry Guidance](#)

Foreign Manufacturer details

Address Details

Product Details

BA/BE Study Details

Internal Action

Go Back ✕

Seek Info

Send Back

Approve Application

Reject Application

Send To

Notesheet

Generate Covering Letter

Generate Draft Covering Letter

Generate Final Covering Letter

Conditions, if any

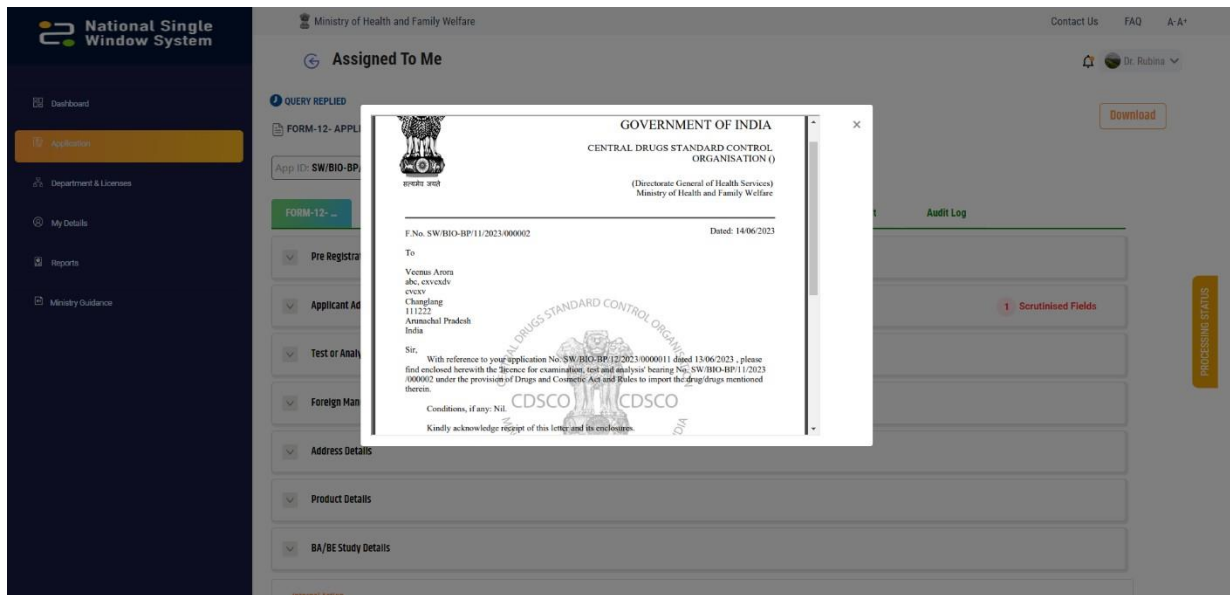
Nill

Cancel

Generate Final Covering Letter

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[Terms of Use](#)
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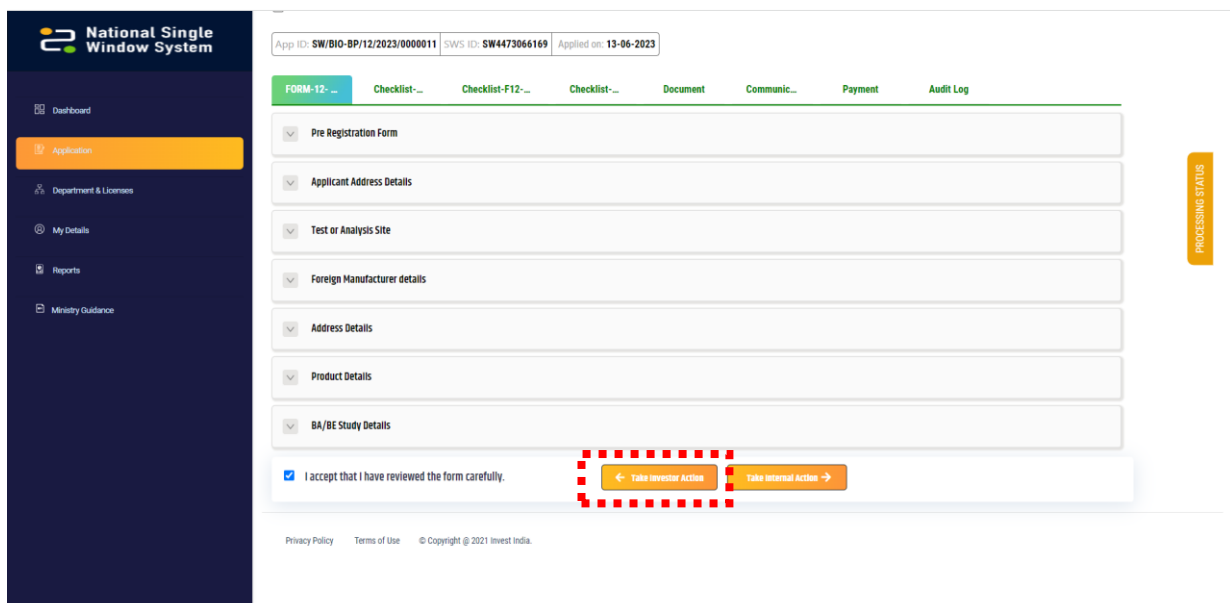
The document will be generated



Condition: In case the user wants to “Generate Covering Letter” , the ministry user has to first generate the “Permission License” first.

3.2.2 Take Investor Action

In order to have communication with the investor, user needs to click on “Take Investor Action”



User will be provided with two options.

3.2.2.1 Scrutinize Individual Fields

Scrutiny process is a functionality added by NSWS in the Mistry User's Dashboard which is used as an intimation sent by Ministry to the Investor in cases where the Ministry thinks that Investor has given incorrect information in any field(s). Consequently, the Investor will be given an option to re-fill those fields and Resubmit the Application. Note: User will have to generate Notesheet before performing such scrutiny.

Process for the same is captured below:

- ❖ Click on "Scrutinise individual fields".

- ❖ Click on the arrow for the desired section

National Single Window System

Dashboard Application Department & Licenses My Details Reports Ministry Guidance

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

App ID: SW/BIO-BP/12/2023/0000011 SWS ID: SW4473066169 Applied on: 13-06-2023

