

**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 Raghuvanshi)
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
INDIA'S GROWTH PARTNER

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National Single Window System

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STATE APPROVALS
Issued by States of Gov. of India

GOVERNMENT SCHEMES
 Avail the benefits by Gov. of India

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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GOVERNMENT SCHEMES
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LOGIN

58 Approvals

Filter by: Directorate General of Health Services General

Ministries

- Industry (143)
- Ministry of Communications (47)
- Ministry of Consumer Affairs, Food and Public Distribution (24)
- Ministry of Corporate Affairs (6)
- Ministry of Culture (8)
- Ministry of Defence (1)
- Ministry of Education (3)
- Ministry of Environment, Forest and Climate Change (18)
- Ministry of Finance (35)

Departments

- Department of Water Resources (3)
- Directorate General of Health Services (50)
- DPI (10)
- Ministry of Civil Aviation (10)

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

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
DEVICES FOR THE

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

Ministry of Health and Family Welfare

Ministry of Health and Family Welfare

Ministry of Health and Family Welfare

Click on "Add to Dashboard"

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



How to view, add approval through Central KYA

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DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE

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National Single Window System

CENTRAL APPROVALS
Issued by Ministries of Govt. of India

STATE APPROVALS
Issued by States of Govt. of India

GOVERNMENT SCHEMES
Avail the benefits by Govt. of India

LOGIN

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 the list of Approvals and Registrations that may be required for Your business. This list does not constitute a legal opinion or any other form of professional advice. We recommend you to undertake your own independent analysis and your application falls under the respective Ministry/ Department's jurisdiction.

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



How to view, add approval through Central KYA

Click on 'Business Activity Details'

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

Click here to read more information

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

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.

My Approvals(4)

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

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

Buttons: Add to Dashboard, Know State Approvals, Save PDF

Users will be redirected to the 'Sign In' Page

Sign In
To access your dashboard and apply for approvals.

Email Address

Password

Sign In

Existing users can 'Sign In' with their credentials

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 Madhya Pradesh

Government of Maharashtra

Government of Odisha

Government of Punjab

Government of Rajasthan

Government of Tamil Nadu

Government of Uttar Pradesh

Government of West Bengal

Government of Jammu and Kashmir

Government of Ladakh

Government of Chandigarh

Government of Delhi

Government of Puducherry

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 and 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

Setup your profile

Select your legal entity type

Select the applicable option

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 My Documents Members Profile

Add the details in the Profile section

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
MHL_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

Click on 'Apply Now' to proceed with the Application

← GO Back

Fill Application Form

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

FILL FORM REVIEW FORM MAKE PAYMENT

Click here to expand all section at once

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

Click on the downward arrow against the section names to expand and fill the form

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

Navigate through different forms for the approval from here



How to fill the application form

National Single Window System | **CENTRAL APPROVALS** Issued by Ministries of Govt. of India | **STATE APPROVALS** Issued by States of Govt. of India | **GOVERNMENT SCHEMES** Avail the benefits by Govt. of India | **MY DASHBOARD**

Pre Registration Form

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

Biological - Blood Products

COSCO 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. *

Applicant Address Details

Name of the Applicant: * **←** Some Data will be pre-populated as filled up in the profile

Mukul

City *

Product Details

For each strength make new section application

Type of Drug * Bulk Drug Finished Formulation

Name of Drug/Formulation *

Class of Drug *

Quantity

Quantity

Unit *

← This button will create a duplicate section for the selected section

+ Add 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 *

+ 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 *

Address Line 1 *

Address Line 2 *

State/Province/Region *

City *

Zip/Postal code *

Fax No *

Landline No *

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

Please Include Country Code - State Code - Landline Number



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	The anticipated prorated payment, if any, to the Subject for participation
<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
<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 ⓘ	
<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) *

← 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 *

→ 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

The screenshot shows the 'National Single Window System' interface. At the top, there are navigation tabs for 'CENTRAL APPROVALS', 'STATE APPROVALS', and 'GOVERNMENT SCHEMES'. The main content area contains a text box with the following text: "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". Below this is a 'Browse File' button and a list of supported files (PDF) including 'dummy.pdf'. A 'Remarks' field contains the text 'Document'. A section titled '10. Performance evaluation report from a laboratory designated under sub-rule (1) of rule 19' follows, with another 'Browse File' button and a 'Remarks' field containing 'Uploaded'. At the bottom, there is a 'Review & Submit' button. A yellow arrow points to this button with the text: "Once filled, click on Review and Submit".

The screenshot shows the 'National Single Window System' interface for 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS'. The progress bar at the top indicates 'FILL FORM' is complete, 'REVIEW FORM' is in progress, and 'MAKE PAYMENT' is pending. The 'Part A' section shows 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, ...' with a page number '2'. An 'Application Fee' of ₹5,000 is displayed. The 'Pre Registration Form' includes fields for 'Select Department' (Biological - Blood Products), 'Purpose of Application' (For Examination, Test or Analysis), and 'CDSCO Applicable zone/HQ' (CDSCO HQ). A declaration is provided: "I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division." Below this is the 'Applicant Address Details' section. A yellow arrow points to the 'Application Fee' with the text: "Applicable fee will be visible here". At the bottom, there is a confirmation statement: "I have reviewed all the information provided by me and confirm that it is correct to the best of my knowledge." and two buttons: 'Pay & Submit' and 'Back to edit details'. A yellow arrow points to the 'Pay & Submit' button with the text: "Review the application and click here for final submission".



How to fill the application form

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

Pay the amount using the Bharatkosh portal

Non-Tax Receipt Portal

Payment Purpose Depositor's Details Confirm Info Pay

Payment Mode Online

Depositor's Details

Name	HOPSE, KUMAR		
Address 1	0550	Address 2	
City	WEST DELHI	District	
State	DELHI	Country	INDIA
Pincode/Zipcode	110003	Email	mkul642317@gmail.com
Mobile No. (+91)	7042977139		
TAN		TIN	

Purpose Details

Sr. No.	Sl-Entry	PNO Name	DDO Name	Purpose and Payment Type	Payment Period / Frequency	Amount (₹- INR)
1	HEALTH and FAMILY WELFARE	DCO(DHHS), New Delhi(20244)	Section Officer, CENCO (HQ), New Delhi(202700)	Import and Registration	One Time	9000
						Total: 9000

← 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

Document for sign: MOH_Certificate for Registration

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

Provider: Microsoft Windows Store

Certificate: Class 3 Individual Test

Token Password: ****

Sign & Submit

Fill Application 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	msuskan9675@gmail.com

Done

This screen confirms the submission of application



How to fill the application form

The screenshot shows the 'My Dashboard' interface. At the top, there are navigation tabs: 'My Dashboard', 'My Documents', 'Members', and 'Profile'. Below this, a summary section shows '1 My Central Approvals' and '0 My State Approvals'. A section titled 'Central Approvals in List (1 approvals)' contains a table with columns: Approval Name, Applied on, Last Submitted By, Assigned to, Application Status, Application fees, and Action. One approval is listed with status 'Submitted' and a fee of ₹ 25000. A callout box points to the 'Application Status' column with the text: 'Once submitted, user can track the 'Application Status' from here'. Another callout box points to the 'upload doc' button in the 'Action' column with the text: 'In case the user wants to submit any additional document. They can click here'.

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

The screenshot shows the '5. Additional Documents' form. It includes a 'Document Type' dropdown menu with the selected option '1.2 Organization profile of notified body including organogram, busin...'. Below this is an 'Upload document' section with a file type dropdown set to 'Other' and a 'Browse File' button. A note states 'Supported files are PDF'. There is also a 'Remarks' text area and an '+ Add Section' button. At the bottom, there are three buttons: a back arrow, 'Review & Submit', and 'Save as Draft'. A callout box points to the 'Browse File' button with the text: 'Upload the documents, add the information'. Another callout box points to the 'Review & Submit' button with the text: 'Click on review and submit, and verify the application again using DSC as shown earlier'.

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

How to view the application form (Legal Form)

The screenshot shows the user interface of the National Single Window System. At the top, there are navigation links for 'About', 'FAQs', 'Guide', and 'Contact', along with a language selector set to 'ENG'. Below this, there are sections for 'National Single Window System', 'CENTRAL APPROVALS', 'STATE APPROVALS', and 'GOVERNMENT SCHEMES'. A 'MY DASHBOARD' button is visible on the right. The main content area displays application details for 'MOH_Certi' with a status of 'Submitted'. It includes buttons for 'Go-Back', 'Save PDF', and 'Approval Details'. A callout box points to the 'Download Digitally Signed Application' button with the text: 'In Case the user wishes to see the Legal form they can do so by clicking on this button'. Other details include 'Applied on: 26/06/2023 12:18 pm', 'App ID: SW/MD/MD-1/2023/0000300', and the 'Directorate General of Health Services, Ministry of Health and Family Welfare'. A progress bar shows 'Form 1' as the current step, with 'Form 2', 'Document', and 'Payment' as subsequent steps. A 'Processing Details' sidebar on the right shows a submission timestamp of '26 Jun 2023, 02:23PM' and a message: 'Upload Document: You have successfully uploaded the document.' by 'Muskan..'

The screenshot displays the legal form 'Form MD-1' for the 'APPLICATION FOR ISSUE OF CERTIFICATE OF REGISTRATION OF NOTIFIED BODY'. The form is titled 'Form MD-1 (See sub-rule (3) of rule 13)'. It contains the following fields:

- 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: 06/26/2023
- 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 Device Rules, 2017, duly signed by me.

At the bottom, there is a declaration: '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.' The form is signed by 'Shaik Gajuria' on '26/06/2023' at 'delhi'. A callout box on the left states: 'The legal form can be previewed/downloaded'.

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...

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. *

National Single Window System

CENTRAL APPROVALS
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STATE APPROVALS
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GOVERNMENT SCHEMES
 Avail the benefits by Govt. of India

MY DASHBOARD

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...

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

The screenshot shows the 'Form CT-12 - Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or...' page. The progress bar indicates 'FILL FORM' is the current step. The active checklist is 'Form 9: CT12-BIO-rDNA-FFBD-Clinical Trial-Checklist'. The checklist items are:

- 1. Covering Letter
 - 1. Covering Letter *
 - CDSO Checklist (dropdown) | Browse File
 - Supported files are PDF: dummy.pdf, CDSO Checklist
 - 1 Remarks *
NA
- 2. Justification of Quantity
 - 2. Justification of Quantity *
 - Select Document Type (dropdown) | Browse File
 - Comments filed are DDC

User will land on checklist enabled for them to fill up

The screenshot shows the same 'Form CT-12' page, but the active checklist is 'Form 2: CT12-ND-FFBD-Test & Analysis-Checklist'. The checklist items are:

- 1. Covering Letter of the firm *
 - Select Document Type (dropdown with error icon) | 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 (dropdown) | 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.

