



# Central Drug Standard Control Organization (CDSCO)

## User Manual

For

## e-Governance Solution for CDSCO

Version 1.0

### Centre for Development of Advanced Computing

(A Scientific Society of the Ministry of Electronics and Information Technology, Govt. of India)

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## ACKNOWLEDGEMENTS

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## Summary

SUGAM is e-Governance system to discharge various functions performed by CDSCO under Drugs and Cosmetics Acts, 1940. The software system developed is an online web portal where applicants can apply for NOCs, licenses, registration certificates, permissions & approvals. It provides an online interface for applicants to track their applications, respond to queries and download the permissions issued by CDSCO. It also enables CDSCO officials to process the applications online and generate the permissions online and generate MIS reports.

This document contains step-by-step guidance to the Applicants (Industry association) of the SUGAM portal with screenshots of the workflow for various application submissions. Following are the sections detailed in this document:

- ❖ User Registration & Login
- ❖ Applicant Dashboard
- ❖ Managing Sub login Accounts
- ❖ Form Submission for various processes
- ❖ Post Approval Changes



**SUGAM**  
**ONLINE LICENSING**

**Central Drugs Standard Control Organization (CDSCO)** is the drug regulatory agency under the Central Government primarily vested to implement the provisions of the Drugs and Cosmetics Act, 1940 which include approval of New Drugs, conduct of their clinical trials, regulation of imported drugs, Pharmacovigilance and coordinating the activities of the States so as to achieve uniformity throughout the country in the administration of the said Act.

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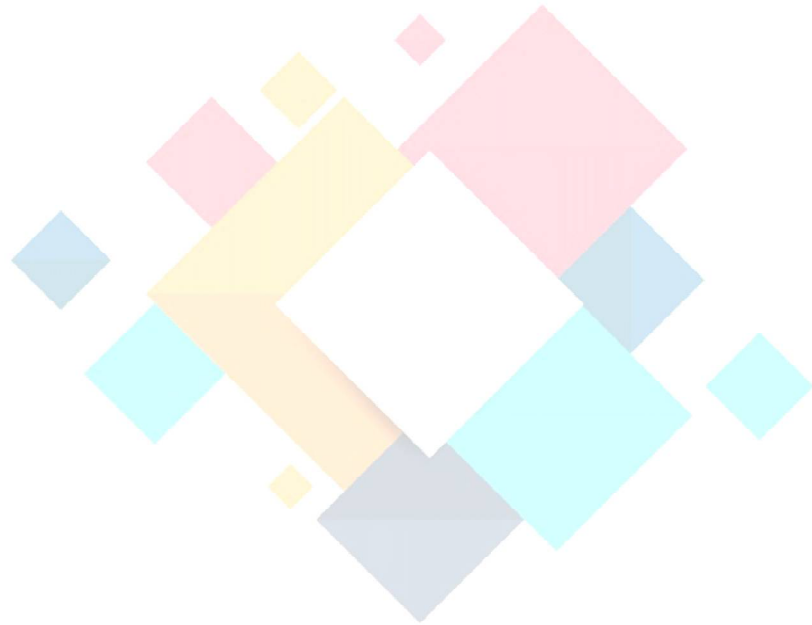
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# Chapter-1

## User Registration & Login



## 1. User registration & Login

SUGAM portal is a single window interface for stakeholders to access the online services provided by CDSCO. In order to apply for any form user needs to register on the portal.



### 1.1 User Registration

User is required to fill in the details of the registration form. After submission, CDSCO administrator either approves or rejects the user registration request made by the user. If approved, the user can login to the portal else if the application is rejected an email is sent to the user with the reason for rejection. Once user registration is approved by CDSCO, user can login to the portal using the login credentials.

➤ **Note:-**

- Authorized Signatory / Responsible person of the organization should fill the registration form.
- After submitting the Registration Form, Check Registered email for E-mail Verification.
- Submit ID proof, Undertaking, Address Proof Document in hard copy to CDSCO office.
- Registration will be approved by CDSCO only after evaluation of the submitted documents. Check your registered email id for all communications.

### 1.2 Registration Steps

- Open link "[www.cdsoonline.gov.in](http://www.cdsoonline.gov.in)" and then click on "**Sign up here**" (highlighted) to register on the portal.



Figure 1 : Homepage Screen for Signup

**Note:-**

- Applicants who can register on the portal are **Corporate, Indian Agent, Importer, Foreign Enterprise holding Indian Subsidiary, Cosmetics, Ethics Committee, Formulation R&D Organization, BA/BE Approved Sites, Sponsors(BA/BE & CT).**
  - If Applicant has more than one Manufacturing units of his organization then Applicant must register with its corporate organization on to SUGAM portal then he can register his different sub-units of Organization on to SUGAM portal.
  - Manufacturing Unit cannot directly register on the portal.
  - Corporate will create login credentials for the manufacturing unit and the manufacturing unit for login on the portal will use these credentials.
- After clicking on "**Sign up Here**" link for "**Registration Purpose**" on the portal, a new window will open.

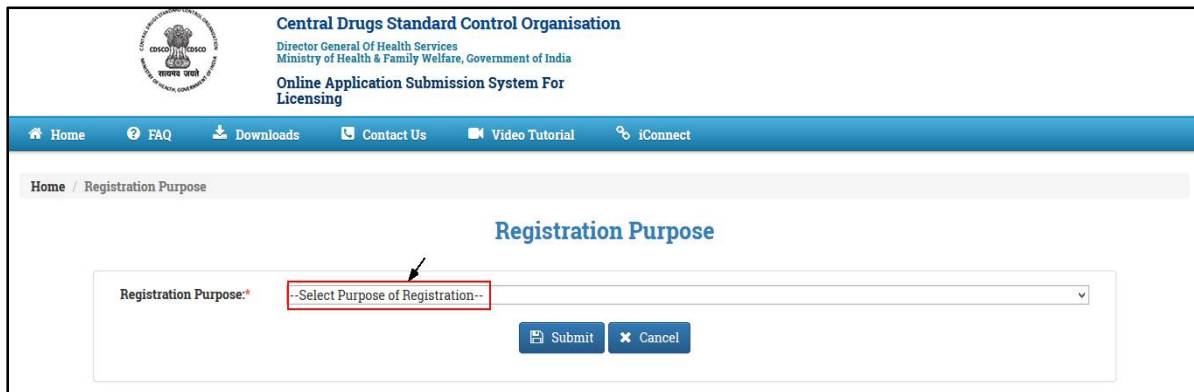


Figure 2 : Screen of Registration Purpose

### 1.3 Purpose of Registration

- Applicant can register with different purposes with the assigned roles and forms given below:

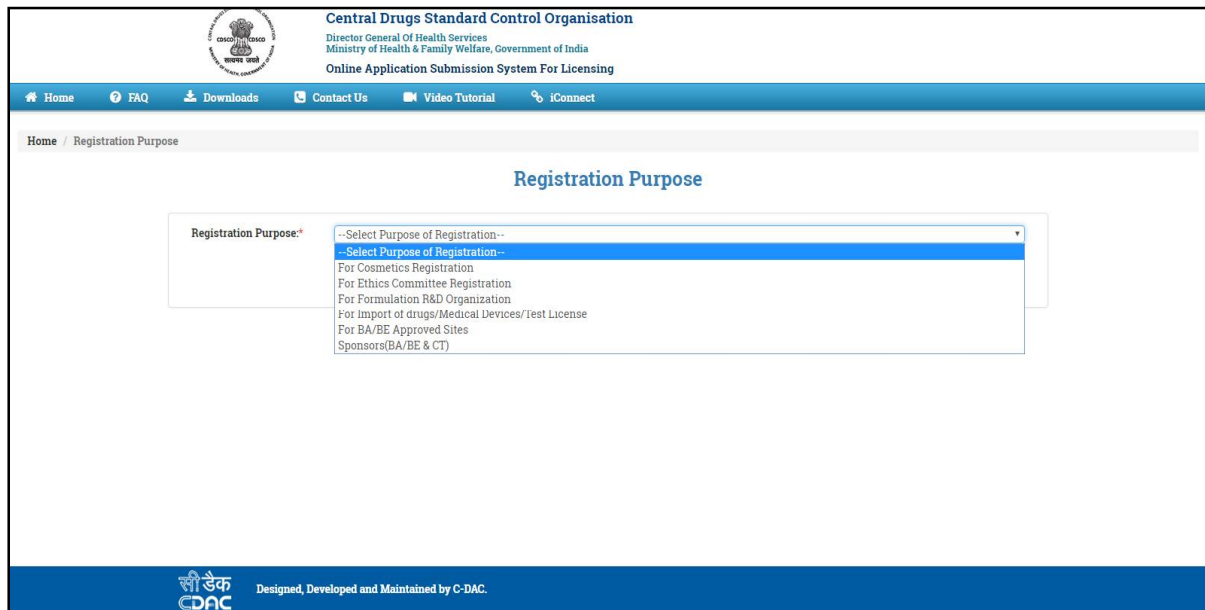
Table 1 : Purpose of Registration& Documents Required

Purpose of Registration	Roles on SUGAM	Document Requirement	Forms Available
Cosmetics Registration	Applicant for Cosmetics	ID Proof Details, Power Of Attorney, Corporate Address Proof	Form 42
Ethics Committee Registration	Ethics Committee	ID Proof Details, Power Of Attorney, Corporate Address Proof	Ethics Committee Registration
Formulation R&D Organization	Formulation R&D Organization	ID Proof Details, Power Of Attorney	Form44,Form12



Import of drugs/Medical Devices/Test License	Corporate Importer (Application in Form 8) Foreign Enterprise holding Indian Subsidiary Indian Agent	ID Proof Details, Power Of Attorney, Corporate Address Proof and Manufacturing License or Wholesale Licenses (Form 20B & Form 21B)	Form 40, Form 8 Form 8 Form 40, Form 8 Form 40, Form 8
BA/BE Approved Sites	BA/BE Approved Sites	ID Proof Details, Power Of Attorney, Corporate Address Proof	Form 44
Sponsors (BA/BE & CT)	Sponsors (BA/BE & CT)	ID Proof Details, Power Of Attorney, Corporate Address Proof	Form 44, Form 12

➤ After clicking on the drop down, list for the **Purpose of Registration** is shown.



**Figure 3 : Screen of Purpose of Registration**

➤ **Note**

- User can choose any of the registration purpose from the drop down list.
- After selecting the Registration Purpose, user has to submit by clicking on the **"Submit"** button.
- User can cancel the Registration Purpose, by clicking on the **"Cancel"** button.

## 1.4 Registration Form

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

**Online Application Submission System For Licensing**

Home
FAQ
Downloads
Contact Us
Video Tutorial
iConnect

### Applicant Registration

Registration Guidelines

**Note:**

- Authorized Signatory / Responsible person of the organization should fill the form.
- All fields marked with asterisk (\*) are mandatory. Only PDF documents with size not more than 10 MB are permitted.
- Registration Steps**
  - After submitting the Registration Form, Check Registered email for E-mail Verification
  - Submit ID proof (Authorised Person), Undertaking (Issued by Government authority on the name of the Company and address), Address Proof Document in hard copy to CDSCO office.
  - Registration will be approved by CDSCO only after evaluation of the submitted documents. Check your registered email id for all communications.
- If the **Undertaking PDF** does not contain interactive fields, you can use the **Fill & Sign** tools to fill out the form. Save the form on your computer, and then open it directly in Acrobat Reader
- All the documents should be self-attested by the person who signs on undertaking with stamp and seal of the company.
- It is mandatory to upload **Copy of Manufacturing License**, in case applying for **Test License Division**.

**Applicant Details**

**Applicant Type\***

**User-Name\***

**Password\***

**Confirm Password\***

Only Best Passwords are accepted

**Name\***

**Mobile Number\***

**Gender\***  Male  Female

**Nationality\***

**ID Proof Details\*** (Single PDF < 10 MB)  
     
If identity proof is other than Aadhar card, then Applicants are required to upload their Aadhar details in SUGAM Portal within 2 months of obtaining Login Credentials.

**Undertaking\*** (Single PDF < 10 MB)  
  [Download, Fill and Sign this Undertaking PDF Template and Upload the same here](#)  
 - Available in Enterable PDF Format

**Designation\***

**Alternate Email ID:**

**Registering for Division\***   
Multiple Divisions can be selected

**Registered Indian Address** (This address will be referred in all the forms submitted to CDSCO office)

**Organization Name\***

**Organization Type\***

**CIN (Corporate Identification Number):**

**Address Line 1\***  **Address Line 2\***

**Country\***  **State\***  **District\***

**City/Taluka/Mandal/Tehsil\***  **Pin Code\***

**Contact No.\*** (Please include STD Code - Phone Number)  
   
Multiple Contact Numbers can be added with comma separation

**Fax No.\*** (Please include STD Code - Fax Number)  
   
Multiple Fax Numbers can be added with comma separation

**Upload Your Corporate Address Proof Details (Certificate of Incorporation):\*** (Single PDF < 10 MB)

It is mandatory to upload Copy of Manufacturing License, in case applying for Test License Division.

**Copy of Manufacturing License or Wholesale Licenses (Form 20B & Form 21B):\*** (Single PDF < 10 MB)

Please tick (✓) this option if you want to receive SMS alerts.

**PbjFS**

I agree to the [terms, conditions and privacy policy](#) laid down by Central Drugs Standard Control Organisation, DGHS, Ministry of Health & Family Welfare for availing the online services provided under this portal. \*

Designed, Developed and Maintained by C-DAC.

Figure 4 : Registration Form

## 1.5 Registration Guidelines

- User can register by filling the form.
- Username will be corporate email id and it should be unique, which can be used as user name for future communication.
- Password length should be at least six characters with at least one number, one lowercase, one uppercase letter and one special character.
- User must upload necessary documents like **ID Proof Details, Power Of Attorney, Corporate Address Proof and Manufacturing License or Wholesale Licenses (Form 20B & Form 21B)** and should keep these documents ready in PDF format before sign up process.
- **DST Registration Number** is mandatory to fill the **Formulation R&D Registration Form**.
- If you select the checkbox for "Do you want to receive SMS alerts? "At the time of registration, you will receive the registration and verification message on your registered mobile number.
- User can also go to homepage by clicking on the "**Previous**" button.
- After clicking on "Submit" button, a confirmation link will be sent to user's registered email id to verify registration.
- User can verify account by clicking on the link sent to the registered email id.
- After clicking the verification link, registration application of the user will be sent for approval to the concerned authority (CDSCO Officials).
- In case of approval/rejection of the application, a mail will be sent to user's registered email id.

## 1.6 Registration Form Confirmation

- After successful submission of registration application below screen will appear.

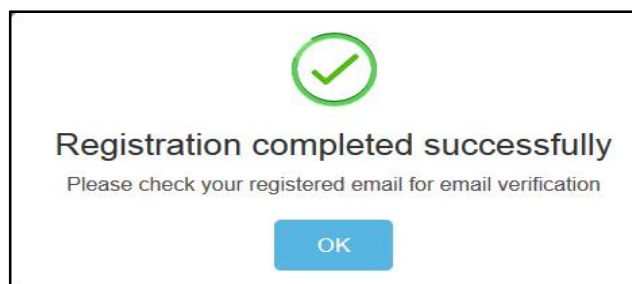


Figure 5 : Screen of Registration Completed Successfully'

- **Note:-**
  - After getting Successful Registration message, a confirmation link will be sent to user's registered email id.
  - User can verify account by clicking on the link sent to the registered email id.
  - After clicking on the link, registration application will be sent for approval to the concerned authority(**CDSCO Officials**)

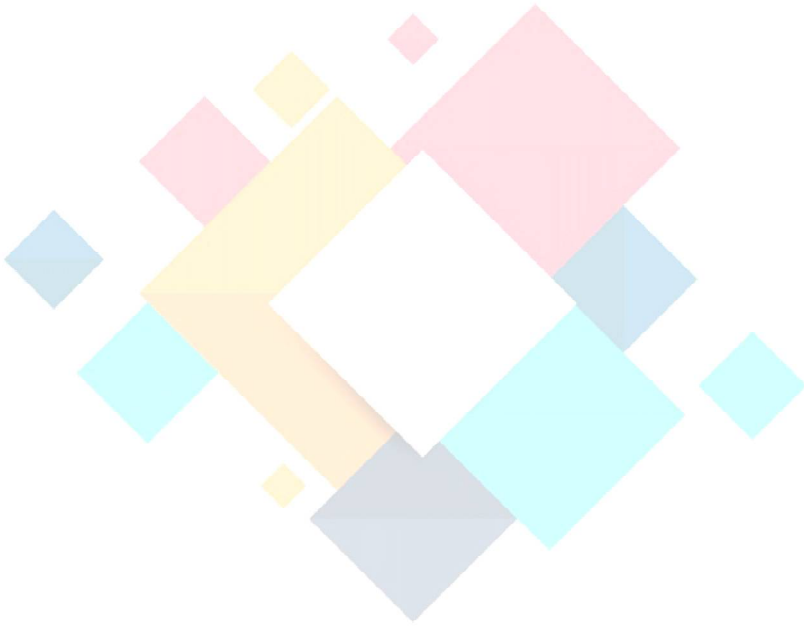
- In case of approval/rejection of the application, a mail will be sent to user's registered email id.

### 1.7 Portal Login

- After user received approval mail from CDSCO for their user registration, User can login into the system with User Name and Password as entered in user registration form, as shown in the Figure.

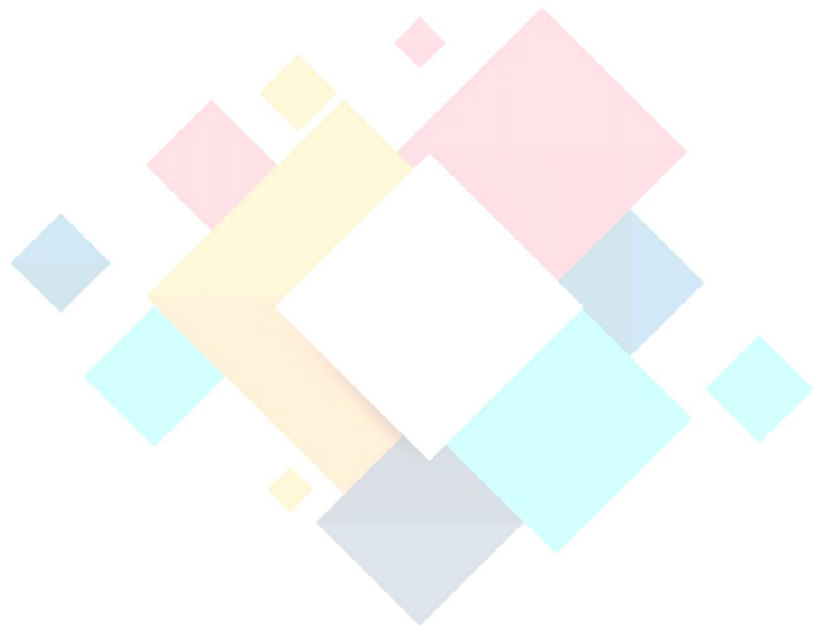


Figure 6 : Login Screen



## Chapter – 2

# SUGAM Applicant Dashboard



## 2. SUGAM Applicant Dashboard

After successful login from the homepage of the portal, applicant will be directed to the dashboard depending upon his default role as shown in the below **Figure**.

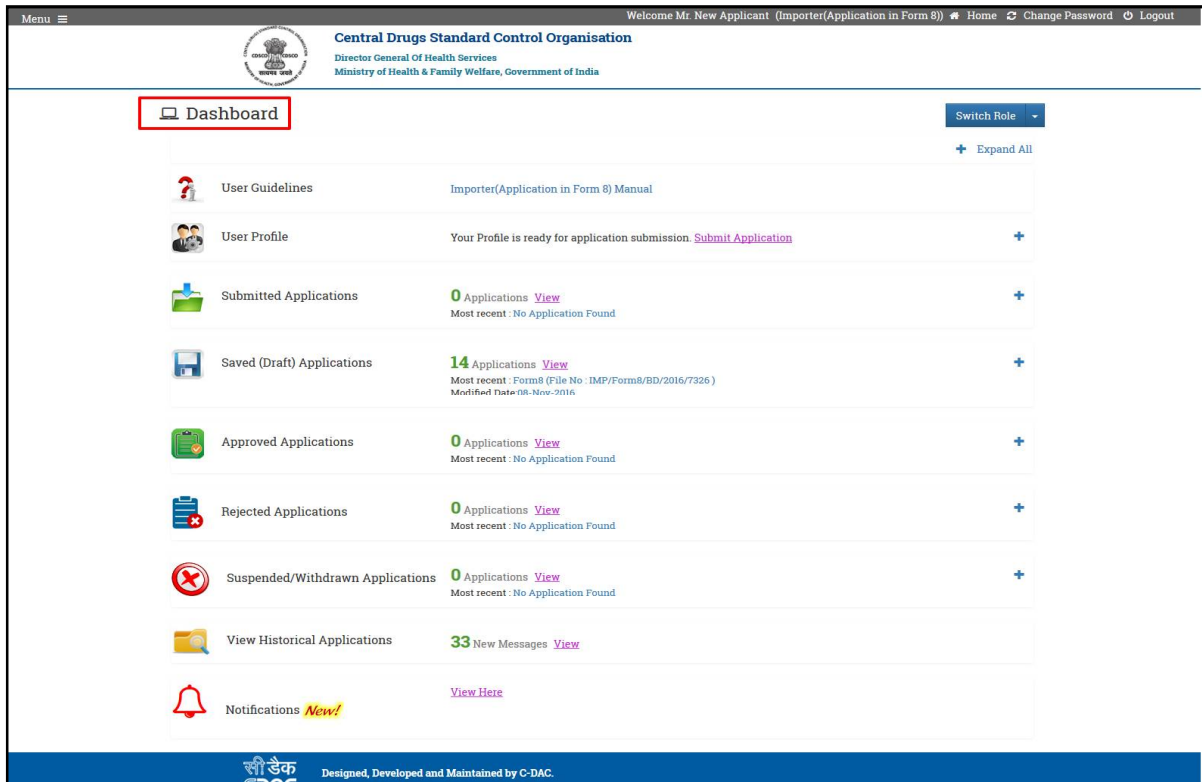


Figure 7 : Dashboard Screen

### 2.1. Dashboard Options

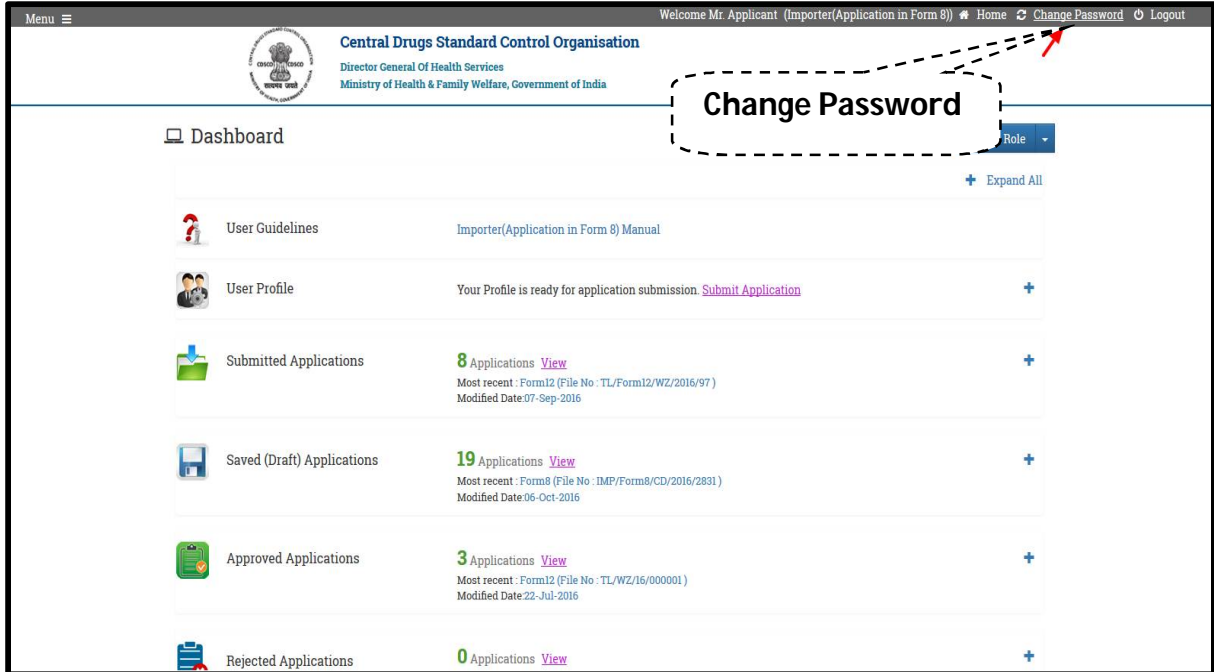
Following are the options available on the Applicant dashboard of SUGAM portal



Figure 8 : Dashboard Option (SUGAM Applicants)

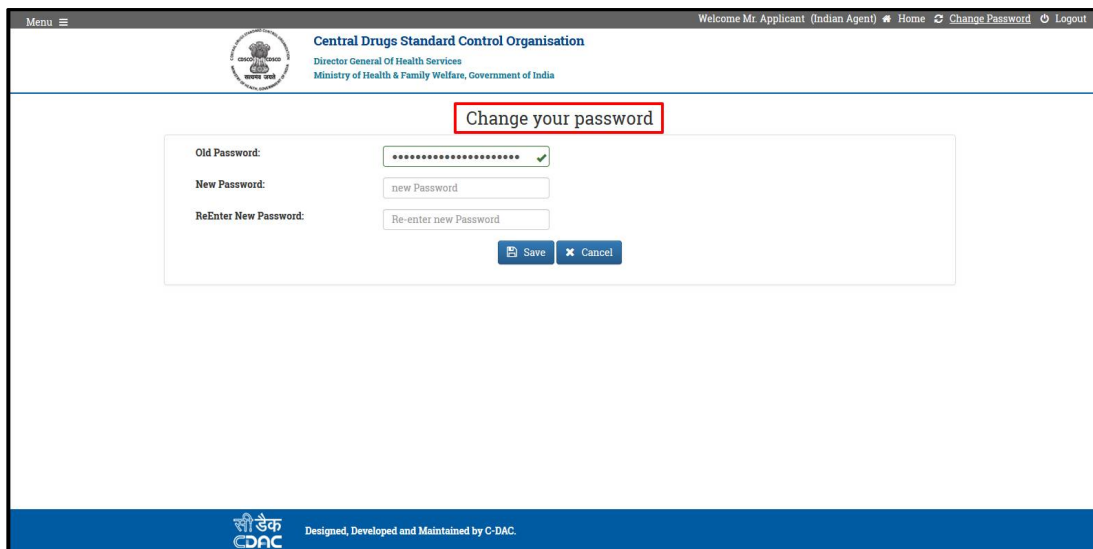
## 2.2. Password Change

- If the user wants to change their password then they can click on 'Change Password' link, as shown in **Figure**.



**Figure 9 : Screen of Change Password Option**

- After clicking the "Change Password" link, user needs to enter the old password and then enter the new passwords depicted in below:



**Figure 10 : Screen of change password (Continue)**

- After clicking on "save" button, your password will be updated.



### 2.3. Switch Role

- Switch Role is the functionality provided to the users of SUGAM portal possessing multiple roles. E.g. A user from pharmaceutical industry can possess roles of corporate/ Indian Agent/Importer/sponsor etc. The applications & data pertaining to each role will be accessed through its individual dashboard but through the same login ID. It is for this purpose switch role functionality is available on the portal.
- At the top-right of the Applicant Dashboard you can see a **“Switch Role”** button there user can select the desired role approved for him and as shown in **Figure**.

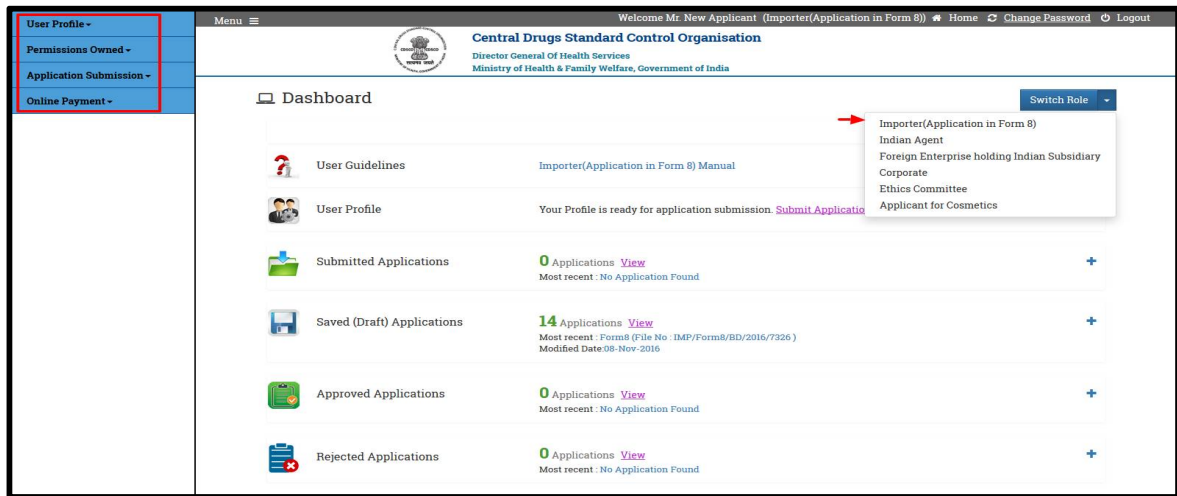


Figure 11 : Switch Role

### 2.4. User Profile

- User can view his registration details under view profile option in user profile section. All the details that user entered during user registration are available here.
- User can change the details like User ID& other details; however organization details could only be changed via processes for post approval changes.

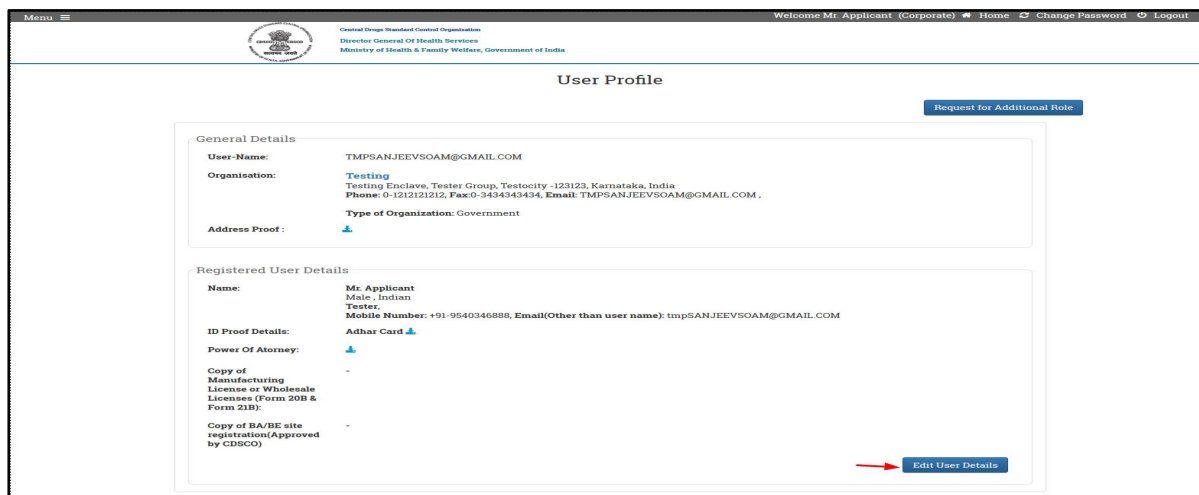
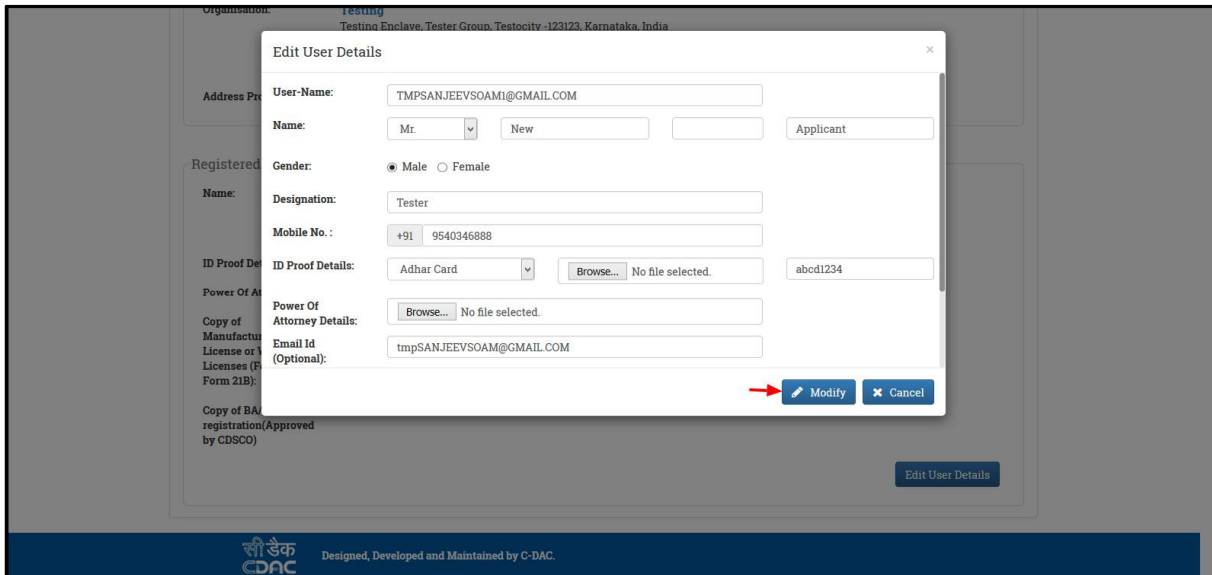


Figure 12 : View Profile

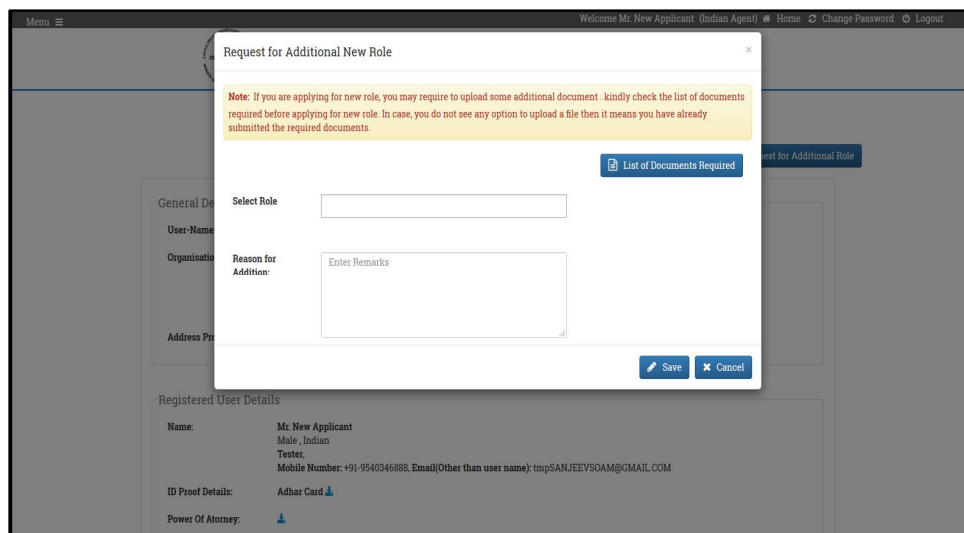
**Note:** If you click on “Edit User Details” then a new pop-up window will open, where user can make the changes, as shown in **figure**.



**Figure 13 : Screen of Edit User Detail**

## 2.5. Request for Additional Role

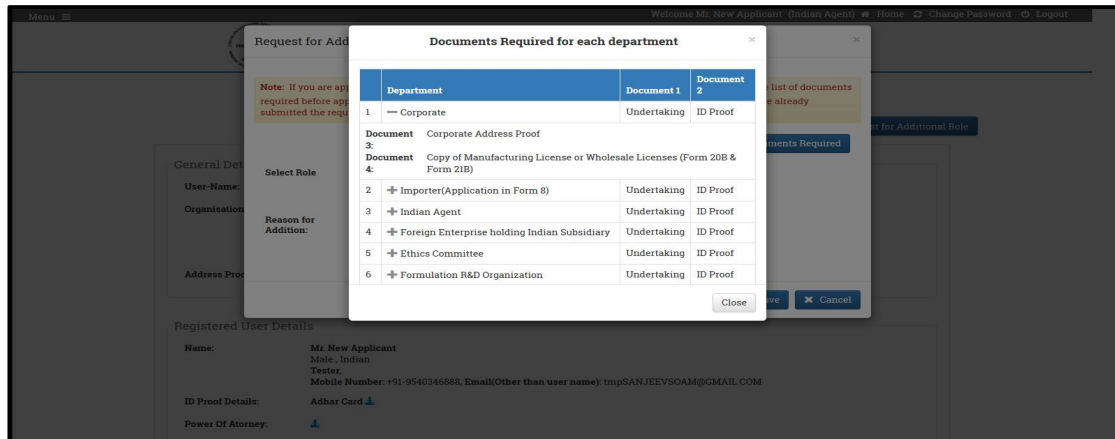
- A user on SUGAM portal can request for the additional role by clicking on “**Request for Additional Role**” on view user profile page as shown in **figure below**.
- While applying for an additional role you are required to upload the necessary documents for the same.
- Select the role which you want and add some remarks. After filling the details save on click “save” button.



**Figure 14 : Screen of Request for Additional New Role**

**Note**

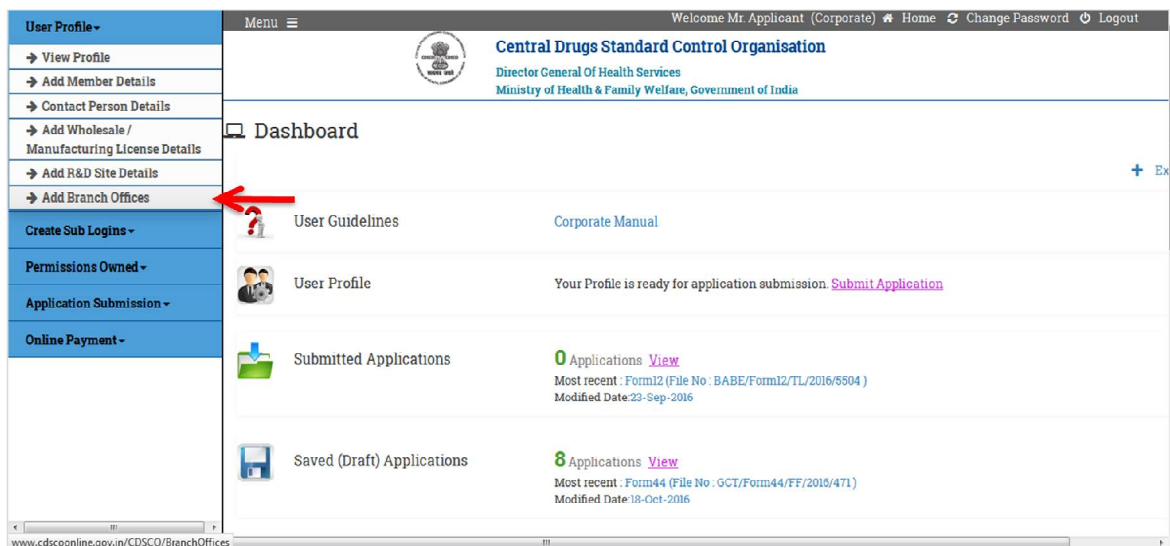
- Please read the points mentioned in note before filling the form.
- If there is no option to upload a file then it means you have already submitted the required documents for that role.
- You can check the necessary documents by clicking on “ **List of Documents Required**”



**Figure 15 : Screen of List of Documents Required**

## 2.6. Additional User Profile Details

It is mandatory for users to fill the complete user profile to apply for the application form through the portal. User can fill in his additional profile details like member details, contact person details, wholesale/manufacturing license details and other R&D sites & branch office details through the options available in left menu.



**Figure 16 : Adding User Profile Details**

➤ **Add Member Details**

- Using this option manufacturer/corporate will be able to add authorized member details, as shown in below **figure**.

**Organization Member Details**

Name	Gender	Designation	Mobile No	ID Proof Details	Date	Action
Mr. Ankit	M	Import Executive	4444444444	Adhar Card	10/29/20	<a href="#">Delete</a> <a href="#">Edit</a>

**Figure 17 : Add Members Details**

**IMPORTANT:**

- Details of atleast one user is required for completion of User Profile.
- On completion of User Profile, Form Submission will be enabled.
- In case, the added member resigns from the organization, status should be made **Inactive** by clicking the button available in the Edit column of table.
- All fields marked with asterik (\*) are mandatory.