FORM-12-... Checklist-... Checklist-F12-... Checklist-... Document Communic... Payment Audit Log

Pre Registration Form

Applicant Address Details

Select All

Name of the Applicant: Venus Arora

Designation: Chairman

City: ZKCK

Address: Address Line 1: abc Address Line 2: cxcvdr

Download

PROCESSING STATUS

- ❖ Click on the Circle against the field(s) where action is required and add the required remarks and click on “Save”

National Single Window System

Dashboard Application Department & Licenses My Details Reports Ministry Guidance

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

App ID: SW/BIO-BP/12/2023/0000011 SWS ID: SW4473066169 Applied on: 13-06-2023

FORM-12-... Checklist-... Checklist-F12-... Checklist-... Document Communic... Payment Audit Log

Pre Registration Form

Applicant Address Details

Select All

Name of the Applicant: Venus Arora

Please provide the full name of the applicant with proper salutation

Cancel Save

Designation: Chairman

City: ZKCK

Address: Address Line 1: abc

Download

PROCESSING STATUS

- ❖ Finally click on “Submit Scrutiny” tab provided at the end of the page.

App ID: SW/BIO-BP/12/2023/0000011 | SWS ID: SW44/3066169 | Applied on: 13-06-2023

FORM-12: ... Checklist-... Checklist-F12-... Checklist-... Document Communic... Payment Audit Log

☒ Pre Registration Form

☒ Applicant Address Details

Select All ☐

Name of the Applicant: Venus Arora ☒

Please provide the full name of the applicant with proper salutation

Cancel Save

Designation: Chairman ☐

City: ZKCXX ☐

Address: abc ☐

Address Line 1: ☐

Address Line 2: ☐

Add Generic Remarks Submit Scrutiny

PROCESSING STATUS

- ❖ Ministry User can also add some remarks in case they want to explain the issue more clearly.