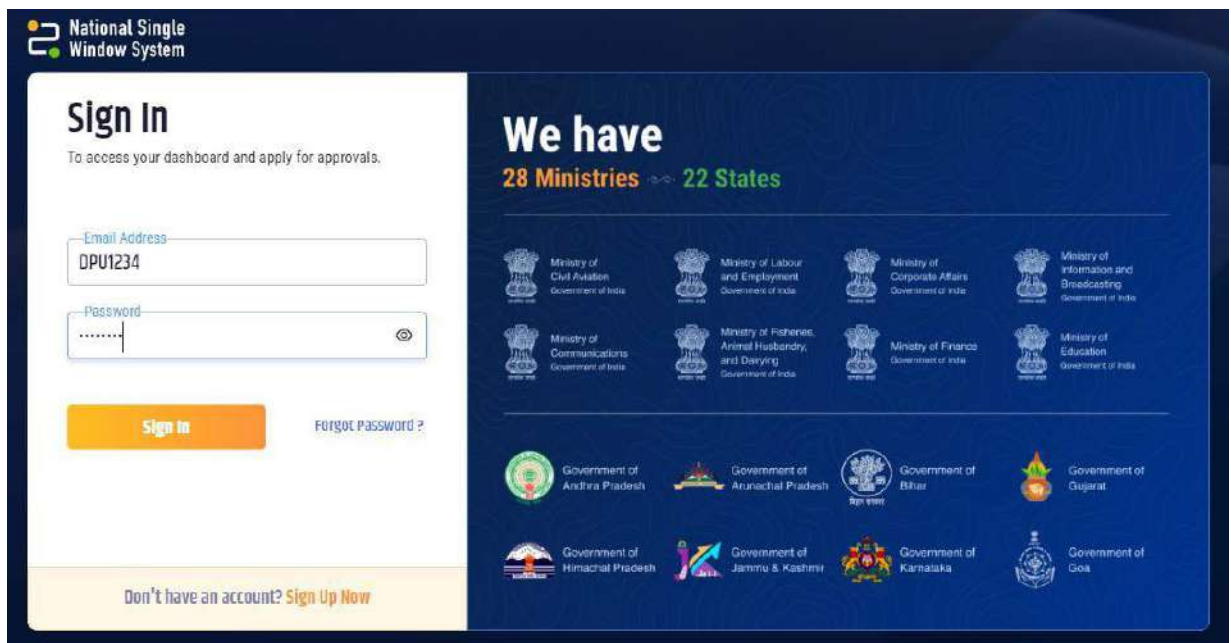
- ❖ Provides a unified document repository to where investors can upload and save their documents, and view and download documents issued to them by authorities.
- ❖ Provides an intuitive and easy to use communication module to respond to any clarifications or additional information requests raised by 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

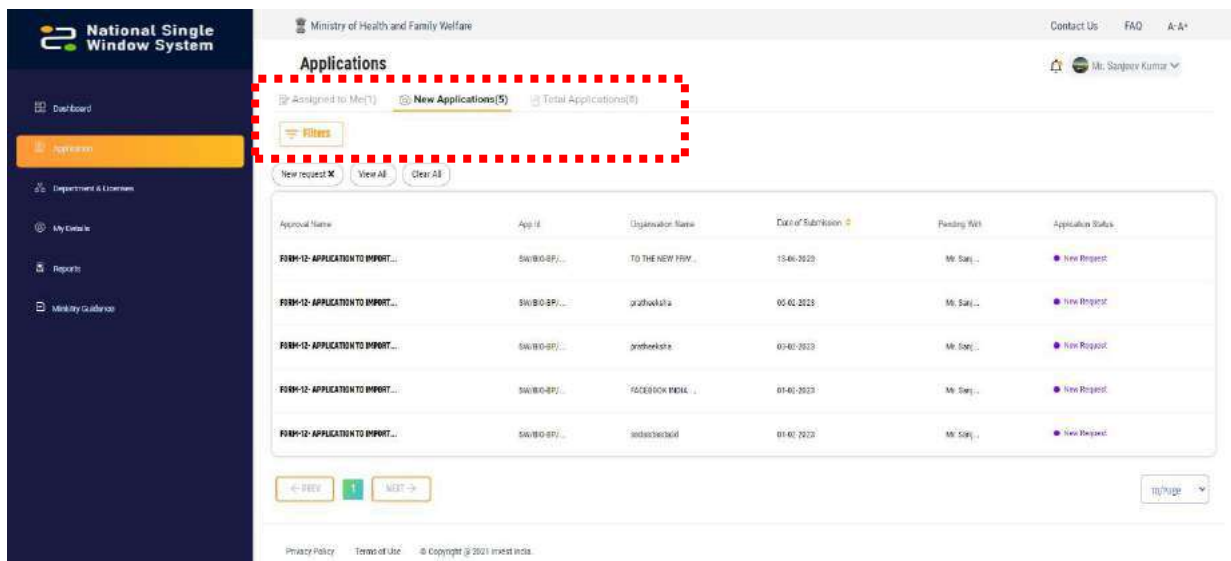
3.1.1 Ministry User Login

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:

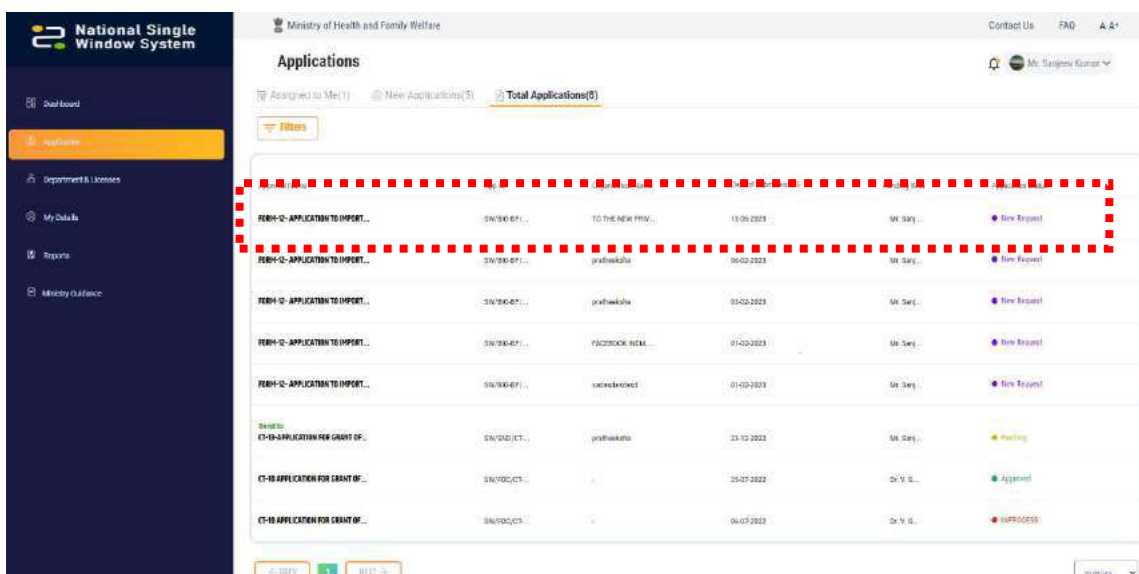
- ❖ **Assigned to me:** The applications that are pending for the specific logged in Ministry User to review.
- ❖ **New Application:** The fresh application that are applied by the investor and are yet to be reviewed.
- ❖ **Total Applications:** The total of the above stated Applications.



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



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

The screenshot shows the 'National Single Window System' interface. On the left is a dark blue sidebar with navigation options: Dashboard, Applications (highlighted), Department & Licenses, My Details, Reports, and Ministry Guidance. The main content area is titled 'Total Applications' and shows a 'New Request' for 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS'. The application details are: App ID: SW/BIO-BP/12/2023/0000011, SWS ID: SW4473066169, Applied on: 13-06-2023. A red dashed box highlights a horizontal menu with tabs: FORM-12, Checklist, Checklist-F12, Checklist, Document, Communic, Payment, and Audit Log. Below this menu is a vertical list of sections, each with a dropdown arrow: 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 'I accept that I have reviewed the form carefully.' and two buttons: 'Take investor action' and 'Take internal action'. On the right side, there is a vertical orange button labeled 'PROCESSING STATUS'.

Ministry User can navigate the through a single form vertically.

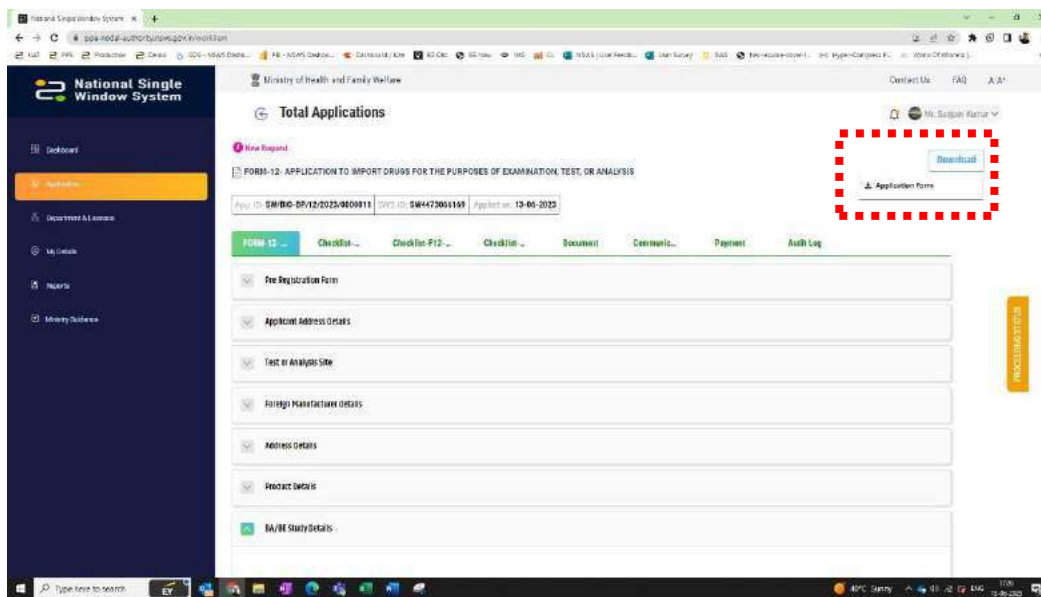
This screenshot shows a detailed view of the 'Pre Registration Form' within the 'National Single Window System'. The sidebar is the same as in the previous screenshot. The main content area shows the application details: App ID: SW/BIO-BP/12/2023/0000011, SWS ID: SW4473066169, Applied on: 13-06-2023. A red dashed box highlights the 'FORM-12' tab in the horizontal menu. Below the menu, the 'Pre Registration Form' section is expanded, showing a vertical list of fields: 'Select Department' (Biological - Blood Products), 'Purpose of Application' (For Examination, Test or Analysis), 'CDSCO Applicable zone, HD' (CDSCO HQ), 'CDSCO Applicable zone', and a declaration: '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). Below these fields are dropdown arrows for 'Applicant Address Details', 'Test or Analysis Site', 'Foreign Manufacturer details', and 'Address Details'. The vertical orange 'PROCESSING STATUS' button is visible on the right.