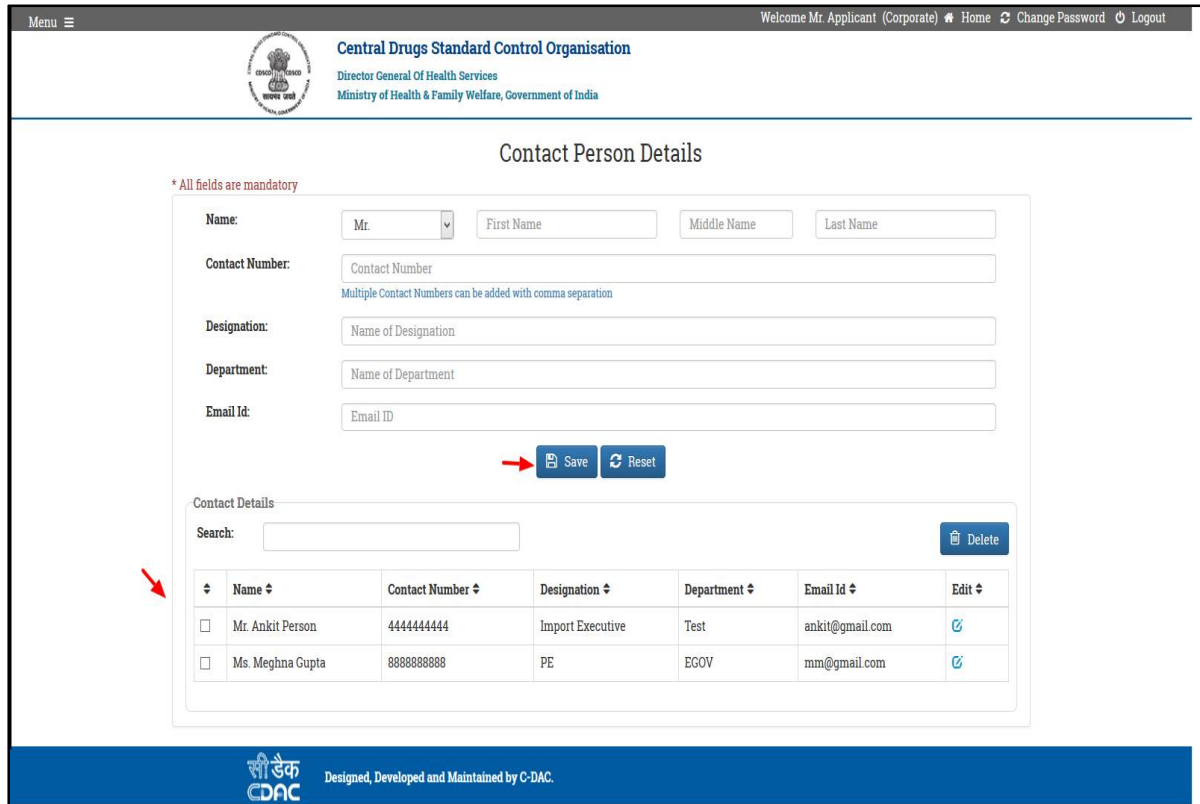
**Figure 18 : Add Director Details**

**Note:**

- Member Details will depend on the type of organization.
- On clicking "Add", a new member detail will be added.
- Details can be edited and deleted.
- In case, the added member resigns from the organization, status can be changed from Active to Inactive by editing the details.
- All mandatory fields are marked by asterisk (\*).

➤ **Contact Person Details**

- Manufacturer/Corporate can add '**Contact Person Details**', as shown in **Figure**.
- Fill all the details and click on save button as shown in **Figure**.



**Contact Person Details**

\* All fields are mandatory

**Name:**

**Contact Number:**   
Multiple Contact Numbers can be added with comma separation

**Designation:**

**Department:**

**Email Id:**

➔

**Contact Details**

Search:

☐	Name	Contact Number	Designation	Department	Email Id	Edit
<input type="checkbox"/>	Mr. Ankit Person	4444444444	Import Executive	Test	ankit@gmail.com	
<input type="checkbox"/>	Ms. Meghna Gupta	8888888888	PE	EGOV	mm@gmail.com	

**Figure 19 : Contact Person Details**

**Note**

- Contact person is an alternative to the registered user, whom CDSCO official can contact in absence of registered user for any clarification.
- You can reset the details by clicking on 'Reset' button. Also the details saved can be edited or deleted.

➤ **Add Wholesale/ Manufacturing License Details**

- This form is to add multiple License type (CRO Approval, Manufacturing site etc.).
- On clicking on "Save" a new Wholesale license detail will be added as shown in **Figure**.

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

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

### Add License Details

\* All fields are mandatory

**Licensing Details**

License Type:

Issuing Authority:

Licence No./Approval:

Valid From:

Valid Upto:

Upload Licence / Approval:  No file selected.

**Address Details**

Choose Premises:

**Address Details**

Search:

License Type	Premises Name	Address	License No	Licence	Edit
<input checked="" type="checkbox"/> Manufacturing Site	GHAZIABAD	Test, Test, Nicobar, Test, Andaman And Nicobar, India, 111111	LN-123	Download	<input checked="" type="checkbox"/>
<input type="checkbox"/> Manufacturing Site	GHAZIABAD	Test, Test, Nicobar, Test, Andaman And Nicobar, India, 111111	FF-421-24387	Download	<input type="checkbox"/>
<input type="checkbox"/> Wholesale License Site	Test Dispatch	119/203, A-58, Majlis Park, Kheda, Kheda, Gujarat, India, 208012	LN-245	Download	<input type="checkbox"/>
<input type="checkbox"/> Wholesale License Site	Meghna & CDSCO Co.	Blidg 1 & 2, 119/203, Vijay Nagar, Spcl Address 2, New Delhi, Delhi, Delhi, India, 110011	LN-1234	Download	<input type="checkbox"/>
<input type="checkbox"/> Wholesale License Site	M/s Unit Name	Address Line One; Address Line Two; Raigarh, Cityname: Chhattishgarh; India, 232323	LN-123	Download	<input type="checkbox"/>
<input type="checkbox"/> Manufacturing Site	Test Pharmacy	Block No.10, 1st Floor; Udyog Bhawan; Pune; Pune, Maharashtra, India, 400126	280018	Download	<input type="checkbox"/>
<input type="checkbox"/> Wholesale License Site	Test Pharmacy	Block No.10, 1st Floor; Udyog Bhawan; Pune; Pune, Maharashtra, India, 400126	FF-125-607	Download	<input type="checkbox"/>
<input type="checkbox"/> CRO Approval	Test	Tester, Testing, Chandigarh, Chandigarh, Chandigarh, India, 234556	12345	Download	<input type="checkbox"/>

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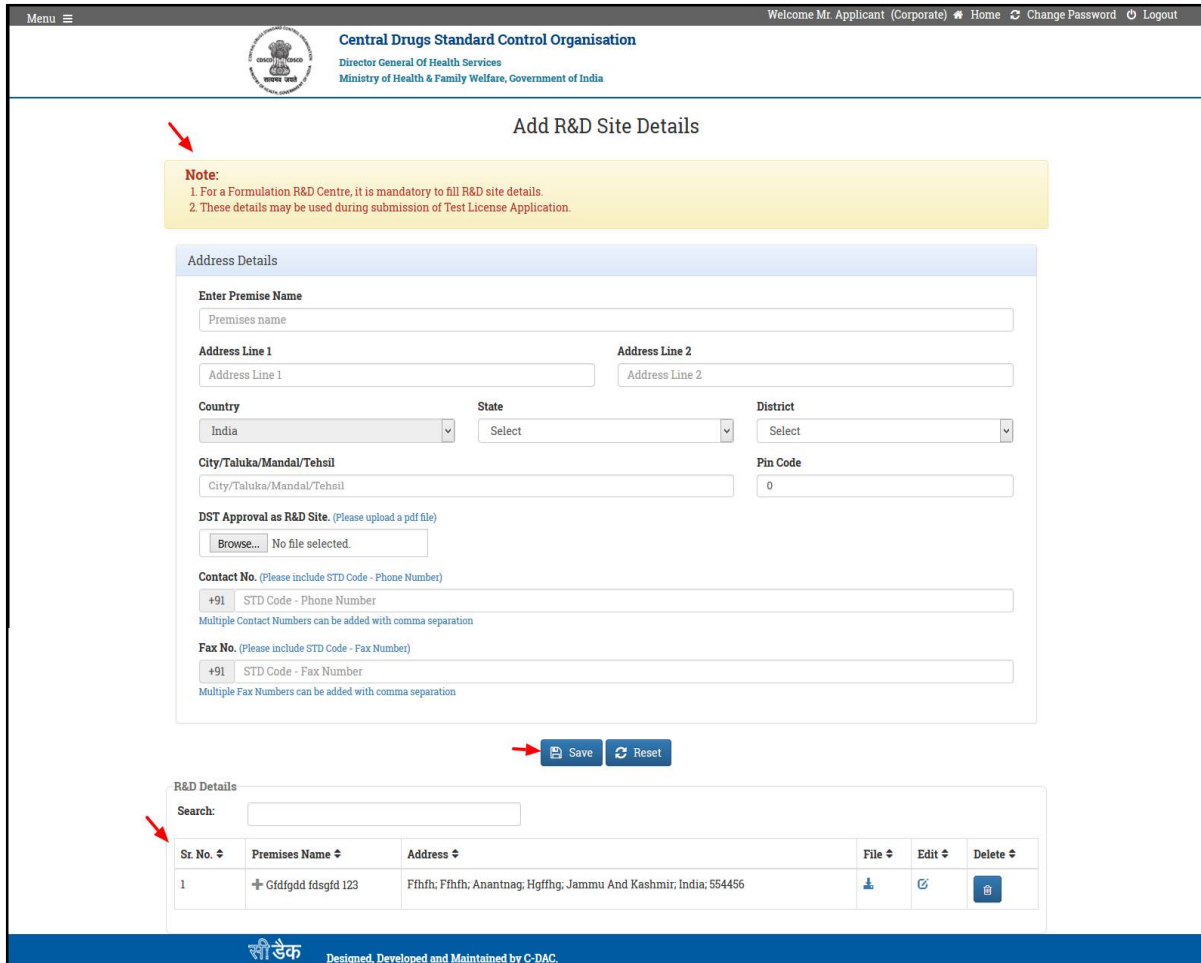
**Figure 20 : Add Wholesale License Details**

**Note**

- User can select any one of the License type, fill the required information and upload the supporting documents.

➤ **Add R&D Site Details**

- For a Formulation R&D Centre, it is mandatory to fill R&D site details, as shown in **Figure**.



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

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

### Add R&D Site Details

**Note:**  
1. For a Formulation R&D Centre, it is mandatory to fill R&D site details  
2. These details may be used during submission of Test License Application.

**Address Details**

**Enter Premise Name**  
Premises name

Address Line 1  Address Line 2

Country  State  District

City/Taluka/Mandal/Tehsil  Pin Code

**DST Approval as R&D Site.** (Please upload a pdf file)  
 No file selected.

**Contact No.** (Please include STD Code - Phone Number)  
+91   
Multiple Contact Numbers can be added with comma separation

**Fax No.** (Please include STD Code - Fax Number)  
+91   
Multiple Fax Numbers can be added with comma separation

**R&D Details**

Search:

Sr. No.	Premises Name	Address	File	Edit	Delete
1	Gtfdgdd fdsgrtd 123	Ffhfu, Ffhfu, Anantnag, Hgffhg, Jammu And Kashmir, India, 554456	<input type="button" value="📎"/>	<input type="button" value="✎"/>	<input type="button" value="🗑"/>

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Figure 21 : Add R&D Site Details

**Note**

- These details may be used during submission of Test License Application.

➤ **Add Branch Office Details**

- To create Branch Office Login , User has to first register the Branch office details through User Profile Section by clicking on '**Add Branch Offices**' link in '**User Profile**' Tab.

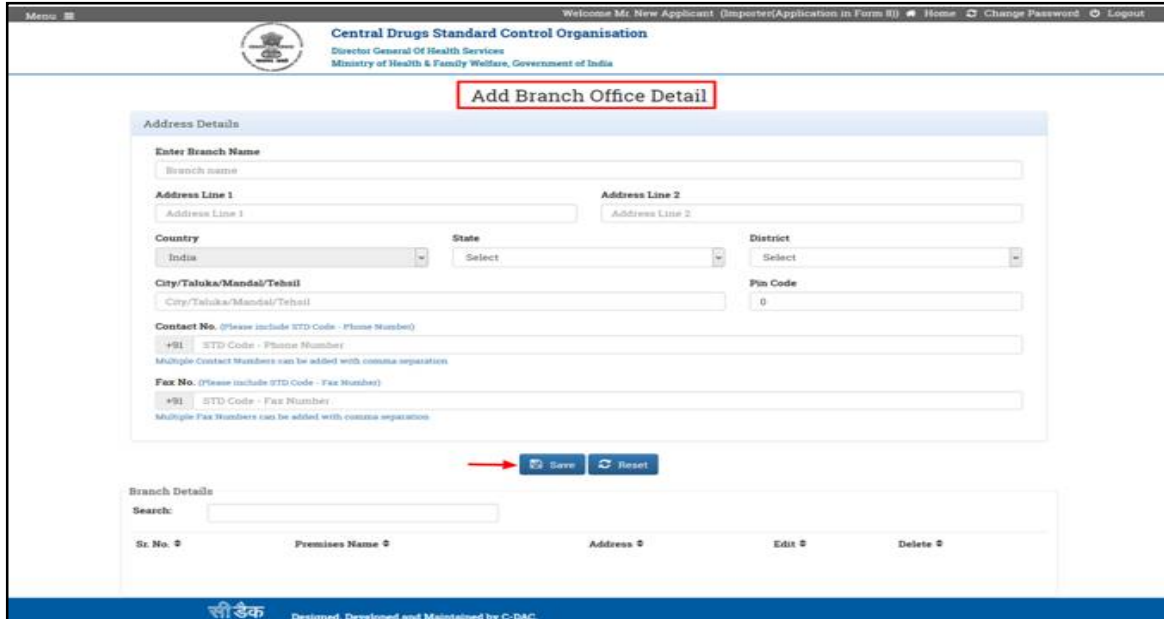


Figure 22 : Add Branch Office Details

### Note

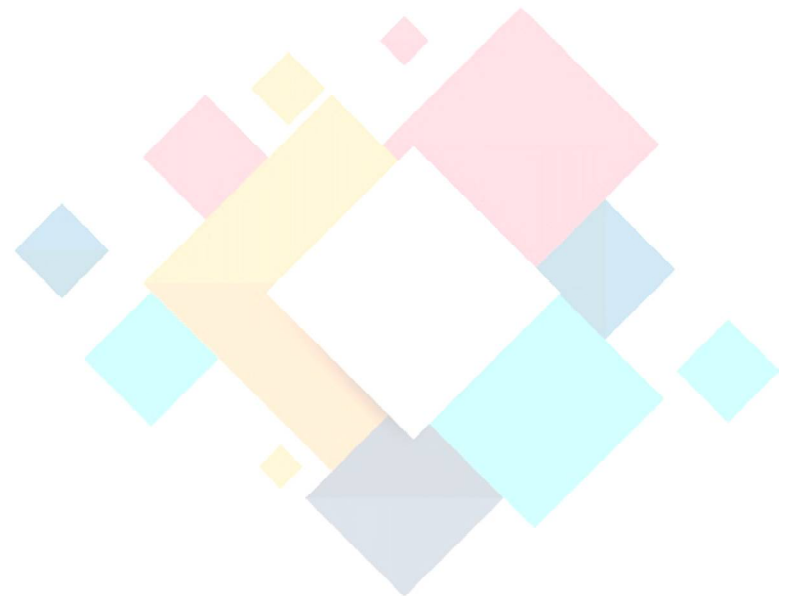
- The login credentials of the users can be created, only if their details are added in user Profile section in the '**Add Member Details**' for manufacturer and CRO login and '**Add Branch Offices**' for branch office section of the '**User Profile**'.
- It is mandatory for the user to fill all the details. After filling all the details, click on the '**Save**' button to save all the details (as shown in Figure), the saved details can be viewed in the '**Branch Details**' section. The saved details can be modified or deleted.





# Chapter- 3

## Guidelines for Creation of Sub-Login Accounts



### 3. Guideline for Creation of Sub-Login Accounts

- As per CDSCO policies for online portal, SUGAM allows creation of only single account (Corporate Account) that will be approved by CDSCO for single legal entity of a Pharmaceutical company. However, SUGAM allows corporate user accounts to create Sub-Login accounts under their umbrella for filing independent applications by manufacturing units/R &D units or any other units. This facility allows corporate users to create sub-login credentials for the following:-
  - Branch Office
  - CRO
  - Manufacturing Site



**Note:** To create sub login credentials users has to first add the details of the other offices under user Profile section in the 'Add Manufacturing License details' / 'Add R&D Sites' / 'Add Branch Offices'. Once you add these details, the list of offices will be available for you to create sub-login accounts under create Sub-logins section.

To create sub-logins, follow the following steps:

#### 3.1 Add Office Details

- To create Branch Office Login , User has to first enter the Branch office details through User Profile Section by clicking on 'Add Branch Offices' link in 'User Profile' Tab, as shown in the below Figure.

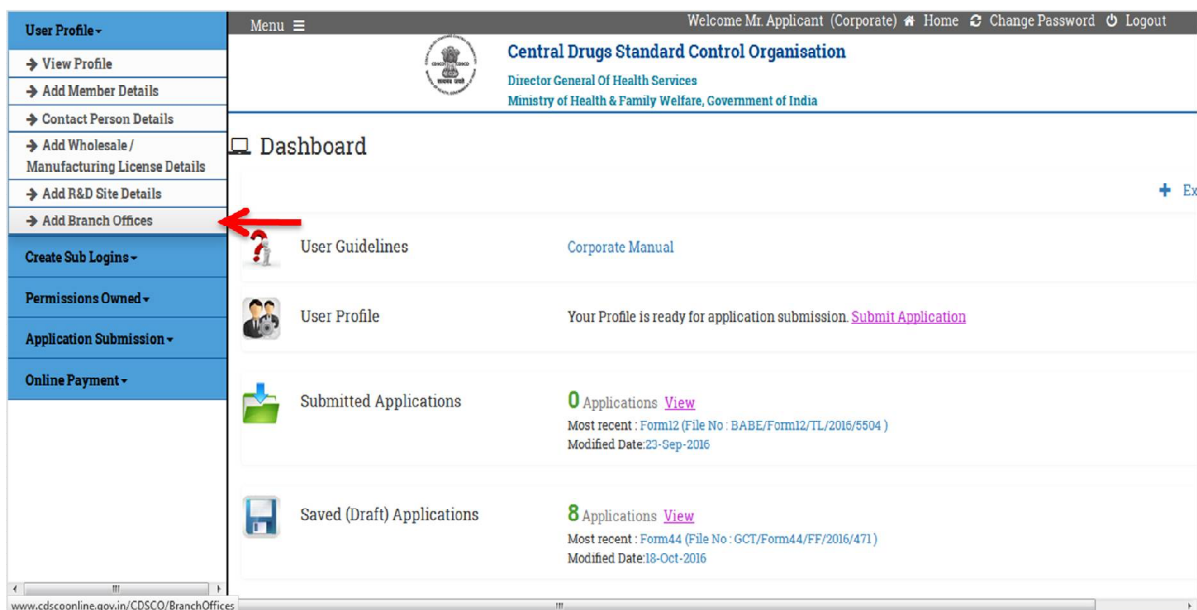


Figure 23 : Option to Add Branch office Details

Figure 24 : Add Branch office Details

- It is mandatory to fill all the details. After filling the details, click on 'Save' button to save the details (as shown in **Figure**), The entered details is visible in the 'Branch Details' section which can be modified or deleted.

### 3.2 Create Sub-Login

- User can now create the Login Credentials for registered Branch Offices by clicking on 'Create Branch Office Login Credentials' under 'Create Sub Login' Tab, as shown in the below the mention **Figure**.

Figure 25 : Option to Create Branch Office Login

- The Registered Branch Office details will be shown in branch office dropdown, as shown in Figure.

Branch Offices	Username	Name	Gender	Designation	Mobile No	Undertaking	Edit
<input type="checkbox"/> Dfsdfs,sdfsdfsdsd	TMPTESTER@GMAIL.COM	Mr. fgdfg dfgdg	M	Dfgdfg	5656565655		

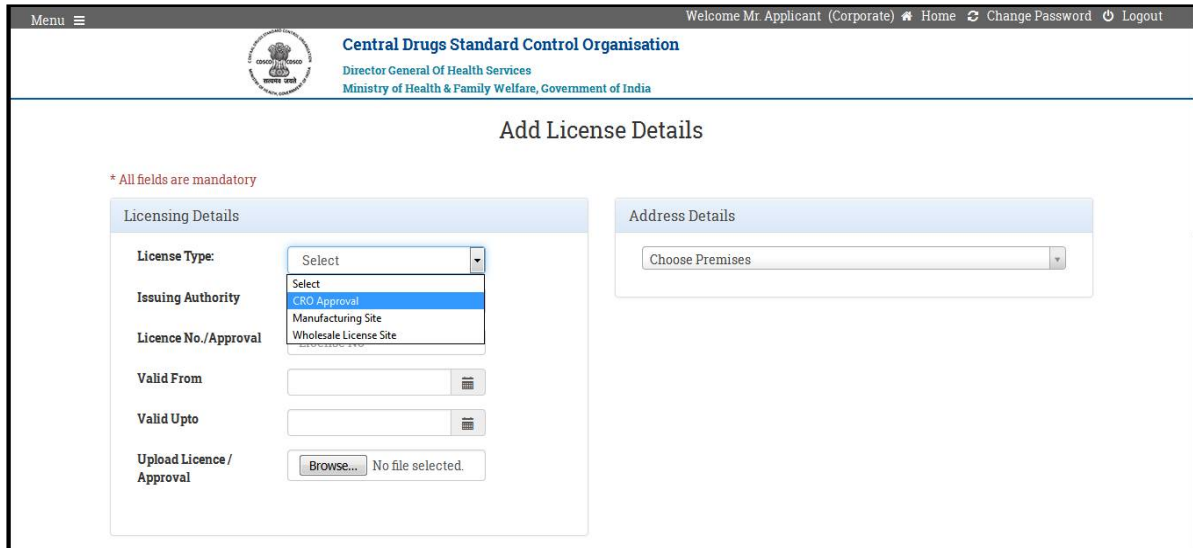
Figure 26 : Screen of Branch Office Login

- It is mandatory for the user to fill all the details of the branch office. Once the details are saved, the login credentials for that particular branch office is created and user can now login using that credentials.
- **NOTE : It is also mandatory to upload the duly signed undertaking (as per the template provided in undertaking section)**

### 3.3 CRO Login Credentials

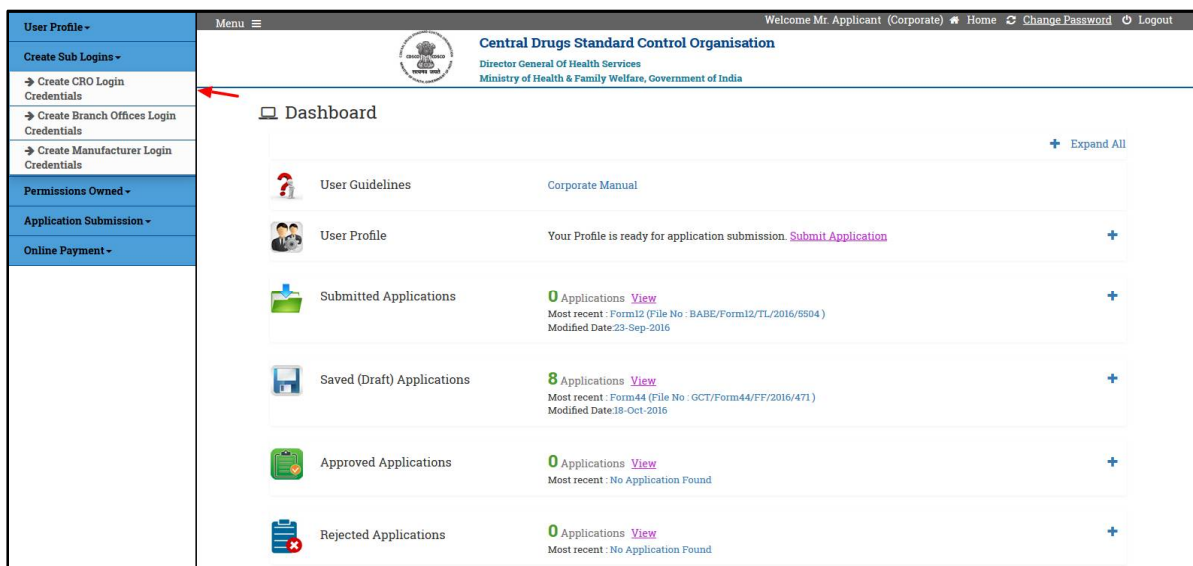
Figure 27 : User Profile - Add Wholesale/Manufacturing License Details

- To create CRO Login , User has to first register the CRO Premises details through user profile by clicking on '**Add Wholesale/Manufacturing Licenses Details**' link in '**User Profile**' Tab, as shown in **Figure**.



**Figure 28 : Add CRO details**

- It is mandatory for the user to fill the details .Once the details have been saved the same can be viewed details in table format at the bottom of the page. The saved details can be modified or deleted.
- User can now create the Login Credentials for registered CRO Premises by clicking on '**Create CRO Login Credentials**' under '**Create Sub Login**' Tab.



**Figure 29 : Create CRO Login**

- The Registered CRO Unit details will be shown in CRO Unit dropdown

Figure 30 : CRO Login Credential

- It is mandatory for the user to fill all the details.  
**NOTE: It is also mandatory to upload the duly signed undertaking (as per the template provided in undertaking section).**
- Once the details are saved, the login credentials for that particular CRO Unit is created and user can now login using that credentials.

### 3.4 Manufacturing Login Credentials

Figure 31 : User Profile - Manufacturer Login

- To create Manufacturing Login, User has to first register the Manufacturing Premises details by clicking on 'Add Wholesale/Manufacturing Licenses Details' link in 'User Profile' Tab, as shown in Figure.

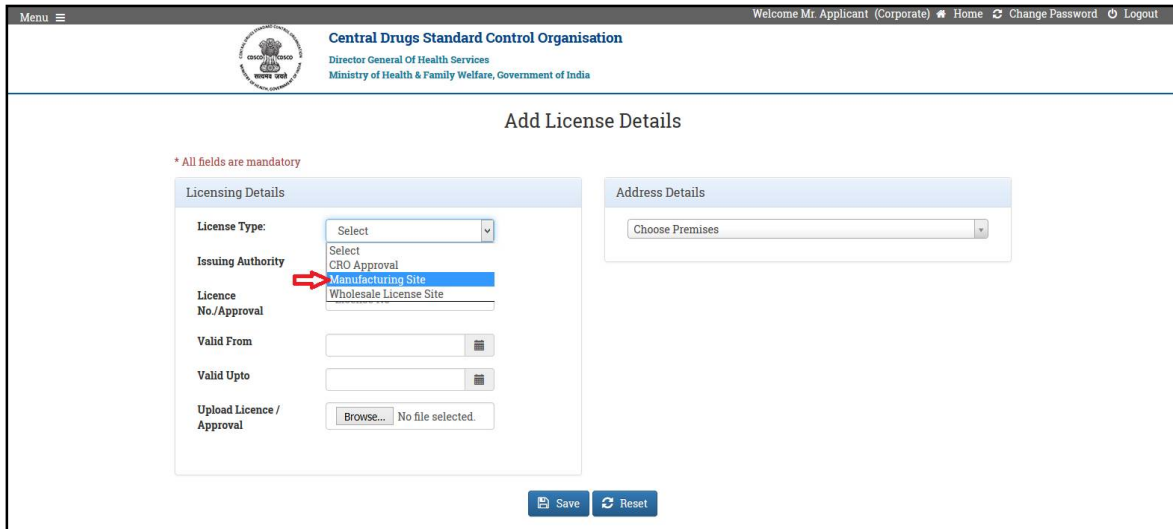


Figure 32 : Manufacturer Login

**Note-**

- It is mandatory for the user to fill all the details .Once the details have been saved, the same can be viewed in table format at the bottom of the page. The saved details can be modified or deleted.
- User can now create the Login Credentials for registered manufacturing Premises by clicking on 'Create manufacturing Login Credentials' under 'Create Sub Login' Tab, as shown in Figure.

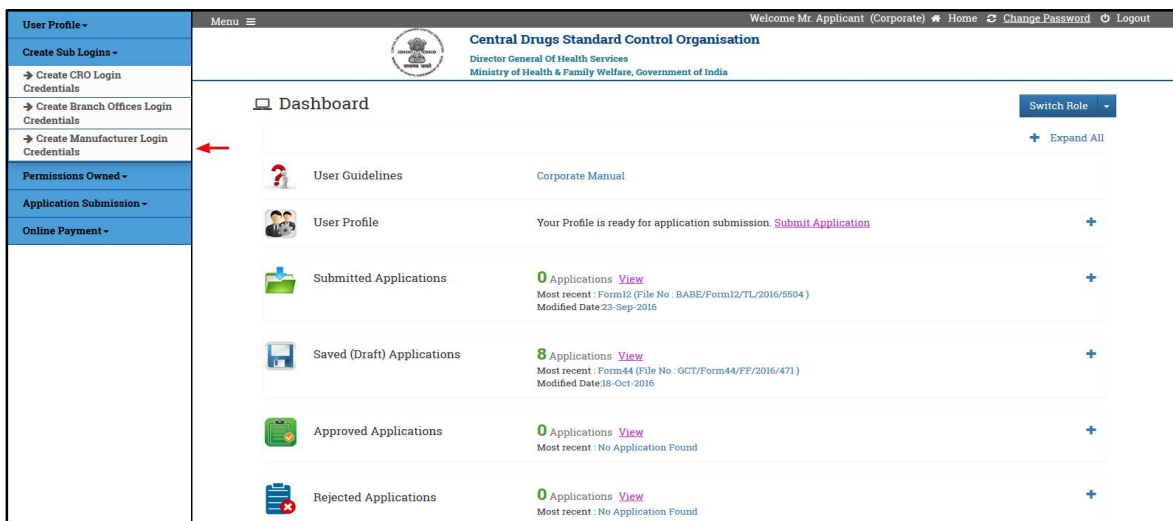
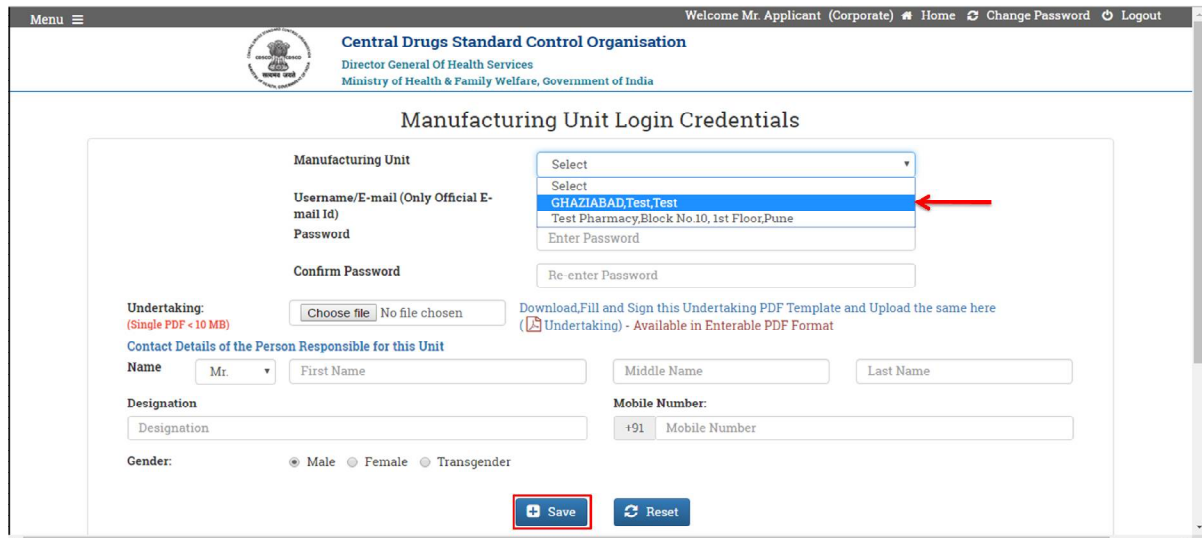


Figure 33 : Create Manufacturer Login

- The Registered manufacturing Unit details will be shown in manufacturing Unit dropdown



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

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

### Manufacturing Unit Login Credentials

**Manufacturing Unit** Select ▼

Select

**GHAZIABAD,Test,Test** ←

Test Pharmacy,Elock No.10, 1st Floor,Pune

**Username/E-mail (Only Official E-mail Id)**

**Password**

**Confirm Password**

**Re-enter Password**

**Undertaking:**  No file chosen Download,Fill and Sign this Undertaking PDF Template and Upload the same here  
(Undertaking) - Available in Enterable PDF Format

**Contact Details of the Person Responsible for this Unit**

**Name**

**Designation**

**Mobile Number:**

**Gender:**  Male  Female  Transgender

**Figure 34 : Manufacturer Login Credentials**

**Note-**

- It is mandatory for the user to fill all the details. Once the details are saved, the login credentials for that particular manufacturing Unit is created and user can now login using that credentials.

### 3.5 Format for Undertaking

- It is mandatory for the user to fill the details in the Enterable PDF Format and upload the same.



**UNDERTAKING**

1. I declare that I, .....s/o, w/o,  
..... Age:.....  
am working as  Managing Director  Director  CEO  COO  Company Secretary  
 Proprietor/Partner (select whichever is applicable)  
of M/s.....  
having registered office at .....  
..... (complete address).  
My contact details are landline.....,  
e-mail id:.....
2. I undertake that I am representing the firm  
M/s.....
3. I am authorised by the competent authority of the above said firm to delegate this power of attorney.
4. I have read the terms, conditions and privacy policy of the portal [www.cdscoonline.gov.in](http://www.cdscoonline.gov.in) and agree to them.
5. I declare that I have authorized Mr/Ms .....s/o,w/o  
....., Age.....  
working in the aforementioned firm at Sr. No. 2 as .....  
(designation) to register on the portal [www.cdscoonline.gov.in](http://www.cdscoonline.gov.in)
6. I declare that I have authorized Mr/Ms. .... to access  
[www.cdscoonline.gov.in](http://www.cdscoonline.gov.in) in addition to the person whose name is mentioned at S.No.5 to file application under the overall supervision of the authorized person whose name is mentioned at Sr. No. 5.
7. I undertake that the firm mentioned at Sr. No. 2 will be held responsible for all the acts and deeds performed on [www.cdscoonline.gov.in](http://www.cdscoonline.gov.in) subsequent to the registration.
8. I undertake that the login password will be kept confidential and will be held responsible for sharing with unauthorized persons.
9. The information submitted above is true and correct and no part of it is false and nothing misleading has been stated.
10. I declare that no other person has been authorized by the firm mentioned at Sr. No. 2 above, to register on the portal.

Signed on .....

Place:

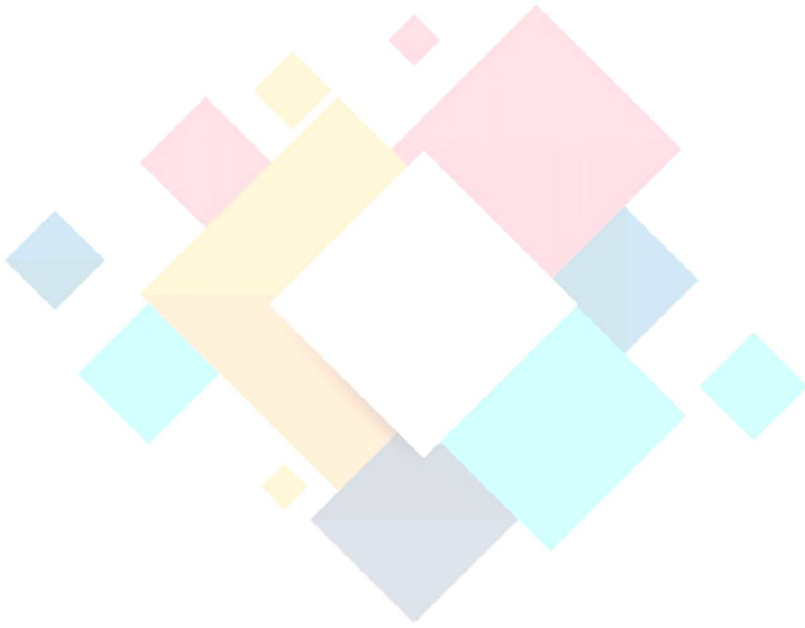
Name:

Designation:

Firm's Name:

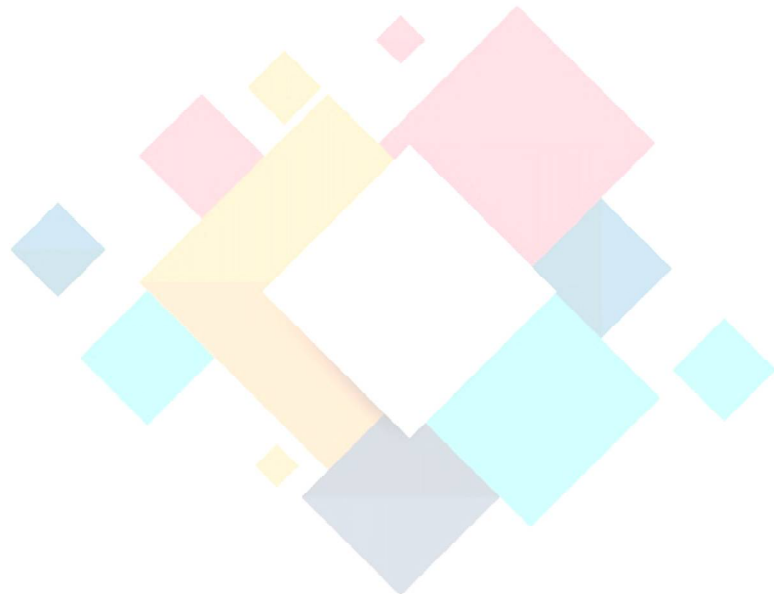
Seal:

**Figure 35 : Format for Undertaking**



# Chapter- 4

## Form Submission



## 4. Form Submission

- To submit a form, user must have valid login credentials and should fill up the basic details in User profile section like member details & contact details. If the user is approved by the CDSCO authorities he/she can login to the portal and submit the form.
- As shown in the figure below, after login user will be redirected to the dashboard and then click on submit application link to proceed further for submission of application.

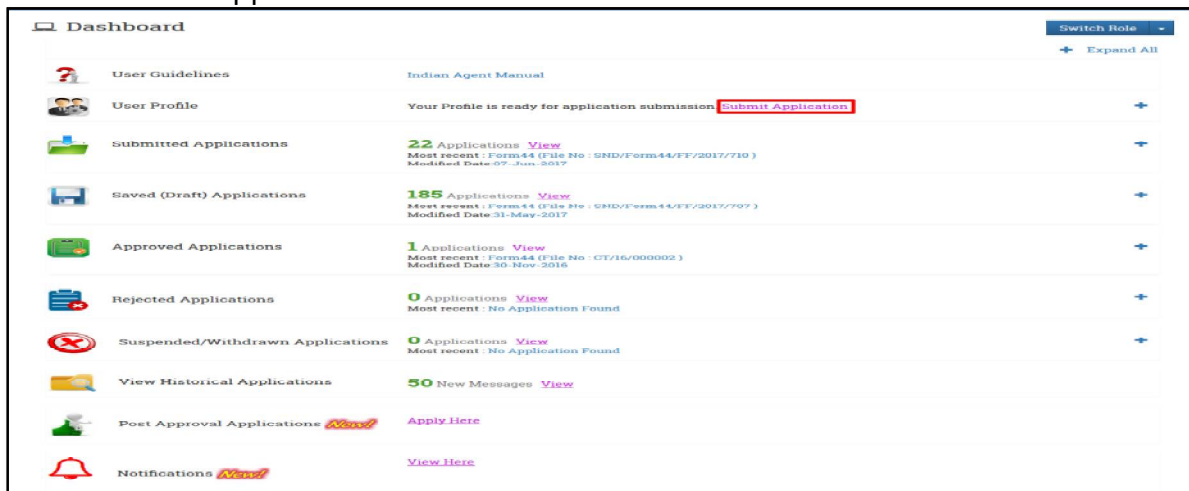


Figure 36 : Form Submission

- After clicking on “Submit Application” user will be redirected to a new page where he/she will select the department followed by the selection of the form. User should also read the general instruction provided on the same page and click on the declaration box before clicking on proceed to form as shown in the figure below.