Reopen Form for Scrutiny

Add Generic Remarks

Type your remarks here

Note: Maximum 2000 characters are allowed for remarks.

Save Remark

- ❖ The new input of the field will be visible on Ministry End once the investor will correct it and resubmit the Application.

Note: After the Investor resolves such query raised by Ministry user of any level, the application will automatically be assigned to the Reviewing Officer (Level 2).

3.2.2.2 Request Additional Information

- ❖ In case the Ministry User want some general clarifications from the investor they can use this option.
- ❖ Ministry User has to click on “Request Additional Information” button. Add the required remarks and send the request.

National Single Window System

Dashboard Application Department & Licenses My Details Reports Ministry Guidance

FORM-12-... Checklist-... Checklist-F12-... Checklist-... Document Communic... Payment Audit Log

Pre Registration Form

Applicant Address Details 1 Scrutinised Fields

Test or Analysis Site

Foreign Manufacturer details

Address Details

Product Details

BA/BE Study Details

Investor Action

Scrutinise Individual Fields Request Additional Information Go Back

Please let us know the Pincode of your "Test or Analysis Site"

Note: Maximum 2000 characters are allowed for remarks.

Attach File Send Request

PROCESSING STATUS

❖ Once the investor replies on it, the same will appear on the communication tab as shown below

National Single Window System

Dashboard Application Department & Licenses My Details Reports Ministry Guidance

Ministry of Health and Family Welfare Contact Us FAQ A A+

Assigned To Me Dr. Rubina

QUERY REPLIED

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

App ID: SW/BIO-BP/12/2023/0000011 SWS ID: SW4473066169 Applied on: 14-06-2023

FORM-12-... Checklist-... Checklist-F12-... Checklist-... Document Communic... Payment Audit Log

Query History 01

Responses	Value/Attachment
<p>Dr. Rubina Bose 14 June, 2023 12:29 PM (Auto)</p> <p>Please let us know the Pincode of your "Test or Analysis Site"</p>	
<p>Veenus 14 June, 2023 12:31 PM</p> <p>Greetings, The Pincode is 110034.</p>	

Scrutiny History 01

Internal Communications

☐ I accept that I have reviewed the form carefully.