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.

This is a close-up screenshot of the application details section. It shows a 'New Request' for 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS'. A red dashed box highlights the 'App ID: SW/BIO-BP/12/2023/0000011' field. To its right are the 'SWS ID: SW4473066169' and 'Applied on: 13-06-2023' fields.

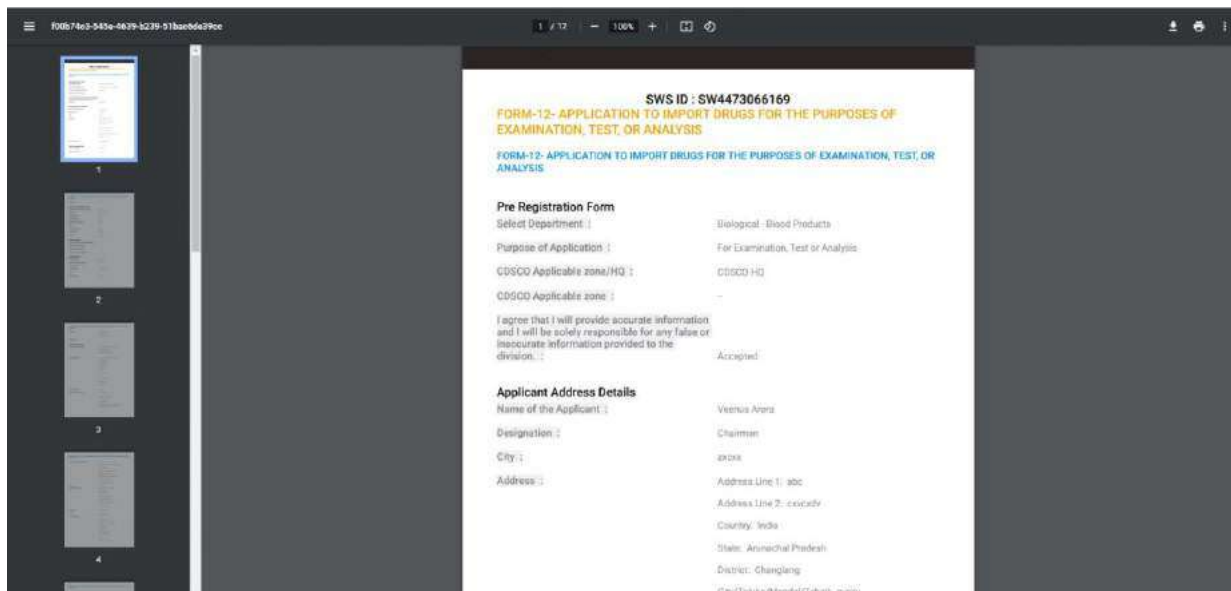
3.1.4 Download Application and Documents



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.

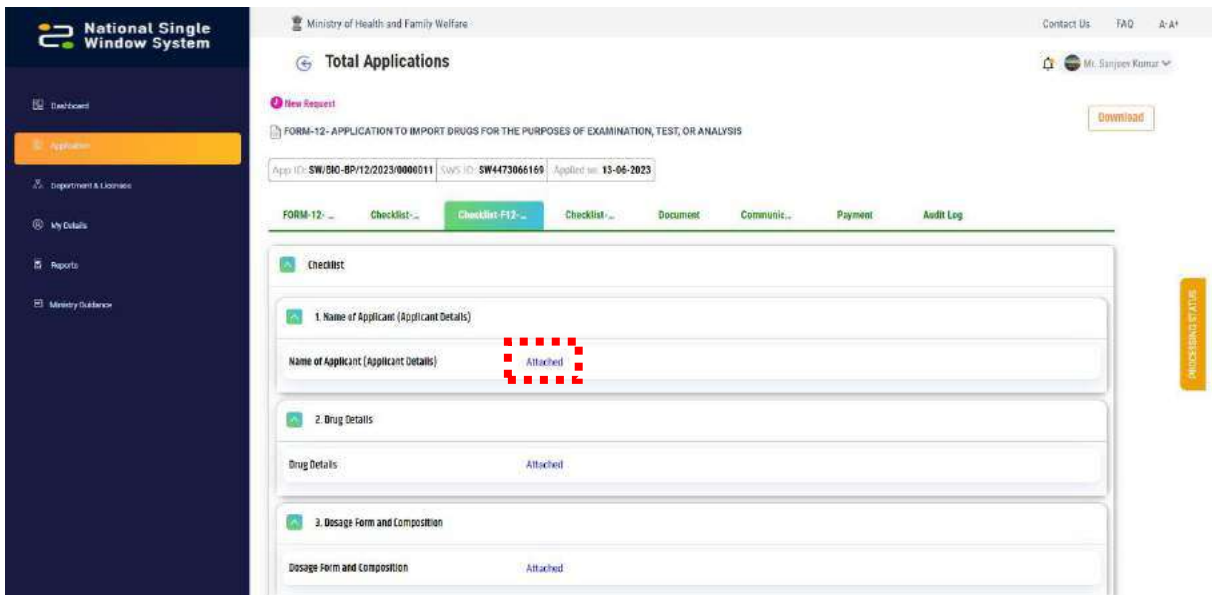
This Document will include application inputs by the investor and the Payment Receipt Details

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

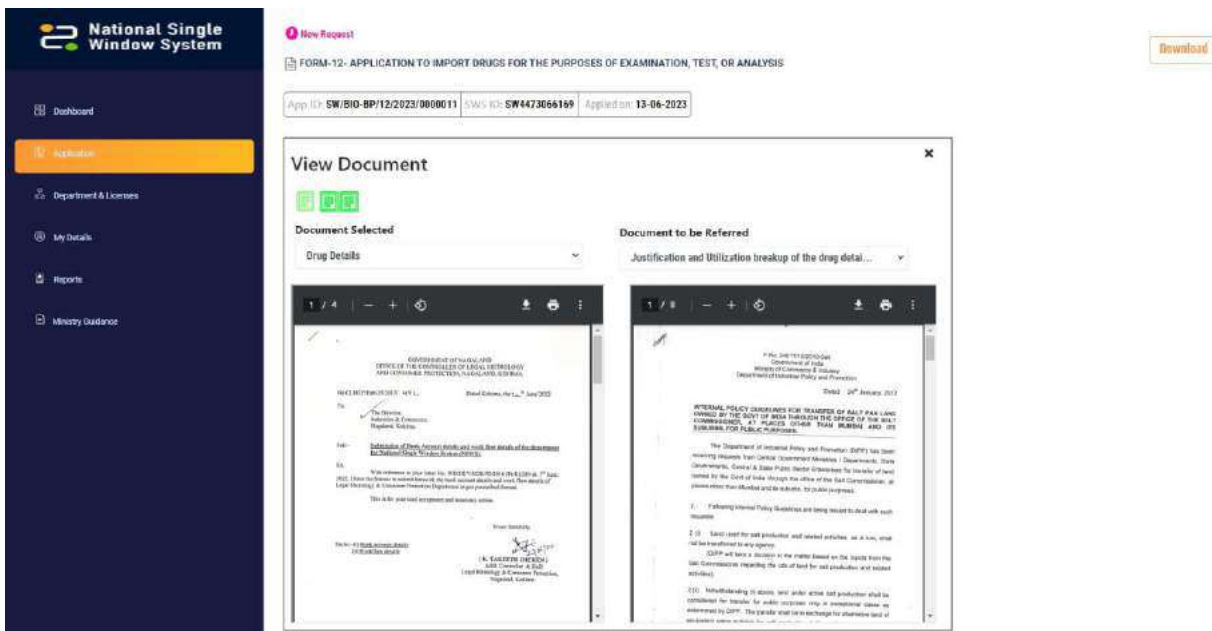


3.1.5 Viewing Documents

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.



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.



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](#)



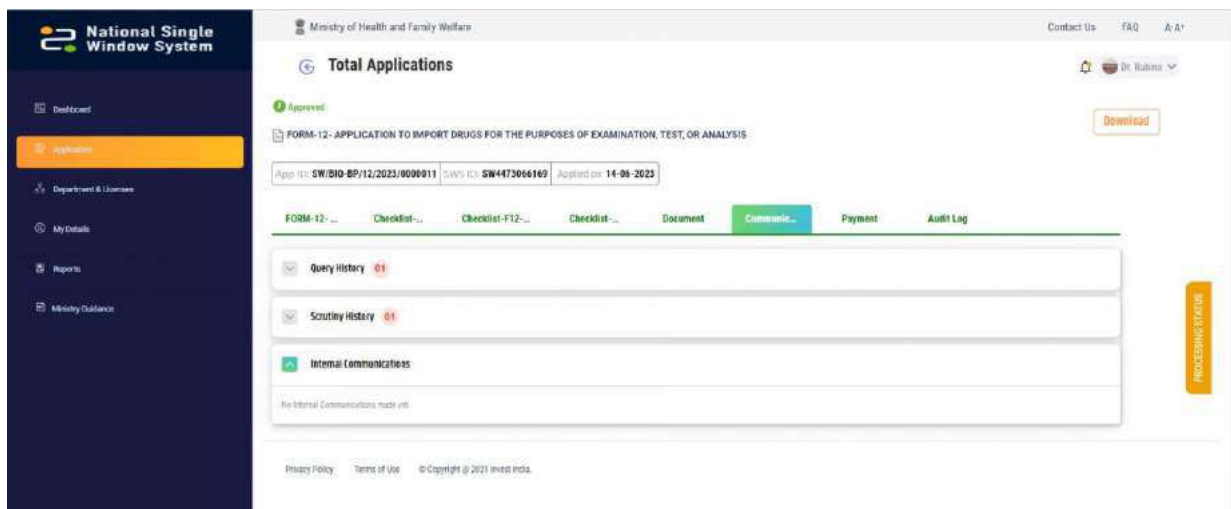
The download invoice button will download a PDF having the payment receipt as shown below

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.