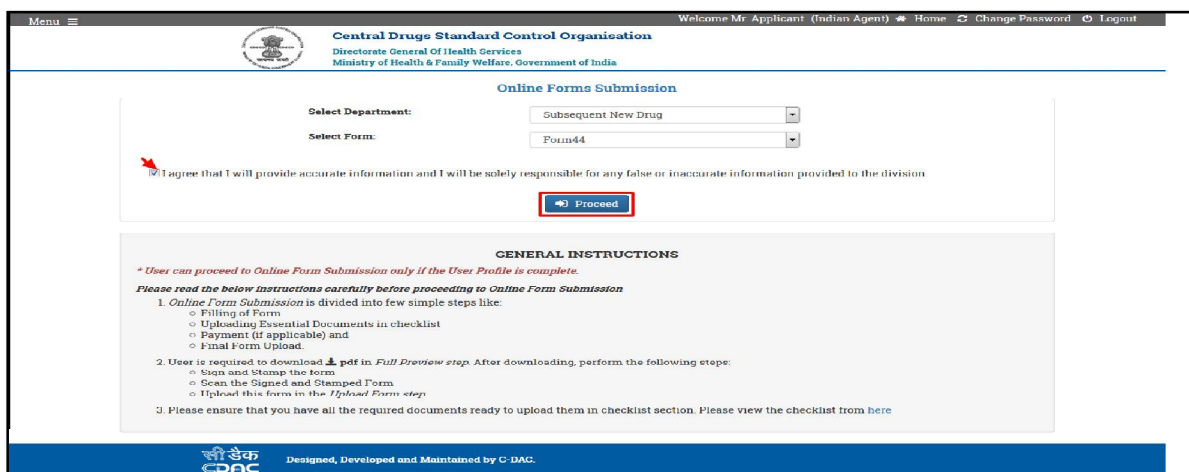


Figure 37 : Screen of after clicking on Submit Button

➤ For departments and forms available refer the table below.

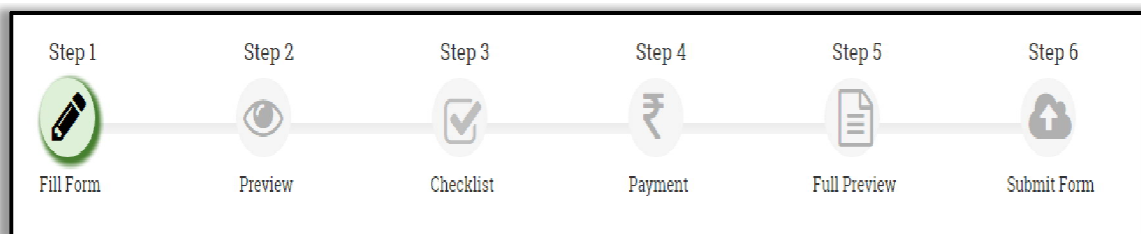
**Table 2 : Departments and Forms available**

S. No.	Modules	CDSCO Departments / Stakeholders	Processes	Forms Available
1.	CDSCO HQ	Import & Registration	Fresh Registration certificate(RC), Endorsement & re-registration, Post submission & Post Approval Changes (PAC)	Form 40 / 41 Form 8 / 10 Form 12AA 17 Cases of PAC
		Medical Devices & Diagnostics	Fresh Registration certificate(RC), Endorsement & re-registration, Post submission & Post Approval Changes	Form 40 / 41 Form 8 / 10 17 Cases of PAC
		Cosmetics Registration	Fresh RC, Endorsement, Re-registration	Form 42 / 43 4 Cases of PAC
		Ethics Committee Registration	Ethics committee registration & re-registration	
		Global Clinical Trials	NOC to conduct Clinical Trials Import license for Test & Analysis	Form 44 / NOC Form12 / 11 11 Cases of PAC
		BA/BE	NOC for BA/BE studies, Import license for Test & Analysis	Form 44/ NOC Form 12/11
		Biological – New Drugs-Vaccines	Permission to Market / Import / Conduct Clinical trials	Form 44/45/46 NOC
2.	New Drug	New Drugs/ SND/ FDC	Permission to Market / Import / Conduct Clinical trials	Form 44/45/46 NOC
3.	CDSCO HQ/ZONE/ST ATE FDA	CLAA Processes	Grant & Renewal of Licenses for : <ul style="list-style-type: none"> <li>• Blood Bank</li> <li>• Anti sera</li> <li>• Stem Cells</li> </ul>	Form 27C / 28 C Form 26G Form 27F /Form28 F
4.	CDSCO Port Offices	Port Offices ( 7 Locations)	Permission to Import Drugs in small quantity	Form 12A/ 12B

			for personal use	
5.	CDSCO Zone	Zonal / Sub Zonal Offices	Import License for Test & Analysis, for Drugs more than 4 years (Old Drugs)	Form 12 / 11
6.	Granting of NOC's and Registration of Drugs meant for export	CDSCO Zonal/Sub zonal offices	Export NOC for manufacturing ( 5 Cases) – Export purpose- BD,FF, material transfer, Exhibit Batches-BD,FF	Application From/ NOC

➤ **Submission of any form involves 6 steps:**

- Filling of the form: user will fill all the details required for the form. For example for Form 44 filling of form is further divided into 3 parts. Part 1 captures the purpose application and basic details of the drugs. Part 2 captures more details of the drugs entered in part 1. Part 3 captures details related to CT (Clinical trial) study.
- First Preview: Based on the details filled by the applicant first preview of the legal form is generated. If the user has any issue with the details, he/she can modify it at this stage. User should ensure all the details are filled correctly because after this step the details cannot be edited.
- Checklist: Once the preview is verified by the user, they will proceed further to upload the documents required for the form they are filling. Every form has a different checklist of documents based on the form type. User is allowed to upload a PDF document of size not more than 10MB
- Payment: After uploading the checklist user will be redirected to the payment page. User can make the payment either by uploading a challan or by doing in online.
- Final Preview: Once payment is done user can view the complete legal form with payment details and download the system generated form for signature.
- Submit Form: After signing the form user will scan the signed copy and upload the document after which the form will be submitted and a file number will be generated. The status of the file can be tracked using the same file number.



**Figure 38 : 6 steps for Submission of form**

#### 4.1 Submission of Form 44

- Application for Form44 can be done for Grant of permission to manufacture, import or to conduct clinical trial for Drugs:
  - Manufacture a New Drug / fixed dose combination / subsequent new drug for already approved new drug
  - To import a New Drug / fixed dose combination / subsequent new drug for already approved new drug
  - To undertake Clinical Trial (Phase1/Phase2/Phase3/Phase4)
- An Applicant can apply for **Multiple Strengths for One drug Product** in a Form 44 Application. However, all of them will be treated as separate Drug Products.
- In Form 44 Application, A Drug Product can have multiple indications and multiple pack sizes. However, for one drug product only **one Route of Administration, one Dosage Form and one Pharmacological Classification of Drug** will be accepted.
- Following tables depict the broad categories of cases for which application in Form44 can be filled:

**Table 3 : Reason for Form 44 Application**

S. No.	Drug Type		Reason For Form 44 Application
1.	Bulk Drug (BD)	Single Ingredient	Permission required for <b>Import/Marketing Authorization</b> of Drug Substance
2.	Finished Formulation (FF)	Single Ingredient and Fixed Dose Combination	Permission required for <b>Import/Marketing Authorization</b> of Drug Product
3.	Both (BD&FF)	Single Ingredient	Permission required for <b>Marketing Authorization of Drug Product as well as for its Drug substance</b>
4.	Both (BD&FF)	Fixed Dose Combination	Permission required for <b>Marketing Authorization of Drug Product as well as for one or more of its Drug substance</b>

S. No.	Division	Category	Detail	Drug Type		Remarks
1	New Drug	1. Drug Approve in another country/Salt of an Approved Drug	New Drug	BD, FF, Both	SND	
		2. One or more of the ingredients of the combination is a New Drug not approved individually	FDC is New Drug and one of the ingredient is also New Drug	FF, Both	FDC	<p><b>CASE 1: Permission for FF</b> One of the ingredients of the FF which is a New Drug should have status: 'Application filed by other company simultaneously'.</p> <p><b>CASE 2 (BOTH): Permission for FF and one or more of the ingredients which are New Drug</b> In this case, if Applicant also want to get the permission to manufacture an ingredient which is not a New Drug i.e. its status is 'Approved by CDSCO 'then for such permission applicant needs to file separate Application to SND division</p>
2	IND	1. Investigational New Drug	IND	BD,FF, Both	SND	
		2. One of the Ingredients of the combination is an Investigational New Drug(IND)	FDC and one of the ingredient is IND	FF, Both	FDC	<p><b>CASE 1: Permission for FF</b> One of the ingredients of the FF which is a IND should have status: 'Application filed by other company simultaneously'.</p> <p><b>CASE 2 (BOTH): Permission for FF and one or more of the ingredients which are IND</b> In this case, if Applicant also want to get the permission to manufacture an ingredient which is not an IND i.e. its status is 'Approved by CDSCO ' then for such</p>

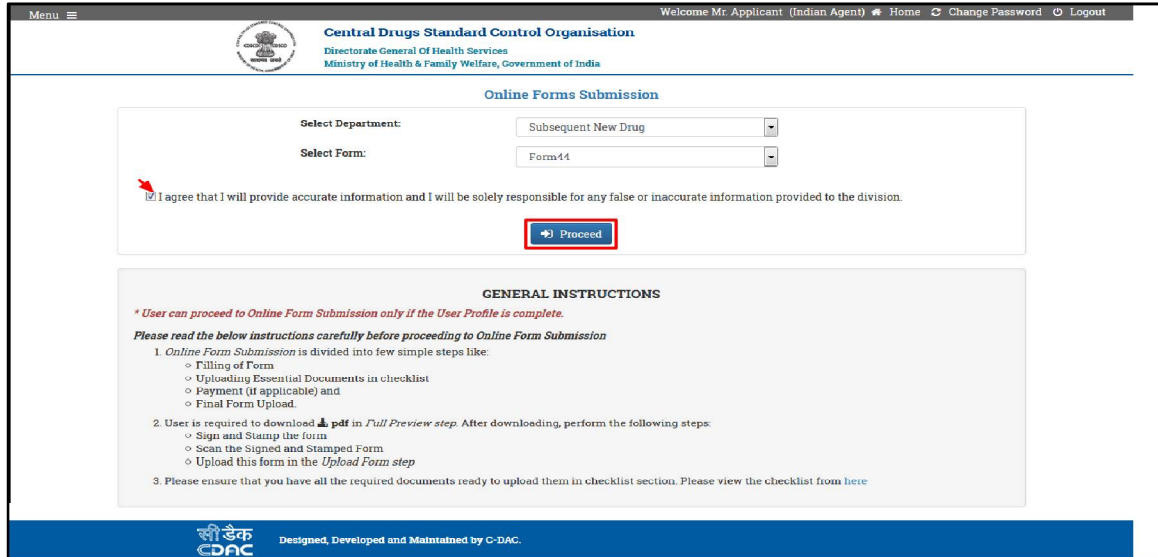
						permission applicant needs to file separate Application to SND division
3.	<b>Biological</b>	1. Drug Approve in another country/Salt of an Approved Drug		BD, FF, Both	SND, FDC	5 Module checklist will get displayed
		2. Investigational New Drug		BD, FF, Both	SND, FDC	5 Module checklist will get displayed
		3. Approved New Drug		BD, FF, Both	SND, FDC	5 Module checklist will get displayed
		4. New Dosage Form		FF	FDC	Post Approval checklist
		5. New Indication		FF	FDC	Post Approval checklist
		6. New Route of Administration		FF	FDC	Post Approval checklist
4.	<b>SND</b>	1. New Indication		FF	SND	
		2. New Dosage Form		FF	SND	
		3. New Route of Administration		FF	SND	
		4. Additional Strength		FF	SND	
		5. Drug already approved in the country		BD, FF, Both	SND	
		6. Modified Release Dosage Form		FF	SND	
5.	<b>FDC</b>	1. Not marketed anywhere but individual components used concomitantly		FF	FDC	All active ingredients are already approved by CDSCO
		2. Not marketed anywhere and individual components not used concomitantly		FF	FDC	All active ingredients are already approved by CDSCO
		3. FDC - Marketed abroad		FF	FDC	All active ingredients are already approved by CDSCO
6.	<b>BA/BE for Export</b>	1. New Drugs Approved in India within period of 1 year		FF	SND, FDC	
		2. New Drugs Approved		FF	SND,	



		within period of more than 1 year & less than 4 years			FDC	
		3. Drug Product in Modified release form irrespective of their approval status		FF	SND, FDC	
		4. New molecule (New Chemical Entity) not approved in India but approved in other countries		FF	SND, FDC	
7.	<b>Global Clinical Trial</b>	1. New Chemical Entity(NCE)		FF	SND, FDC	
		2. Drug Approved in other countries		FF	SND, FDC	
		3. Drug Approved in India and other countries outside India		FF	SND, FDC	

Table 4 : CDSCO Division / Category / Drug type

- The online application submission of Form44 has been divided into 5 steps :
  - **Select Division:** Select the Division to which application has to be submitted and then select the form as Form44.



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

Online Forms Submission

Select Department: Subsequent New Drug  
Select Form: Form44

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

**Proceed**

**GENERAL INSTRUCTIONS**

*\* User can proceed to Online Form Submission only if the User Profile is complete.*

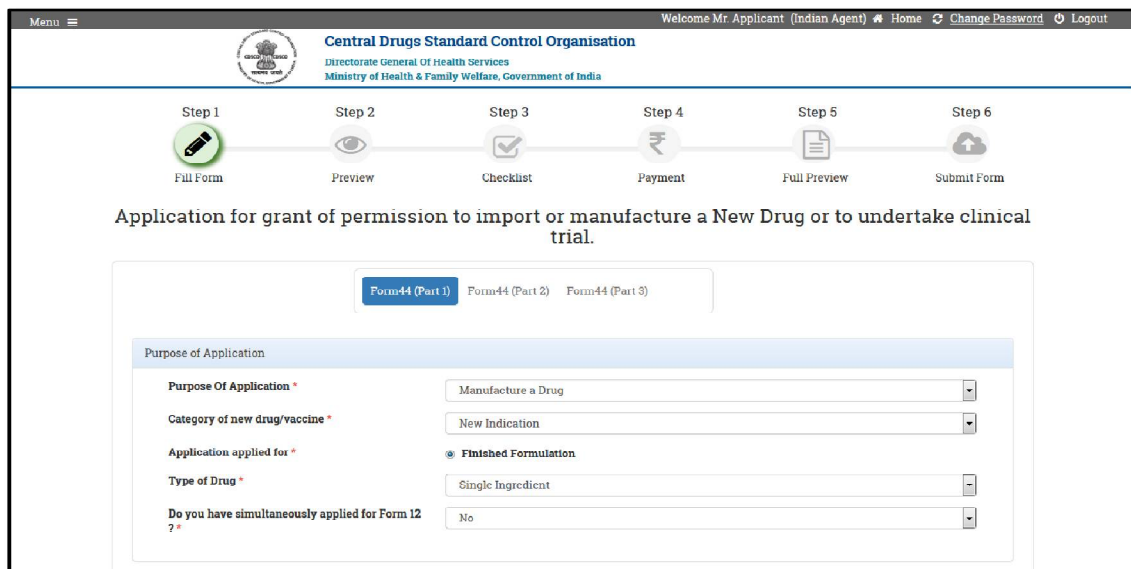
**Please read the below instructions carefully before proceeding to Online Form Submission**

- Online Form Submission is divided into few simple steps like:
  - o Filling of Form
  - o Uploading Essential Documents in checklist
  - o Payment (if applicable) and
  - o Final Form Upload.
- User is required to download pdf in Full Preview step. After downloading, perform the following steps:
  - o Sign and Stamp the form
  - o Scan the signed and Stamped Form
  - o Upload this form in the Upload Form step
- Please ensure that you have all the required documents ready to upload them in checklist section. Please view the checklist from [here](#)

Designed, Developed and Maintained by C-DAC.

Figure 39 : Select Division -- Select the Form 44

- **Part-I, Application Details :** Fill the following Part-1 details of the form :
  - o Purpose of application - Manufacture a drug, Import the drug, Conduct Clinical Trial for the drug
  - o Category of the Drug
  - o Type of Drug
  - o Information about the Form12 , if simultaneously applied



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

Step 1: Fill Form | Step 2: Preview | Step 3: Checklist | Step 4: Payment | Step 5: Full Preview | Step 6: Submit Form

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

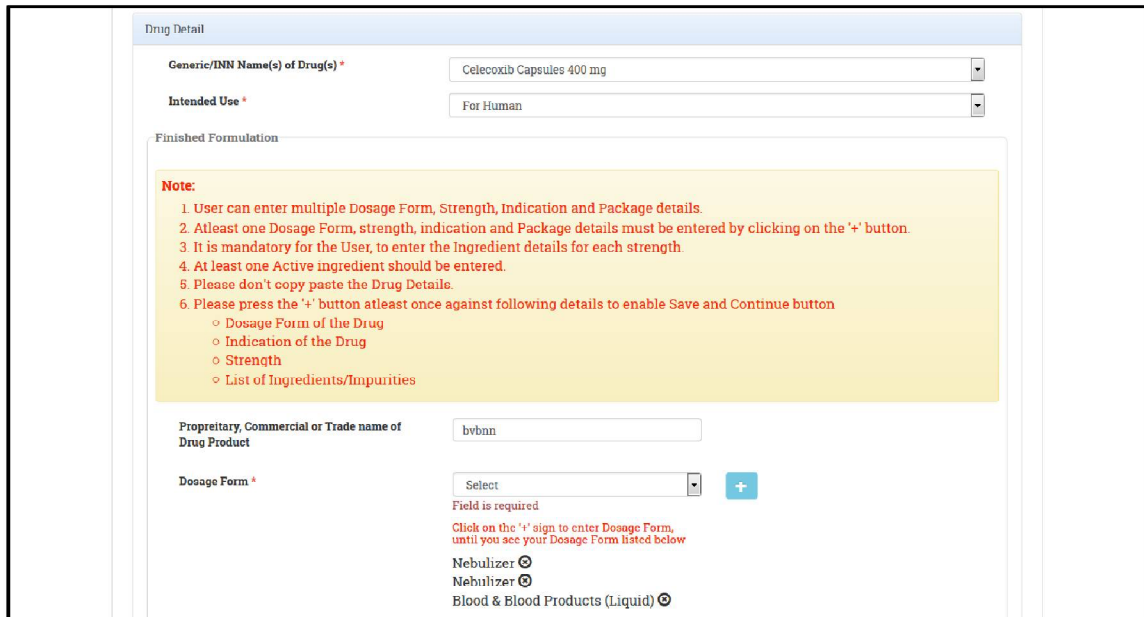
Form44 (Part 1) | Form44 (Part 2) | Form44 (Part 3)

**Purpose of Application**

Purpose Of Application \* Manufacture a Drug  
Category of new drug/vaccine \* New Indication  
Application applied for \*  Finished Formulation  
Type of Drug \* Single Ingredient  
Do you have simultaneously applied for Form 12 ? \* No

Figure 40 : Application Details

- **Drug Details** : Fill in the following details about the Drug for which permission has to be taken, as depicted in below figures:
  - Generic Name
  - Dosage Form
  - Indication
  - Route of Administration
  - Pharmacological Classification
  - Pack presentation
  - Storage Conditions-Light, Humidity ,Temperature
  - List of Ingredients



**Drug Detail**

Generic/INN Name(s) of Drug(s) \*

Intended Use \*

Finished Formulation

**Note:**

1. User can enter multiple Dosage Form, Strength, Indication and Package details.
2. Atleast one Dosage Form, strength, indication and Package details must be entered by clicking on the '+' button.
3. It is mandatory for the User, to enter the Ingredient details for each strength
4. At least one Active ingredient should be entered.
5. Please don't copy paste the Drug Details.
6. Please press the '+' button atleast once against following details to enable Save and Continue button
  - Dosage Form of the Drug
  - Indication of the Drug
  - Strength
  - List of Ingredients/Impurities

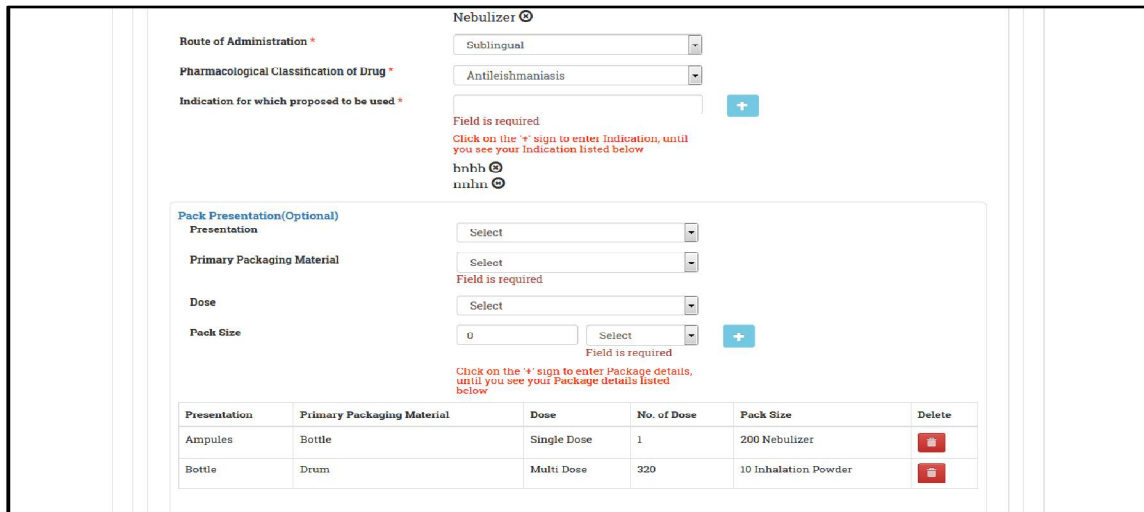
Proprietary, Commercial or Trade name of Drug Product

Dosage Form \*  +

Field is required  
Click on the '+' sign to enter Dosage Form, until you see your Dosage Form listed below

Nebulizer ⊕  
Nebulizer ⊕  
Blood & Blood Products (Liquid) ⊕

Figure 41 : Drug Details



Route of Administration \*

Pharmacological Classification of Drug \*

Indication for which proposed to be used \*

Field is required  
Click on the '+' sign to enter Indication, until you see your Indication listed below

hnhh ⊕  
nhln ⊕

**Pack Presentation(Optional)**

Presentation

Primary Packaging Material

Dose

Pack Size   +

Field is required  
Click on the '+' sign to enter Package details, until you see your Package details listed below

Presentation	Primary Packaging Material	Dose	No. of Dose	Pack Size	Delete
Ampules	Bottle	Single Dose	1	200 Nebulizer	<input type="button" value="X"/>
Bottle	Drum	Multi Dose	320	10 Inhalation Powder	<input type="button" value="X"/>

Figure 42 : Drug Details (Continue)

**IMPORTANT POINTS:**

- An applicant may apply in Form 44 with multiple strengths for same drug.
- User can enter multiple Dosage Form, Indication and Package details.
- It is mandatory for the User, to enter the Ingredient details for each strength.
- At least one Active ingredient should be entered.

**Storage Condition**

Temperature \* below 25°C

Humidity 57

Light 46

Proposed Shelf Life \* 20 in months

Strength \*  
 Field is required Select +  
 Click on the '+' sign to enter Strength, until you see your strength listed below  
 30 mm  
 89 %

**List of Ingredients/Impurities for Strength(30 mm)**

Category \*  
 Select  
 Field is required

Ingredient \*  
 Field is required

Pharmacopial Monograph \*  
 Field is required

Strength \*  
 Select 0  
 Only Digits and Dot are allowed

Unit of Strength \*  
 Select  
 Field is required

Percentage of Claim of Quantity \*  
 0 % 0 %  
 Only digits and dot are allowed Only digits and dot are allowed

Label Claim

+

**Figure 43 : Storage Condition & List of Ingredients**

Name of Ingredients	Pharmacopial Monograph	Strength	Category	Percentage of Claim	Label Claim	Source of Bulk Drug	Manufacturer Name	Edit
Celecoxib Capsules 400 mg	B.P.E.P.	< 58 Weight/Volume(W/v)	Active	30% to 40%	Yes	Already Approved by CDSCO	bgbbg	

**List of Ingredients/Impurities for Strength(89 %)**

Category \*  
 Select  
 Field is required

Ingredient \*  
 Field is required

Pharmacopial Monograph \*  
 Field is required

Strength \*  
 Select 0  
 Only Digits and Dot are allowed

Unit of Strength \*  
 Select  
 Field is required

Percentage of Claim of Quantity \*  
 0 % 0 %  
 Only digits and dot are allowed Only digits and dot are allowed

Label Claim

+

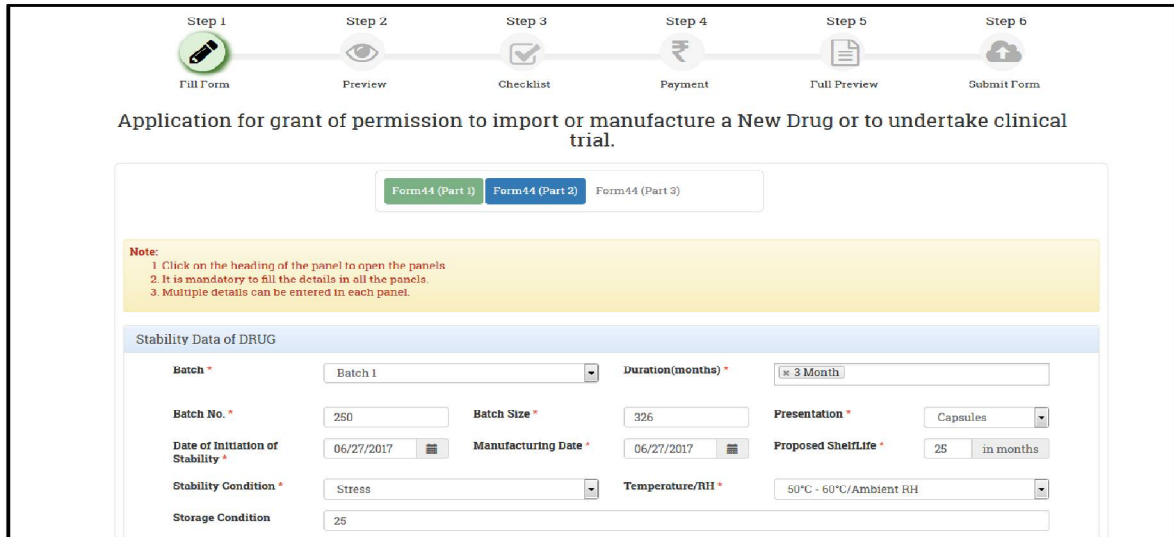
**Save and Continue**

**Figure 44 : Click on Save and Continue button**

## IMPORTANT POINTS

- In Part 1, User needs to enter the Diluents details if the Dosage form selected is of type Lyophilized (e.g. Vaccines (Lyophilized), Blood & Blood Products (Lyophilized), Parenteral Preparation (Lyophilized), rDNA (Lyophilized) )

- **Part-II, Drug Stability Details:** Fill in the following details about the stability as depicted in below figures:
  - Batch Details
  - Duration
  - Stability Condition
  - Storage Condition
  - Assay Parameters



Step 1: Fill Form | Step 2: Preview | Step 3: Checklist | Step 4: Payment | Step 5: Full Preview | Step 6: Submit Form

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

Form44 (Part 1) | Form44 (Part 2) | Form44 (Part 3)

**Note:**  
 1. Click on the heading of the panel to open the panels  
 2. It is mandatory to fill the details in all the panels.  
 3. Multiple details can be entered in each panel.

**Stability Data of DRUG**

Batch \* : Batch 1 | Duration(months) \* : 3 Month  
 Batch No. \* : 250 | Batch Size \* : 326 | Presentation \* : Capsules  
 Date of Initiation of Stability \* : 06/27/2017 | Manufacturing Date \* : 06/27/2017 | Proposed ShelfLife \* : 25 in months  
 Stability Condition \* : Stress | Temperature/RH \* : 50°C - 60°C/Ambient RH  
 Storage Condition : 25

Figure 45 : Drug Stability Details

Parameters	Specification	Result(3 Months)	Remarks
Assay(Celecoxib Capsules 400 mg)	30% - 40%	Field is required	Field is required
Water Content			
Others			
Others			
Others			
Others			
Others			
Others			
Others			
Others			
Others			
Others			
Others			
Others			
Others			
Others			
Others			
Others			

Stability Details Search:

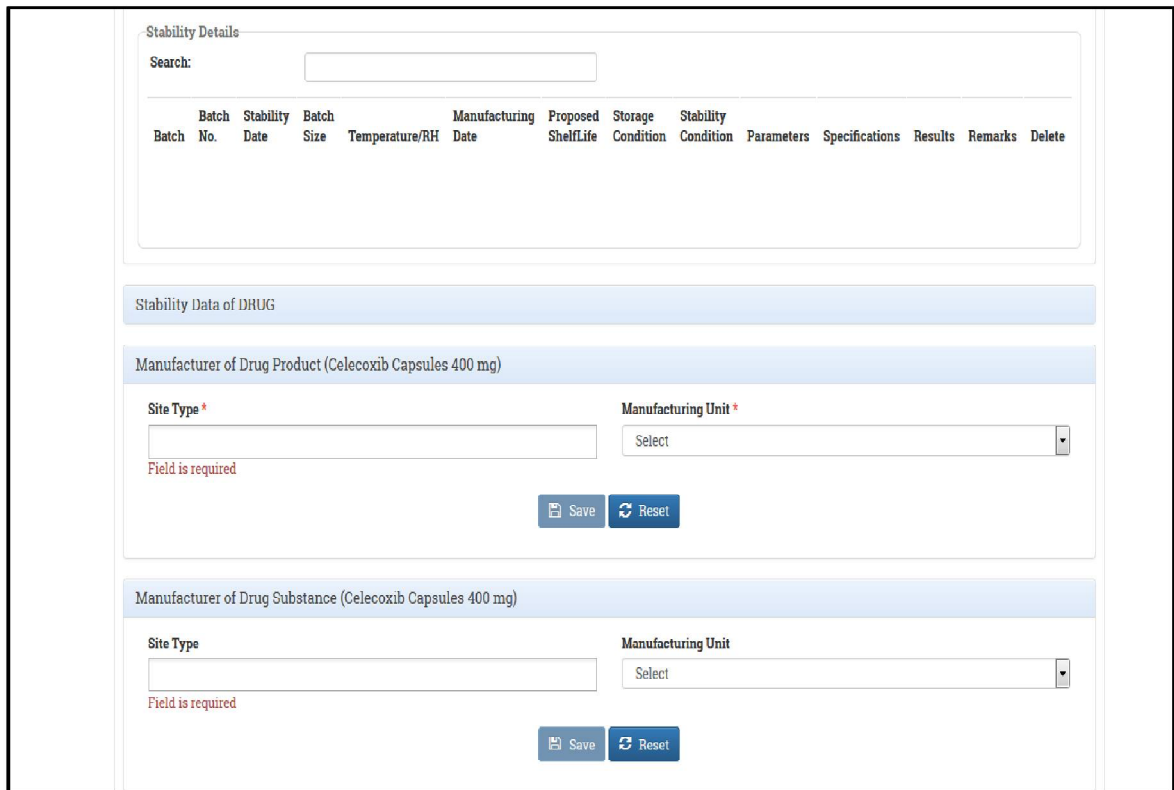
Reset | Save Stability

Figure 46 : Fill Drug Stability Details

**IMPORTANT POINTS:**

- In part 2, Stability Data of Diluents is mandatory if the Dosage form selected is of type Lyophilized.
- Stability Data of Drug: This panel is repeated for each drug strength.
- Under Stability Data details, the assay parameter is repeated for each active ingredient entered for this drug strength. Also the Results column for each parameter is added based on the selection of Duration (in Months)

- **Manufacturer & Site Details :** Fill in the following details about the stability as depicted in below figures :



Stability Details

Search:

Batch No.	Stability Date	Batch Size	Temperature/RH	Manufacturing Date	Proposed ShelfLife	Storage Condition	Stability Condition	Parameters	Specifications	Results	Remarks	Delete

Stability Data of DRUG

Manufacturer of Drug Product (Celecoxib Capsules 400 mg)

Site Type \*  Manufacturing Unit \*

Field is required

Manufacturer of Drug Substance (Celecoxib Capsules 400 mg)

Site Type  Manufacturing Unit

Field is required

**Figure 47 : Manufacturer & Site Details**

- **Patent ,Regulatory Status, CT & BA/BE Study Details :** Fill in the following details about the stability as depicted in below figures :

The screenshot shows a web form with several sections:

- Patent Details in India:** Includes radio buttons for 'Applicable' and 'Not Applicable', and an 'Add Details' button.
- Clinical Trial and BA/BE Study Status:** A table with columns 'Item No.', 'Clinical Trial', and 'Status'.
 

Item No.	Clinical Trial	Status
1	Phase-I	Select
2	Phase-II	Select
3	Phase-III	Select
4	BA/BE	Select
- Regulatory Status of the Investigational Product in other countries, as appropriate(Celecoxib Capsules 400 mg):** Two identical empty text input fields.
- Animal Toxicology Status:** A table with columns 'Item No.', 'Title', and 'Status'.
 

Item No.	Title	Status
1	Single-dose Toxicity Studies	Select

Figure 48 : Patent, Regulatory Status, CT & BA/BE Study Details

**IMPORTANT POINTS:**

- **Manufacturer of Drug Substance:** This panel is repeated for each active ingredient.
- **Regulatory Status of the Investigational Product in other countries:** This panel is repeated for each drug strength.

- **Animal Toxicology & Pharmacology Details:** Fill in the details as depicted in below figures:

The screenshot shows the 'Animal Toxicology & Pharmacology Details' section of the form. It includes a table for toxicology studies and a section for 'Animal Pharmacology Status'.

**Animal Toxicology Studies:**

4	Female Reproduction and Developmental Toxicity Studies	Study Conducted
5	Local Toxicity	Literature Survey
6	Allergenicity/Hypersensitivity	Study Not Required
7	Genotoxicity	Study Conducted
8	Carcinogenicity	Study Not Required

**Animal Pharmacology Status:**

Item No.	Title	Status
1	Specific Pharmacological Actions	Literature Survey
2	General Pharmacological Actions	Literature Survey
3	Follow-up and Supplemental Safety Pharmacology Studies	Literature Survey
4	Conditions under which Safety Pharmacology Studies are not necessary	Study Conducted
5	Timing of Safety Pharmacology Studies in relation to Clinical Development	Study Conducted
6	Application of Good Laboratory Practices (GLP)	Literature Survey

A dashed callout box with the text 'Save and Continue' points to a 'Save and Continue' button at the bottom of the form.

Figure 49 : Click on Save and Continue Button

## IMPORTANT POINTS

In Part-III, Clinical Trial and BA/BE Study Status: Under this panel if the status of items is selected as Study permission required then CT Study Form or BE Study Form will open as next part3.

- **Part –III Clinical Trial Details** : Fill in the following details as depicted in below figures 47 :
  - Trial scope/objective
  - Sponsor Details
  - Comparator Drug details
  - Disease under investigation
  - Protocol Details
  - CT Site Details
  - Laboratory Details
  
- **Part –IV Undertaking for checklist documents:** In this section, user is required to provide the undertaking that he will be submitting the below mentioned documents in checklist section as shown in figure 48.



Welcome Mr. Applicant (Indian Agent) Home Change Password Logout

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

Step 1 Fill Form    Step 2 Preview    Step 3 Checklist    Step 4 Payment    Step 5 Full Preview    Step 6 Submit Form

**Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.**

Form44 (Part 1)
Form44 (Part 2)
Form44 (Part 3)
Form44 (Part 4)

**CT Study Details**

**Clinical Trial**

Scope/Objective of Trial \*

Study Design \*

Is it a Global Clinical Trial? \*  Yes  No

[Modify](#)

**Sponsor Details**

**NOTE : Kindly select the sponsor whose address you want on your NOC.**

Sponsor \*  Self Sponsored  Sponsored by Others

**Sponsor Details**

M/s.

Address Line \*

Country \*  State/Province \*  City \*  Pincode/PostCode \*

Landline No. \* (Please include Country Code - STD Code - Phone Number)  Fax \* (Please include Country Code - STD Code - Fax Number)  Email \*

Multiple Contact Numbers can be added with comma separation

[Modify](#)

**Comparator Drug Details (Optional)** [Add Details](#)

S.No.	Comparator Drug Name	Dosage Form	Composition	Route of Administration	Name of Company	Name of Country	Delete
1	+ anbv	Blood & Blood Products (Lyophilized)		Dermal	xcxcx	India	<a href="#">Delete</a>

**Disease Under Investigation** [Add Details](#)

S.No.	Disease Name	Delete
1	+ Asthma	<a href="#">Delete</a>

**CT Site Details** [Add Details](#)

S.No.	Hospital	No. of Beds	Ethics Committee	Delete
1	+ 33-25-33, Ch. Venkata Krishnappa Street, Suryareo Pet, Vijaywada, Not Available, Andhra Pradesh(India)	50	Academic Research Projects	<a href="#">Delete</a>

**Protocol Details** [Add Details](#)

S.No.	Protocol No.	Version No.	Date of Protocol	Dosage	Subject Details	Age Group	Proposed Study Period	Delete
1	+ 564	225	28 Jun 2017	Multiple Dose	Female	Children(2-11 Years)	25 Weeks	<a href="#">Delete</a>

**Local Clinical Laboratory Details** [Add Details](#)

S.No.	Principal Investigator	Lab Name	Lab Address	Telephone No.	Fax	Email	Delete
1	+ bovb	test	Add 1, uttar pradech, Noida-201301(India)	1265431646	36532653626	aaa@gmail.com	<a href="#">Delete</a>

**Central Clinical Laboratory Details (Optional)** [Add Details](#)


S.No.	Lab Name	Lab Address	Telephone No.	Fax	Email	Delete
1	+ aacaca	aaasa, II D, Noida-201301(India)	1564451546156	321133113313	aaa@gmail.com	<a href="#">Delete</a>

[Continue](#)


Designed, Developed and Maintained by C-DAC.


Figure 50 : Clinical Trial Details


Menu ☰
Welcome Mr. Applicant (Indian Agent) # Home ↻ Change Password ↻ Logout





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


Step 1  
  
Fill Form

Step 2  
  
Preview

Step 3  
  
Checklist

Step 4  
  
Payment

Step 5  
  
Full Preview

Step 6  
  
Submit Form

### Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

Form44 (Part 1)
Form44 (Part 2)
Form44 (Part 3)
Form44 (Part 4)

Part 3


#### Documents to be uploaded in the checklist

*Note: You will be required to upload below listed documents in the checklist section for successful submission of application.*

- **1 Test specification:**
  - Active Ingredients:
  - Inactive Ingredients:
- **2 Permission to market a new drug:**
  - Chemical and Pharmaceutical Information :
  - Bio-availability, dissolution and stability study Data :
  - Marketing information:
    - Proposed product monograph :
    - Drafts of label and cartoons:
  - Application for test license :
- **Subsequent approval/permission for manufacturer of already approved new drug:-**
  - Formulation:
    - Bio-availability/bio-equivalence protocol :
    - Name of the investigator/centre :
    - Source of raw material (bulk drug substances) and stability study data :
  - Raw material (bulk drug substances):
    - Manufacturing method :
    - Quality control parameters and or analytical specification, stability report :
    - Animal toxicity data :
- **Approval/permission for fixed dose combination:-**
- **Subsequent approval or approval for new indication-new dosage form:**
  - Number and date of approval/permission already granted :
  - Therapeutic Justification for new claim/modified dosage form:
  - Data generated on safety or quality parameters .

I hereby declare that I will enclosed the above listed documents in the Checklist and I will be solely responsible for any false or inaccurate document provided to the division.

→ Continue



Designed, Developed and Maintained by C-DAC.