Take Investor Action Take Internal Action

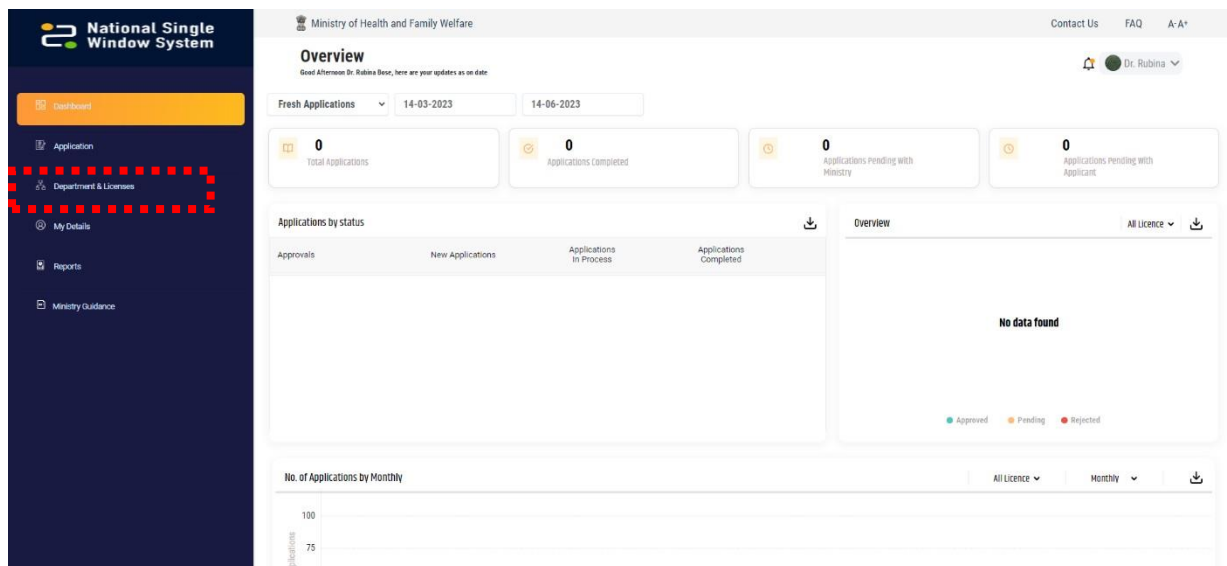
PROCESSING STATUS

3.3 Ministry Users and Actions they can perform

Level	Officer	Actions they can perform
1	N.O. (Nodal Officer)	<ul style="list-style-type: none"> • Seek Info • Pull Back and Reassign • Send To
2	R.O (Reviewing Officer)	<ul style="list-style-type: none"> • Notesheet Generation • Forward to next level • Send To, Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License
3	N.O. (Nodal Officer)	<ul style="list-style-type: none"> • Send To • Send Back • Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License • Notesheet
4	D.D.A. (Deputy Deciding Authority)	<ul style="list-style-type: none"> • Send To • Send Back • Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License • Notesheet
5	D.A. (Deciding Authority)	<ul style="list-style-type: none"> • Send To • Send Back • Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License • Notesheet
6	L.A. (Licensing Authority)	<ul style="list-style-type: none"> • Send To • Send Back • Seek Info • Generate Draft Covering Letter • Notesheet • Approve • Reject • Generate Final Permission Letter • Generate Final Covering Letter

4 Approval and Form Linking

Ministry User can also use the Ministry Dashboard for knowing the status of their Approvals for KYA and Form Linking. Ministry User upon login to the Ministry Dashboard should select the “Department and Licenses” tab.



The page will show the list of Approvals under CDSCO. The table will show status of each approval for their KYA and Form Alignment.

The screenshot shows the Ministry of Health and Family Welfare dashboard, specifically the 'Department and Licenses' section for the Directorate General of Health Services (62). The table lists various approvals and their status regarding KYA alignment and form upload.

Approval/Registration	KYA Aligned	Form Uploaded
CDSCO Checklists: Bulk Drug - Endorse	Yes	Yes
CDSCO Checklists: Bulk Drug - Fresh Applications	Yes	Yes
CDSCO Checklists: Fresh Formulation - Endorse	Yes	Yes
CDSCO Checklists: Fresh Formulation - Fresh Applications	Yes	Yes
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	Yes	Yes
CT-16 Application for grant of license to import new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study	Yes	Yes
Form 8 (See rule 24A) Application for License to Import Drugs(Excluding those specified in schedule X) to the Drugs and Cosmetics rules, 1945	Yes	Yes
Form CT-10 Application for grant of permission to manufacture new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis	Yes	Yes
Form CT-12 - Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or bioavailability or bioequivalence study	Yes	Yes

To know which forms are linked to an Approval the User should click on the Approval name (If the Form Uploaded Status is given as Yes). Clicking on the form name will open it in “Preview Mode”.

5 NSWS Support Center

NSWS has set-up a dedicated team for catering to the queries by Ministry personnel. NSWS also answers the queries of the users through the FAQs provided on the Help Page.

The SPOC (Single Point of Contact) from NSWS for CDSCO are

Mr. Agni Jasthi <ganesh.agni@investindia.org.in>

Mr. Vaibhav Yadav <vaibhavyadav@investindia.org.in>

Ministry users can directly coordinate with the SPOC for clarification of their queries.

If the Ministry wants to change anything on their Ministry Portals then they can contact the Invest India SPOC for the same.

--- END OF GUIDE ---