The screenshot shows the 'National Single Window System' interface. The user is logged in as 'Dr. Rubina'. The main content area displays 'Total Applications' with a status of 'Approved'. The application details are: 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS', Application ID: SW/BIO-BP/12/2023/0000011, SWS ID: SW4473066169, and Applied on: 14-06-2023. The 'Communication' tab is active, showing sections for 'Query History' (01), 'Scrutiny History' (01), and 'Internal Communications' (No Internal Communications made yet). A 'Download' button is visible next to the application title. A vertical 'PROCESSING IS IN PROGRESS' banner is on the right side.

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' section of the National Single Window System. The header includes the application ID 'SW/BIO-SP/12/2023/000011', SWS ID 'SW4473066169', and the application date '14-06-2023'. The main content area displays a table of actions taken on the application for 'ABCD Ltd.'. The table has columns for Date, Action, Remark, Action Taken by, and Attachment. The actions include 'Investor files application', 'Send to', 'Forward', and 'Verified, please review'. The 'Action Taken by' column lists users like 'Vijaya', 'Mr. Sarjeyv Kumar Gupta - Accountant', and 'Dr. Pulama Bose-Deputy Drug Controller (Jalgaon)'. A 'Download' button is visible in the top right corner. A vertical orange banner on the right side of the page reads 'PROCESSING STATUS'.

Date	Action	Remark	Action Taken by	Attachment
13-06-2023 14:54:06	Investor files application		Vijaya	-
14-06-2023 00:25:50	Send to	Sir, I have reviewed and it looks fine, sending it for your review and action	Mr. Sarjeyv Kumar Gupta - Accountant	-
14-06-2023 10:54:24	Forward	File according to rule, Please review	Mr. J. Satish Kumar - Accountant	-
14-06-2023 12:04:19	Send to	Verified, please review	Mr. Sarjeyv Kumar Gupta - Accountant	-
14-06-2023 10:34:21	Forward	verified, please review	Dr. Pulama Bose-Deputy Drug Controller (Jalgaon)	-

3.2 Process for Application Review

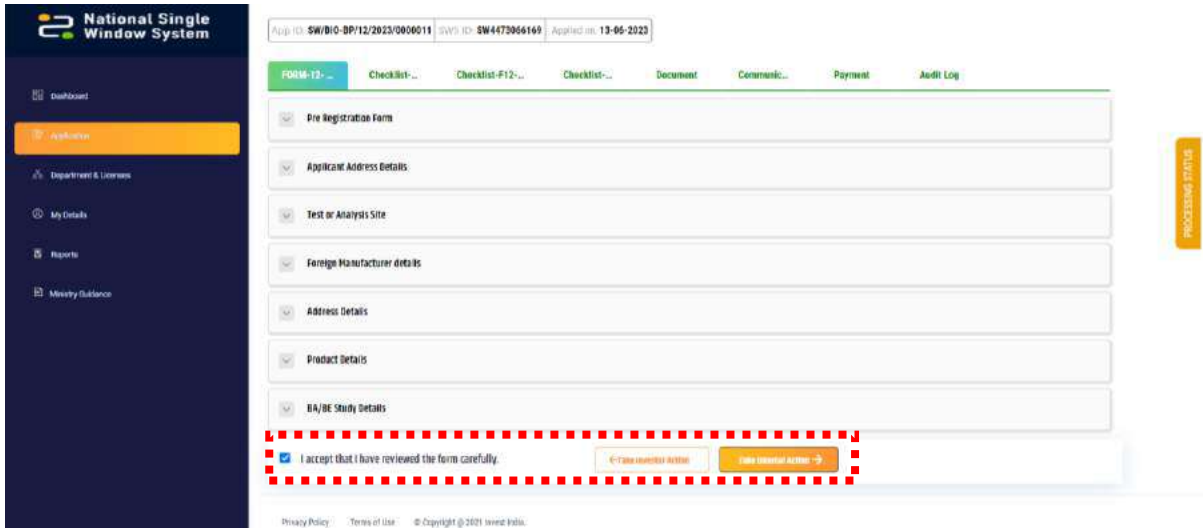
Ministry User will be provided with two tabs as shown below

The screenshot shows the 'Application Review' section of the National Single Window System. The header includes the application ID 'SW/BIO-SP/12/2023/000011', SWS ID 'SW4473066169', and the application date '13-06-2023'. The main content area displays a list of application details, including '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 Internal Action' and 'Take External Action'. A red dashed box highlights these two buttons. A vertical orange banner on the right side of the page reads '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:

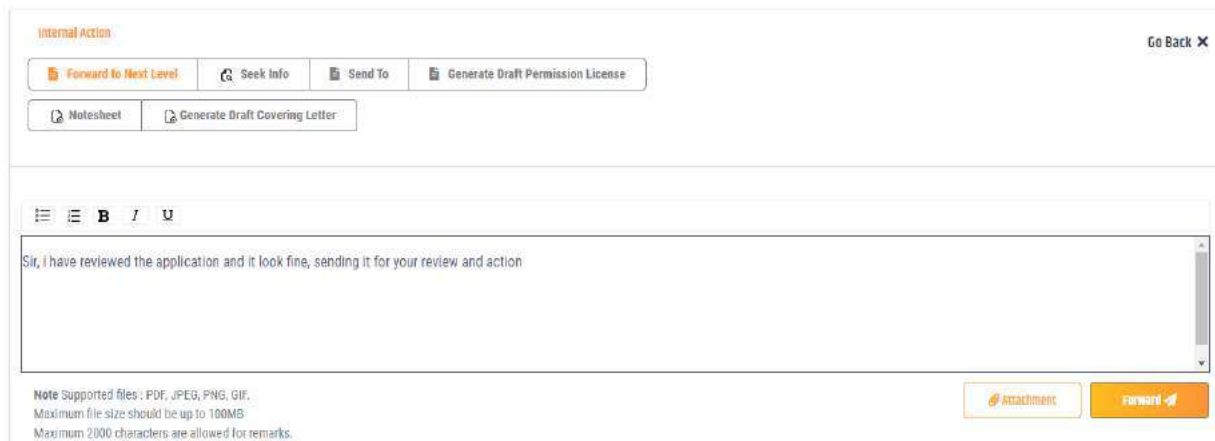
3.2.1.1 Seek Info

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' menu with options: Forward to Next Level, Seek Info, Send To, Generate Draft Permission License, Notesheet, and Generate Draft Covering Letter. The 'Send To' option is selected, opening a 'Select User' dropdown menu. The menu lists five 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. Below the menu, there is a note about supported file formats (PDF, JPEG, PNG, GIF), a maximum file size of 100MB, and a maximum of 2000 characters for remarks. There are also buttons for Attachment and Send.

3.2.1.4 Pull Back and Reassign

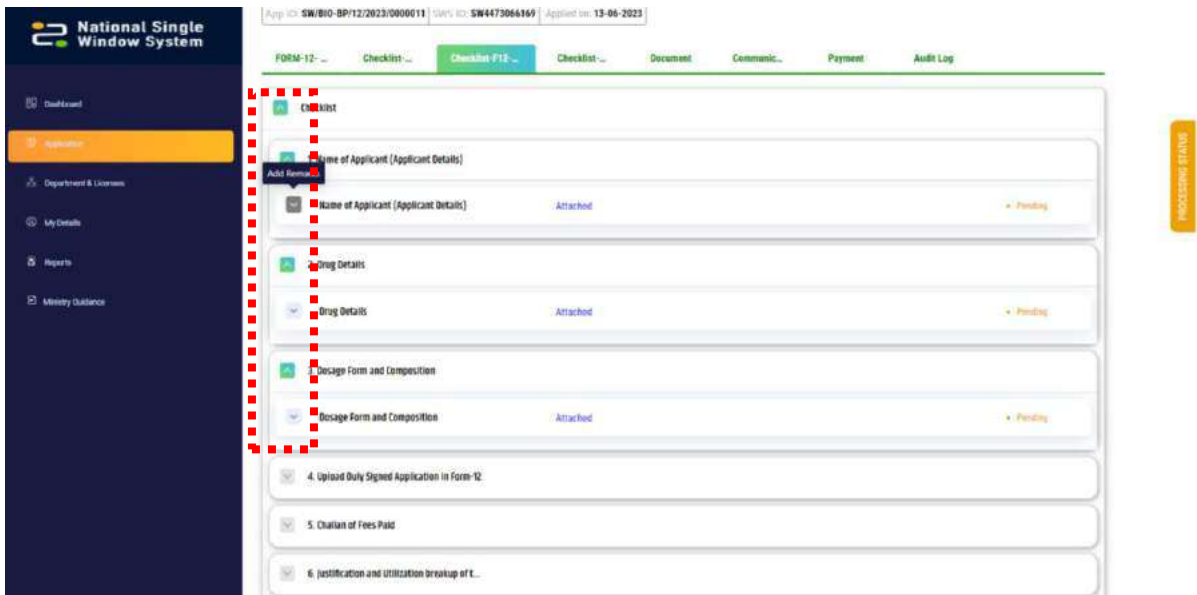
If the application is with a particular officer and they may not be able to process it (for example a leave or any official engagement), then the higher-level user to such officer can use this function to pull back the license from such user and reassign it to another officer.

The screenshot shows the 'Internal Action' menu with options: Seek Info, Pull Back and Reassign, Send To, and Notesheet. The 'Pull Back and Reassign' option is selected, opening a 'Select User' dropdown menu. The menu lists one user: Mr. Sanjeev Kumar Gupta - Accountant-Level No:4-DDA. Below the menu, there is a text box with the text 'Pulling back and reassigning to D.D.A. (Deputy Deciding Authority)'. There is also a button for Assign/Reassign.