Figure 51 : Undertaking for checklist documents

• First Preview of the Form 44

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

Welcome Mr. Applicant (Initial Agent)
Home
Change Password
Logout

Step 1  
Fill Form
Step 2  
Preview
Step 3  
Checklist
Step 4  
Payment
Step 5  
Full Preview
Step 6  
Submit Form

### FORM 44

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

I/We, Applicant of M/s. **Testing, Testing Enclave, Tester Group, Testcity -121123** Telephone No. **1212121212** Fax : **3434343434** E-Mail : **TMPSAHJEEVSOAM@GMAIL.COM** hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information/data is given below:

**1. Particulars of new drug**

1.1. Name of the drug: **Celecoxib Capsules 400 mg**

1.2. Dosage form: **Blood & Blood Products (Liquid)**

1.3. Composition Of Formulation:

S.No.	Ingredient	Quantity	Pharmacopial Monograph	Active/Inactive
For Strength 25.0 mm				
1	Celecoxib Capsules 400 mg	25.0 Weight/Volume(W/v)	B.P., I.P.	Active

1.4. Test identification:  
 1.4.1. Active Ingredients: **Enclosed in the checklist.**  
 1.4.2. Inactive Ingredients: **Enclosed in the checklist.**

1.5. Pharmacological classification of the drug: **Antimicrobial**

1.6. Indication for which purpose to be used: **[gtgt]**

1.7. Manufacturer of the raw material (bulk drug substances):

S.No.	Premises Name	Premises Type	Premises Address
For Ingredient Celecoxib Capsules 400 mg			
1	Other	(Disposal Site)	address line 1, , Noida, U.P (India) - 201301

1.8. Patent status of the drug:

Patent Status	Patent Number	Country	Description

**2. Data submitted along with the application (as per Schedule Y with indexing and page nos.)**

2.1. Permission to market a new drug:

2.1.1. Chemical and Pharmaceutical Information: **Enclosed in the checklist.**

2.1.2. Animal pharmacology:

Study	Status
Specific Pharmacological Actions	Study Not Required
General Pharmacological Actions	Study Conducted
Follow-up and Supplemental Safety Pharmacology Studies	Literature Survey
Conditions under which Safety Pharmacology Studies are not necessary	Waiver Requested
Application of Good Laboratory Practices (GLP)	Waiver Requested

2.1.3. Animal Toxicology:

Study	Status
Single-dose Toxicity Studies	Literature Survey
Repeated-dose Systemic Toxicity Studies	Study Conducted
Male Fertility Study	Literature Survey
Female Reproduction and Developmental Toxicity Studies	Study Conducted
Local Toxicity	Study Conducted
Allergenicity/Hypersensitivity	Study Not Required
Genotoxicity	Study Conducted
Carcinogenicity	Literature Survey

2.1.4. Human/Clinical Pharmacology (Phase I) (Not Applicable) **Enclosed in the checklist.**

2.1.5. Exploratory Clinical Trials (Phase II) (Literature Survey) **Enclosed in the checklist.**

2.1.6. Confirmatory Clinical Trials (Phase III) (including published review articles) (Study Permission Required) **Enclosed in the Checklist.**

2.1.7. Bio-availability, dissolution and stability study Data: **Enclosed in the checklist.**

2.1.8. Regulatory status in other countries:

S.No.	Regulatory Status	Approval/Withdrawal Date	Country	Reason for Withdrawal
For Strength 25.0 mm				
1	Approved	12-Jun-2017	Austria	-

2.1.9.1. Proposed product monograph: **Enclosed in the checklist.**

2.1.9.2. Drafts of label and cartons: **Enclosed in the checklist.**

2.1.10. Application for test license: **Enclosed in the checklist.**

2.2. Subsequent approval/permission for manufacturer of already approved new drug:-

2.2.1. Formulation:

2.2.1.1. Bio-availability/bio-equivalence protocol: **Enclosed in the checklist.**

2.2.1.2. Name of the investigator/centre: **Enclosed in the checklist.**

2.2.1.3. Source of raw material (bulk drug substances) and stability study data: **Enclosed in the checklist.**

2.2.2. Raw material (bulk drug substances):

2.2.2.1. Manufacturing method: **Enclosed in the checklist.**

2.2.2.2. Quality control parameters and/or analytical specification, stability report: **Enclosed in the checklist.**

2.2.2.3. Animal toxicity data: **Enclosed in the checklist.**

2.3. Approval/permission for fixed dose combination:-

2.3.1. Therapeutic Justification (authentic literature in peer-reviewed journals/text books): **Not Applicable.**

2.3.2. Any other data generated by the application on the safety and efficacy of the combination: **Not Applicable.**

2.3.2. Data on pharmacokinetics/pharmacodynamics combination: **Not Applicable.**

2.4. Subsequent approval or approval for new indication-new dosage form:

2.4.1. Number and date of approval/permission already granted: **Enclosed in the checklist.**

2.4.2. Therapeutic justification for new indication/new dosage form: **Enclosed in the checklist.**

2.4.3. Data generated on safety or quality parameters: **Enclosed in the checklist.**

Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: **07-Jun-2017** Designation: \_\_\_\_\_

(Note: - Delete, whichever is not applicable.)

Figure 52 : First Preview of the Form 44

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### ANNEXURE

**Stability Details**

<b>Batch:</b>	Batch 3	<b>Batch No:</b>	134
<b>Batch Size:</b>	4344524	<b>Presentation:</b>	Creams
<b>Stability Date:</b>	06/05/2017	<b>Manufacture Date:</b>	07/18/2017
<b>Storage Condition:</b>	Accelerated Temperature	<b>Proposed ShelfLife:</b>	25
<b>Stability Condition:</b>	25°C ± 2°C/60%RH ± 5%RH		
<b>Stability Condition:</b>	test.		

Parameter	Specification	Result (3 Months)	Remarks
Assay(Celecoxib Capsules 400 mg)	95%-105%	aaa	bbb

**Manufacture Details (Drug Product)**

S.No.	Premises Type	Premises Name	Premises Address
1	Formulation Site, Batch Release Site	GHAZIABAD	Test,Test,Test,Andaman And Nicobar,India,(1111)

**Clinical Trial Study Details**

Whether Global Clinical Trial ?

Scope/Objective of Trial	Study Design	In Global Clinical Trial	Participating Countries	Planned No. of Subjects Globally	Planned No. of Subjects in India
Therapeutic	Single Arm Trial	No		0	0

**Sponsor Details**

Sponsor: abc test1, null Noida, U.P India- 201301 Telephone: 9956696325 Fax: 2563256325 Email: aaa@gmail.com

**Comparator Drug Details**

S.No.	Comparator Drug Name	Brand Name	Dosage Form	Drug Composition	Route of Administration	Name of Company	Name of Country
1	anbv	Test Sample	Blood & Blood Products (Lyophilized)		Dermal	xxxxx	India

**Disease Under Investigation**

S.No.	Disease Name
1	Autism

**CT Site Details**

S.No.	Hospital	No. of Beds	Ethics Committee	Laboratory Details
1	City Cancer centre 33-28-33, Ch. Venkata Krishnamaya Street, , Suryanagar Pali, Vijaywada, Dist Avulabidole, Andhra Pradesh	50	Academic Research Projects	test AM 1, null Noida, Gautam Buddha Nagar Uttar Pradesh- 201301(India) Whether GLP/ISO/NABL/Other Certified: Yes

**Protocol Details**

S.No.	Protocol No.	Version No.	Date of Protocol	Dosing	Subject Details	Age Group	Proposed Study Period
1	BB4	225	20-Jun-2017	Multiple Dose	Female	Children(2-11 Years)	25 Weeks

**Centralized Laboratory Details**

S.No.	Lab Name	Lab Address	Email	Whether GLP/ISO/NABL/Other Certified
1	axaxaxa	axaxaxa , Noida U.P. 201301 (India)	aaa@gmail.com	Yes

Edit Form

Edit Form

Proceed To Checklist

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Figure 53 : First Preview of the Form 44 (Continue)

- Confirmation alert to proceed to checklist

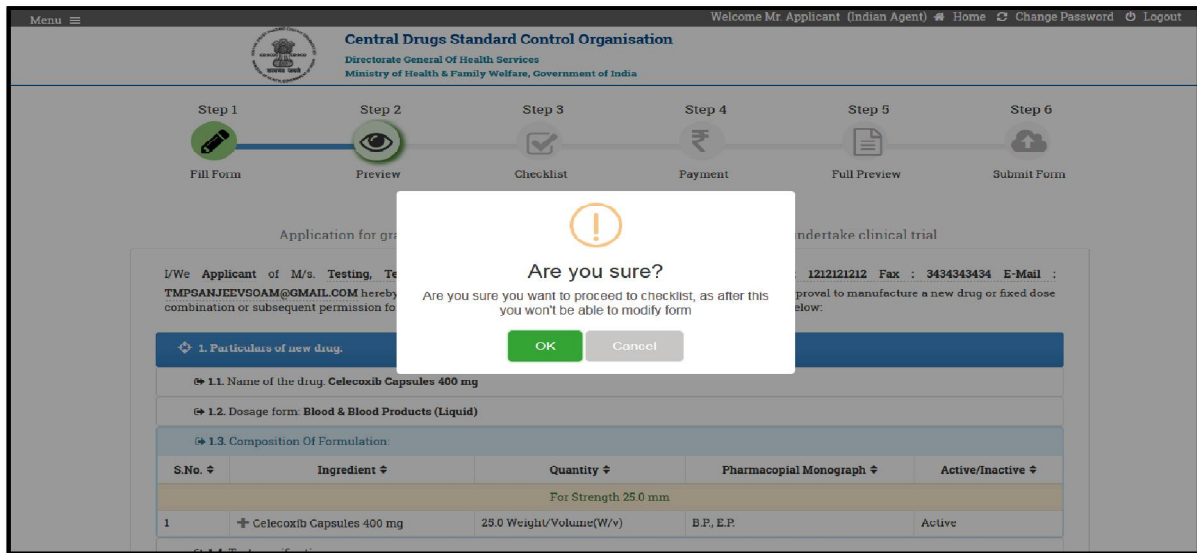


Figure 54 : Popup Message: Confirmation alert to Proceed to Checklist

- Checklist to upload the documents

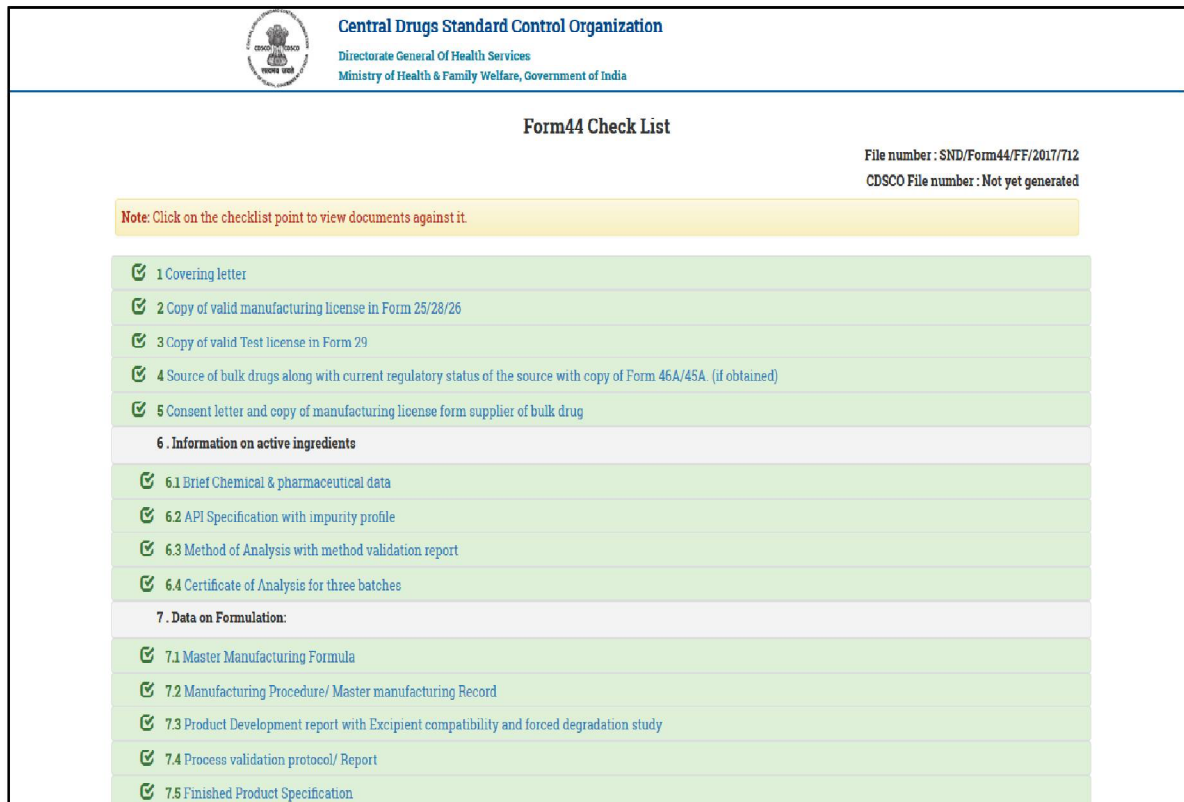


Figure 55 : Checklist to upload the documents

<b>6. Information on active ingredients</b>
<input checked="" type="checkbox"/> 6.1 Brief Chemical & pharmaceutical data
<input checked="" type="checkbox"/> 6.2 API Specification with impurity profile
<input checked="" type="checkbox"/> 6.3 Method of Analysis with method validation report
<input checked="" type="checkbox"/> 6.4 Certificate of Analysis for three batches
<b>7. Data on Formulation:</b>
<input checked="" type="checkbox"/> 7.1 Master Manufacturing Formula
<input checked="" type="checkbox"/> 7.2 Manufacturing Procedure/ Master manufacturing Record
<input checked="" type="checkbox"/> 7.3 Product Development report with Excipient compatibility and forced degradation study
<input checked="" type="checkbox"/> 7.4 Process validation protocol/ Report
<input checked="" type="checkbox"/> 7.5 Finished Product Specification
<input checked="" type="checkbox"/> 7.6 Finished Product Method of Analysis
<input checked="" type="checkbox"/> 7.7 Finished Product Analytical method validation report
<input checked="" type="checkbox"/> 7.8 Finished Product Certificate of Analysis for three consecutive batches/three validation batches
<input checked="" type="checkbox"/> 7.9 In process quality control check specifications
<input checked="" type="checkbox"/> 7.10 Stability study data report as per requirements of schedule Y mentioning batch size (should be presented in tabular form with details of Batch No., Batch size, Date of Manufacturing, Date of initiation, Packaging details)
<input checked="" type="checkbox"/> 7.11 Dissolution Release Profile (in case of oral dosage form)
<input checked="" type="checkbox"/> 7.12 Comparative Dissolution Release Profile with the Approved formulation (in case of oral dosage form)
<input checked="" type="checkbox"/> 7.13 Comparative evaluation with international brand(s) or approved Indian brands, if applicable.
<input checked="" type="checkbox"/> 7.14 Copy of proposed Package Insert which should include generic name of all active ingredients; composition; dosage form/s, indications; dose and method of administration; use in special populations; contraindications; warnings; precautions; drug interactions; undesirable effects; overdose; pharmacodynamics and pharmacokinetic properties, incompatibilities; shelf-life, packaging information, storage and handling instructions.
<input checked="" type="checkbox"/> 7.15 Draft specimen of the label and carton.

Figure 56 : Checklist to upload the documents (Continue)

<input checked="" type="checkbox"/> 11.5 Compensation clause as per Rule 122 DAB
<input checked="" type="checkbox"/> 11.6 Copy of "Ethics Committee" approval letters along with registration details
<input checked="" type="checkbox"/> 11.7 Case record form (CRF)
<input checked="" type="checkbox"/> 11.8 Site details, which includes Investigators name and address, Type of Hospital (Multispecialty/ Government/ Private) , Number of beds, emergency facilities, Ethics Committee registration details, etc)
<input checked="" type="checkbox"/> 12 Bio Equivalence study requirement (in case of oral dosage form as appropriate as per Appendix X of Schedule Y)
<input checked="" type="checkbox"/> 13 Justification on Clinical trial and Bio equivalence study waiver, if requested.
<b>14. Animal toxicology data as per Schedule Y.</b>
<b>14.1. Systemic toxicity studies</b>
<input checked="" type="checkbox"/> 14.1.1 single dose toxicity
<input checked="" type="checkbox"/> 14.1.2 repeated dose toxicity
<b>14.2. Local toxicity</b>
<input checked="" type="checkbox"/> 14.2.1 Dermal toxicity
<input checked="" type="checkbox"/> 14.2.2 Ocular toxicity
<input checked="" type="checkbox"/> 14.2.3 Inhalation toxicity
<input checked="" type="checkbox"/> 14.2.4 Vaginal toxicity
<input checked="" type="checkbox"/> 14.2.5 Photoallergy or dermal phototoxicity
<input checked="" type="checkbox"/> 14.3 Rectal tolerance test
<input checked="" type="checkbox"/> 15 Published report of Clinical trial/Journal/literature with respect to proposed Dosage Form
<input checked="" type="checkbox"/> 16 Upload Justification for Quantity applied in Form-12, if applicable
<b>17. Form 12</b>
<input checked="" type="checkbox"/> 18 Application in Form 44
<input checked="" type="checkbox"/> 19 TR-6 Challan

Figure 57 : Checklist to upload the documents (Continue)

- Payment for the form

Figure 58 : Payment for the form

S.No.	Form Name	Fee Amount	Remarks
1.	Form 44 (Biologicals)	INR 50,000	Drug Already Approved in our country Or Already Approved in other country Or IND Or Clinical Trial Phase I
		INR 25,000	Clinical Trial Phase II, III and IV
2.	Form 44 (BA/BE)	INR 25,000	New molecule not approved in India but approved in other countries Or New Drugs approved in India within period of 1 year
		INR 15,000	New Drugs approved within period of more than 1 year & less than 4 years Or Drug product in modified release form irrespective of its approval status
3.	Form 44 (SND)	INR 15,000 / 50,000	INR 15,000 New Drug approved in India for more than one year, or INR 50,000 of New Drug is approved for less than one year
		INR 50,000	Clinical Trial Phase I
		INR 25,000	Clinical Trial Phase II, III and IV
4.	Form 44 (New Drugs)	INR 50,000	New drugs going to be introduced for the first time in the country for sale or to undertake Clinical Trial Phase-I
		INR 25,000	Clinical Trial Phase II, III and IV
5.	Form 44 (IND)	INR 50,000	Investigational New Drug Or One of the ingredients of the combination is an Investigational New Drug Or Clinical Trial Phase I
		INR 25,000	Clinical Trial Phase II, III and IV
6.	Form 44 (FDC)	INR 15,000 / 50,000	INR 15,000 if all active ingredients are approved in India for more than one year, or INR 50,000 in case any of the active ingredients is approved for less than one year
		INR 15,000	Not marketed anywhere but individual components used concomitantly

Figure 59 : Screen of Fee Details

- Final preview of the form with download option

Menu
Welcome Mr. Applicant (Indian Agent) | Home | Change Password | Logout

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

Step 1  
Fill Form

Step 2  
Preview

Step 3  
Checklist

Step 4  
Payment

Step 5  
Full Preview

Step 6  
Submit Form

**FORM 44**  
Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial

I/We Applicant of M/s. **Testing, Testing Enclave Tester Group Testcity -123123 Telephone No.: 1212121212 Fax : 3434343434 E-Mail : TMPANJEVSOAM@GMAIL.COM** hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information/data is given below.

**1. Particulars of new drug:**

1.1. Name of the drug: **Celecoxib Capsules 400 mg**

1.2. Dosage form: **Blood & Blood Products (Liquid)**

1.3. Composition Of Formulation:

S.No.	Ingredient	Quantity	Pharmacopial Monograph	Active/Inactive
For Strength 25.0 mm				
1	+ Celecoxib Capsules 400 mg	25.0 Weight/Volume(W/v)	B.P., E.P.	Active

1.4. Test specification:

1.4.1. Active Ingredients: **Enclosed in the checklist.**

1.4.2. Inactive Ingredients: **Enclosed in the checklist.**

1.5. Pharmacological classification of the drug: **Antimalarial**

1.6. Indication for which purpose to be used: **[fgfgf]**

1.7. Manufacture of the raw material (bulk drug substances):

S.No.	Premises Name	Premises Type	Premises Address
For Ingredient Celecoxib Capsules 400 mg			
1	+ other	[Dispatch Site]	address line 1, , Noida , U.P (India) -201301

1.8. Patent status of the drug:

Patent Status	Patent Number	Country	Description

**2. Data submitted along with the application (as per Schedule Y with indexing and page nos.)**

2.1. Permission to market a new drug:

2.1.1. Chemical and Pharmaceutical Information : **Enclosed in the checklist.**

2.1.2. Animal pharmacology :

Study	Status
Specific Pharmacological Actions	Study Not Required
General Pharmacological Actions	Study Conducted
Follow-up and Supplemental Safety Pharmacology Studies	Literature Survey
Conditions under which Safety Pharmacology Studies are not necessary	Waiver Requested
Application of Good Laboratory Practices (GLP)	Waiver Requested

2.1.3. Animal Toxicology :

Study	Status
Single-dose Toxicity Studies	Literature Survey
Repeated-dose Systemic Toxicity Studies	Study Conducted
Male Fertility Study	Literature Survey
Female Reproduction and Developmental Toxicity Studies	Study Conducted
Local Toxicity	Study Conducted
Allergenicity/Hypersensitivity	Study Not Required
Genotoxicity	Study Conducted
Carcinogenicity	Literature Survey

2.1.4. Human/Clinical Pharmacology (Phase I) : **(Not Applicable) Enclosed in the checklist.**

2.1.5. Exploratory Clinical Trials (Phase II) : **(Literature Survey) Enclosed in the checklist.**

2.1.6. Confirmatory Clinical Trials (Phase III) (including published review articles) : **(Study Permission Required) Enclosed in the checklist.**

2.1.7. Bio-availability, dissolution and stability study Data : **Enclosed in the checklist.**

2.1.8. Regulatory status in other countries :

Figure 60 : Final preview of the form with download option



S.No.	Regulatory Status	Approval/Withdrawal Date	Country	Reason for Withdrawal
1	Approved	12-Jun-2017	Austria	

**For Strength 25.0 mm**

> 2.1.9.1. Proposed product monograph: **Enclosed in the checklist.**

> 2.1.9.2. Drafts of label and cartons: **Enclosed in the checklist.**

⊖ 2.1.10. Application for test license: **Enclosed in the checklist.**

⊕ 2.2. Subsequent approval/permission for manufacturer of already approved new drug.

⊖ 2.2.1. Formulation:

> 2.2.1.1. Bio-availability/bio-equivalence protocol: **Enclosed in the checklist.**

> 2.2.1.2. Name of the investigator/centre: **Enclosed in the checklist.**

> 2.2.1.3. Source of raw material (bulk drug substances) and stability study data: **Enclosed in the checklist.**

⊖ 2.2.2. Raw material (bulk drug substances):

> 2.2.2.1. Manufacturing method: **Enclosed in the checklist.**

> 2.2.2.2. Quality control parameters and/or analytical specification, stability report: **Enclosed in the checklist.**

> 2.2.2.3. Animal toxicity data: **Enclosed in the checklist.**

⊕ 2.3. Approval/permission for fixed dose combination:

⊖ 2.3.1. Therapeutic Justification (authentic literature in peer-reviewed journals/text books): **Not Applicable.**

⊖ 2.3.3. Any other data generated by the application on the safety and efficacy of the combination: **Not Applicable.**

⊖ 2.3.2. Data on pharmacokinetics/pharmacodynamics combination: **Not Applicable.**

⊕ 2.4. Subsequent approval or approval for new indication-new dosage form.

⊖ 2.4.1. Number and date of approval/permission already granted: **Enclosed in the checklist.**

⊖ 2.4.2. Therapeutic Justification for new combination/ dosage form: **Enclosed in the checklist.**

⊖ 2.4.3. Data generated on safety or quality parameters: **Enclosed in the checklist.**

3. A total fee of rupees 150000 (in words) has been credited to the government under the Head of Account

Place: ..... Signature: .....

Date: 07-Jun-2017 Designation: .....

(Note: - Delete, whichever is not applicable).

### ANNEXURE

**Stability Details**

Batch:	Batch 2	Batch No:	124
Batch Size:	4244524	Presentation:	Creams
Stability Date:	06/05/2017	Manufacture Date:	07/18/2017
Storage Condition:	Accelerated Temperature		Proposed ShelfLife: 24
Stability Condition:	test..	25°C ± 2°C/60%RH ± 5%RH	

Parameter	Specification	Result (3 Months)	Remarks
Assay(Celecoxib Capsules 400 mg)	95%-98%	aaa	bbb

**Manufacture Details (Drug Product)**

S.No.	Premises Type	Premises Name	Premises Address
1	→ [Formulation Site, Batch Release Site]	CHAZIARAD	Test,Test,Test,Andaman And Nicobar,India,11111

**Clinical Trial Study Details**

Whether Global Clinical Trial?

Scope/Objective of Trial	Study Design	Is Global Clinical Trial	Participating Countries	Planned No. of Subjects Globally	Planned No. of Subjects in India
Therapeutic	Single Arm Trial	No		0	0

**Sponsor Details**

Sponsor: abc test1, null Noida, U.P India- 201301 Telephone: 5956896325 Fax: 2563256325 Email: aaa@gmail.com

**Comparator Drug Details**

S.No.	Comparator Drug Name	Brand Name	Dosage Form	Drug Composition	Route of Administration	Name of Company	Name of Country
1	antiv	Test Sample	Blood & Blood Products (Lyophilized)		Oral	ACARG	India

**Disease Under Investigation**

S.No.	Disease Name
1	→ Asthma

**CT Site Details**

S.No.	Hospital	No. of Beds	Ethics Committee	Laboratory Details
1	→ City Cancer Centre 33-28-88, Ch. Venkates Krishnaayya Street, Surpasee Dist, Vijaywada, Not Available, Andhra Pradesh	50	Academic Research Projects	test Add 1, null Noida, Gautam Buddha Nagar, Uttar Pradesh, 201301 (India) Whether GLP/ISO/NABL/Other Certified: Yes

**Protocol Details**

S.No.	Protocol No.	Version No.	Date of Protocol	Dosing	Subject Details	Age Group	Proposed Study Period
1	→ 564	99%	01-Jun-2017	Multiple Dose	Female	Children(2-11 Years)	24 Weeks

**Centralized Laboratory Details**

S.No.	Lab Name	Lab Address	Email	Whether GLP/ISO/NABL/Other Certified
1			aaa@gmail.com	Yes

Download PDF
Continue

Download PDF
Continue

Figure 61 : Final preview of the form with download option (Continue)

- **Uploading & Submitting Form44:** Upload the signed system generated form after which file number will be generated.

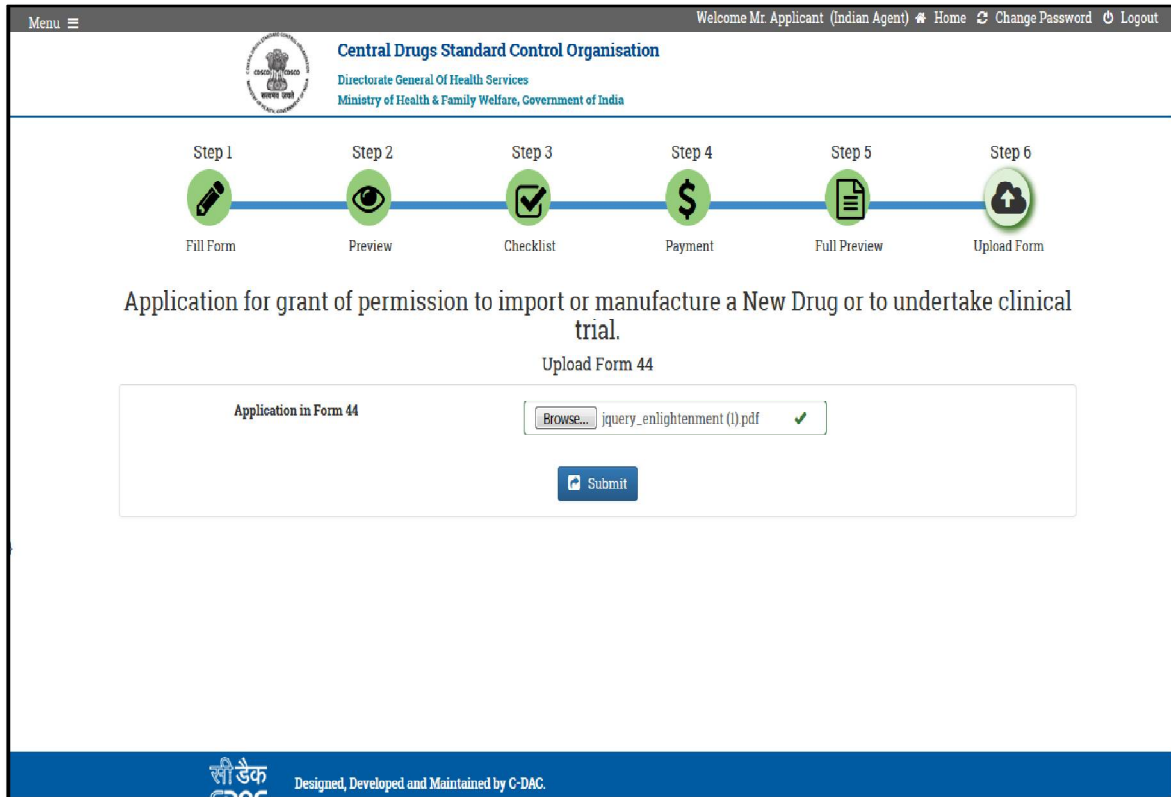


Figure 62 : Uploading & Submitting Form44

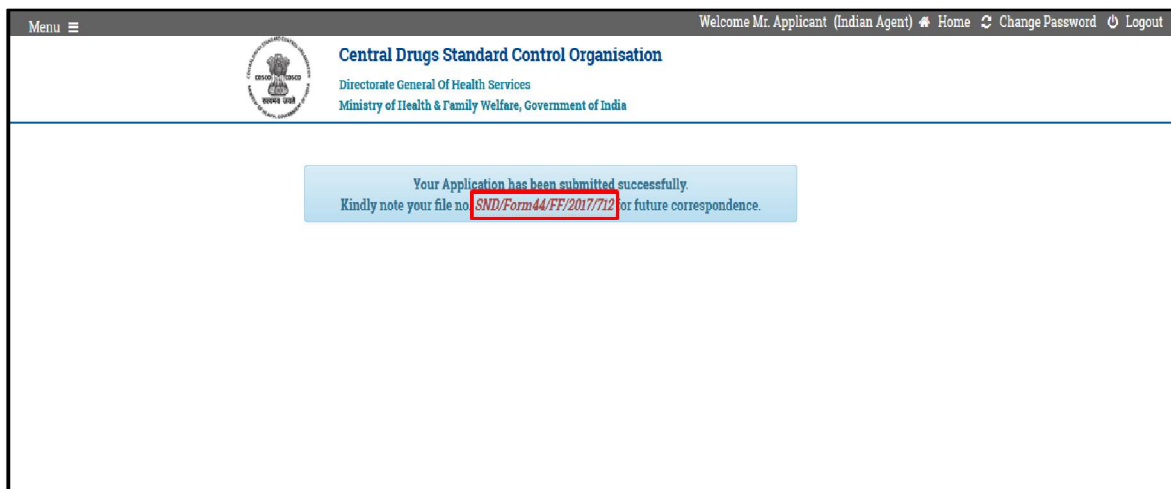


Figure 63 : Application Submitted Successfully

## 4.2 Application Submission for Import & Registration

- Applications to Import & Registration division is done for the cases as depicted in the below table:

**Table 5 : Application Submission for Import & Registration**

S. No	Purpose of Application	Type of Application	Category	Form Number
1.	Application for grant of Registration certificate(RC) for drugs (6 Cases)	Fresh, Endorsement & Re-registration	Bulk Drugs, Finished Formulation	Form 40/41
2.	Application for grant of Import License for Drugs against approved RC	Fresh, Endorsement & Re-registration	Bulk Drugs, Finished Formulation	Form 8/10

- **Application for Grant of Registration Certificate (RC)** : Applicant can apply for Grant of registration certificate in Form40 by selecting Import & Registration department and choosing Form40, as shown below:

**Online Forms Submission**

Select Department:

Select Form:

**GENERAL INSTRUCTIONS**

*Please read the below instructions carefully before proceeding to Online Form Submission*

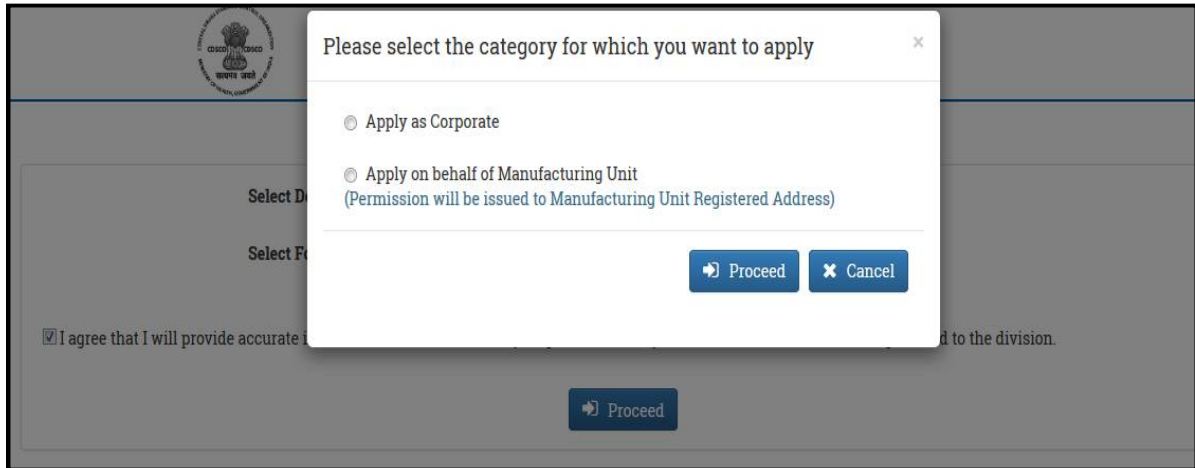
- Online Form Submission is divided into few simple steps like:
  - Filling of Form
  - Uploading Essential Documents in checklist
  - Payment (if applicable) and
  - Final Form Upload.
- User is required to download pdf in *Full Preview step*. After downloading, perform the following steps:
  - Sign and Stamp the form
  - Scan the Signed and Stamped Form
  - Upload this form in the *Upload Form step*
- Please ensure that you have all the required documents ready to upload them in checklist section. Please view the checklist from [here](#)

**Figure 64 : Application for Grant of Registration Certificate (RC)**

**Note:-**

- Form40 is applied for the issue of “**Registration Certificate (RC)**” for import of drugs.
- Applicant can be an **Indian Manufacturer** or **Indian Agent**.

➤ After clicking on **Proceed** a new window will open, as shown in below **Figure**

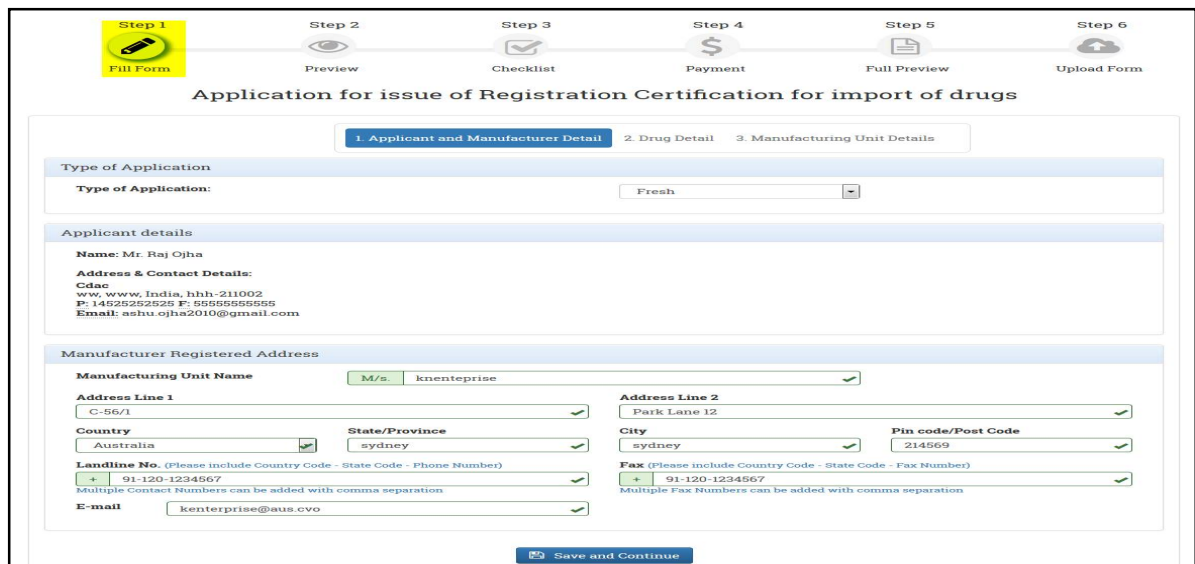


**Figure 65 : Confirmation Message: Proceed**

**Note:-**

- Applicant can apply for the form for self or on behalf of other manufacturing unit.
- After clicking on **proceed** a new window will open ,user can start filling the form
- **The form has been divided into following three broad sections :**
  - Applicant & Manufacturer details
  - Drug details
  - Manufacturing unit details

➤ **Applicant & Manufacturer details:** In this section applicant needs to select the type of application, either Fresh or Endorsement or Re-registration. The applicants details are automatically fetched from user registration details. Here, Applicant needs to fill in foreign manufacturer details.



**Figure 66 : Applicant & Manufacturer details**

- **Drug details:** Following drug details need to be filled by the applicant as shown below:
  - Category of Drug
  - Gene Name
  - Pharmacopial monograph
  - Class of Drug
  - Shelf Life

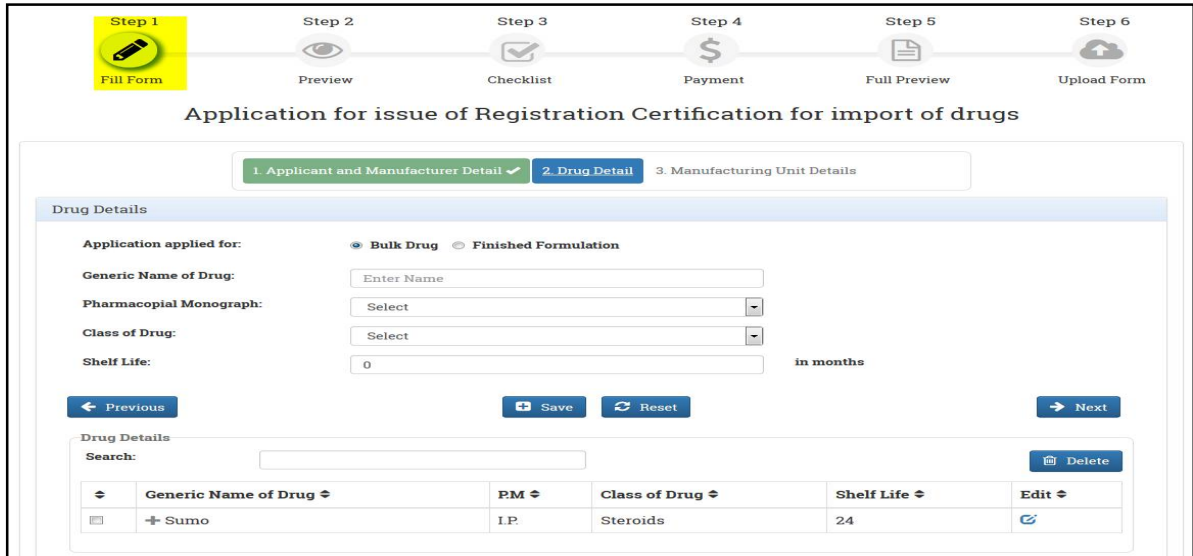


Figure 67 : Drug details

- On clicking Save, Drug Details will be added.
- **Manufacturing Site details:** Applicant needs to select the type of manufacturing site and the site address from the drop down. Manufacturing sites list is populated from the site addresses entered by the applicant in user profile section.

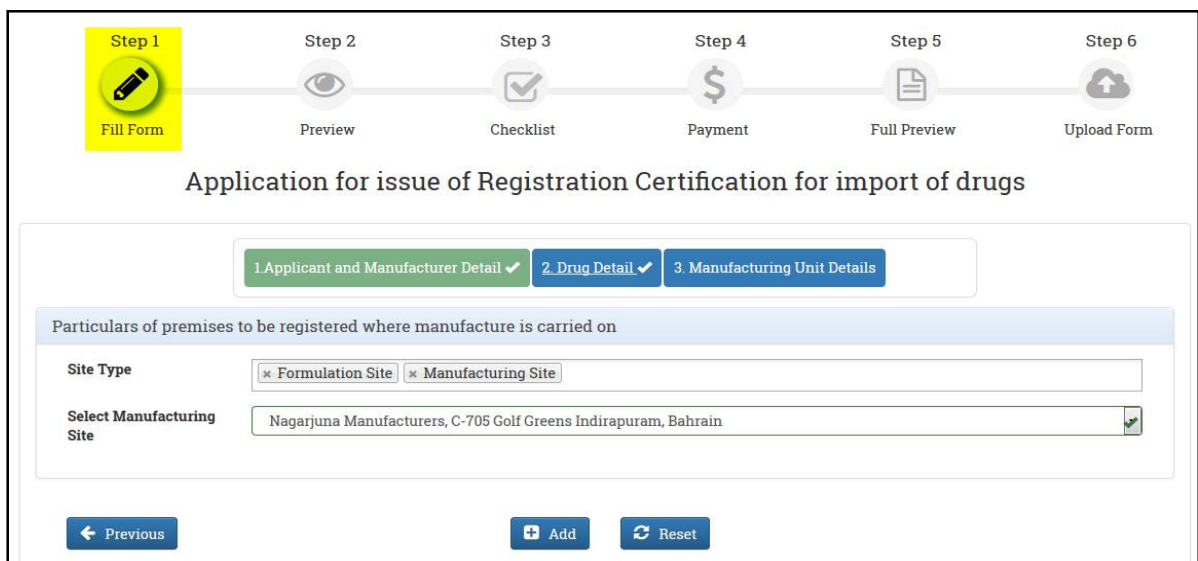


Figure 68 : Manufacturing Site details

- **Case2: Type of Application :- Endorsement**
  - In case of **Endorsement** applications, user needs to enter a valid RC, which will intern fetch all the relevant details pertaining to that RC number like validity, applicant details & manufacturer registered address.

Figure 69 : Type of Application- Endorsement

- User can update the data of the additional drugs in the drug detail section, however user will not be able to edit/add the premises data as depicted in the below figure.

Figure 70 : Update the data of the additional drugs

➤ On clicking save a new window will open as shown in **Figure**.