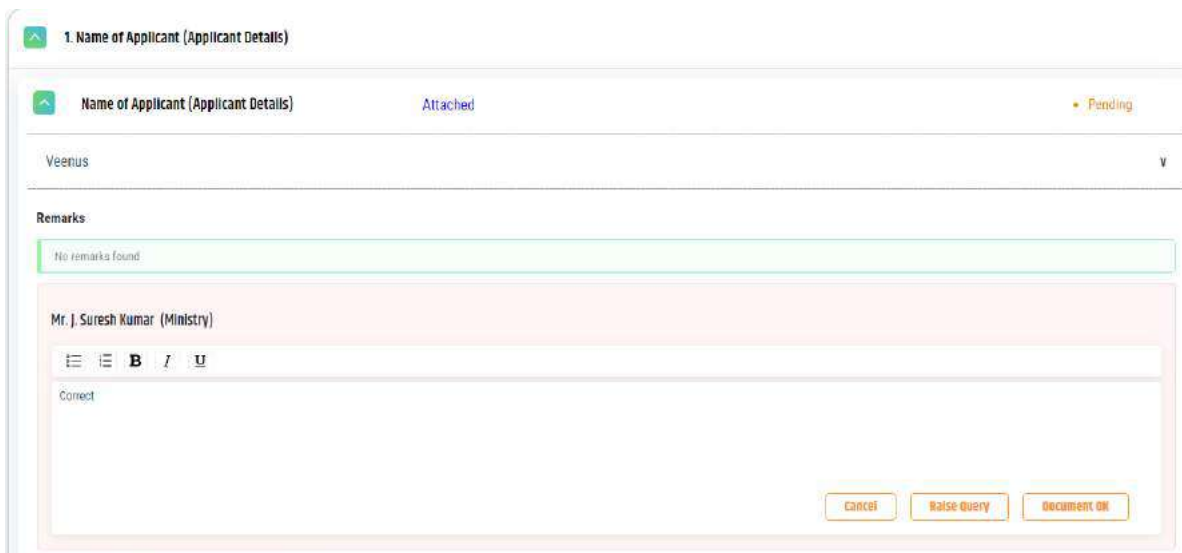
3.2.1.5 Review Checklist items

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.

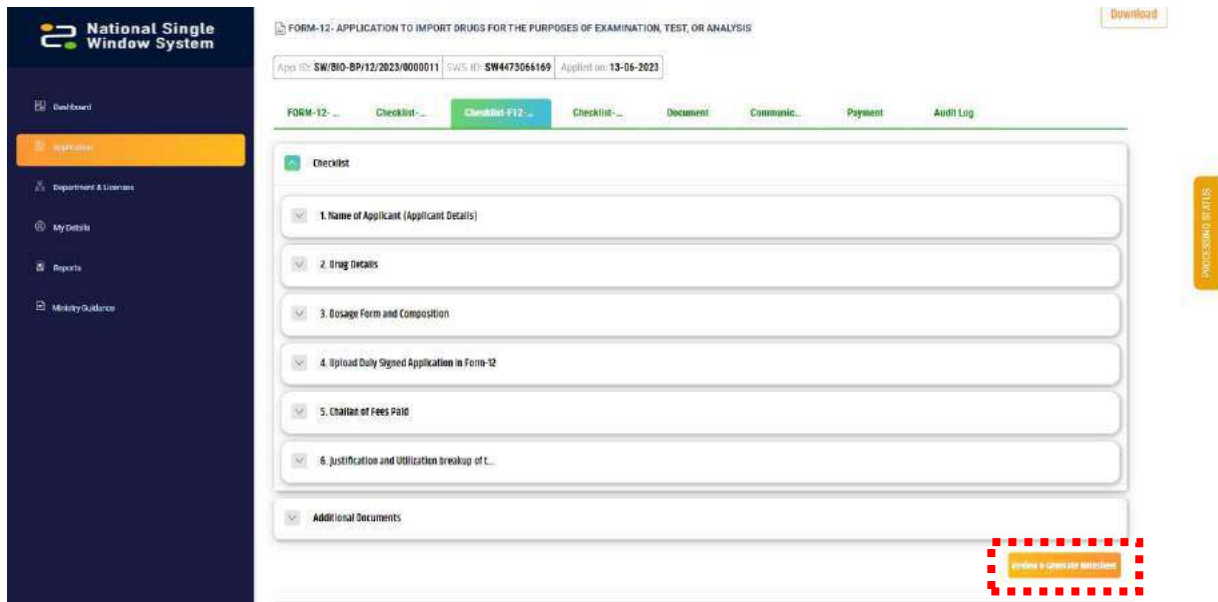


User can either raise query on the document which will be communicated to the investor, or they can provide their confirmation.

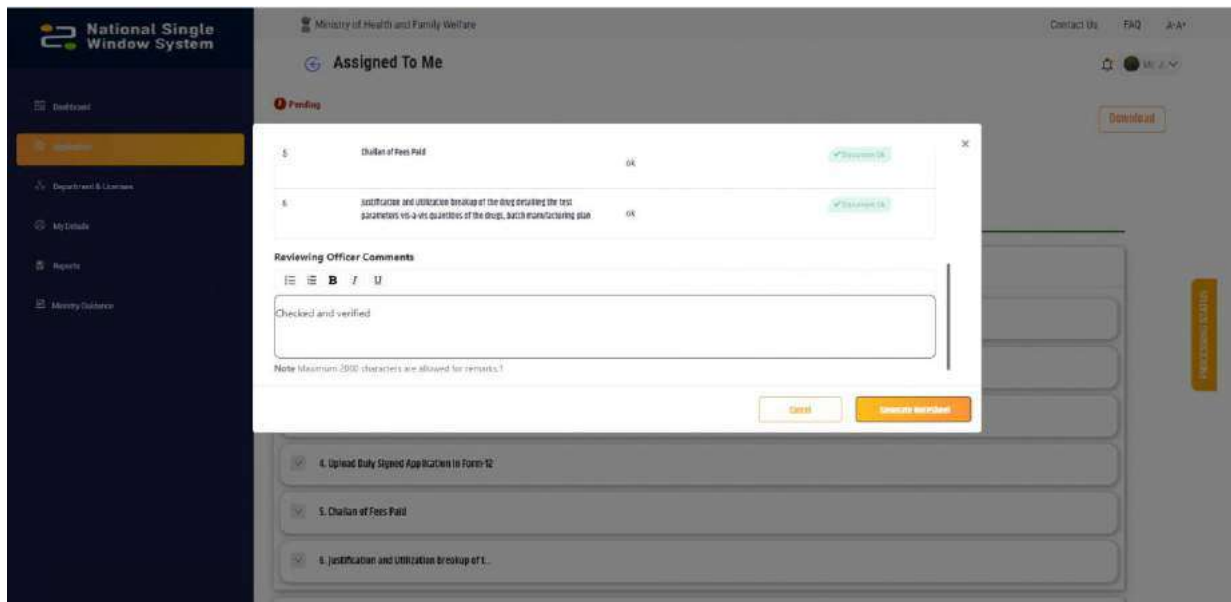


3.2.1.6 Generate Notesheet

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

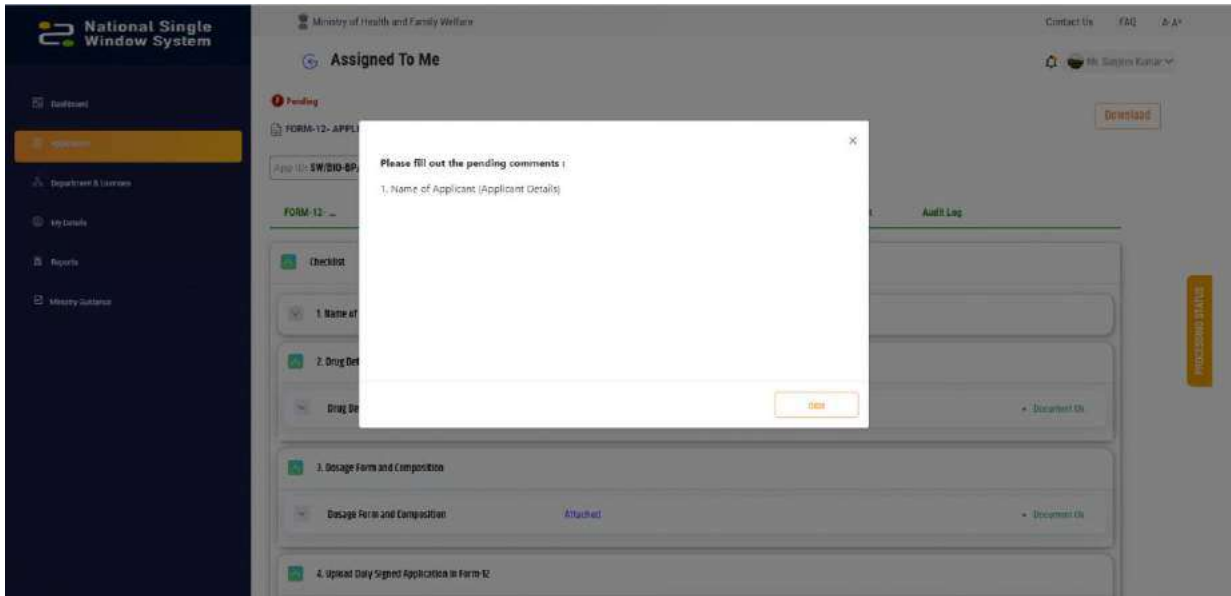


Provide confirmation through the comments and Generate Notesheet



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

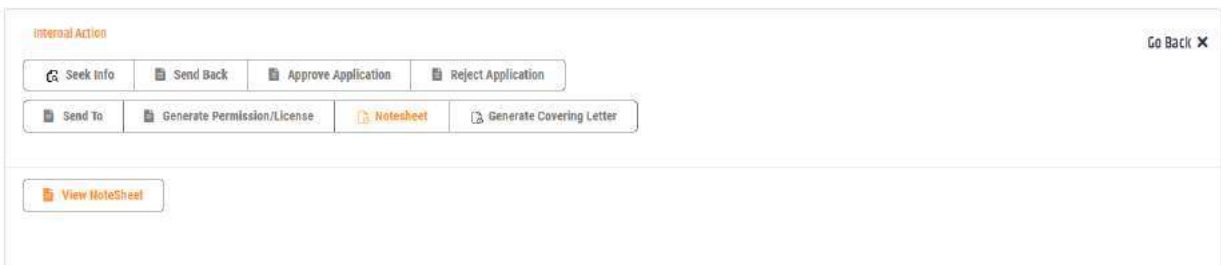


3.2.1.7 Send Back

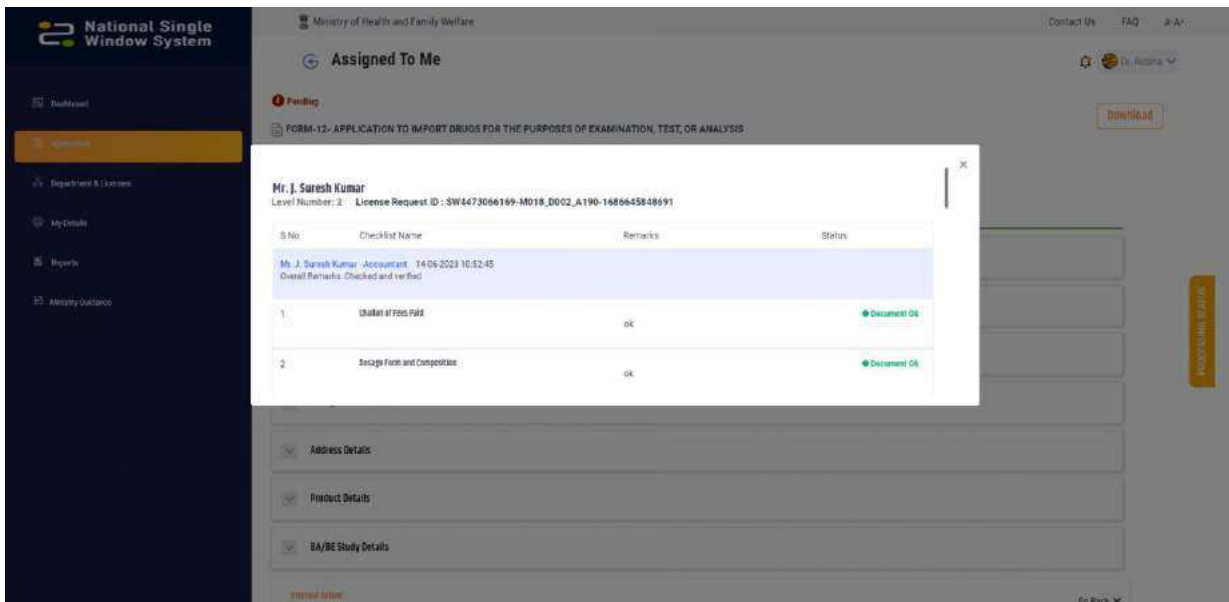
In case the ministry user wants to send it back to the last user for reviewing it again



3.2.1.8 View Notesheet

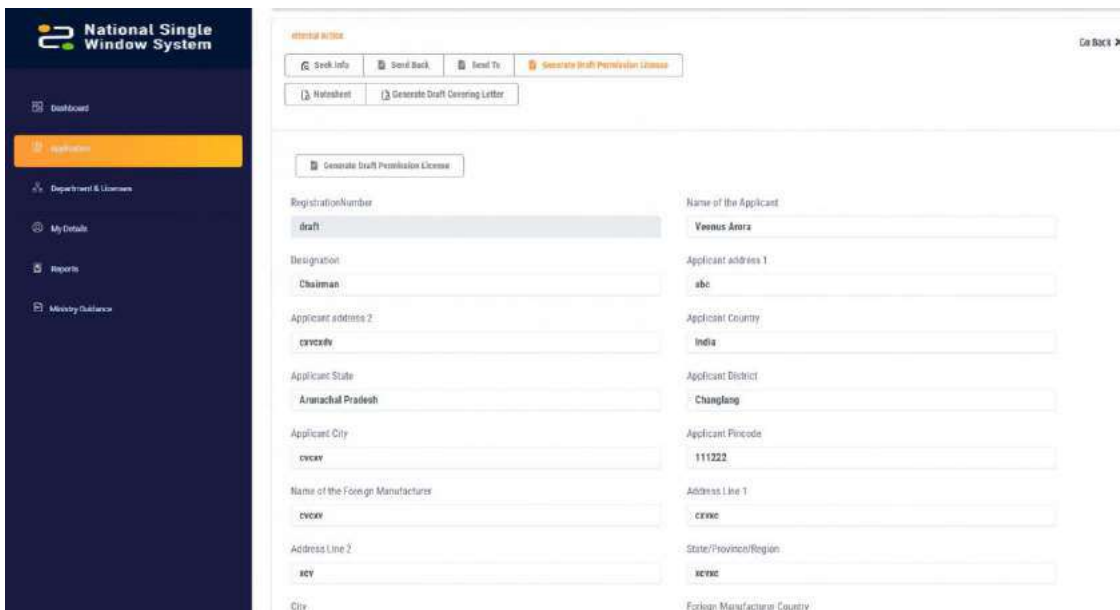


Notesheet captures actions taken by ministry users on checklist documents



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

60 Back X

Generate draft Permission License

Generate draft Permission License

Registration Number: draft

Name of the Applicant: Veenes Anora

Designation: Chairman

Applicant address 1: abc

Applicant address 2: cxvcdv

Applicant State: Arunachal Pradesh

Applicant City: cxvxy

Name of the Foreign Manufacturer: cxvxy

Address Line 1: cxvxy

Address Line 2:

Applicant Country: India

Applicant District: Changlang

Applicant Pincode: 111222

State/Province/Region:

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

Zip/Postal code: cxvxc

Landline No: 1222222

Fax No: 344555

Name of the site: cxvxc

Address: xcvcx

Select Department: Biological - Blood Products

Product Details

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

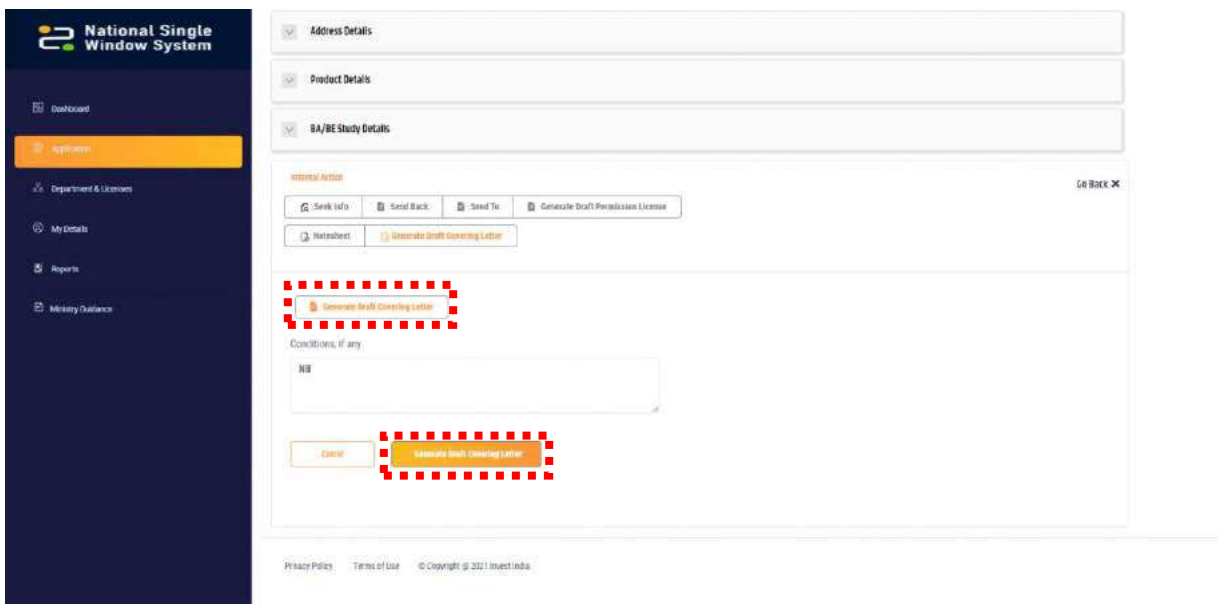
Cancel Generate certificate

- ❖ The Draft License will be generated



3.2.1.10 Generate Draft Covering Letter

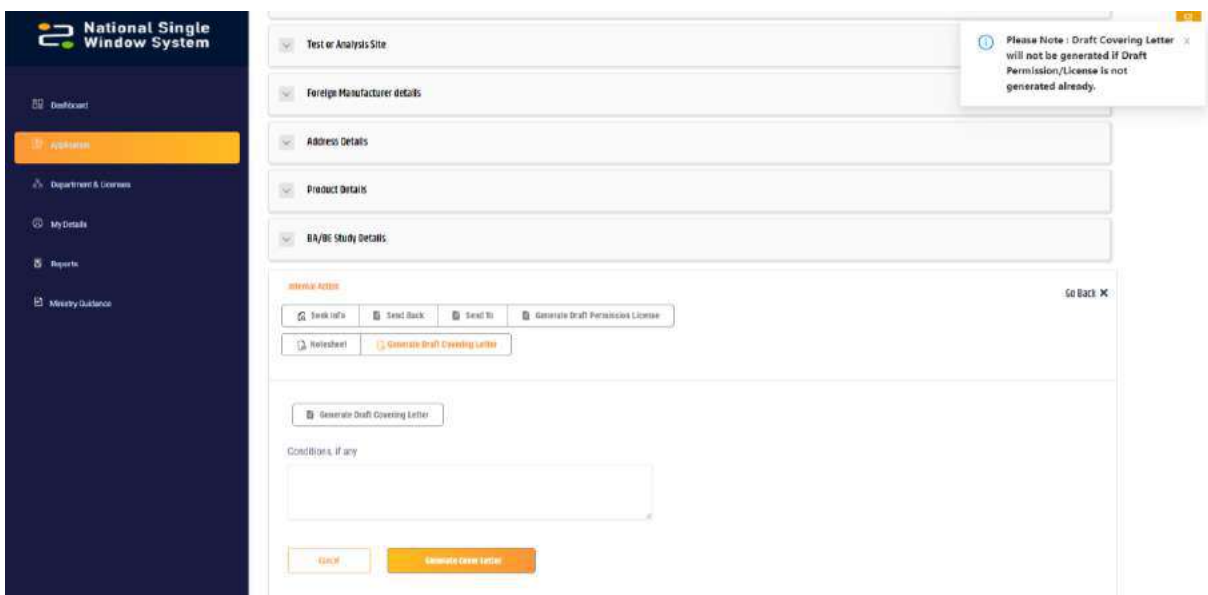
Ministry User can generate Draft Covering Letter using this option. Click on the buttons shown and add remarks.