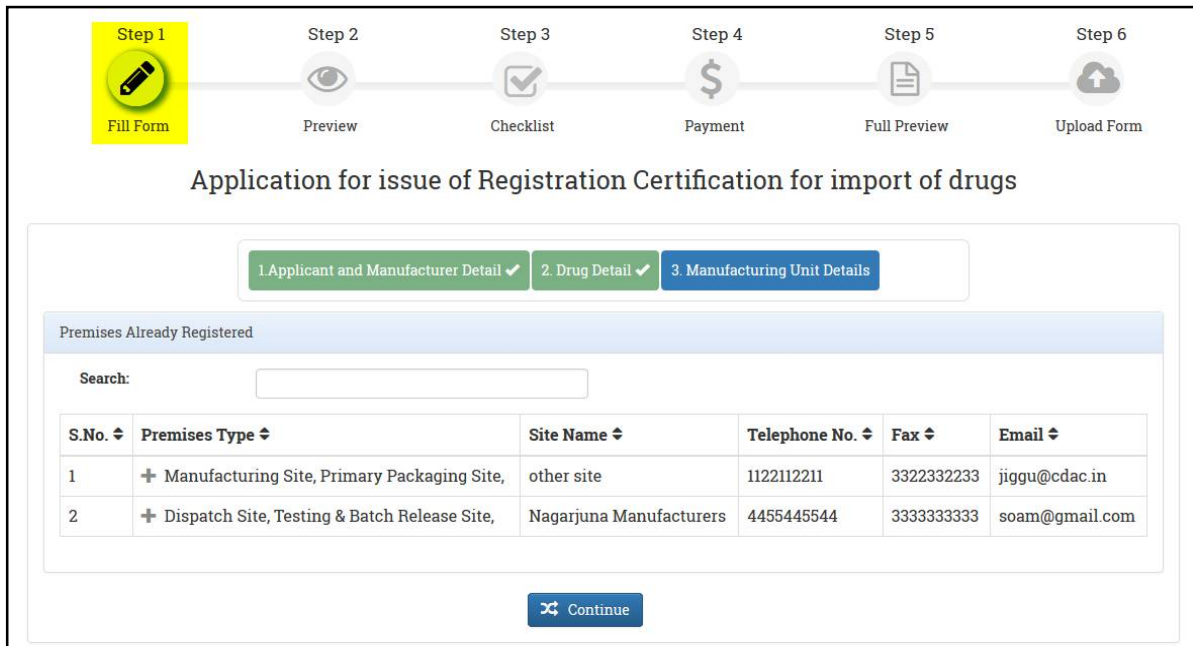


Figure 71 : Screen of after clicking on save button

➤ **Case3: Type of Application: - Re-registration**

- User should apply for re-registration case if he wants to renew the validity of the RC.
- In case of Re-registration applications, user needs to enter a valid RC, which will intern fetch all the relevant details pertaining to that RC number like validity, applicant details product related information & manufacturer registered address.
- User can only select the products for which the validity needs to be renewed; the details related to manufacturing site details cannot be altered.

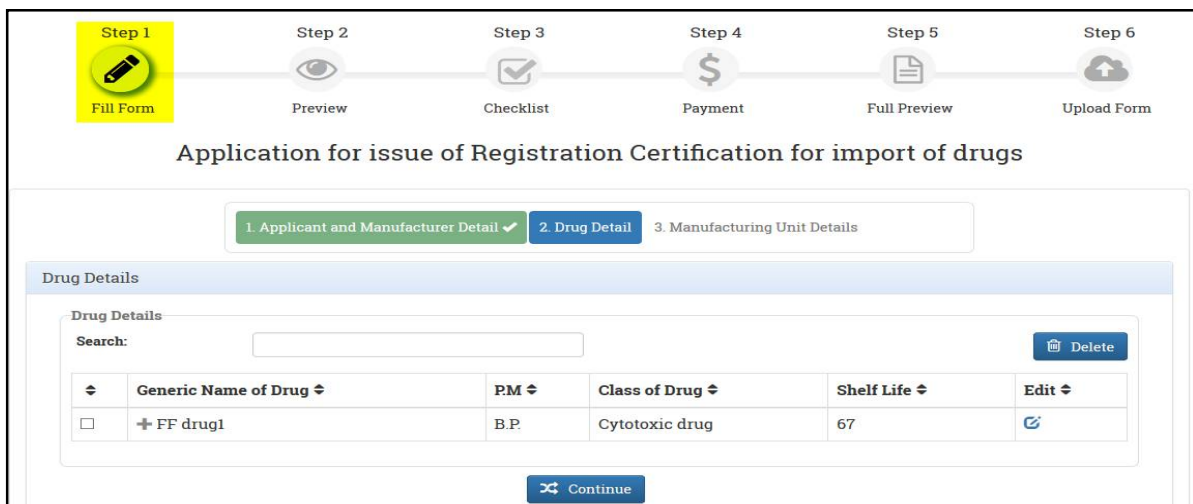



Figure 72 : Type of Application: - Re-registration

- After filling the application form details, user should upload the necessary documents in the checklist upload page, as depicted below:



### Upload Essential Documents of Form 40

**Note:**

1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 10 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.

<input checked="" type="checkbox"/> 1. Covering Letter
<input checked="" type="checkbox"/> 2. Original Power of Attorney
<input type="checkbox"/> 3. Copy of Import permission for new drug (s) in Form-45 (formulation) or in Form-45A (new bulk drug substances)
<input type="checkbox"/> 4. Copy of Whole sale Licence(20B/21C) or Manufacturing Licence of the Indian agent/Corporate office address
<b>5. Authorization letter</b>
<input type="checkbox"/> 5.1 Indian Agents authorization letter (in original) for the signing of Form 40, Power of Attorney Schedule D I and D II to the authorized person
<input type="checkbox"/> 5.2 Foreign Manufacturers authorization letter (in original) for the signing of Form 40, Power of Attorney Schedule D I and D II to the authorized person
<input type="checkbox"/> 5.3 Companys authorization letter (in original) for the bearer to submission and collect letter.
<input type="checkbox"/> 6. Schedule D (I) and Undertaking duly signed, dated and seal/stamped with name and designation of the authorised signatory of the manufacturer or his authorised Indian agent.
<input type="checkbox"/> 6.1 Notarized Site Master File
<input type="checkbox"/> 6.1.1 List of Major equipments in Production and QC
<input type="checkbox"/> 6.1.2 List of key personals with qualification, experience and their responsibilities
<input type="checkbox"/> 6.1.3 Organizational Chart
<input type="checkbox"/> 6.1.4 QA functional Chart
<input type="checkbox"/> 6.1.5 Plant Layout
<input type="checkbox"/> 6.1.6 HVAC system drawing
<input type="checkbox"/> 6.1.7 Water system drawing
<input type="checkbox"/> 6.1.8 Pressure differential drawing
<input type="checkbox"/> 6.1.9 Personal movement drawing
<input type="checkbox"/> 6.1.10 Material movement drawing
<input type="checkbox"/> 6.1.11 Distribution, Complaints & products recall SOP
<input type="checkbox"/> 6.1.12 List of Contract Manufacturing/analysis
<input type="checkbox"/> 7. Schedule D (II) and Undertaking duly signed, dated and seal/stamped with name and designation of the authorised signatory of the manufacturer or his authorised Indian agent.
<input type="checkbox"/> 7.1 Notarized Drug Master File
<input type="checkbox"/> 7.1.1 Process flow chart
<input type="checkbox"/> 7.1.2 Manufacturing process development report
<input type="checkbox"/> 7.1.3 Control of critical steps
<input type="checkbox"/> 7.1.4 Process validation report of three batches
<input type="checkbox"/> 7.1.5 List of by-product
<input type="checkbox"/> 7.1.6 List of Impurities and related substances
<input type="checkbox"/> 7.1.7 Structure elucidation of impurities and its toxicity test report
<input type="checkbox"/> 7.1.8 List of Residual solvents and its limits
<input type="checkbox"/> 7.1.9 Analytical method validation report of drug substances, impurities, related substances and residual substances
<input type="checkbox"/> 7.1.10 Testing procedure of impurities, related substances and residual solvents
<input type="checkbox"/> 7.1.11 Details of the input raw material with their specification and sources
<input type="checkbox"/> 7.1.12 Source and maintenance of reference standards
<input type="checkbox"/> 7.1.13 Container and closure system and its testing procedure
<input type="checkbox"/> 7.1.14 Batch determination: batch numbering system & batch size
<input type="checkbox"/> 7.1.15 Specification of the products & material used in its manufacturing
<input type="checkbox"/> 7.1.16 Justification of the Specification
<input type="checkbox"/> 7.1.17 Certification of analysis of five batches
<input type="checkbox"/> 7.1.18 MSDS

Figure 73 : Screen of Upload Essential Documents of Form 40



<input type="checkbox"/>	7.2 Stability data both accelerated and real time (As per ICH Q1A(R2) and WHO TRS 953)
<input type="checkbox"/>	7.2.1 Long term stability data
<input type="checkbox"/>	7.2.2 Accelerated stability data
<input type="checkbox"/>	7.2.3 Stability study summary
<b>8. Copy of Original Notarised</b>	
<input type="checkbox"/>	8.1 Manufacturing Licence/Product authorisation certificate , in case of China
<input type="checkbox"/>	8.2 GMP Certificate(Duly Apostilled/Notorised copy)
<input type="checkbox"/>	8.3 COPP Certificate (Duly Apostilled/Notorised copy)
<input type="checkbox"/>	8.4 FSC Certificate (Duly Apostilled/Notorised copy)
<b>9. Attested/Appostilled copy of</b>	
<input type="checkbox"/>	9.1 Product Registration Certificate (SFDA), in case of China
<input type="checkbox"/>	9.2 Certificate of suitability from EDQM
<input type="checkbox"/>	10. Original label /specimen label complying with Rule 96 and indicating name of the drug with pharmacopoeial specification, the importer name & address as per Wholesale license and Import License number. If proposed draft label/package insert wherever applicable, then duly attested either by the authorised Indian Agent or by the manufacturer is required to be submitted along with the application.
<input type="checkbox"/>	11. Statement and or undertaking regarding pertaining to quality of the drug in the country of origin or regulatory Authority of any other country where the drug is marketed /distributed
<input type="checkbox"/>	12. Details regarding any administrative action taken by the regulatory authority due to ADR, MARKET WITHDRAWAL, CANCELLATION OF AUTHORISATION ETC.
<input type="checkbox"/>	13. Statements/undertakings regarding any change in manufacturing process/packaging/labelling/testing/ or documentation undertaken during last three years (Drugs Master File)
<input type="checkbox"/>	14. Statements/undertakings regarding any change in the constitution of the firm /address of registered office (Site Master File)
<input type="checkbox"/>	15. Total Quantity of drugs exported to India during last three years
<input type="checkbox"/>	16. Statement and or undertaking regarding pertaining to quality of the drug in the country of origin or regulatory Authority of any other country where the drug is marketed /distributed
<input type="button" value="Submit"/>	

Figure 74 : Screen of Upload Essential Documents of Form 40 (Continue)

**Note:-**

- Applicant should fill the complete checklist otherwise applicant will not be able to proceed further.
- After uploading the necessary documents, user will be directed to the payment page, that has options for challan payment as well as online payment through Bharatkosh

Step 1 Fill Form

Step 2 Preview

Step 3 Checklist

**Step 4 Payment**

Step 5 Full Preview

Step 6 Upload Form

**Payment Details**

Payment has been calculated as below:

- A fee of 1500 USD for Registration of manufacturing site
- A fee of 1000 USD for Registration of Drugs

Today's Exchange Rate is: INR / 1 USD = 64.0

Total Amount in USD	<b>2500</b>	Payable Amount in INR	<b>160000</b>	Head of Account	<b>104 -- Fees and fines</b>
---------------------	-------------	-----------------------	---------------	-----------------	------------------------------

Mode of Payment:  Purpose:

Challan Details		
Challan No.	Challan Date	Amount
<input type="text" value="111"/>	<input type="text" value="05/18/2015"/>	<input type="text" value="160000"/>
Bank Name	Branch Code	Upload Challan
<input type="text" value="sbi"/>	<input type="text" value="12365"/>	<input type="button" value="Browse..."/> Challan.pdf <input type="button" value="+"/>

Total Amount of Uploaded Challans: **160000**

Figure 75 : Payment Details

- After uploading Payment the final preview of the filled form in legal form40 is generated as shown below.
- Applicant can click on **Download PDF** to download the file.

Figure 76 : Final preview of the filled form in legal form40

- After downloading the PDF, the user should sign & stamp, scan and upload the signed document and submit the application.

Figure 77 : Upload the signed document

- On submitting the application, a file no. will be generated for future correspondence purpose.



Figure 78 : Application has been submitted successfully

### 4.3 Application for Grant of Import License

- Applicant need to apply for Grant of Import License in "FORM 8" by choosing **select department** and **select form** from the drop down list, as shown in below **Figure**.

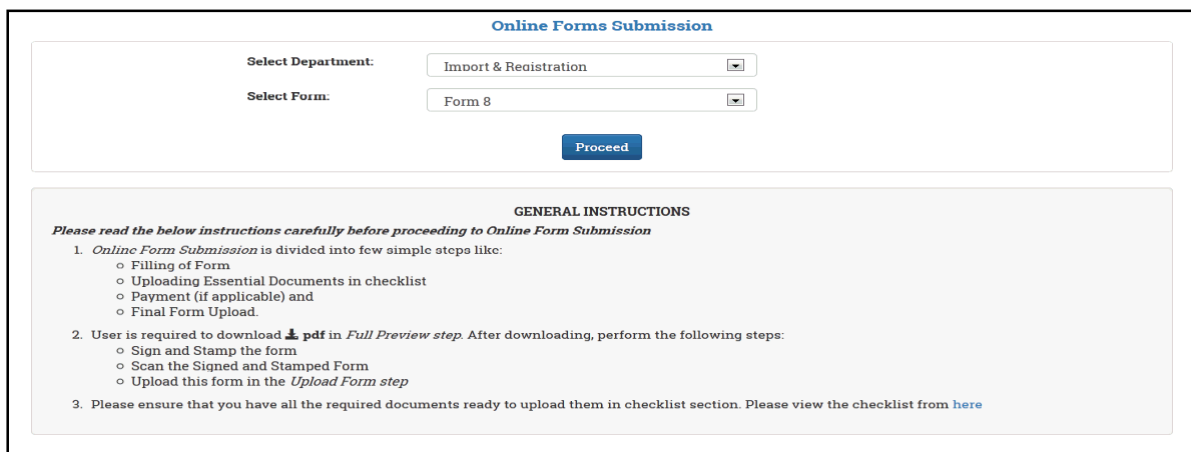


Figure 79 : Application for Grant of Import License

- Applicant can apply for the form for self or on behalf of other manufacturing unit.

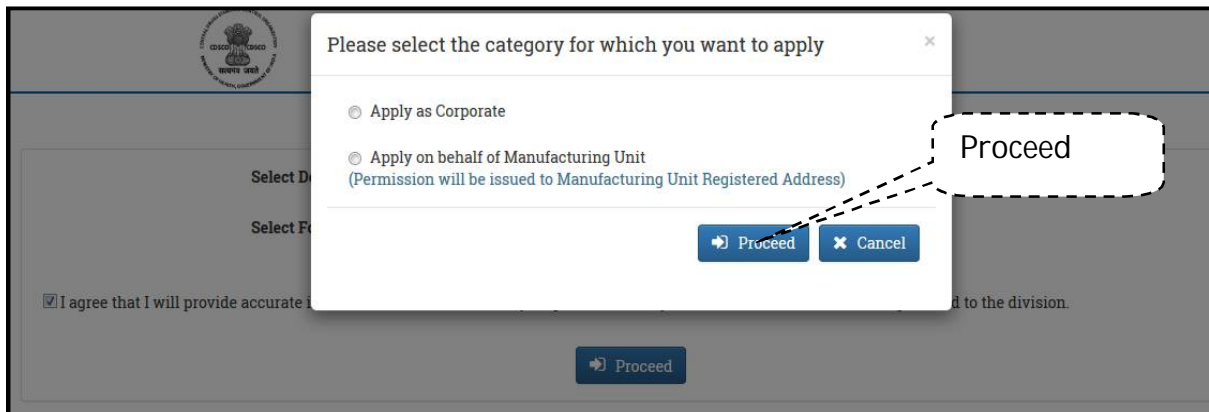
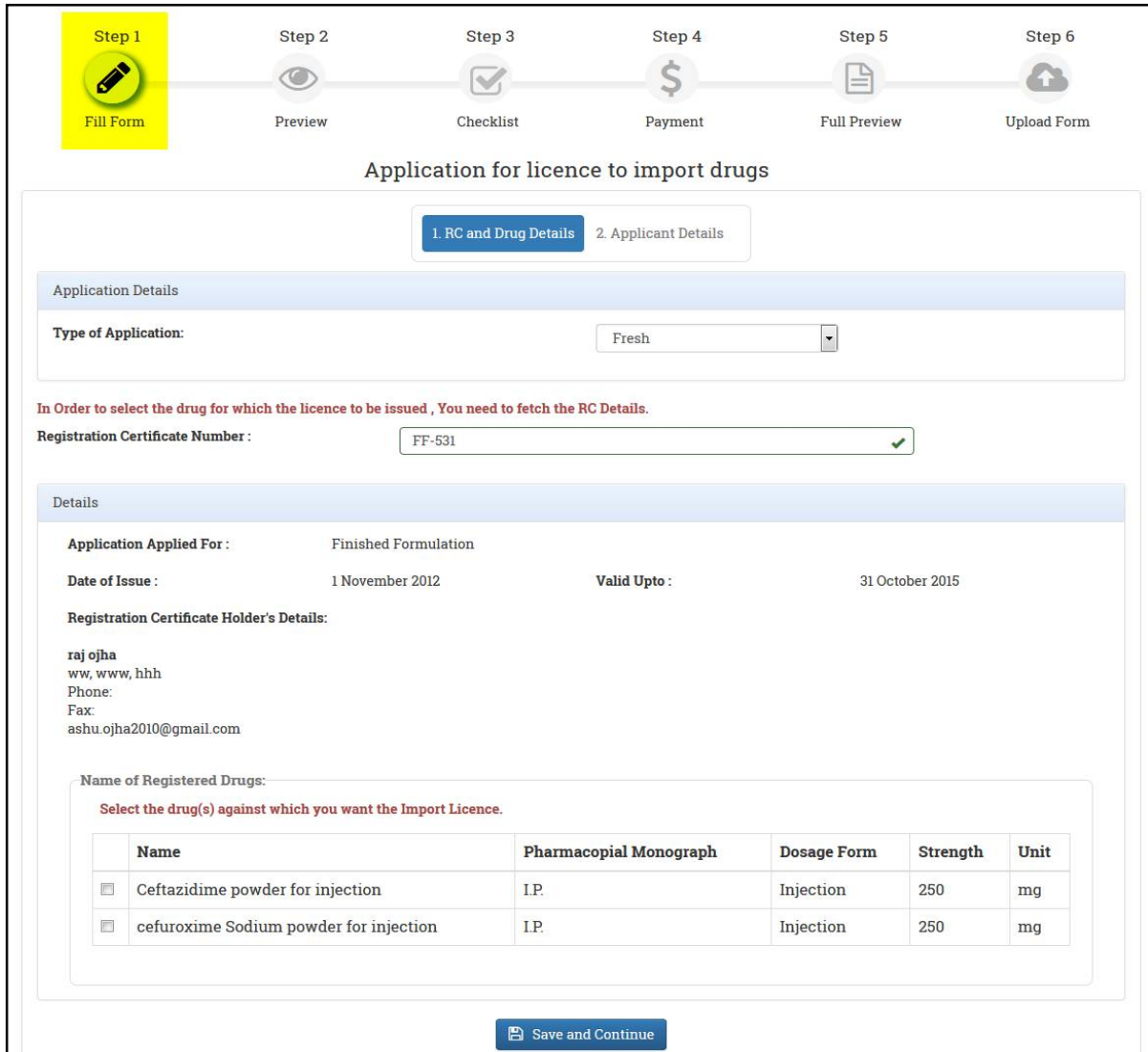


Figure 80 : Confirmation for Proceed

- Form 8 can be applied for the cases of Fresh, Endorsement and re-registration of the Import License. In all the cases, the user should possess the valid RC, details of which needs to be selected by the user on the Part-I of the form as discussed below:
- **Case 1: Type of application: Fresh**  
 Select the type of application as fresh and enter the RC number on which license has to be granted. As soon as RC number is entered by the user the , all details pertaining to that RC will be fetched by the system. User just needs to select the drugs for which he intends to take Import License.



**Application for licence to import drugs**

1. RC and Drug Details    2. Applicant Details

**Application Details**

Type of Application: Fresh

**In Order to select the drug for which the licence to be issued , You need to fetch the RC Details.**

Registration Certificate Number : FF-531 ✓

**Details**

Application Applied For : Finished Formulation

Date of Issue : 1 November 2012      Valid Upto : 31 October 2015

**Registration Certificate Holder's Details:**

raj ojha  
 ww, www, hhh  
 Phone:  
 Fax:  
 ashu.ojha2010@gmail.com

**Name of Registered Drugs:**

Select the drug(s) against which you want the Import Licence.

Name	Pharmacopial Monograph	Dosage Form	Strength	Unit
<input type="checkbox"/> Ceftazidime powder for injection	I.P.	Injection	250	mg
<input type="checkbox"/> cefuroxime Sodium powder for injection	I.P.	Injection	250	mg

Save and Continue

**Figure 81 : Type of application: Fresh**

- Next, user should upload Form 9 issued by the RC holder as should in below figure

**Step 1** (Fill Form) | Step 2 (Preview) | Step 3 (Checklist) | Step 4 (Payment) | Step 5 (Full Preview) | Step 6 (Upload Form)

**Application for licence to import drugs**

1. RC and Drug Details ✓ | 2. Applicant Details

**Applicant details**  
 Name: Mr. Raj Ojha  
 Address & Contact Details:  
 Cdac  
 ww, www, India, hhh-211002  
 P: 14525252525 F: 93593593595  
 Email: ashu.ojha2010@gmail.com

**Form 9 Details**  
 Issued By: Indian Agent  
 Date of Undertaking: 05/09/2013  
 Upload Form 9: Form 9.pdf

Save and Continue

Figure 82 : Upload Form 9

➤ Case 2: Type of application: **Endorsement**

**Step 1** (Fill Form) | Step 2 (Preview) | Step 3 (Checklist) | Step 4 (Payment) | Step 5 (Full Preview) | Step 6 (Upload Form)

**Application for licence to import drugs**

1. RC and Drug Details | 2. Applicant Details

**Application Details**  
 Type of Application: Endorsement

**In Order to select the drug for which the licence to be issued , You need to fetch the RC Details.**

Registration Certificate Number : BD-0987 ✓  
 License Number : bd-0987 ✓

**Details**

R C Details		Licence Details	
Application Applied For :	Bulk Drug	File Number:	null
Date of Issue :	4 May 2015	Applicant Name:	raj ojha
Valid Upto :	9 April 2016	Date of Issue:	
Registration Certificate Holder's Details:	raj ojha ww, www, hhh,P: null,F: null, E-mail:	Valid Upto:	9 April 2016

**Name of Registered Drugs:**  
 Select the drug(s) against which you want the Import Licence.

	Name	Pharmacopial Monograph
<input checked="" type="checkbox"/>	Uglocose	J.P.

Save and Continue

Figure 83 : Type of application: Endorsement

- In case of endorsement, after entering the RC details, user needs to enter the license number for which user needs to take endorsement.

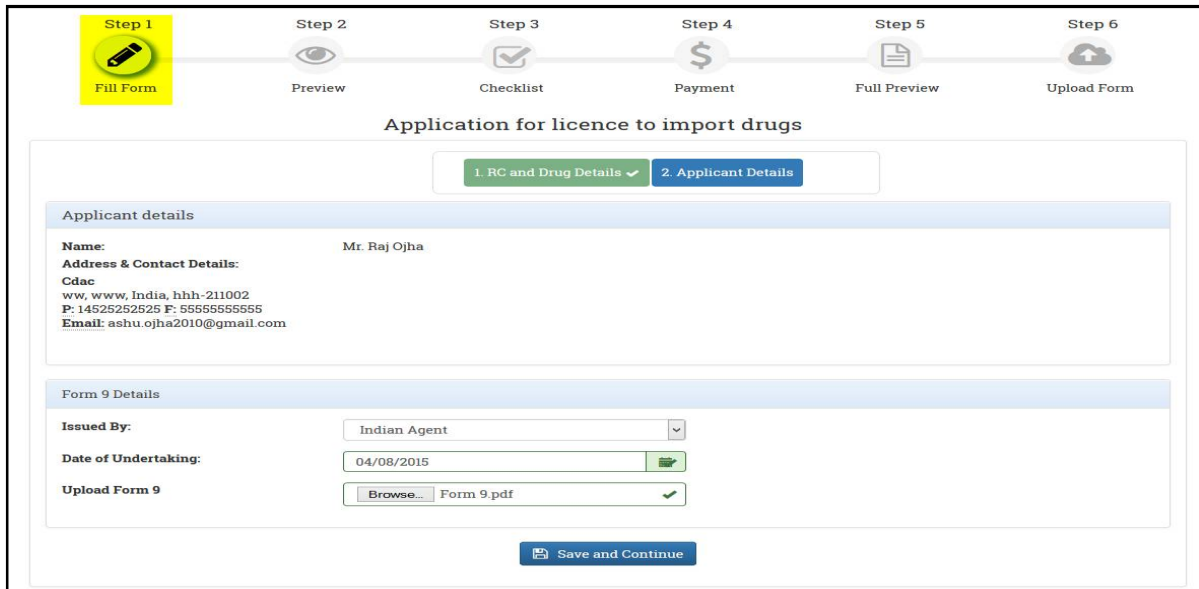


Figure 84 : For Endorsement: Enter License Number

**Note:-**

- Applicant applies for Endorsement case when license number is valid but applicant wants to apply for new drugs against that license number.
- **Case 3: Type of application: Re-registration**  
In case of Re-registration, after entering the RC details, user needs to enter the license number for which user needs to take endorsement.

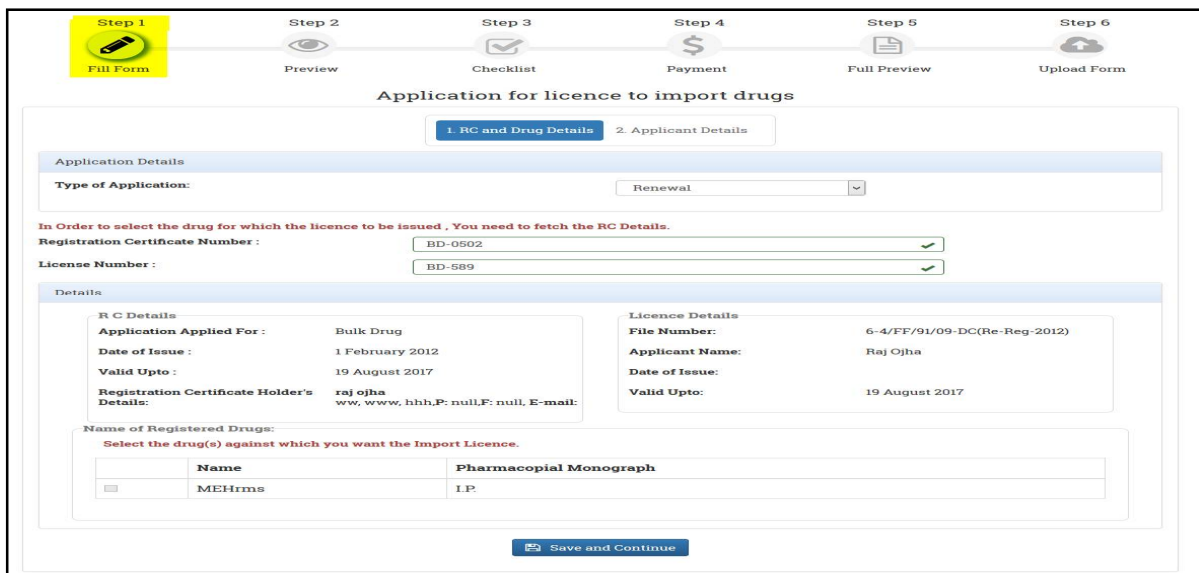


Figure 85 : Type of application: Re-registrations

Figure 86 : for Endorsement – enter License Number

**Note:-**

- Applicant applies for Renewal case when license no expires and applicant wants to apply for renewal of license number.

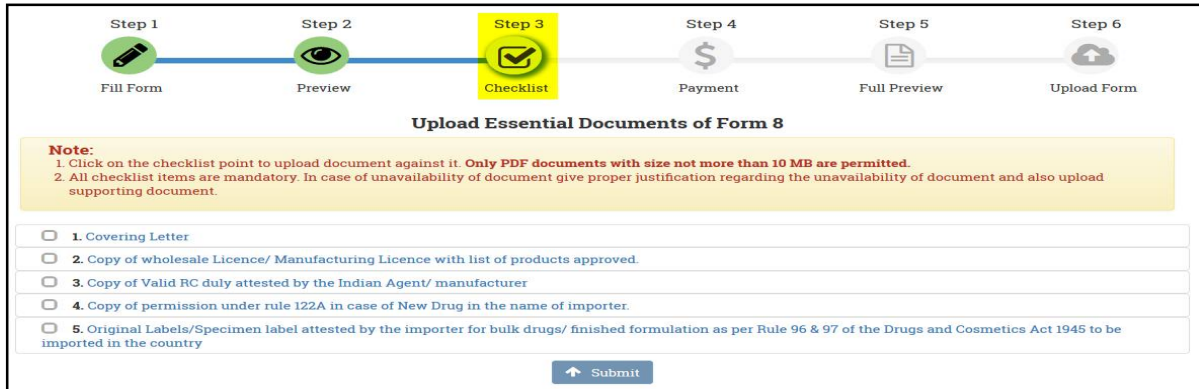
**Note:-**

- After applying for all the three cases i.e. **Fresh, Endorsement, and Renewal** a new window will open and it will remain common for all the three cases.
- After clicking on **Save and Continue** a new window will open, as shown in **Figure**.

Figure 87 : Screen of after clicking on Save and Continue

**Note:-**

- Applicant can click on **Edit Form** to modify entered details.
- Applicant can click on **Proceed To Checklist** to fill the checklist.
- After clicking on **Proceed To Checklist** a new window will open, as shown in below **Figure**.



**Upload Essential Documents of Form 8**

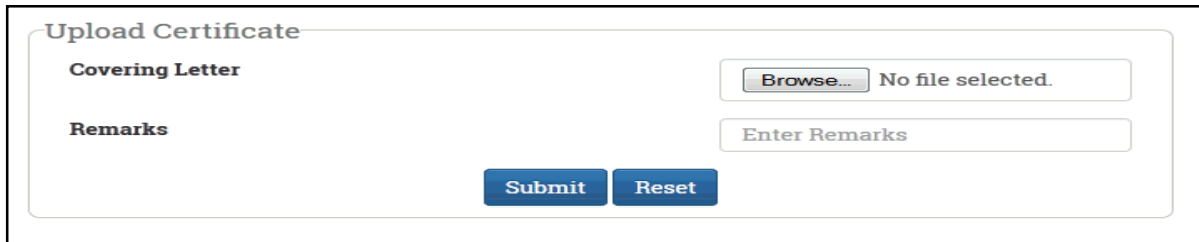
**Note:**  
 1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 10 MB are permitted.**  
 2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.

- 1. Covering Letter
- 2. Copy of wholesale Licence/ Manufacturing Licence with list of products approved.
- 3. Copy of Valid RC duly attested by the Indian Agent/ manufacturer
- 4. Copy of permission under rule 122A in case of New Drug in the name of importer.
- 5. Original Labels/Specimen label attested by the importer for bulk drugs/ finished formulation as per Rule 96 & 97 of the Drugs and Cosmetics Act 1945 to be imported in the country

[Submit](#)

**Figure 88 : Screen of Upload essential Documents of Form 8**

- When applicant will click on first point i.e. **Covering Letter** a new window will open, as shown in **Figure** below.



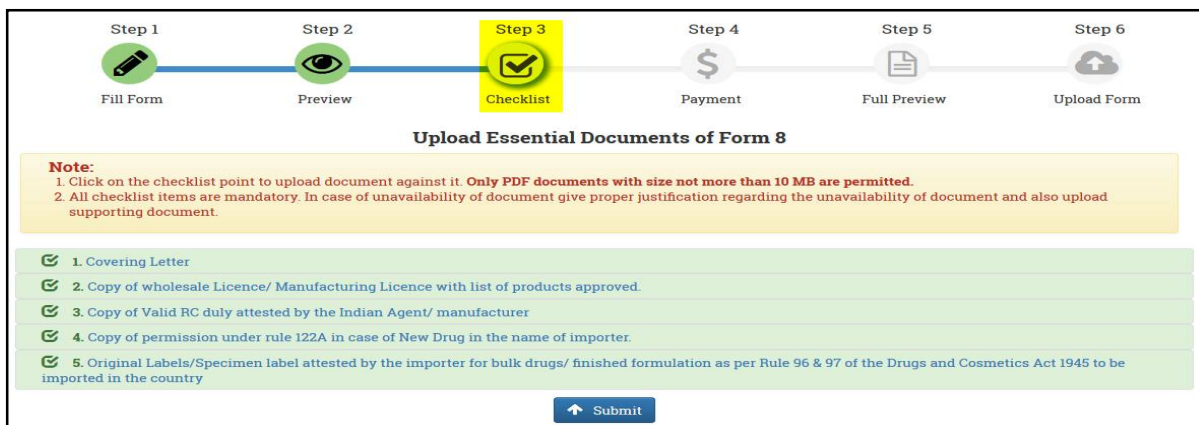
**Upload Certificate**

**Covering Letter** [Browse...](#) No file selected.

**Remarks** Enter Remarks

[Submit](#) [Reset](#)

**Figure 89 : Upload Certificate**



**Upload Essential Documents of Form 8**

**Note:**  
 1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 10 MB are permitted.**  
 2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.

- 1. Covering Letter
- 2. Copy of wholesale Licence/ Manufacturing Licence with list of products approved.
- 3. Copy of Valid RC duly attested by the Indian Agent/ manufacturer
- 4. Copy of permission under rule 122A in case of New Drug in the name of importer.
- 5. Original Labels/Specimen label attested by the importer for bulk drugs/ finished formulation as per Rule 96 & 97 of the Drugs and Cosmetics Act 1945 to be imported in the country

[Submit](#)

**Figure 90 : Fill the complete checklist**

**Note:-**

- Applicant should fill the complete checklist to proceed further otherwise applicant will not be able to proceed further.

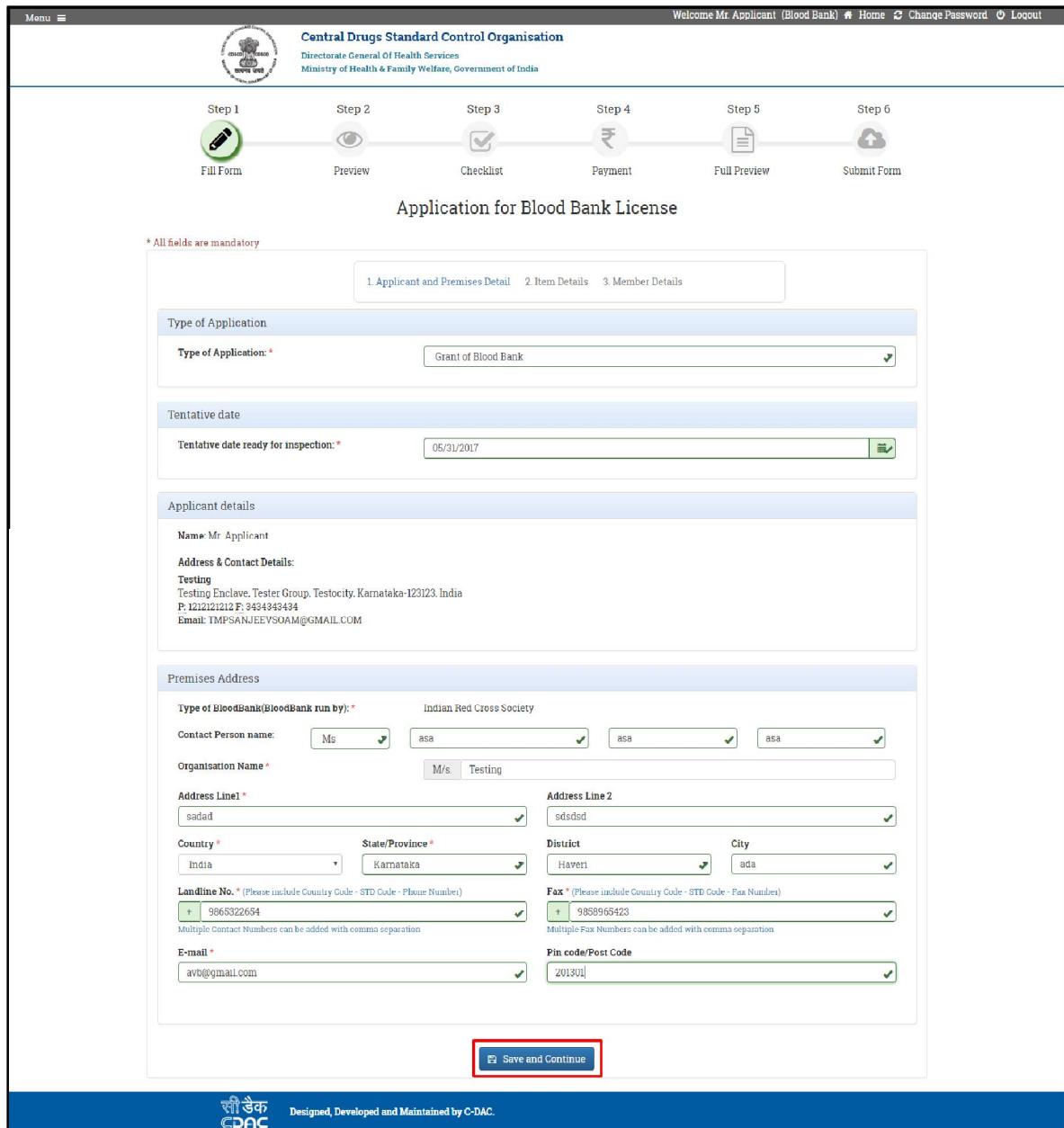


## 4.4 Application for Blood Bank License

Application for Grant of Blood Bank License is applied in online Form 27C. The application once filled and submitted by the user is automatically forwarded to the respective CDSCO Zonal office depending upon the state under which the Blood bank premises are located.

Following are the steps to fill the online application for Blood bank license

- Filling of the form



Menu Welcome Mr. Applicant (Blood Bank) Home Change Password Logout

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

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6  
Fill Form Preview Checklist Payment Full Preview Submit Form

### Application for Blood Bank License

\* All fields are mandatory

1. Applicant and Premises Detail 2. Item Details 3. Member Details

**Type of Application**

Type of Application: \*

**Tentative date**

Tentative date ready for inspection: \*

**Applicant details**

Name: Mr. Applicant

**Address & Contact Details:**

**Testing**  
Testing Enclave, Tester Group, Testocity, Karnataka-123123, India  
P: 1212121212 F: 2434343434  
Email: TMPANJEEVSQAM@GMAIL.COM

**Premises Address**

Type of Blood Bank (Blood Bank run by): \*

Contact Person name:

Organisation Name \*

Address Line 1 \*  Address Line 2

Country \*  State/Province \*  District  City

Landline No. \* (Please include Country Code - STD Code - Prefix Number)  Fax \* (Please include Country Code - STD Code - Fax Number)

Multiple Contact Numbers can be added with comma separation

E-mail \*  Pin code/Post Code


 Designed, Developed and Maintained by C-DAC.