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

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.

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
Applications
 Department & Licenses
 My Details
 Reports
 Ministry Guidance

General Action Go Back X

Registration Number: **SW/BIO-OP/11/2023/000002**
 Name of the Applicant: **Venus Anra**

Designation: **Chairman**
 Applicant address 1: **abc**

Applicant address 2: **cxvcdv**
 Applicant Country: **India**

Applicant State: **Arunachal Pradesh**
 Applicant District: **Changlang**

Applicant City: **cxvzv**
 Applicant Pincode: **111222**

Name of the Foreign Manufacturer: **cxvzv**
 Address Line 1: **cxvzv**

Address Line 2: **cxv**
 State/Province/Region: **cxvzv**

❖ Click on “Generate Final Permission License” as shown

National Single Window System

Dashboard
Applications
 Department & Licenses
 My Details
 Reports
 Ministry Guidance

General Action Go Back X

Registration Number: **SW/BIO-OP/11/2023/000002**
 Name of the Applicant: **Venus Anra**

Designation: **Chairman**
 Applicant address 1: **abc**

Applicant address 2: **cxvcdv**
 Applicant Country: **India**

Applicant State: **Arunachal Pradesh**
 Applicant District: **Changlang**

Applicant City: **cxvzv**
 Applicant Pincode: **111222**

Name of the Foreign Manufacturer: **cxvzv**
 Address Line 1: **cxvzv**

Address Line 2: **cxv**
 State/Province/Region: **cxvzv**

City: **cxvzv**
 Foreign Manufacturer Country: **cxvzv**

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

City: Foreign Manufacturer Country:

Zip/Postal code: Landline No:

Fax No: Name of the site:

Address: Select Department:

Product Details

Name of Drug/Formulation	Brand Name	Class	Quantity	Unit
<input type="text" value="vbvb"/>	<input type="text"/>	<input type="text" value="Analgesic Drugs"/>	<input type="text" value="34353"/>	<input type="text" value="Aerosol"/>

- ❖ 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, cxvcxv, india, Arunachal Pradesh, Changlang, cxvcx-111222 is hereby licensed to import from cxvcx, cxvxc, xcv, cxvcx, xcv, American Samoa -cxvxc, 1222222, 344555 the drugs specified below for the purposes of examination, test or analysis at cxvcx, cxvcx or in such other places as the licensing authority may from time to time authorize.

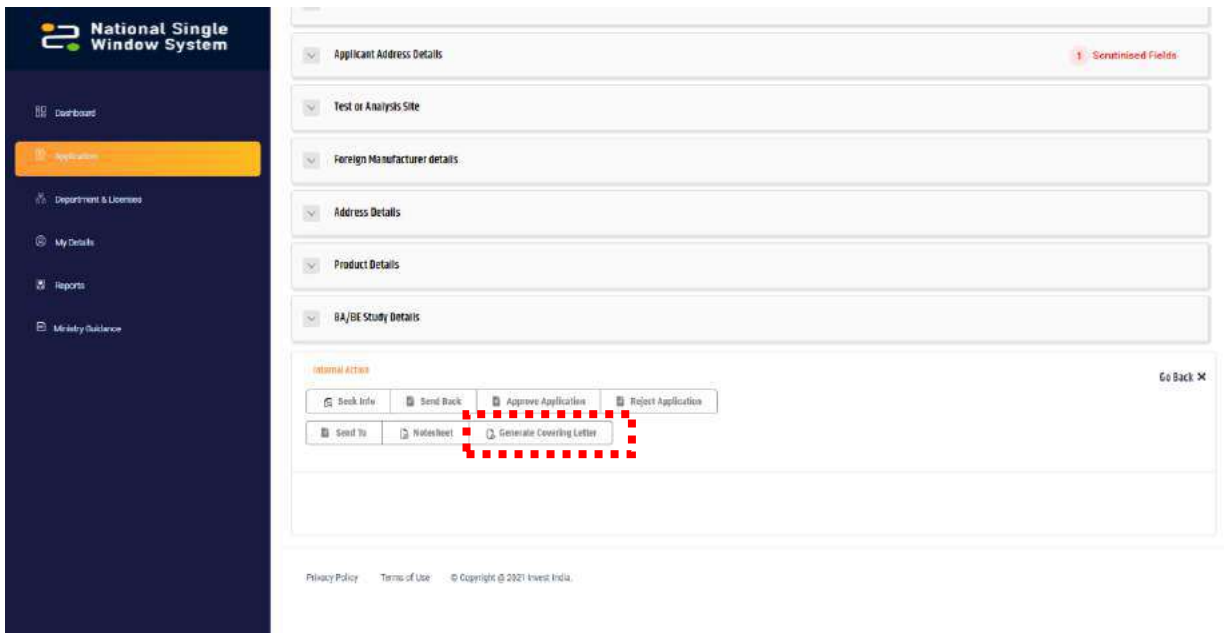
2. This licence is subject to the conditions prescribed in the Rules under the Drugs and Cosmetics Act, 1940.

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

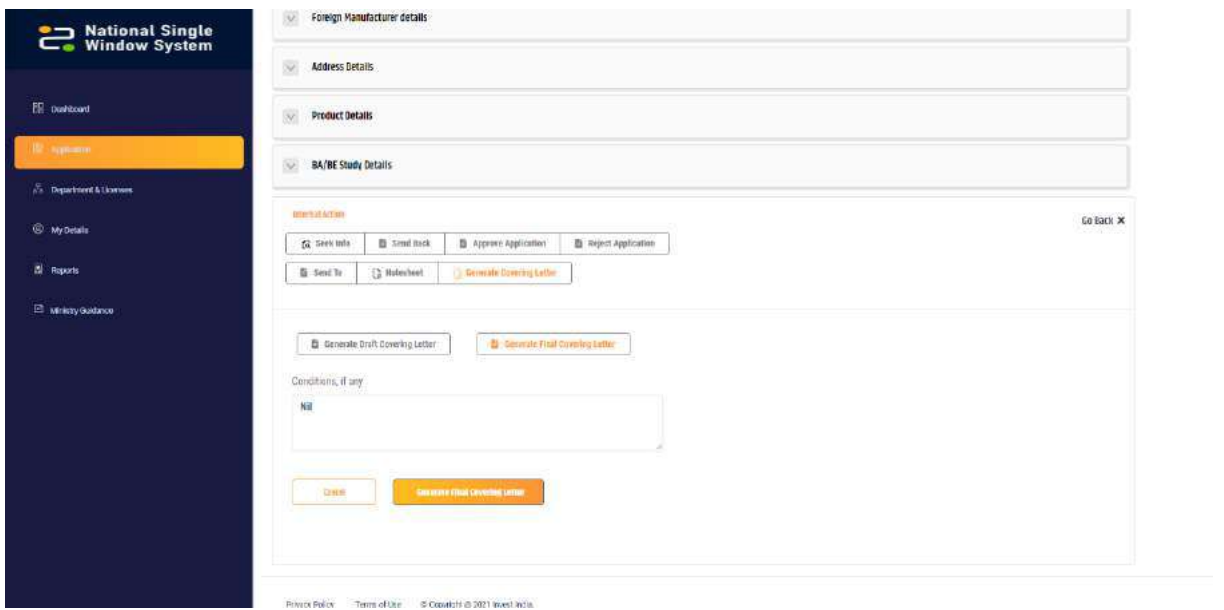
S. No.	Name of drugs	Brand Name	Class of Drug	Quantity which may be imported

3.2.1.14 Generate Covering Letter

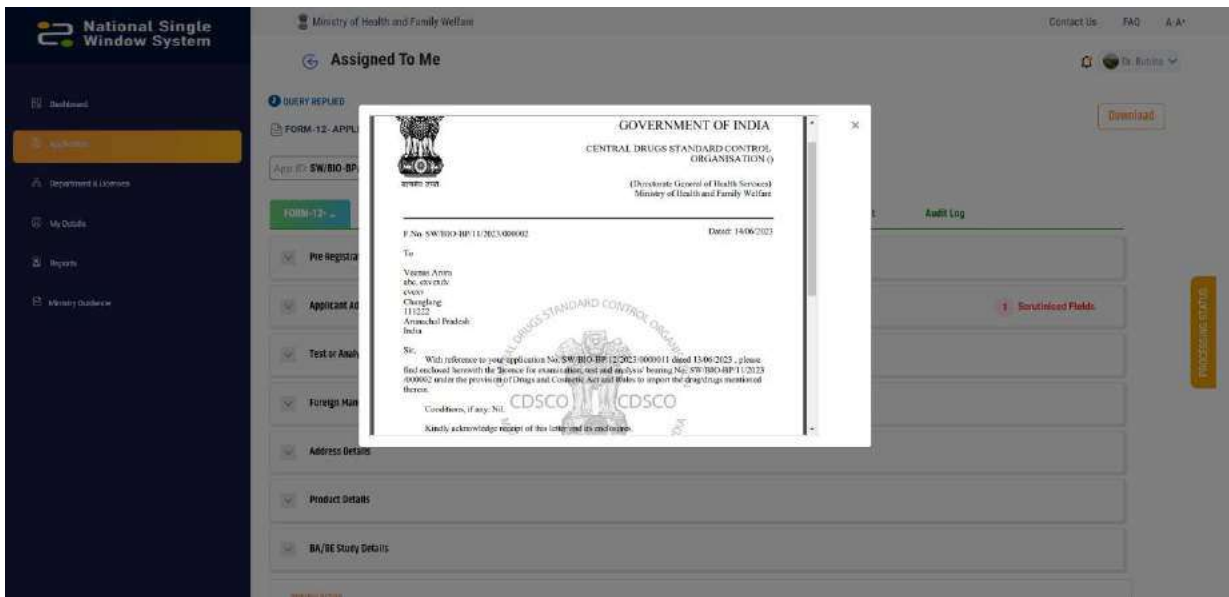
Ministry User can generate Final Covering Letter using this option.



Click on the buttons shown and add remarks.



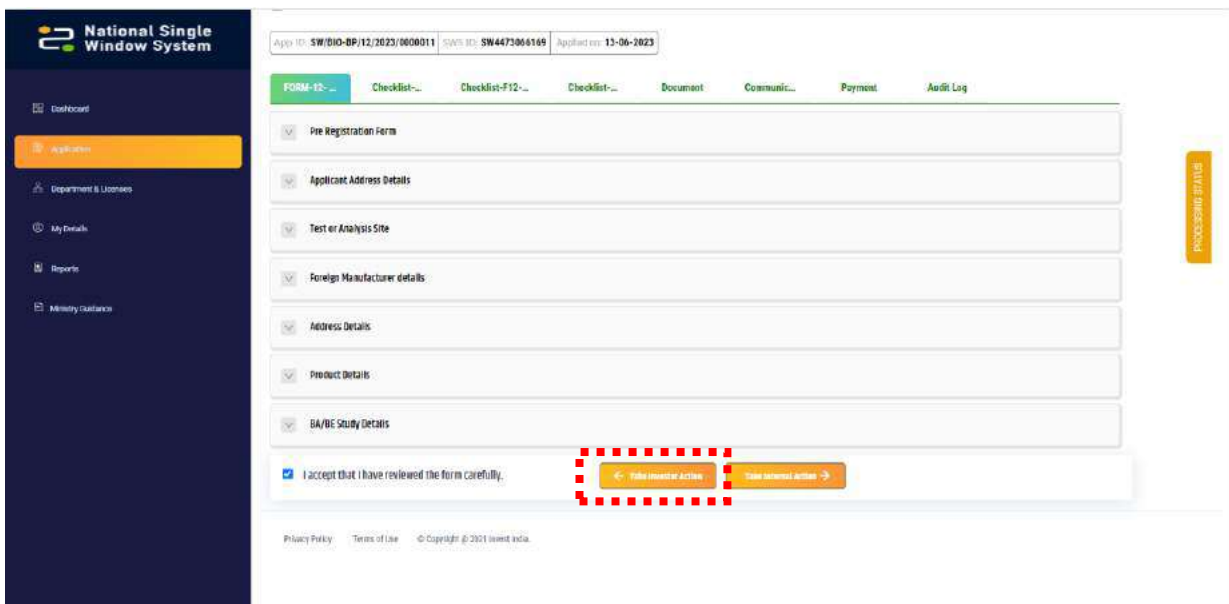
The document will be generated



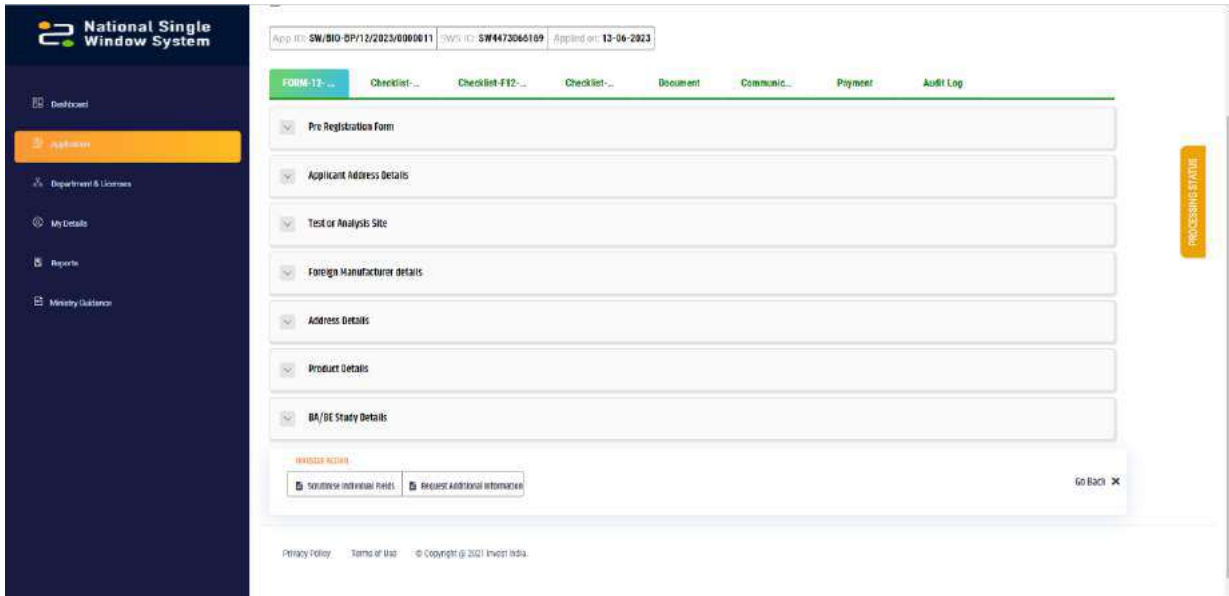
Condition: In case the user wants to “Generate Covering Letter” , the ministry user has to first generate the “Permission License” first.

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.

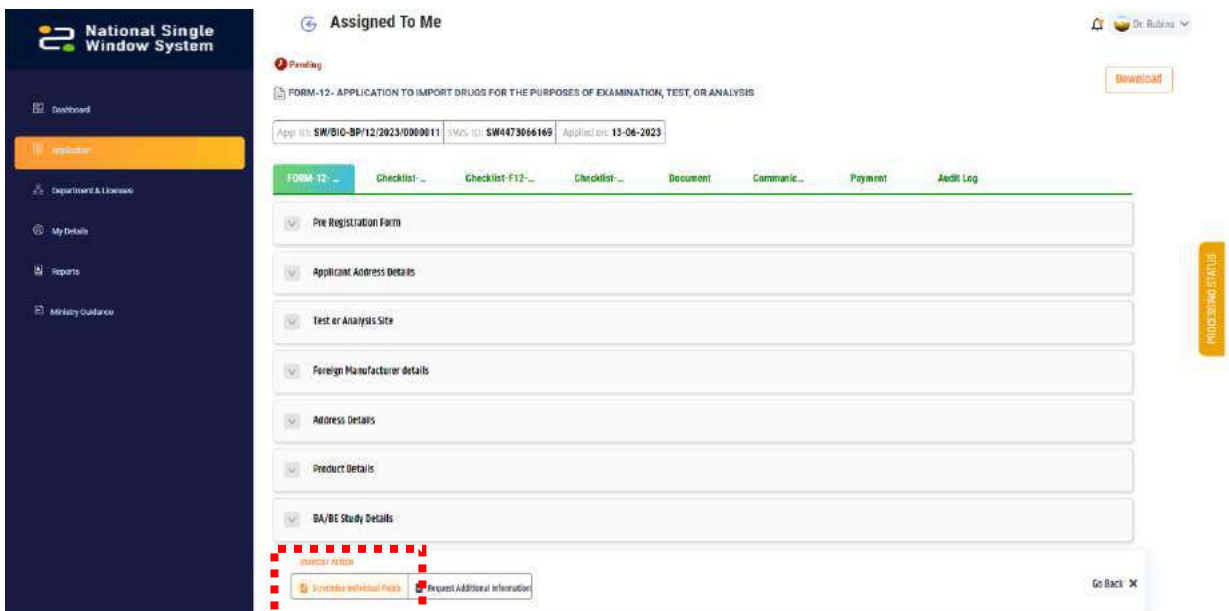


3.2.2.1 Scrutinize Individual Fields

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

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FORM-12: APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS
 App ID: SW/BIQ-EP/12/2023/000011 | 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

Name of the Applicant: Venus Arora Select All

Designation: Chairman

City: zxcxc

Address:
 Address Line 1: abc
 Address Line 2: cxcxcxc

PROCESSING STATUS

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

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FORM-12: APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS
 App ID: SW/BIQ-EP/12/2023/000011 | 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

Name of the Applicant: Venus Arora Select All

Please provide the full name of the applicant with proper validation

Designation: Chairman

City: zxcxc

Address:
 Address Line 1: abc

Cancel Save

PROCESSING STATUS

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

App ID: SW/BID-0P/12/2023/000011 | SW ID: SW447366169 | Appliet on: 13-06-2023

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

Pro Registration Form

Applicant Address Details

Select All

Name of the Applicant: Venus Arora

Please provide the full name of the applicant with proper validation

Cancel Save

Designation: Chairman

City: Jaipur

Address:

Address Line 1: abc

Address Line 2: cde

Add Generic Remarks Resubmit Application

- ❖ 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.

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

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 screenshot shows the Ministry Dashboard Overview page. The sidebar on the left contains navigation options: Dashboard, Application, Department & Licenses (highlighted with a red dashed box), My Data, Reports, and Ministry Guidance. The main content area features an 'Overview' section with filters for Fresh Applications (14-03-2023 to 14-06-2023) and four summary cards for Total Applications, Applications Completed, Applications Pending With Pending, and Applications Pending With Applicant. Below this is a table for 'Applications by Status' with columns for Approvals, New Applications, Applications In Process, and Applications Completed. A chart at the bottom shows 'No. of Applications by Monthly' with a y-axis from 0 to 100.

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 Dashboard Department and Licenses page. The sidebar on the left contains navigation options: Dashboard, Application, Department & Licenses (highlighted with a red dashed box), My Data, Reports, and Ministry Guidance. The main content area features 'Department and Licenses' for Directorate General of Health Services (62). A table lists various approvals with columns for KYA Aligned and Form Uploaded.

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-15 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-18 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”.

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- Dashboard
- Application
- Approval & License**
- My Details
- Reports
- Ministry Guidance

Directorate General of Health Services (62)

Approval/Registration	KYA Aligned	Form Uploaded
CDSCO Checklists: Bulk Drug - Endorse		
CDSCO Checklists: Bulk Drug - Fresh Applications		
CDSCO Checklists: Fresh Formulation - Endorse		
CDSCO Checklists: Fresh Formulation - Fresh Applications		
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 Form 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 Checklist CT13-IND-FFBD-Test & Analysis Checklist CT13-IND-FFBD-Clinical Trial Checklist CT13-SND-FFBD-Test & Analysis Checklist CT13-SND-FFBD-Clinical Trial/BABE Checklist CT13-BIO-Vaccine-FFBD-Test & Analysis Checklist CT13-BIO-rDNA-FFBD-Test & Analysis Checklist CT13-BIO-rDNA-FFBD-Clinical Trial Checklist CT13-ND-FFBD-Test & Analysis Checklist CT13-ND-FFBD-Clinical Trial Checklist CT13-BIO-Vaccine-FFBD-Clinical Trial		
CT-16 Application for grant of license to import new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study		

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 ---