Figure 91 : Application for Blood Bank License

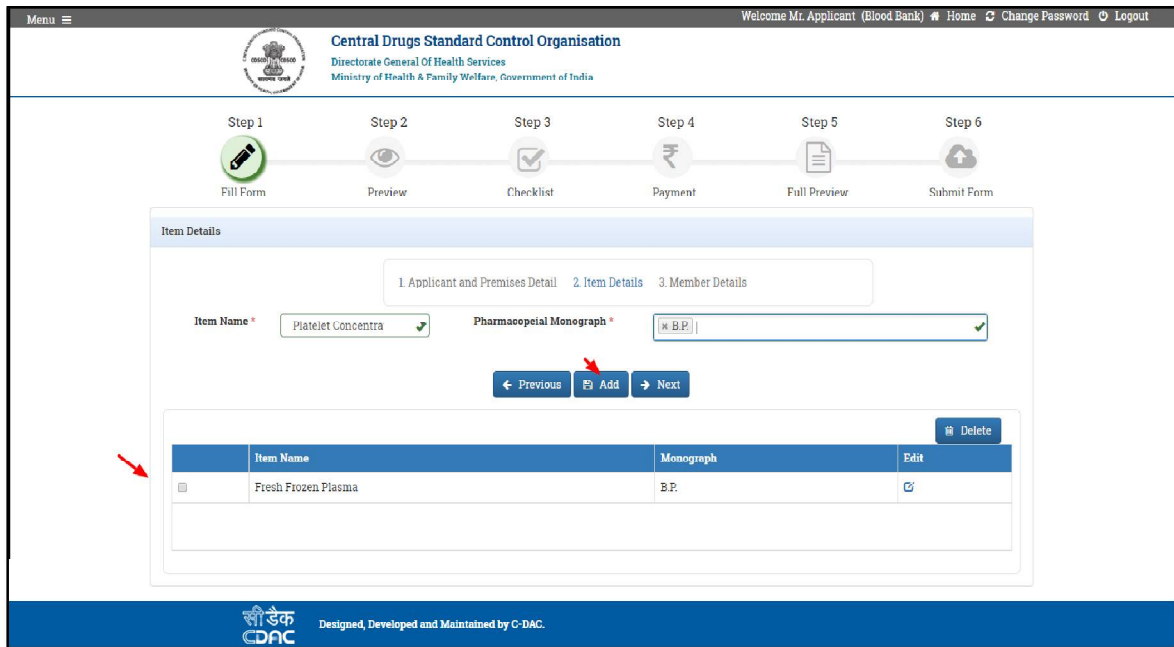


Figure 92 : Application for Blood Bank License (Add Button)

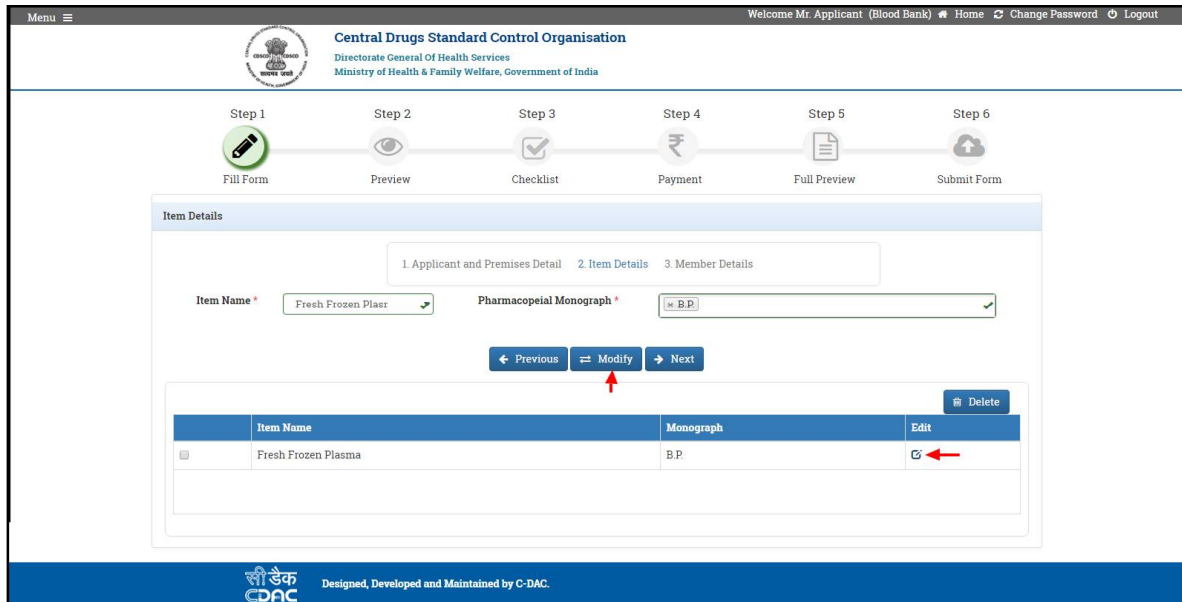


Figure 93 : Application for Blood Bank License (Modify)

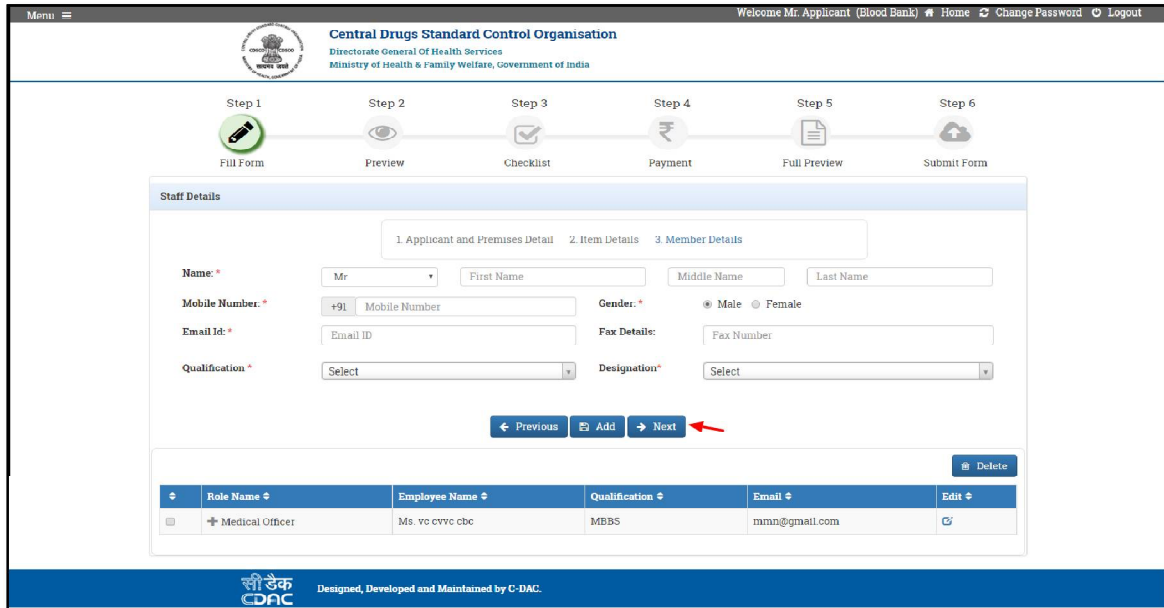


Figure 94 : Next button to Click for Next Step

➤ First Preview of the form

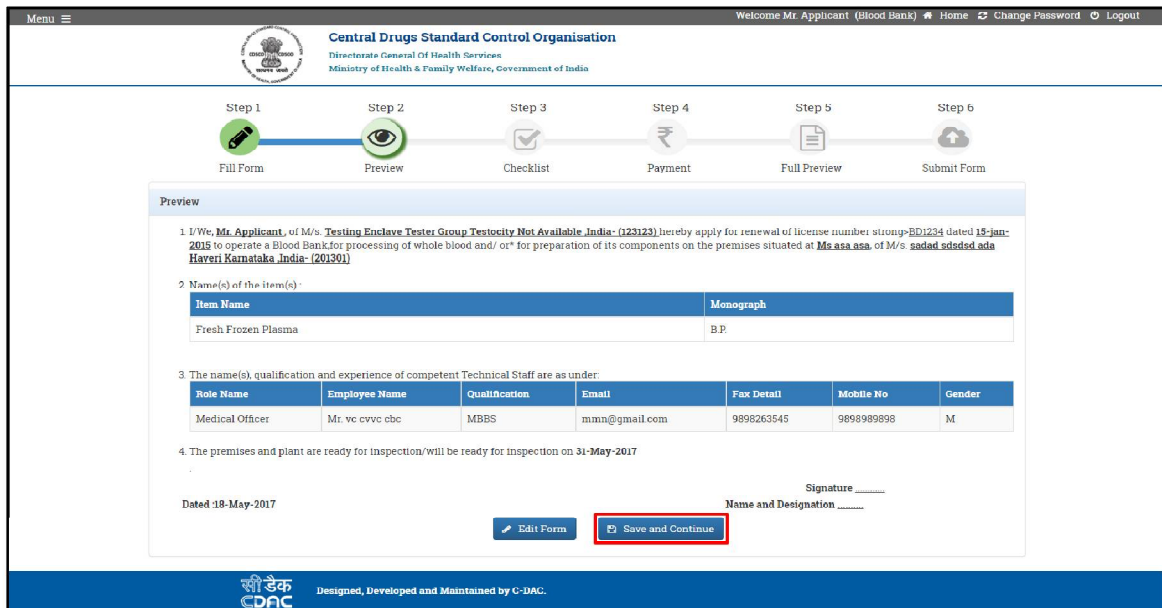


Figure 95 : First Preview of the form

- Confirmation alert to proceed to checklist.

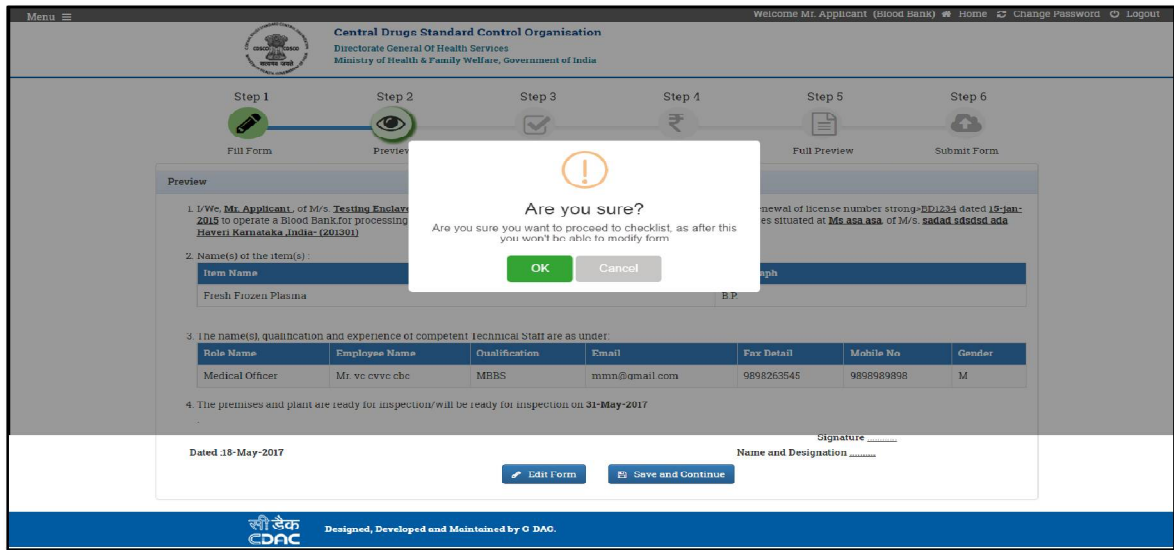


Figure 96 : Confirmation alert to proceed to checklist

- Checklist to upload the documents

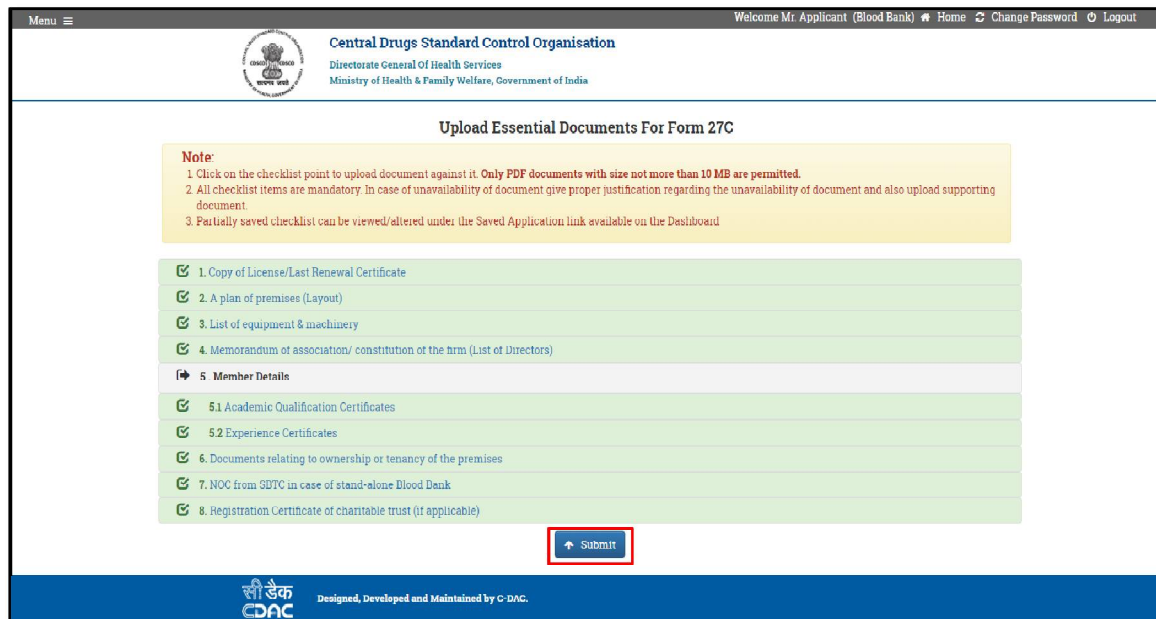


Figure 97 : Checklist to upload the documents

➤ Payment for the form

Figure 98 : Payment for the form

➤ Final preview of the legal form with the option to download the form

Figure 99 : Final Preview of the Legal Form

- Upload the signed system generated form for final submission:

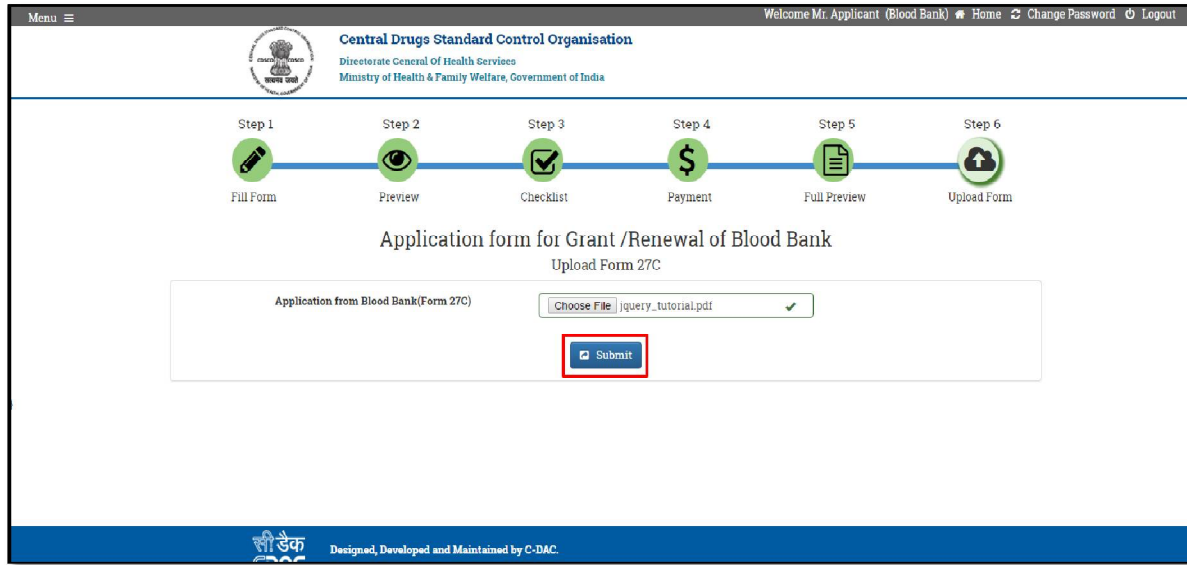


Figure 100 : Generated form for final submission

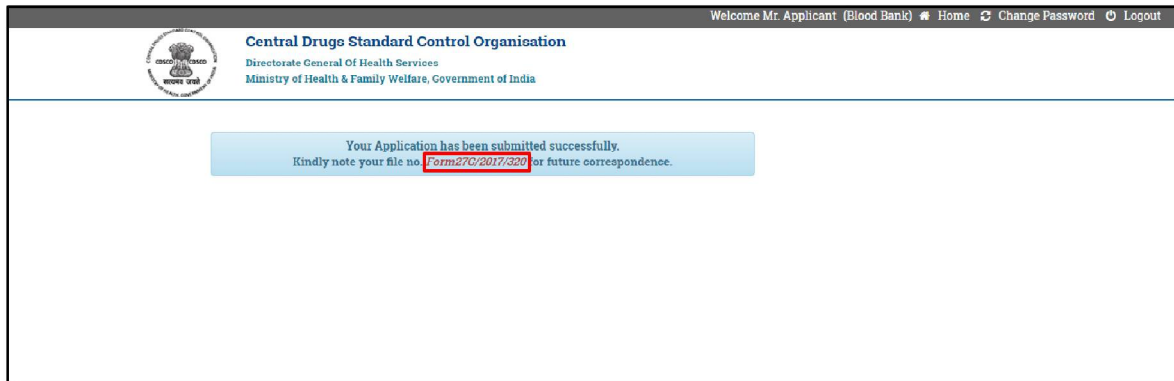


Figure 101 : Application has been submitted successfully

## 4.5 Application for Cosmetics Registration

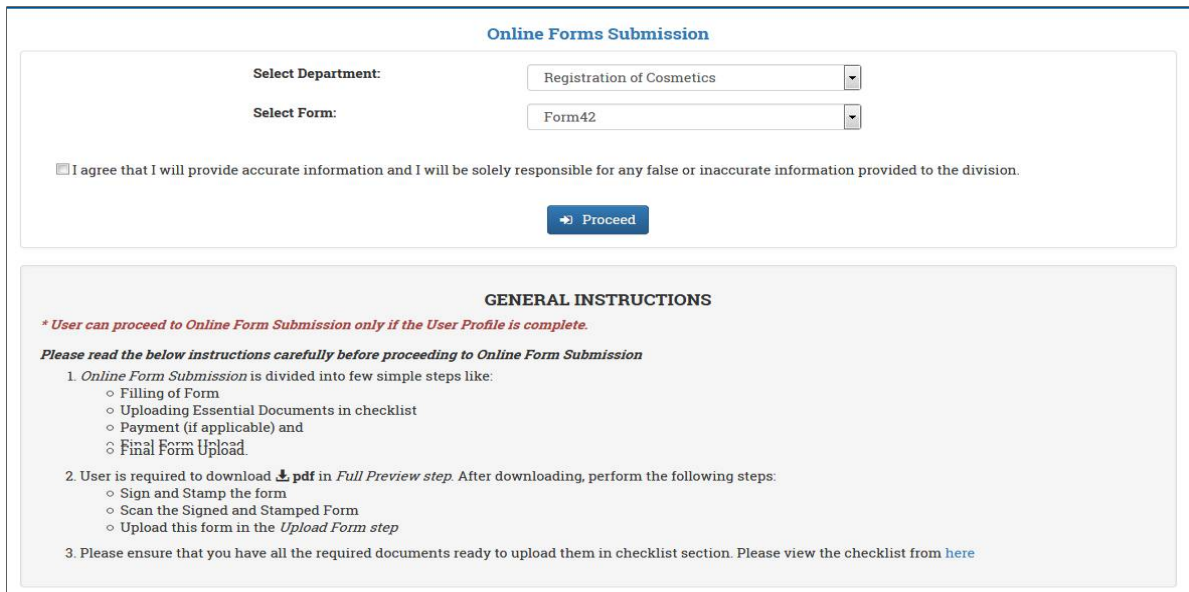
- Applications to Import & Registration division are done for the cases as depicted in the below table:

**Table 6 : Application for Cosmetics Registration**

S. No	Purpose of Application	Type of Application	Category	Form Number
1.	Application for grant of Registration certificate(RC) for Cosmetics ( 3 Cases)	Fresh, Endorsement & Re-registration	---	Form 42/43

**Note:** To apply for the application of cosmetics user must have the role of 'Applicant for cosmetics'.

- Applicant can apply for Grant of registration certificate in Form 42 by selecting Cosmetics department and choosing Form42, as shown below:



**Online Forms Submission**

Select Department: Registration of Cosmetics

Select Form: Form42

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

[➔ Proceed](#)

---

**GENERAL INSTRUCTIONS**

*\* User can proceed to Online Form Submission only if the User Profile is complete.*

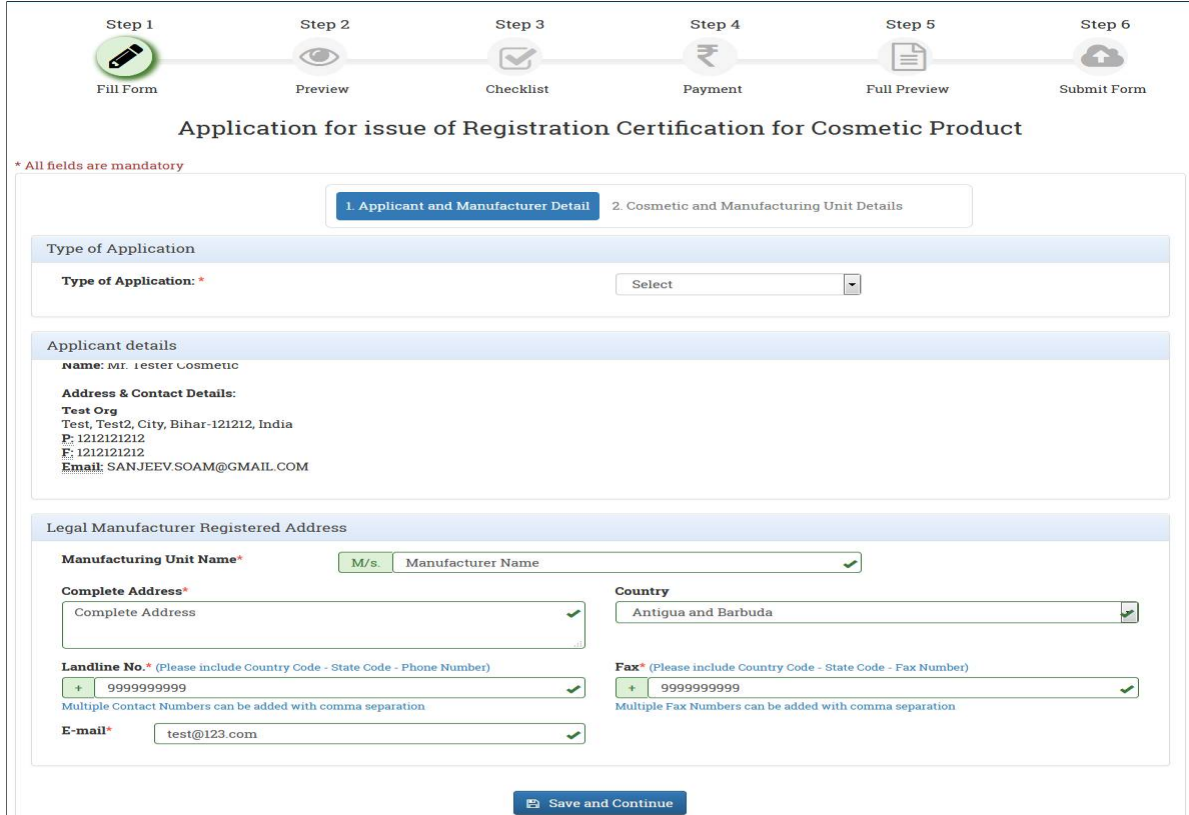
**Please read the below instructions carefully before proceeding to Online Form Submission**

1. *Online Form Submission* is divided into few simple steps like:
  - Filling of Form
  - Uploading Essential Documents in checklist
  - Payment (if applicable) and
  - Final Form Upload.
2. User is required to download [pdf](#) in *Full Preview step*. After downloading, perform the following steps:
  - Sign and Stamp the form
  - Scan the Signed and Stamped Form
  - Upload this form in the *Upload Form step*
3. Please ensure that you have all the required documents ready to upload them in checklist section. Please view the checklist from [here](#)

**Figure 102 : Cosmetic Registration**

- After clicking on **proceed** a new window will open, user can start filling the form
- **The form has been divided into following two broad sections :**
  - Applicant & Manufacturer details
  - Cosmetic and Manufacturing unit details.

- **Applicant & Manufacturer details:** In this section applicant needs to select the type of application, either Fresh or Endorsement or Re-registration. The applicants details are automatically fetched from user registration details. Here, Applicant needs to fill in foreign manufacturer details.



Step 1: Fill Form | Step 2: Preview | Step 3: Checklist | Step 4: Payment | Step 5: Full Preview | Step 6: Submit Form

**Application for issue of Registration Certification for Cosmetic Product**

\* All fields are mandatory

1. Applicant and Manufacturer Detail | 2. Cosmetic and Manufacturing Unit Details

Type of Application  
**Type of Application:** \*

Applicant details  
**Name:** Mr. Jester Cosmetic  
**Address & Contact Details:**  
**Test Org**  
 Test, Test2, City, Bihar-121212, India  
**P:** 1212121212  
**F:** 1212121212  
**Email:** SANJEEV.SOAM@GMAIL.COM

Legal Manufacturer Registered Address  
**Manufacturing Unit Name\***  ✓  
**Complete Address\***  ✓ **Country**  ✓  
**Landline No.\*** (Please include Country Code - State Code - Phone Number)  ✓ **Fax\*** (Please include Country Code - State Code - Fax Number)  ✓  
 Multiple Contact Numbers can be added with comma separation | Multiple Fax Numbers can be added with comma separation  
**E-mail\***  ✓

Figure 103 : Applicant & Manufacturer details

- **Cosmetics and Manufacturing Site details:** Applicant needs to download the excel sheet template and fill the data required for cosmetics products and the manufacturing site with respect to the individual products. Following are the details to be filled by the applicant in the excel sheet:
  - Product Category
  - Product Name
  - Product Brand
  - Product Pack size
  - Variant
  - Is bulk – Yes/No
  - Kit – Yes/No
  - Kit Name – if kit is yes
  - Actual Manufacturing Address
  - Manufacturing Country



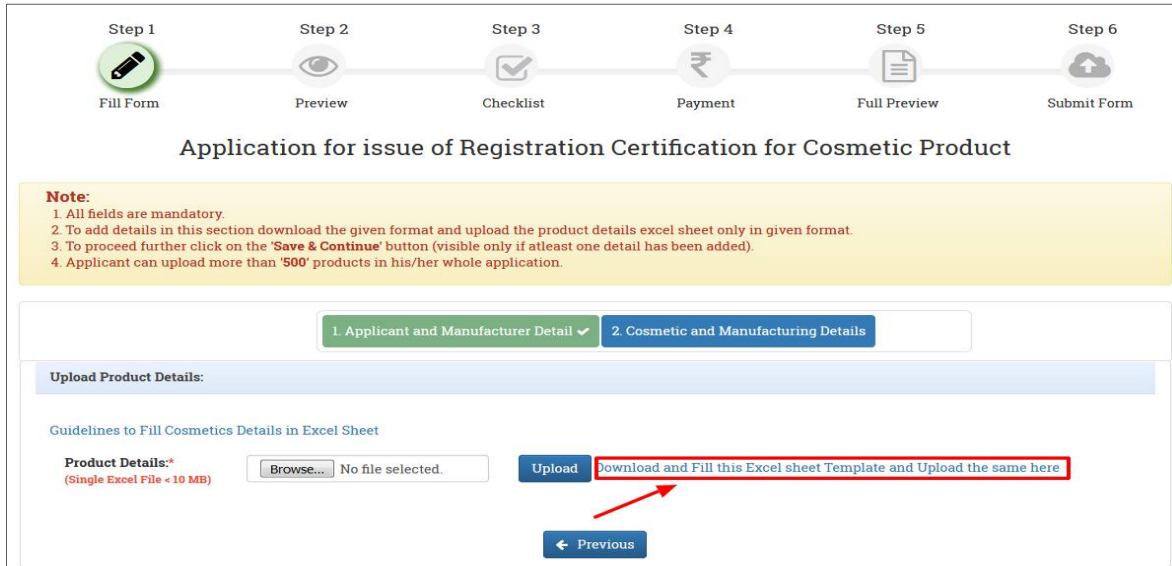


Figure 104 : Cosmetics and Manufacturing Site details

- Browse the filled excel sheet and click on upload.

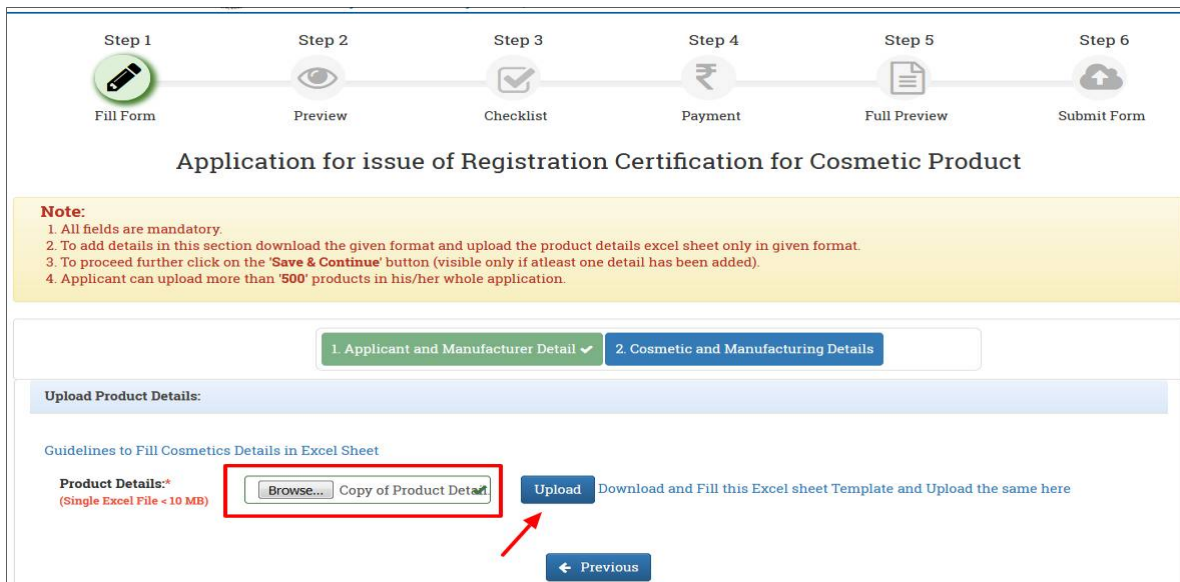


Figure 105 : Upload Excel Sheet

- After clicking on upload the data will be uploaded in the system and visible to the user.

Step 1 Fill Form

Step 2 Preview

Step 3 Checklist

Step 4 Payment

Step 5 Full Preview

Step 6 Submit Form

### Application for issue of Registration Certification for Cosmetic Product

**Note:**

- All fields are mandatory.
- To add details in this section download the given format and upload the product details excel sheet only in given format.
- To proceed further click on the 'Save & Continue' button (visible only if atleast one detail has been added).
- Applicant can upload more than '500' products in his/her whole application.

1. Applicant and Manufacturer Detail ✓    2. Cosmetic and Manufacturing Details

**Upload Product Details:**

*Data uploaded successfully.*  
Guidelines to Fill Cosmetics Details in Excel Sheet

**Product Details:\***  
(Single Excel File < 10 MB)

No file selected.     Download and Fill this Excel sheet Template and Upload the same here

**Premises Details**

Sr. No.	Product Category Type	Product Name Along With Their Brand Name	Product Variant	Pack Size	Actual Manufacturing Premise(s)
1	KIT [NYX PROFESSIONAL MAKEUP IN YOUR ELEMENT AIR - EYESHADOW AND PIGMENT PALETTE] - Other face make-up products	NYX PROFESSIONAL MAKEUP - NYX PROFESSIONAL MAKEUP IN YOUR ELEMENT AIR - EYESHADOW AND PIGMENT PALETTE NYX PROFESSIONAL MAKEUP - PRESSED PIGMENTS	3, 9,11, 12	4 x 1.41 g / 0.05 oz.	1) Zhuhai Sheencolor Biotech Co., Ltd, Lianwan Industry Zone, Pingsha Town, Jinwan District, Zhuhai City, Guangdong Province, China 519055- China
2	KIT [NYX PROFESSIONAL MAKEUP IN YOUR ELEMENT AIR - EYESHADOW AND PIGMENT PALETTE] - Eye shadow	NYX PROFESSIONAL MAKEUP - NYX PROFESSIONAL MAKEUP IN YOUR ELEMENT AIR - EYESHADOW AND PIGMENT PALETTE NYX PROFESSIONAL MAKEUP - EYESHADOW	1,2,4,5,6,7,8,10	8 x 1.41 g / 0.05 oz.	1) Zhuhai Sheencolor Biotech Co., Ltd, Lianwan Industry Zone, Pingsha Town, Jinwan District, Zhuhai City, Guangdong Province, China 519055- China
3	KIT [NYX PROFESSIONAL MAKEUP IN YOUR ELEMENT EARTH - EYESHADOW AND PIGMENT PALETTE]	NYX PROFESSIONAL MAKEUP - NYX PROFESSIONAL MAKEUP IN YOUR ELEMENT EARTH - EYESHADOW AND	2,5,7,8,9	5 x 1.41 g / 0.05 oz.	1) Zhuhai Sheencolor Biotech Co., Ltd, Lianwan Industry Zone, Pingsha Town, Jinwan District, Zhuhai City, Guangdong Province, China 519055-

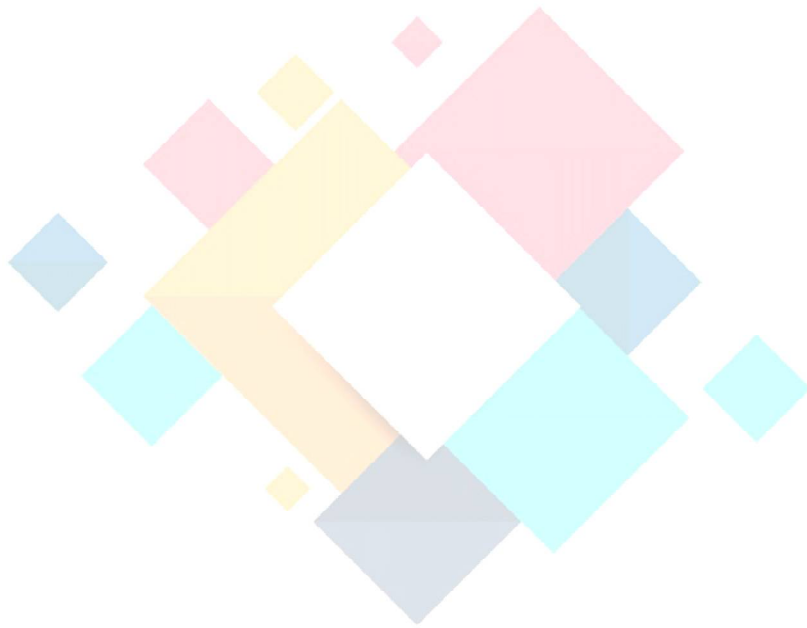
Figure 106 : Upload the data and visible to the user

➤ **Case2: Type of Application: - Endorsement**

- In case of **Endorsement** applications, user needs to enter a valid RC, which will intern fetch all the relevant details pertaining to that RC number like validity, applicant details & manufacturer registered address.
- User can update the data of the additional cosmetics in the cosmetics and manufacturing details section similarly by uploading the excel sheet of the products to be endorsed.

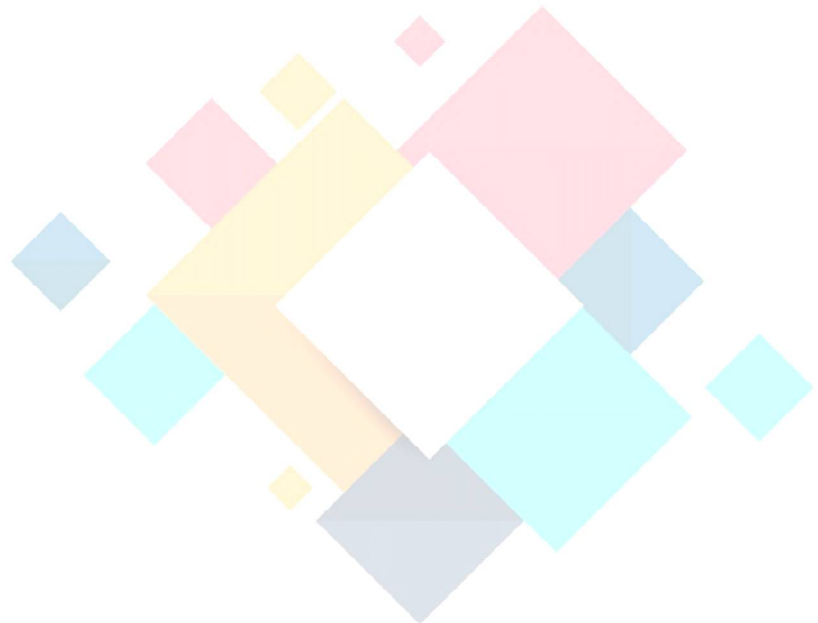
➤ **Case3: Type of Application: - Re-registration**

- User should apply for re-registration case if he wants to renew the validity of the RC.
- In case of Re-registration applications, user needs to enter a valid RC, which will intern fetch all the relevant details pertaining to that RC number like validity, applicant details product related information & manufacturer registered address.



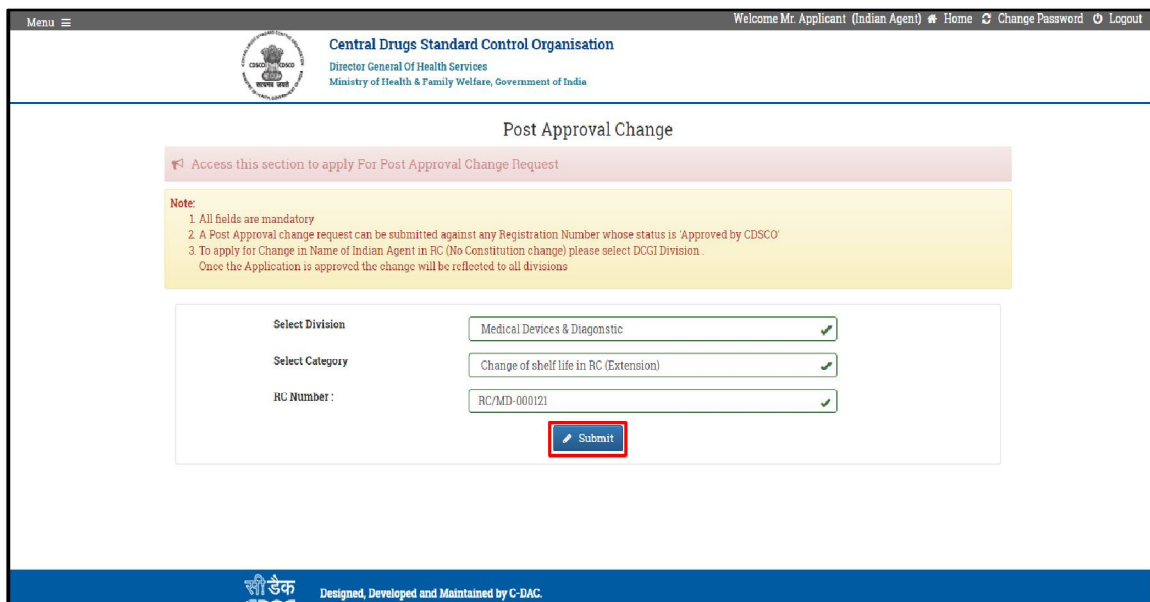
## Chapter- 5

# Post Approval Change Application



## 5. Post Approval Change Application

- User can apply for any changes or amendments in the permission issued to them. According to a latest guidance issued by the drug regulator, in the beginning of this month, the applicants of the biological products who change their product post approval should apply for new drug permission, in case the change makes the product a new drug as per definition under rule 122E of the Drugs and Cosmetics Rules.
- Following are the cases which are common for Import and Drugs division, Medical division:
- **Change of shelf life in RC Extension:** In this case the user can apply to extend the shelf life of medical device/drug of an approved RC.



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

**Post Approval Change**

Access this section to apply For Post Approval Change Request

**Note:**

1. All fields are mandatory
2. A Post Approval change request can be submitted against any Registration Number whose status is 'Approved by CDSCO'
3. To apply for Change in Name of Indian Agent in RC (No Constitution change) please select DOGI Division

Once the Application is approved the change will be reflected to all divisions

Select Division: Medical Devices & Diagnostic ✓

Select Category: Change of shelf life in RC (Extension) ✓

RC Number: RC/MD-000121 ✓

**Submit**

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**Figure 107 : Change of shelf life in RC Extension**

- After clicking on submit button user will be redirected to the page shown in the figure below. The page displays the RC number; devices approved in that RC, device category and existing approved shelf life.
- User needs to select the check box of the device/drug for which the shelf life is to be extended and then enter the new shelf life.
- User can change the shelf life for multiple devices/drugs in single application of same RC.

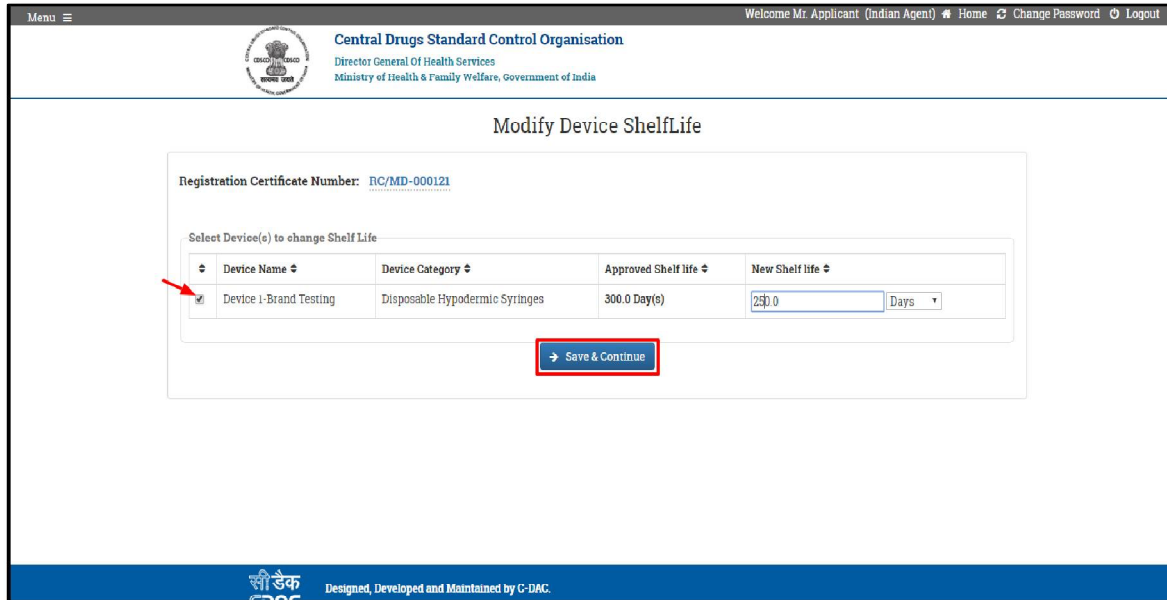


Figure 108 : Screen of Modify Device Shelf Life

- Once you click on 'OK', you will proceed to the checklist and then the shelf life cannot be edited.

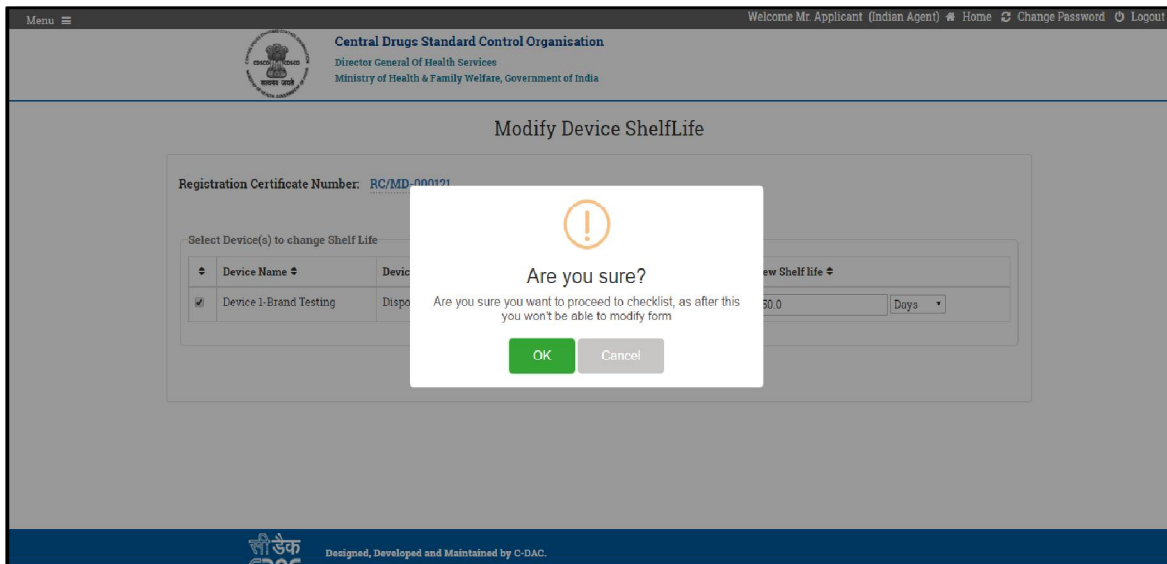
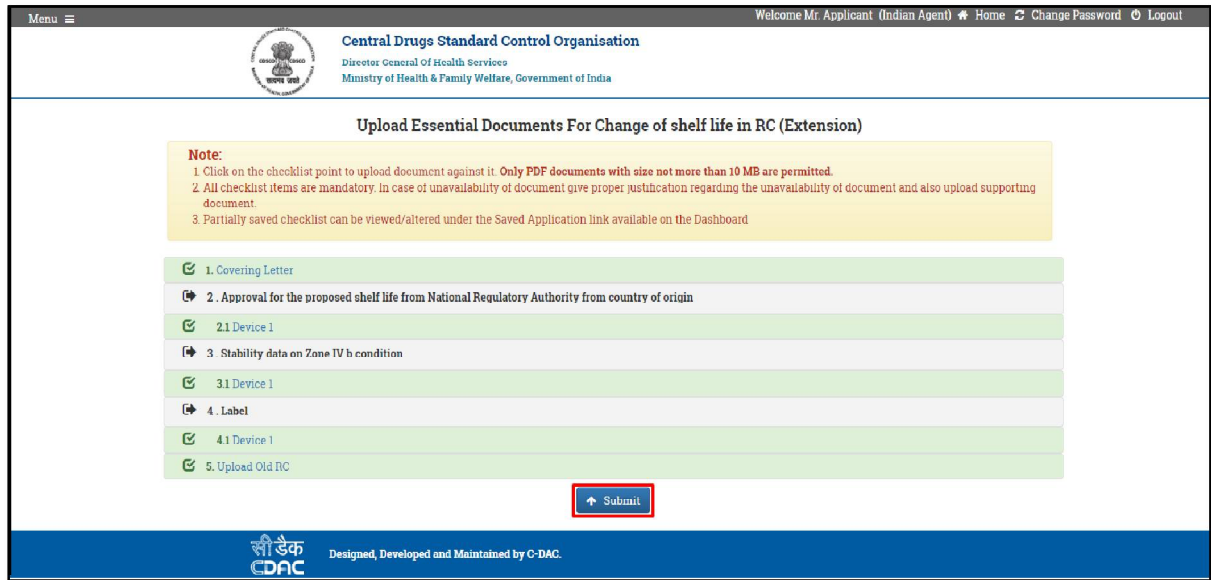


Figure 109 : Popup Message: Proceed to Checklist

- Checklist of documents to be uploaded for the case.



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

**Upload Essential Documents For Change of shelf life in RC (Extension)**

**Note:**  
1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 10 MB are permitted.**  
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.  
3. Partially saved checklist can be viewed/alterd under the Saved Application link available on the Dashboard

- 1. Covering Letter
- 2. Approval for the proposed shelf life from National Regulatory Authority from country of origin
- 2.1 Device 1
- 3. Stability data on Zone IV b condition
- 3.1 Device 1
- 4. Label
- 4.1 Device 1
- 5. Upload Old RC

[Submit](#)


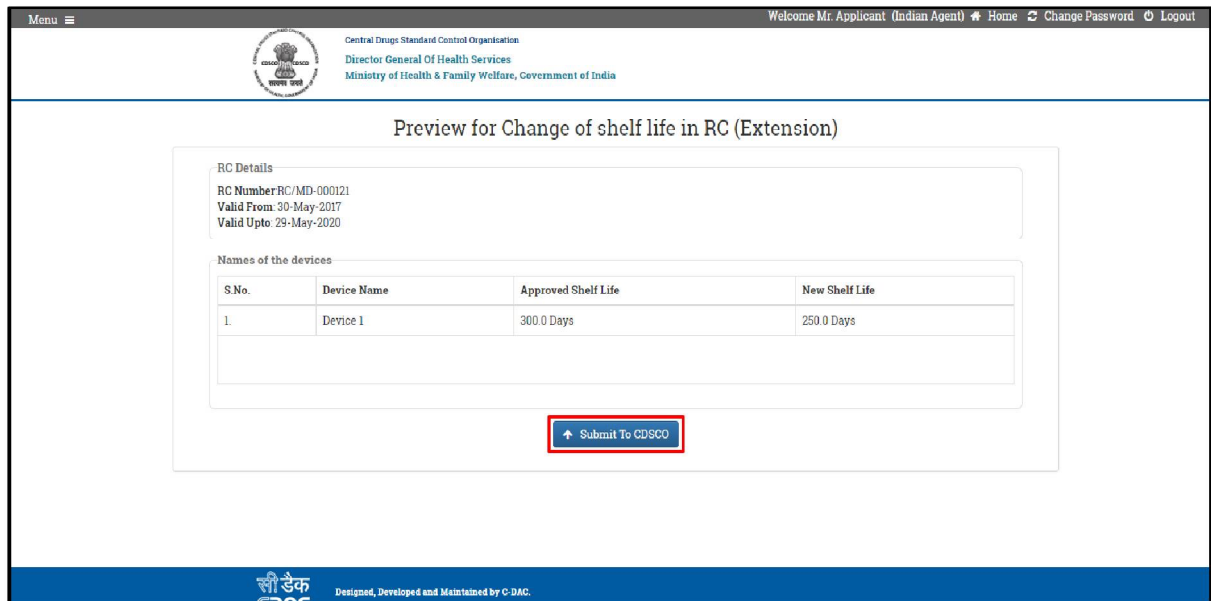
 Designed, Developed and Maintained by C-DAC.

Figure 110 : Checklist of documents to be uploaded

- Preview of the change you have applied for



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

**Preview for Change of shelf life in RC (Extension)**

**RC Details**  
RC Number: RC/MD-000121  
Valid From: 30-May-2017  
Valid Upto: 29-May-2020

**Names of the devices**

S.No.	Device Name	Approved Shelf Life	New Shelf Life
1.	Device 1	300.0 Days	250.0 Days

[Submit To CDSCO](#)


 Designed, Developed and Maintained by C-DAC.

Figure 111 : Preview for change of shelf life

- File number generated after the application is submitted.

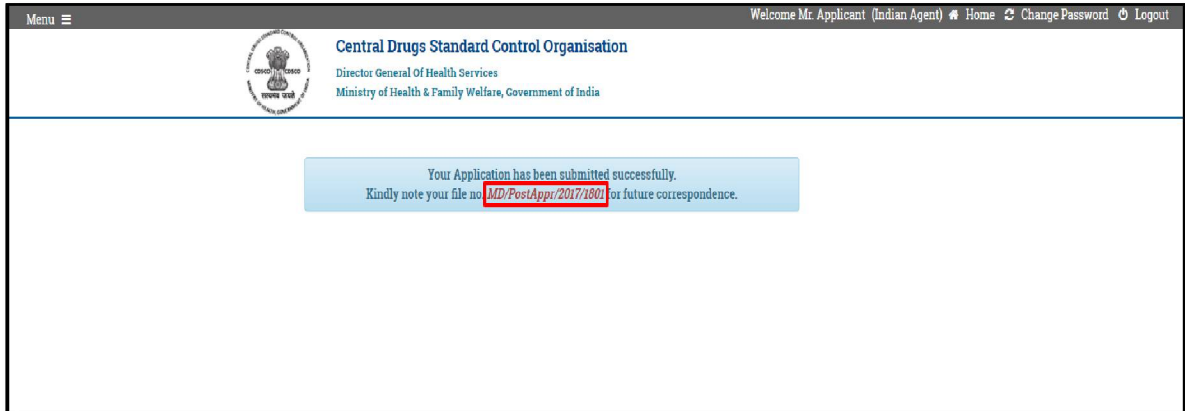


Figure 112 : Application has been submitted successfully

- **Change of shelf life in RC Reduction:** Similarly user can apply for the reduction in shelf life of the devices/drugs of an approved RC. The application process is same as that of change of shelf life in RC extension.
- **Change of (Legal)/ (Registered) address of manufacturer in RC (No location change):** In this user can change the legal address of the manufacturer of an approved RC.
- The page below displays the RC number and the existing approved address of the manufacturer.
- User is required to enter the details of the new address as shown in figure below.

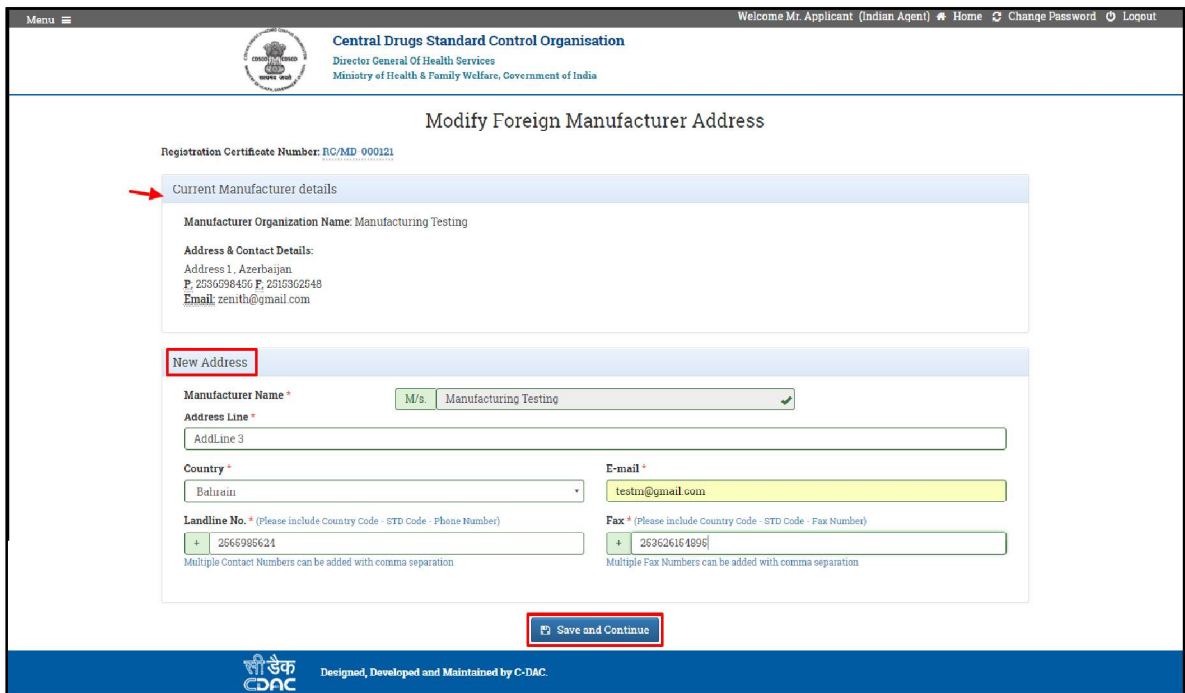
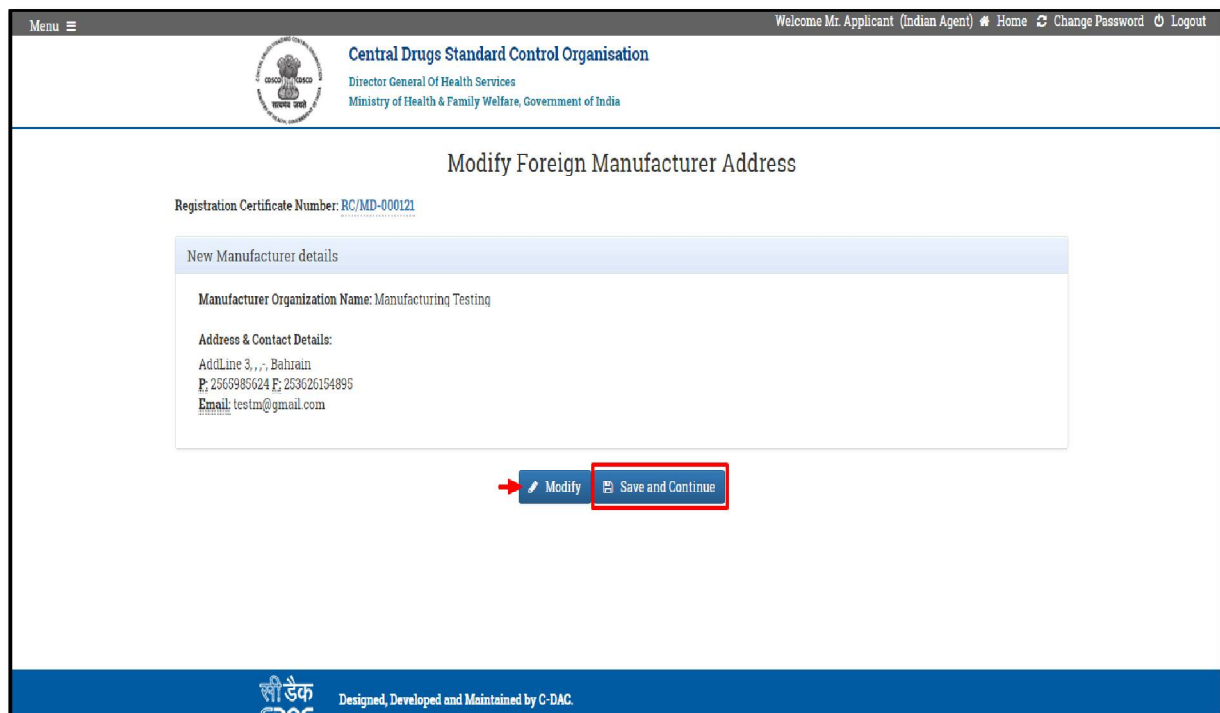


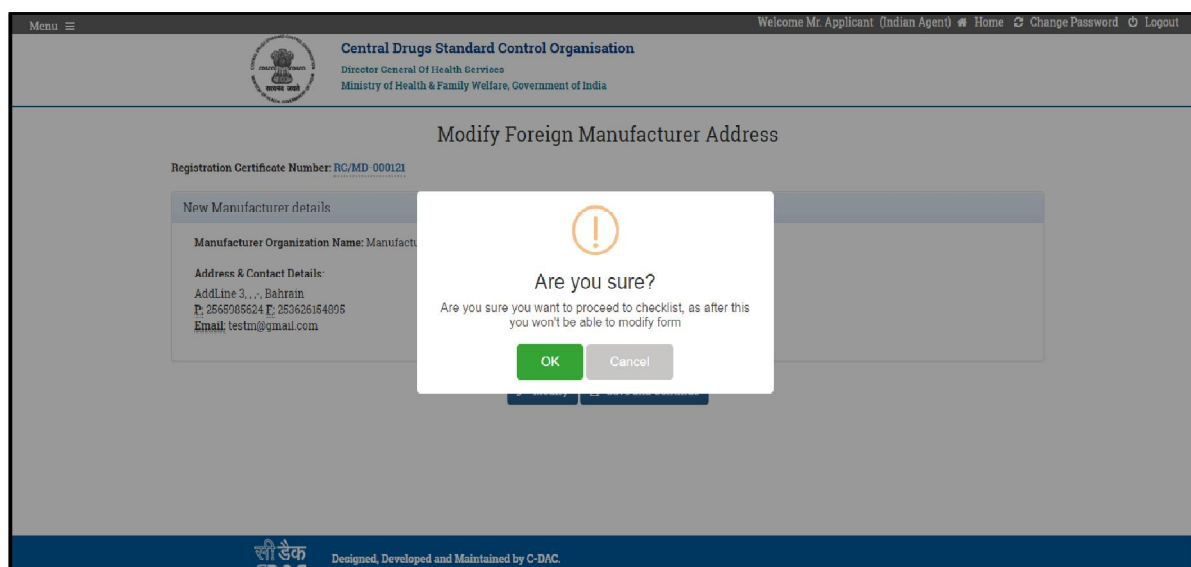
Figure 113 : Enter the Details of the New Address

- After entering the new address details, user you will be redirected to the preview of new address.



**Figure 114 : Modify foreign Manufacturer Address**

- You can modify the details, if not correct, else click on 'save and continue' and then on 'OK' to proceed to checklist.



**Figure 115 : Popup Message -- Proceed to Checklist**



➤ Checklist of the documents to be uploaded for this case

The screenshot shows the 'Upload Essential Documents For Change of (Legal) address of manufacturer in RC(No Location Change)' page. It includes a note about PDF document requirements and a checklist of nine items to be uploaded, such as Covering Letter, Power Of Attorney, Label, Declaration of Conformity, FSC Certificate, CE Design Certificate, Upload Old RC, Schedule D (I) and Undertaking, and Full Quality Assurance Certificate. A 'Submit' button is highlighted with a red box.

Figure 116 : Checklist of the Documents

➤ Preview of Form 40 is generated with the new address. Download the PDF of Form 40.

The screenshot shows the 'Form 40' preview page, titled 'Application for issue of Registration Certification for import of Medical Devices into India under the Drugs and Cosmetics Rules 1945'. It contains application details, a table for device registration, and a table for premises details. A 'Download PDF' button is highlighted with a red box.

S.No.	Device Name	Device Category	Shelf Life	Storage Condition	Package Size	Contains Drug
1	Device 1	Disposable Hypodermic Syringes	300.0 Days	Cool	100	No

Premises Type	Site Name	Telephone No.	Fax	Email
Manufacturing Site, Batch Release Site	Abbott Molecular Inc.	12243617000	12243617438	AM_RA_global_registrations@abbott.com

Figure 117 : Preview of Form 40

- Upload the signed legal form.



Figure 118 : Screen of Upload the signed legal form

- File number is generated after submission of the application.

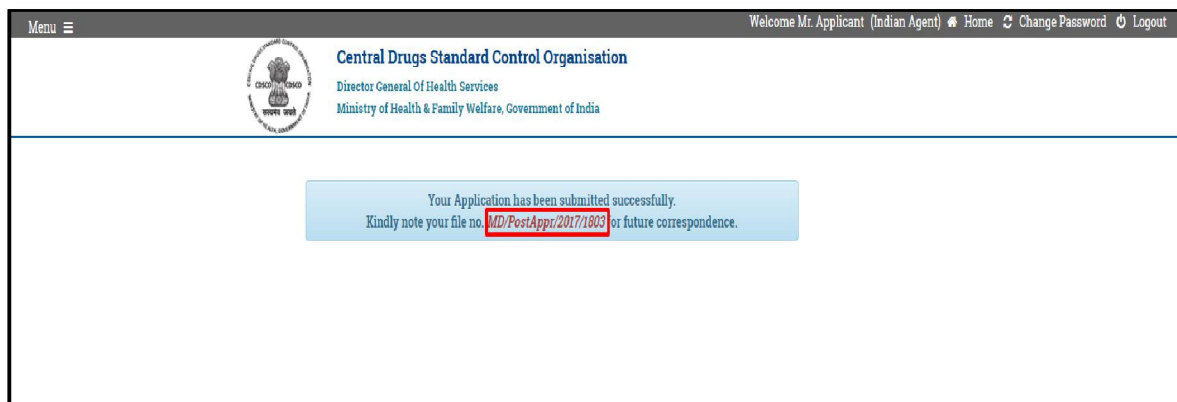


Figure 119 : File number is generated

- **Change of (Legal)/ (Registered) address of manufacturer in RC (Location change):** This case is similar to that of 'Change of (Legal)/ (Registered) address of manufacturer in RC (No Location Change)'.
  - The application process is same but user will have to pay the fees in this case.
  - In this case, if the application is approved, then the current RC of user will be suspended and a new RC with same RC number and new validity is issued to user.
- **Change of (Actual)/ (Foreign) address of manufacturer in RC (No location change):** In this case user can change the actual address of the manufacturer.

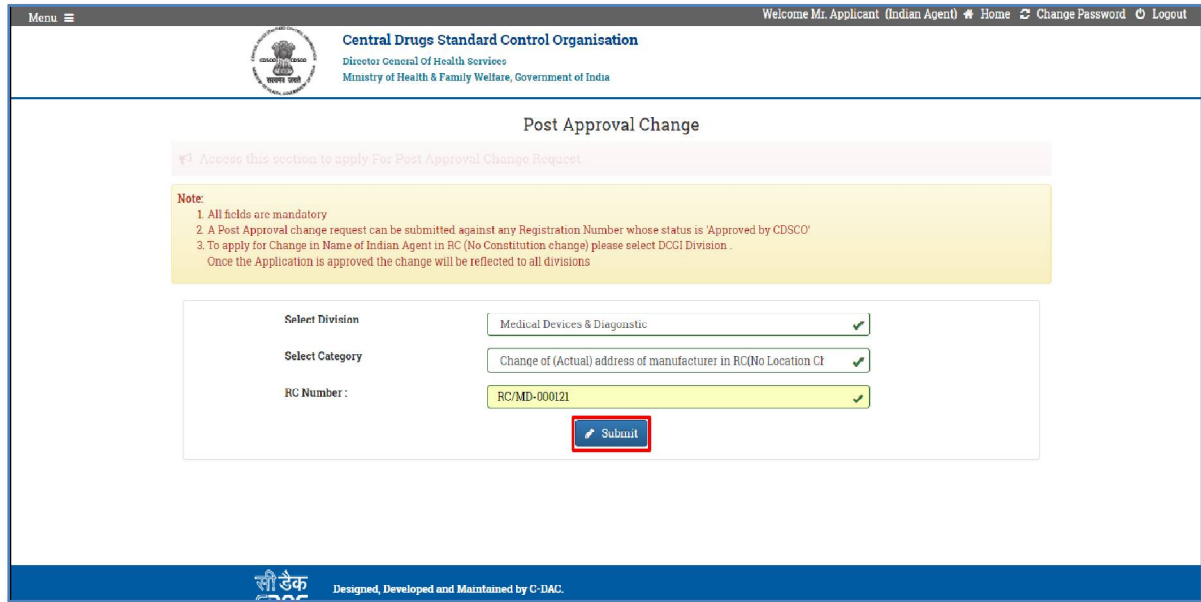


Figure 120 : Screen of Post Approval Changes

- The figure below displays the RC number and the old address of the user. User needs to select the checkbox for which the address is to be changed and enter the details of the new address and then click on modify.

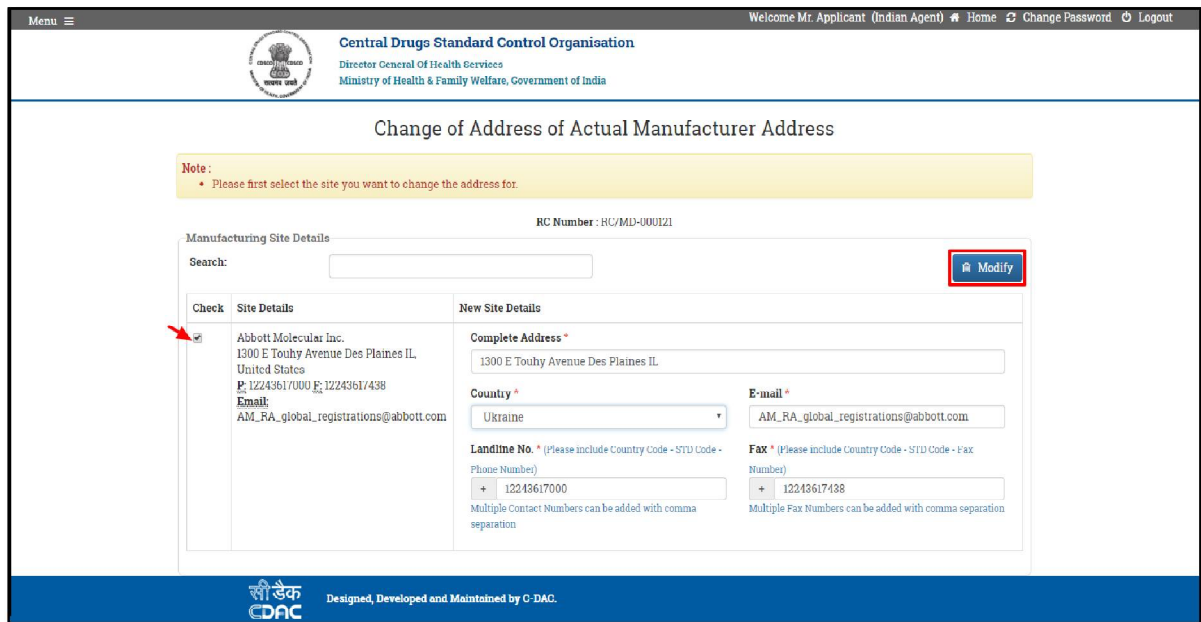


Figure 121 : Enter the details of the new Address

- Once you click on 'OK' you will be redirected to the checklist page after which the address cannot be edited.

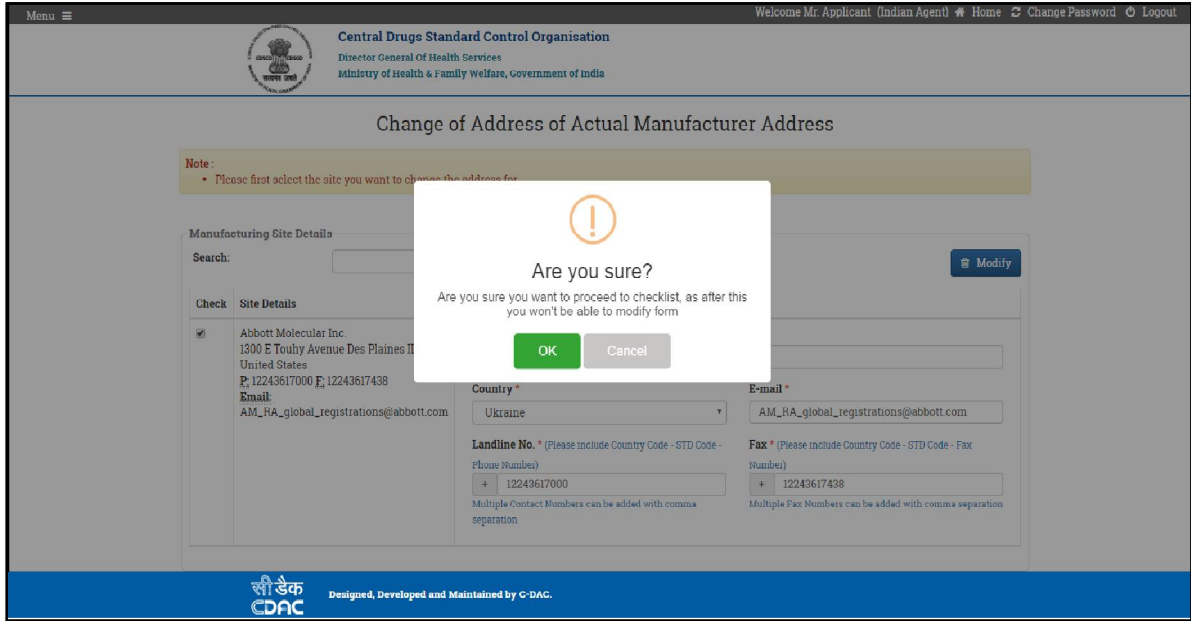


Figure 122 : Popup Message -- Proceed to Checklist

- Checklist of documents to be uploaded for the case.

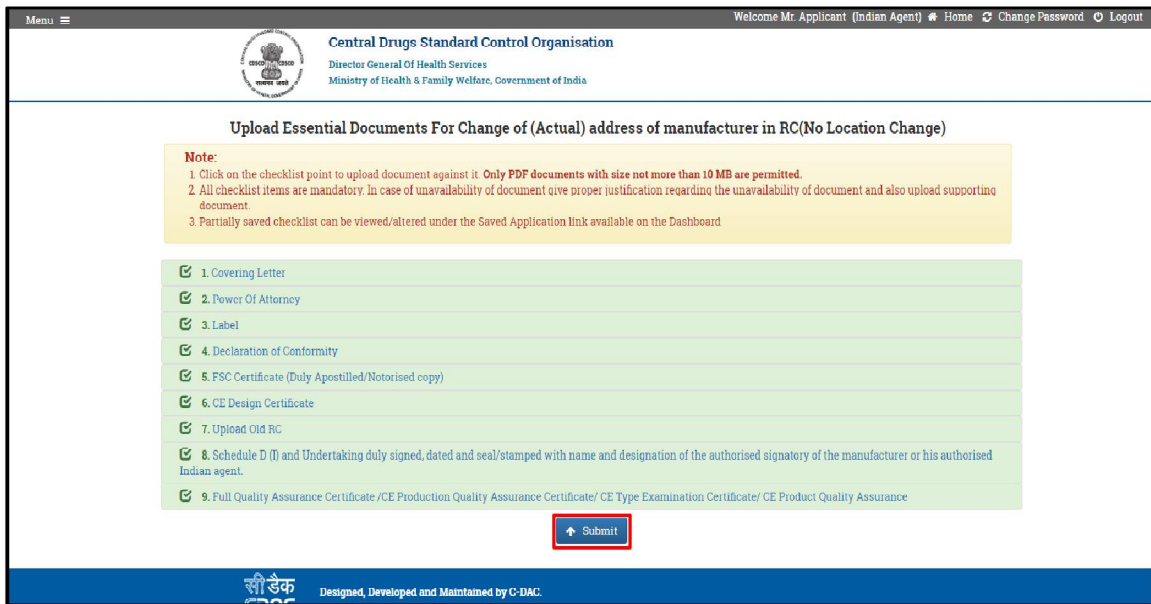


Figure 123 : Upload Essential Documents for Changes

- For change in actual address user need to pay the required fees.

Figure 124 : Screen of Payment Details

- Preview of Form 40 with the new actual address of the manufacturer. Download the system generated Form 40.

**Form 40**  
[See rule 24-A]

Application for issue of Registration Certification for import of Medical Devices into India under the Drugs and Cosmetics Rules 1945

I/We M/s M/s Unit Name, Address Line One Address Line Two, Chhattishgarh, Gityname, Raigash: 232323 (India) hereby apply for the grant of Registration Certificate for the manufacturer, M/s. Manufacturing Testing, Address 1 Country Azerbaijan for his premises, and manufactured devices meant for import into India.

1. Names of Devices for registration.

S.No.	Device Name	Device Category	Shelf Life	Storage Condition	Package Size	Contains Drug
1	+ Device 1	Disposable Hypodermic Syringes	300.0 Days	Cool	100	No

2. I/We enclose herewith the information and undertakings specified in Schedule D (I) and Schedule D (II) duly signed by the manufacturer for grant of Registration Certificate for the premises stated below.

3. A fee of \$200 for registration of premises, the particulars of which are given below, of the manufacturer has been credited to the Government under the Head of Account '0210-Medical and Public Health,04-Public Health, 104-Fees and Fines' under Drugs and Cosmetics Rules, 1945 - Central vide Challan No. 12365, dated 22-May-2017 respectively

4. A fee of \$0 for registration of the devices for import as specified at Serial No.1 above has been credited to the Government under the Head of Account '0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines' under the Drugs and Cosmetics Rules, 1945 Central vide Challan No. NA, dated, NA.

5. Particulars of premises to be registered where manufacture is carried on:

+	Premises Type	Site Name	Telephone No.	Fax	Email
1	+ Manufacturing Site, Batch Release Site,	Abbott Molecular Inc.	12243617000	12243617438	AM_RA_global_registrations@abbott.com

I/We undertake to comply with all terms and conditions required to obtain Registration Certificate and to keep it valid during its validity period.

PLACE  
DATE 30-May-2017  
Signature .....

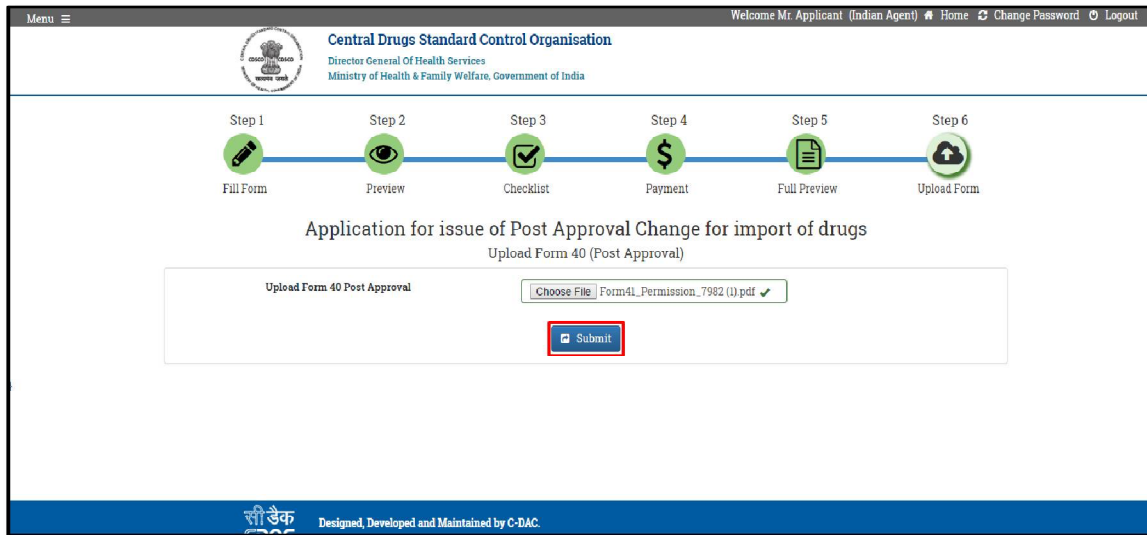
Name :  
Designation :  
Seal/Stamp of manufacturer or his authorized Agent in India

(Note: - in case the applicant is an authorised agent of the manufacturer in India, the Power of Attorney is to be enclosed).

Download PDF Continue

Figure 125 : Download the system generated Form 40

- Upload the signed Legal form



**Figure 126 : Upload the signed Legal form**

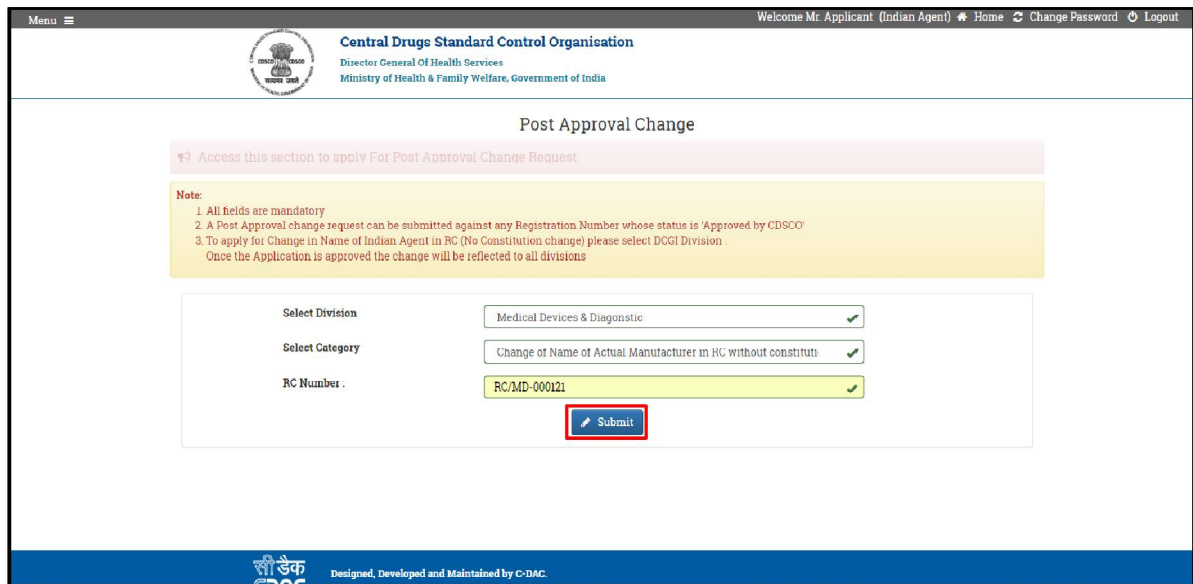
- File number is generated after submission of the application



**Figure 127 : File number is generated**

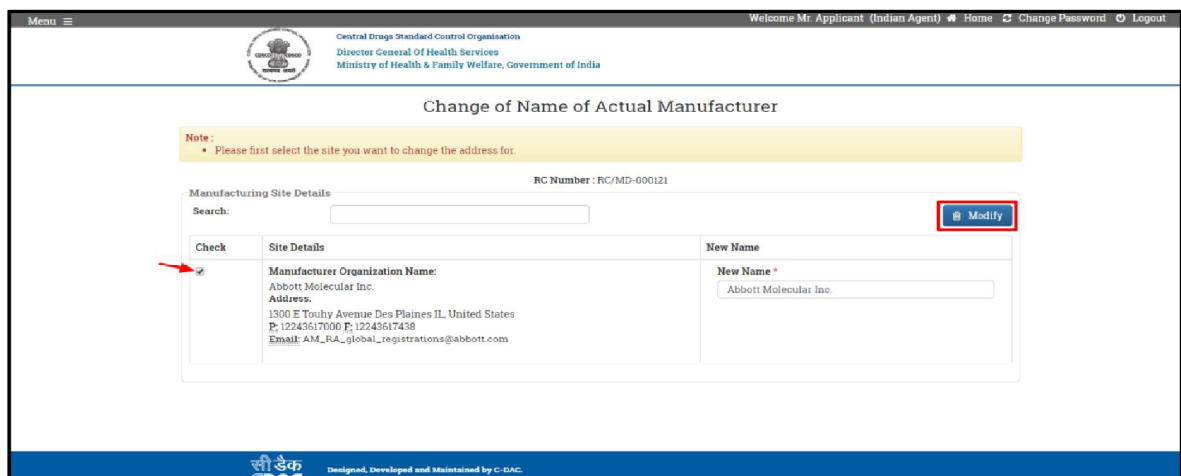
- Change of (Actual)/(Foreign) address of manufacturer in RC (Location change)
- Change of (Legal)/(Registered) name of manufacturer in RC (No constitution change)
- Change of (Actual)/(Foreign) name of manufacturer in RC (No constitution change)
- Change of (Legal)/(Registered) name of manufacturer in RC (Constitution change)
- Change of (Actual)/(Foreign) name of manufacturer in RC (Constitution change)
- Change in address of Indian agent
- Change in name of the firm.

- **Change of (Actual)/ (Foreign) address of manufacturer in RC (Location change):** This case is similar to that of 'Change of (Actual)/ (Foreign) address of manufacturer in RC (No Location Change)'.
  - The application process is same but user will have to pay the fees in this case.
  - In this case, if the application is approved, then the current RC of user will be suspended and a new RC with same RC number and new validity is issued to user.
- **Change of (Actual)/ (Foreign) name of manufacturer in RC (No constitution change):** In this case user can change the name of legal manufacturer of an approved RC.



**Figure 128 : Change the name of legal manufacturer of an Approved RC**

- In the figure below, page displays the RC number, and the complete details of the actual manufacturer address. User will check the checkbox against the address which is to be changed and then enter the new name.



**Figure 129 : Check the checkbox against the address**

- Click on 'OK' to proceed further for checklist.

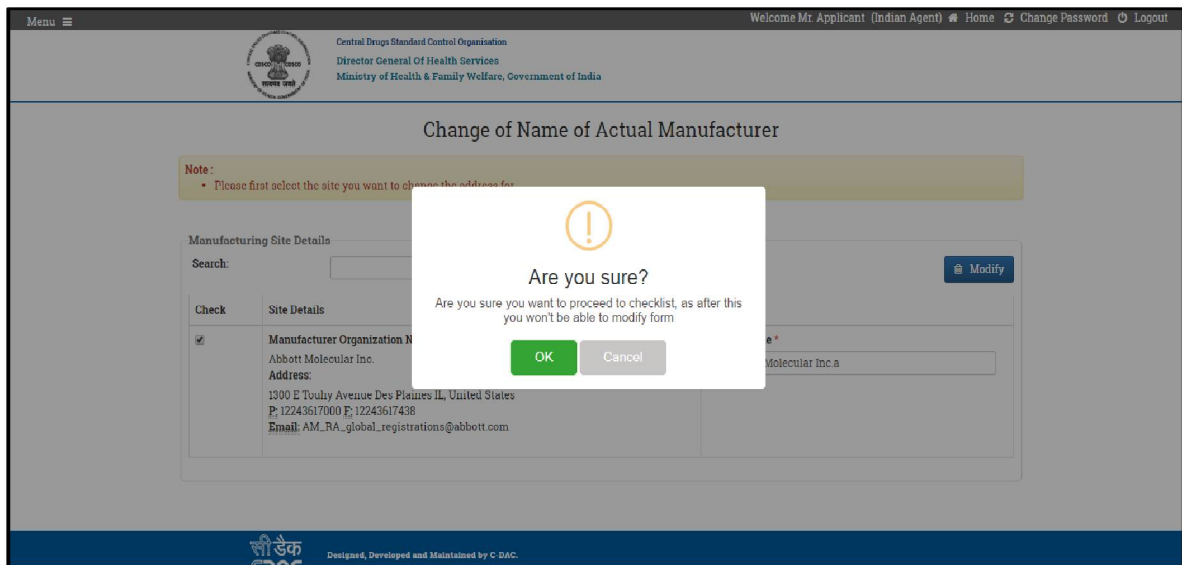


Figure 130 : Popup Message – for confirmation of Proceed to checklist

- Checklist of documents to be uploaded for this case.

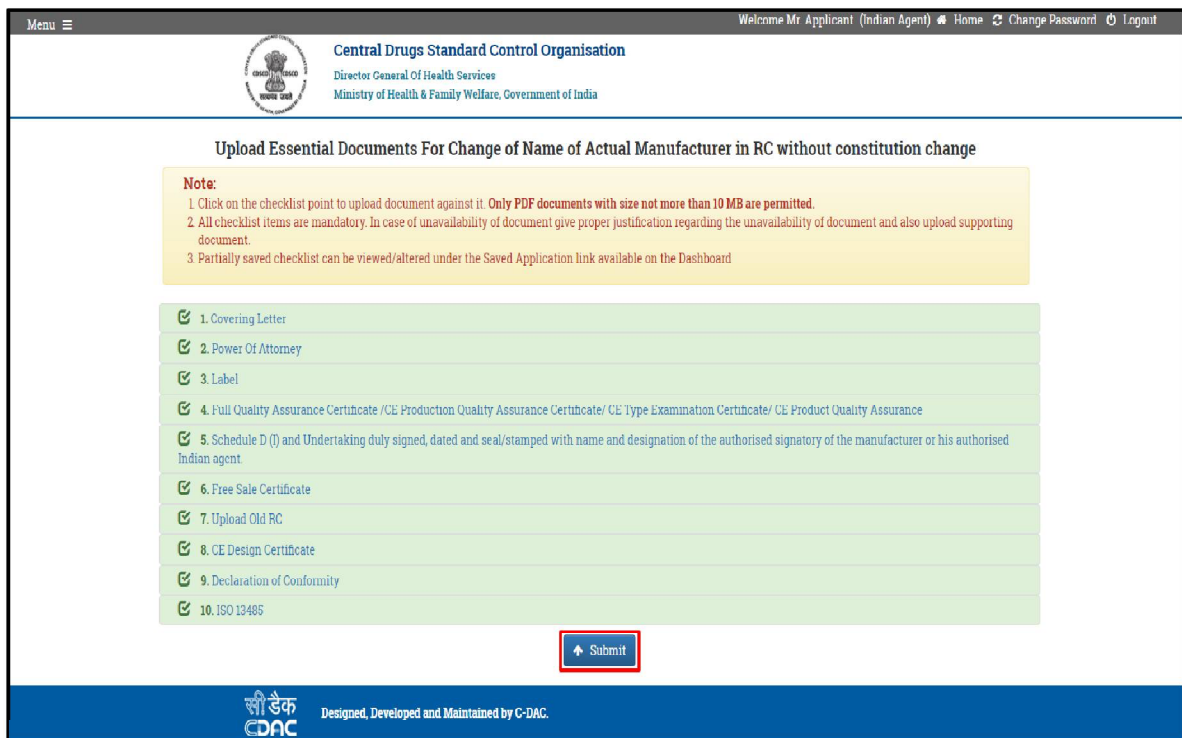


Figure 131 : Checklist of documents to be uploaded for this case



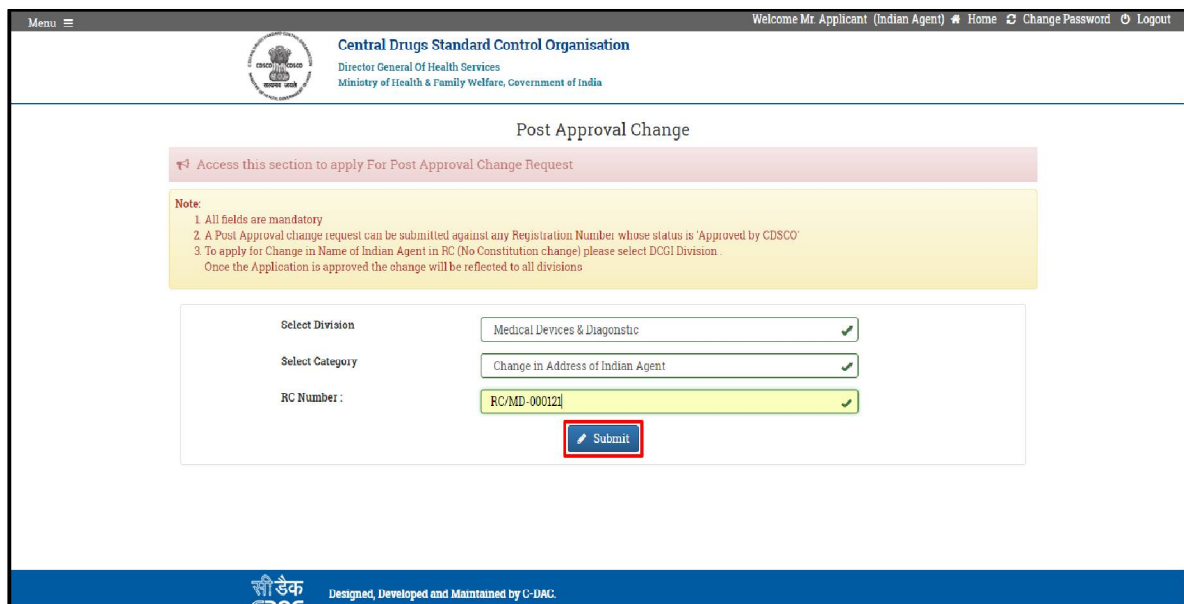
- Preview of **Form 40** with the name change. Download the form.

Figure 132 : Preview Form 40 -- Download the Form

- Upload the system generated Form 40.

Figure 133 : Upload the system generated Form 40

- File number is generated after submission of the application.
- **Change of (Legal)/( Registered) name of manufacturer in RC (No constitution change):** This case is similar to that of 'Change of (Legal)/ (Registered) name of manufacturer in RC (No Constitution Change)'.The application process is same, only the change for registered name is captured instead of foreign manufacturer.
- **Change of (Legal)/ (Registered) name of manufacturer in RC (Constitution change):** This case is similar to that of 'Change of (Legal)/ (Registered) name of manufacturer in RC (No Constitution Change)'.
  - The application process is same but user will have to pay the fees in this case.
  - In this case, if the application is approved, then the current RC of user will be suspended and a new RC with same RC number and new validity is issued to user.
- **Change of (Actual)/ (Foreign) name of manufacturer in RC (Constitution change):** This case is similar to that of 'Change of (Actual)/ (Foreign) name of manufacturer in RC (No Constitution Change)'.
  - The application process is same but user will have to pay the fees in this case
  - In this case, if the application is approved, then the current RC of user will be suspended and a new RC with same RC number and new validity is issued to user.
- **Change in address of Indian agent:** In this user can change the address of the Indian Agent.



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

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

Post Approval Change

Access this section to apply For Post Approval Change Request

**Note:**

- All fields are mandatory
- A Post Approval change request can be submitted against any Registration Number whose status is 'Approved by CDSCO'
- To apply for Change in Name of Indian Agent in RC (No Constitution change) please select DCGI Division  
 Once the Application is approved the change will be reflected to all divisions

Select Division: Medical Devices & Diagnostic ✓

Select Category: Change in Address of Indian Agent ✓

RC Number: RC/MD-000121 ✓

**Submit**

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Figure 134 : Change in address of Indian agent

- In the figure below, screen displays the RC number, old Indian Agent address and a drop down to select the new address. If the required address is not mentioned here then the user needs to save the address in 'Add wholesale/manufacturing license' and then select the address from here.



Figure 135 : 'Add wholesale/manufacturing license'

- After selecting the required address click on 'OK' and proceed further to the checklist.

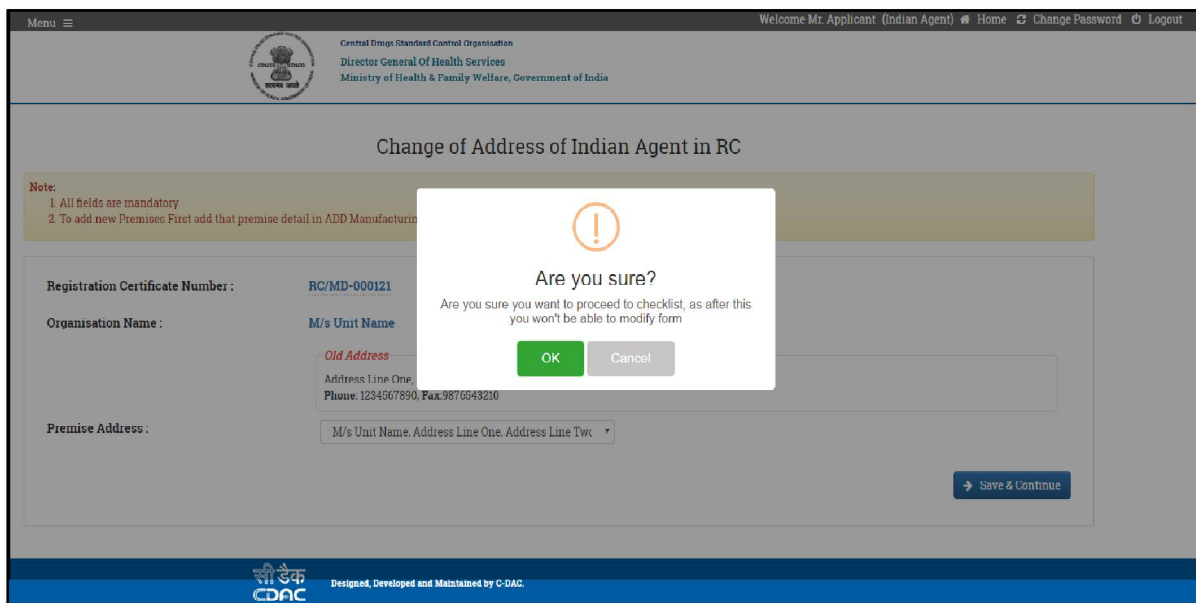


Figure 136 : Popup Message for proceed further

- Checklist of the documents to be uploaded for this case.

Figure 137 : Checklist of the documents to be uploaded

- Payment Details

Figure 138 : Payment Details

- Preview of Form 40 with changed Indian Agent Address. Download the form by clicking on 'Download PDF'.

Figure 139 : Preview of Form 40 with changed Indian Agent Address

- Upload the online generated Form 40.

Figure 140 : Upload the online generated Form 40

- File number is generated after successful submission of the application.

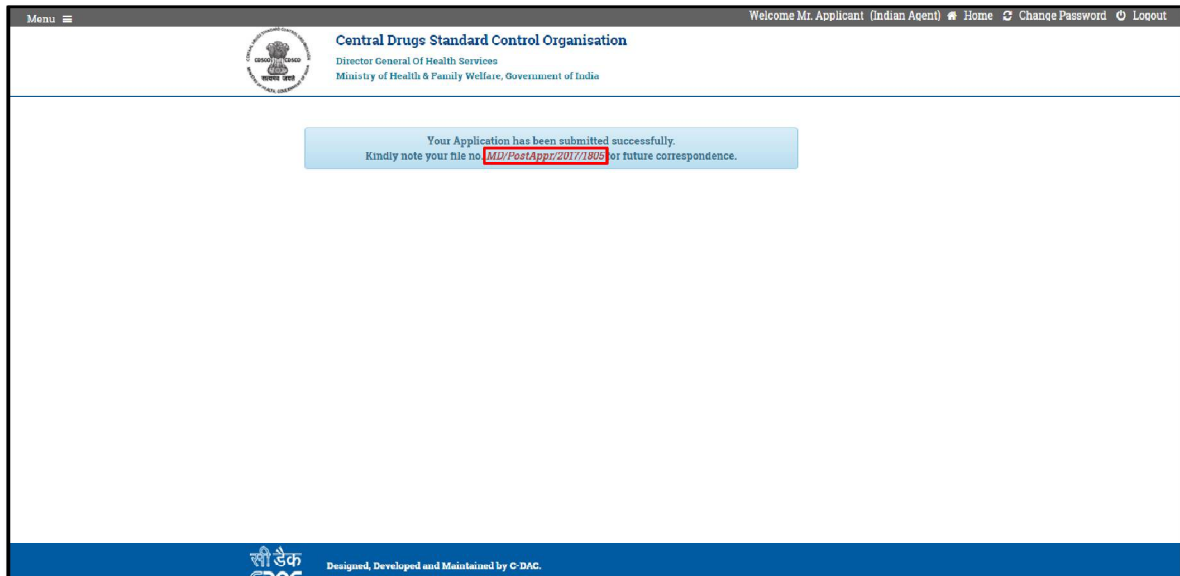


Figure 141 : File number is generated

- **Change in name of the firm:** If the Organization name is changed, the user can apply for change in name of firm and the same is received by DCGI office. If approved an amendment letter is issued to the user.

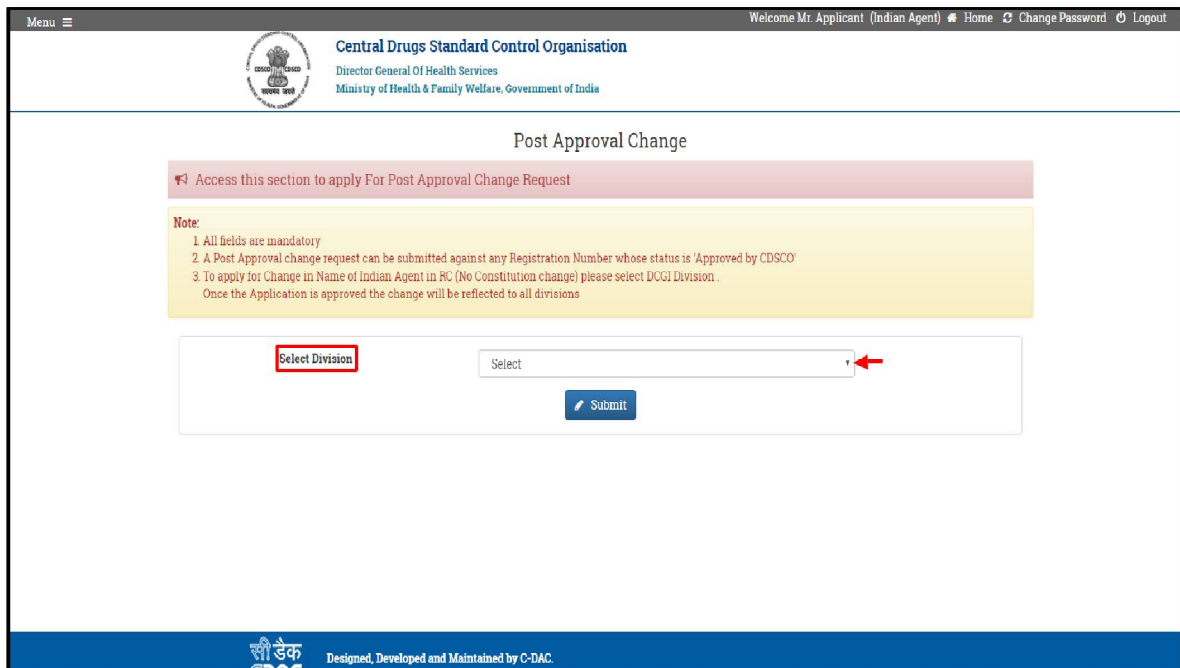


Figure 142 : Change in name of the firm

➤ Post Approval Change (Category & RC Number)

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

### Post Approval Change

Access this section to apply For Post Approval Change Request

**Note:**

- All fields are mandatory
- A Post Approval change request can be submitted against any Registration Number whose status is 'Approved by CUSCO'
- To apply for Change in Name of Indian Agent in RC (No Constitution change) please select DCGI Division. Once the Application is approved the change will be reflected to all divisions

Select Division: DCGI Division ✓

Select Category: Change in name of firm(Indian Agent,Importer,Corporate) ✓

**Submit**

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Figure 143 : Post Approval Change (Category & RC Number)

- After clicking on submit, user will be redirected to a new page where complete details of the firm will be visible along with existing name, permission and license issued on the same.
- To change the name of the firm user should enter the new name and the same will be applicable for all the permissions and license issued.

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

### Change of Name of Firm

Old Detail: Organisation Name: Testing

New Detail: New Organisation Name: Advance Testing ✓

The following rc's will be amended

S.No	rc No	Valid From	Valid Upto	Division
1	RC/BD-002141	25-May-2017	24-May-2020	Import & Registration of drugs
2	COS-333	02-Feb-2015	06-Jun-2018	Registration of Cosmetics

The following Licenses's will be amended

S.No	rc No	License No	Valid From	Valid Upto	Division
No Records Found					

**Save & Continue**

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- Confirmation alert appears before proceeding to the checklist. The name cannot be edited once you click on ok.

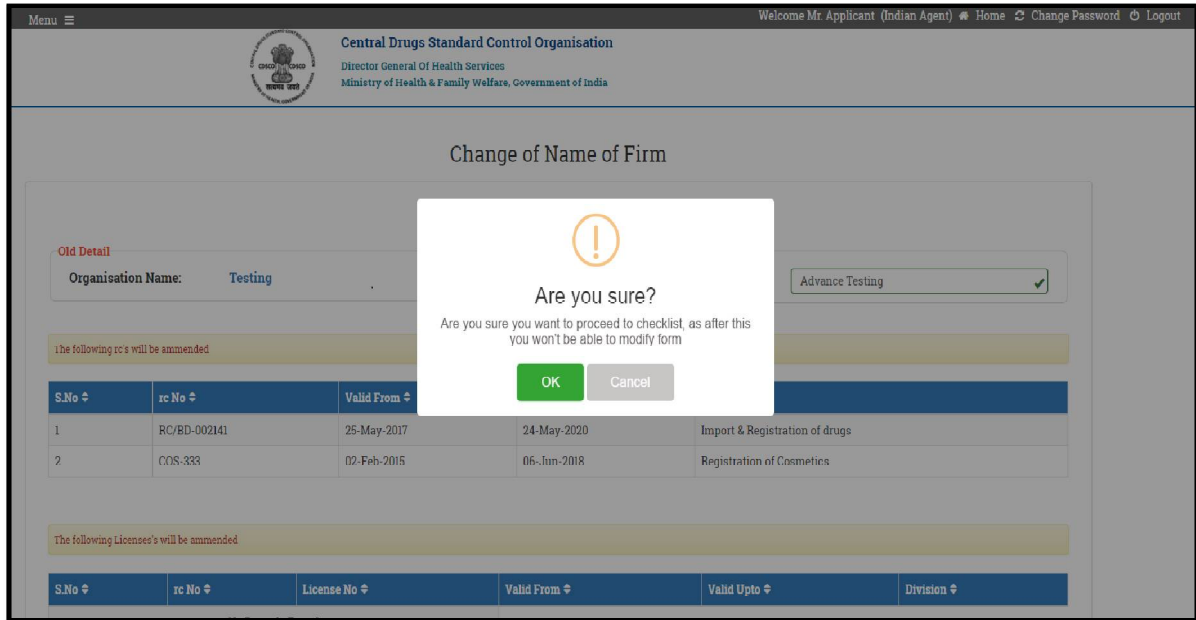


Figure 144 : Confirmation alert -- Proceed to checklist

- Checklist of the documents to be uploaded for the case.

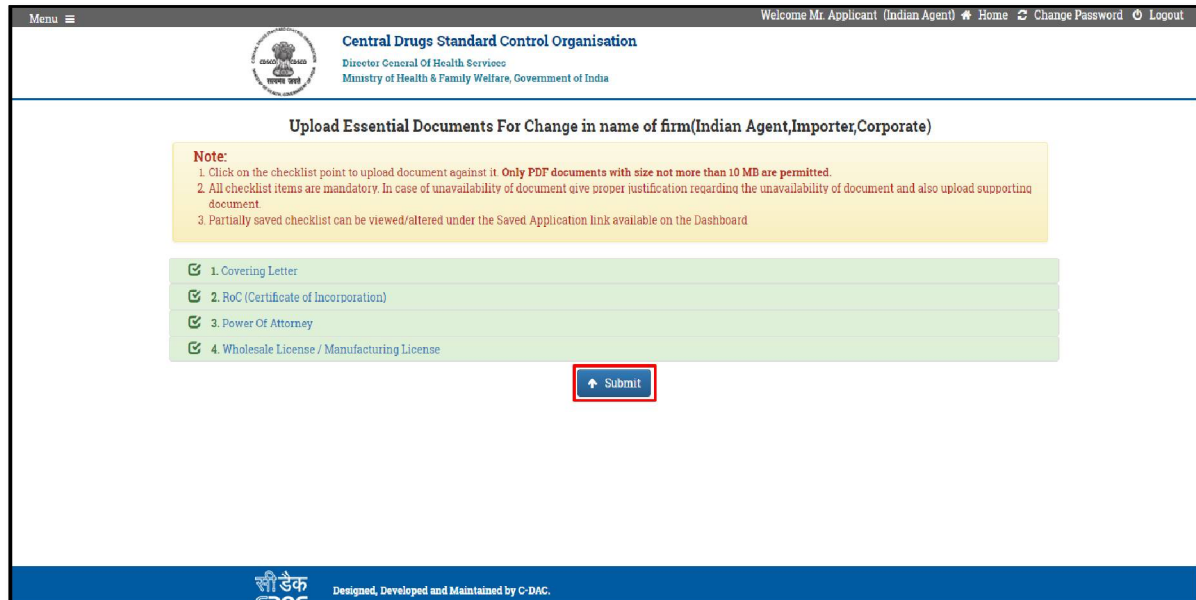
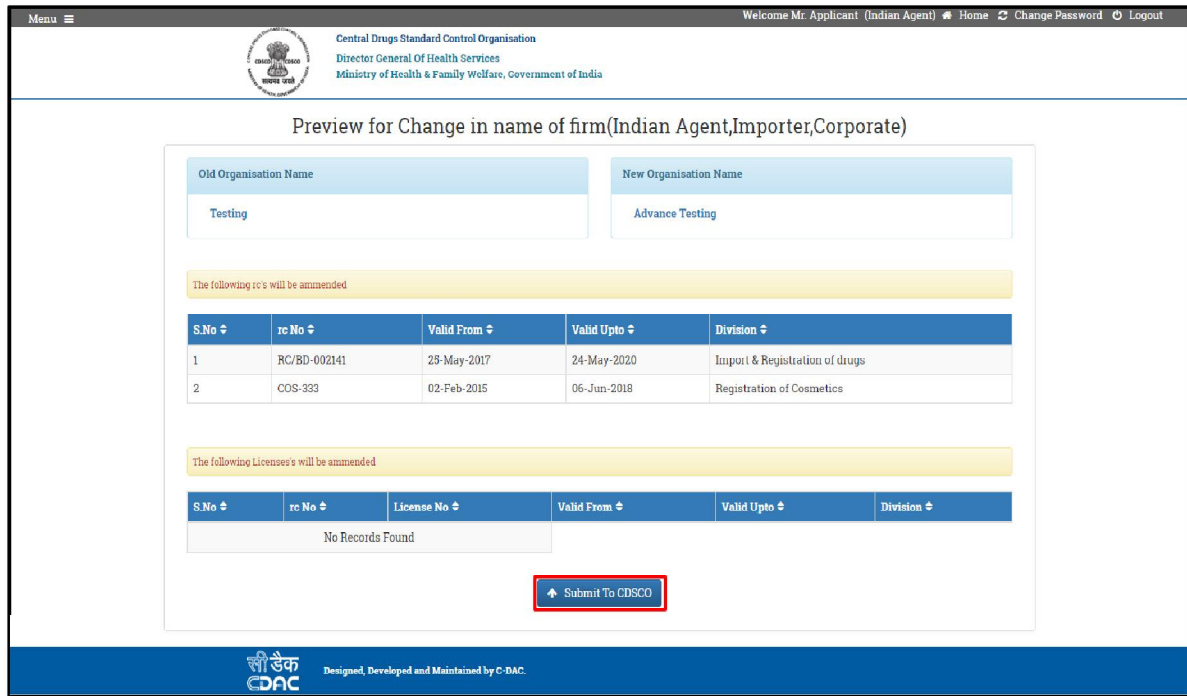


Figure 145 : Checklist of the documents



- Preview of the new name along with the list of permissions and license where it will be reflected.



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

Preview for Change in name of firm(Indian Agent,Importer,Corporate)

Old Organisation Name: Testing

New Organisation Name: Advance Testing

The following rc's will be amended

S.No	rc No	Valid From	Valid Upto	Division
1	RC/BD-002141	23-May-2017	24-May-2020	Import & Registration of drugs
2	COS-333	02-Feb-2015	06-Jun-2018	Registration of Cosmetics

The following Licensee's will be amended

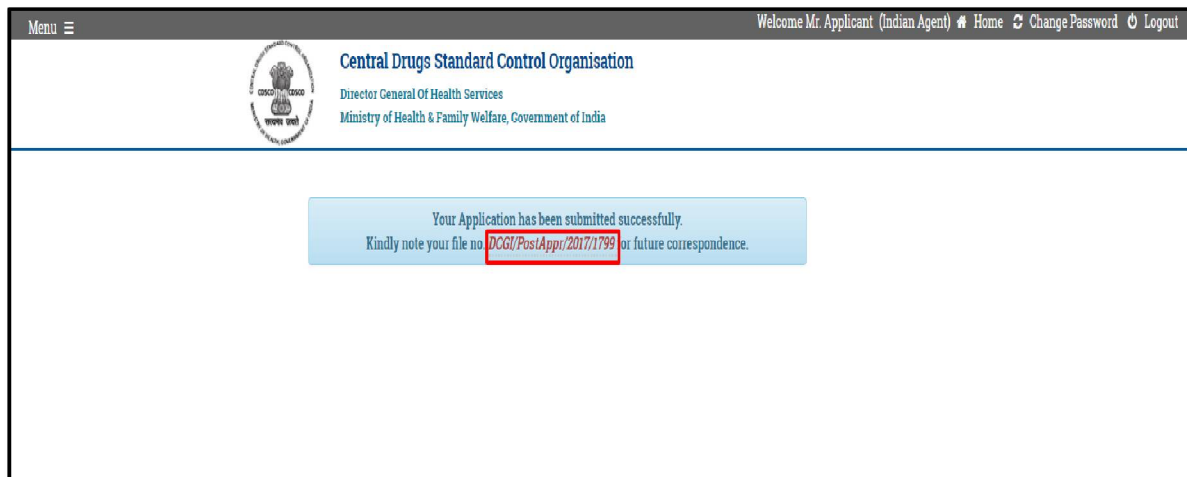
S.No	rc No	License No	Valid From	Valid Upto	Division
No Records Found					

[Submit To CDSCO](#)

सी डैक CDAC  
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Figure 146 : Preview of change in name

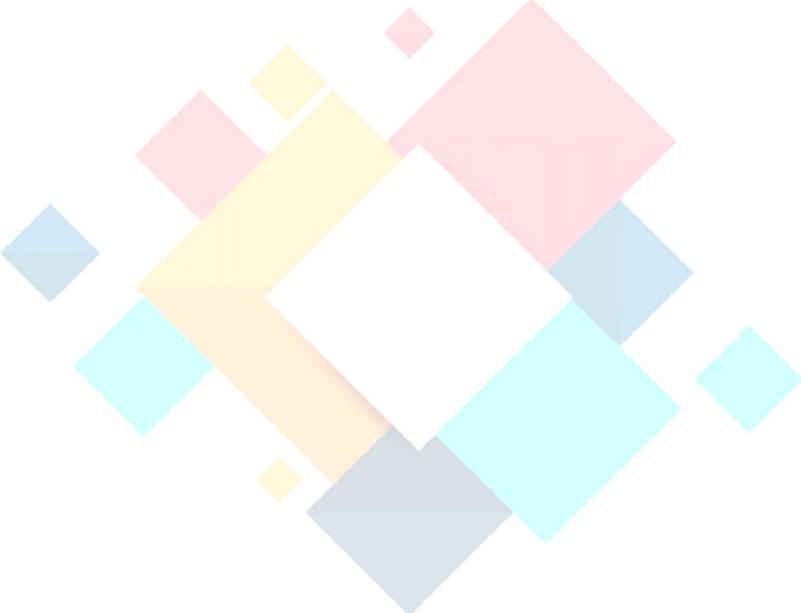
- File number generated after submission of the application



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


Your Application has been submitted successfully.  
Kindly note your file no. **DCGI/PostAppr/2017/1799** or future correspondence.

Figure 147 : File number generated



## **Chapter- 6**

# **Online Payment with “BHARATKOSH”**



## 6. Online Payment using Bharatkosh

### 6.1 Pre requisites for Online Payment

- Valid User Account on SUGAM Portal
- Internet enabled machine like desktop, laptop etc
- Internet browser with updated version such as IE, Chrome, Firefox etc.
- Net banking facility or valid Debit or Credit Card

#### Important Note:

Using this online payment facility, user will be making online payment to Government of India under the head of Fees & Fines. It may be noted the actual fee will be credited to Payment & Account Office (PAO), Govt. of India only after 2-3 days of making the online payment transaction. Hence, users are requested to initiate the payment through online payment services of SUGAM at least 3 days before the submission of application to CDSCO.

### 6.2 Steps to make Online Payment

- Login to SUGAM web portal (URL: <https://www.cdsconline.gov.in>) by using any internet browser and enter your login Credentials in the sign in box and as shown in below **Figure**

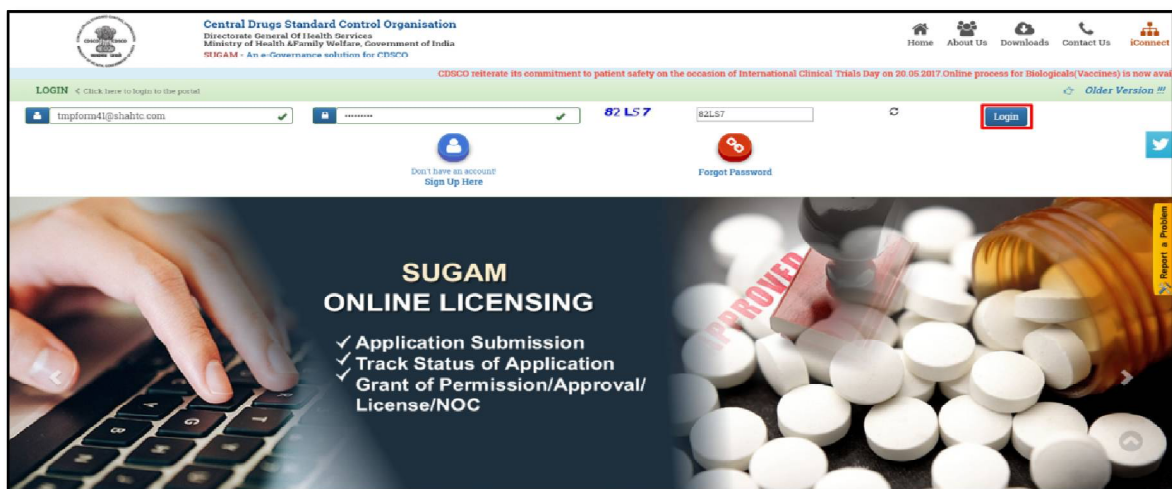


Figure 148 : Login to SUGAM Portal

- After Login, click on the left top menu and select the online payment shown in below

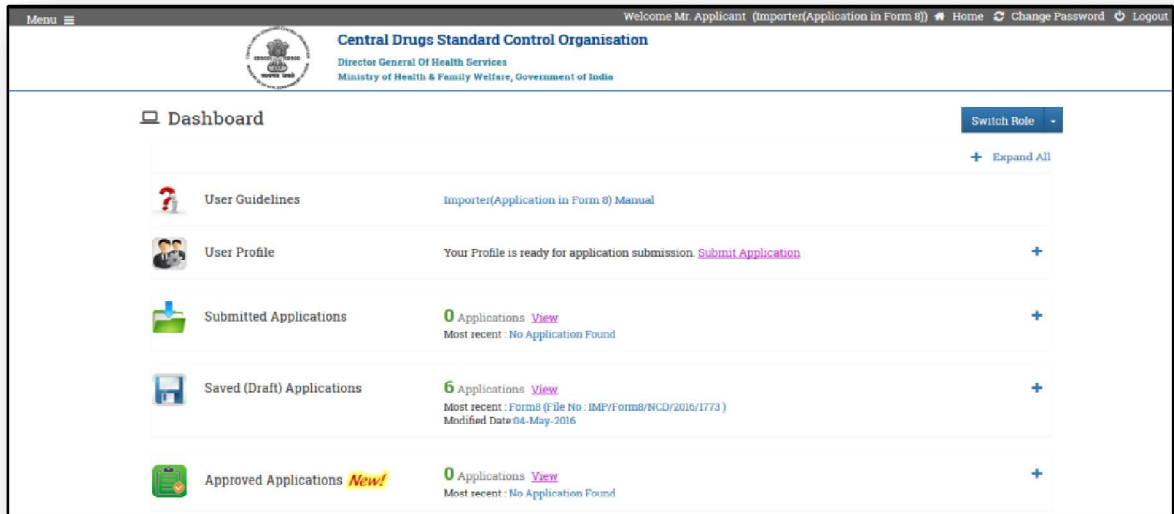


Figure 149 : Select the online payment

- Click on the Online Payment Option and the fill up the Online Payment Details.

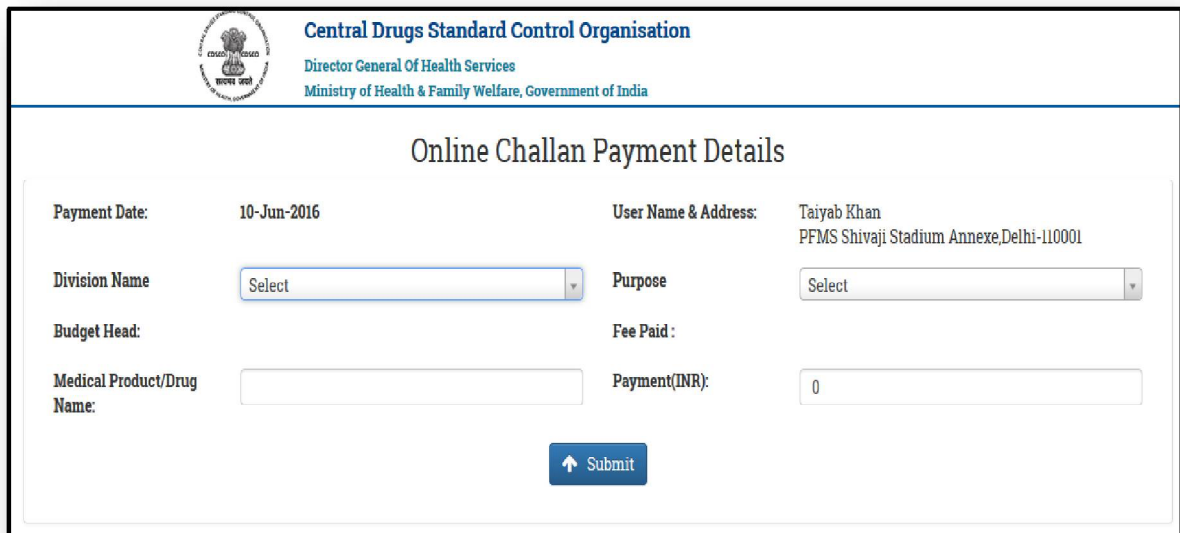


Figure 150 : Online Payment Details

- Payment Date** : By Default, current date of payment is displayed.
- User name &Address** : User Name and Address is fetched from user registration
- Division Name** : Choose “**Division Name**” from the dropdown list to whom the Required online application is to be submitted.
- Purpose** : Choose the “**Purpose**” of payment from the dropdown list of payment Purposes, filler according as per the selection of division name.
- Budget head** : Display the Budget Head Account on which the payment is credited on the CDSCO account.
- Medical Product/Drug** : Enter the Medical Product/Drug Name for which the payment is to be made.
- Payment In (INR/USD)** : Enter the total payment amount in (Rs. /USD) as per the purpose of payment and the total fee is required to be paid as per the table given below.

**Table 7 : Purpose wise Fee's required to be paid**

S. No.	Division Name	Purpose Name	Fee paid
1.	Biologicals	Marketing Authorization (Form 44)	Rs 50000 and Rs 15000 in case of regularization of permission
2.	Biologicals	Application for License to import drugs for examination, test or analysis (Form 12)	Rs 100 for each product and Rs 50 for each subsequent product
3.	Biologicals	Subsequent approval of Marketing Authorization (Form 44)	Rs 15000
4.	Biologicals	Clinical Trial Phase I (Form 44)	Rs 50000
5.	Biologicals	Clinical Trial Phase II (Form 44)	Rs 25000
6.	Biologicals	Clinical Trial Phase III (Form 44)	Rs 25000
7.	Biologicals	Registration of Site (Form 40)	1500 USD for each site
8.	Biologicals	Registration of Product (Form 40)	1000 USD for each product
9.	Biologicals	Import License (Form 8)	Rs 1000 for each product and Rs 100 for each subsequent product

10.	Cosmetics	Fresh (Form 42)	250 USD for each applied category (category as per Column 3 of guideline)
11.	Cosmetics	Endorsement (Form 42)	1. For already registered category- no fees is required 2. For new categories- 250 USD for each applied category
12.	Import & Registration	Registration Certificate (Form 40)	a.) Foreign Manufacturing premises Fee – 1500 USD (or its Eq. Indian Currency). b.) Registration Fee for single drug and 1000 USD (or its Eq. Indian Currency) for each additional drug in case the manufacturing site remain same.
13.	Import & Registration	Import Licence (for Schedule X Drugs - Form 8A)	Rs 1000 for single drug and Rs 100 for additional drug.
14.	Import & Registration	Import License (Form 8)	Fee Rs.1000 for one Product and Rs.100 for each additional Product
15.	Medical Devices & diagnostic	Registration Certificate (Fresh/Endorsement/Re-Registration - Form 40)	USD 1500 for site and USD 1000 for each product
16.	Medical Devices & Diagnostic	Grant of permission to import or manufacture new medical device going to be introduced for the first time in the country for sale or to undertake clinical trials (Form 44)	Rs. 50,000/-/Rs. 25,000/-/Rs 15,000/-
17.	Medical Devices & Diagnostic	Import License (Form 8)	Fee Rs.1000 for one Product and Rs.100 for each additional Product
18.	Medical Devices & Diagnostic	Application for License to import drugs for examination, test or analysis (Form 12)	Rs.100 for One product and Rs.50 for each additional product

19.	BA/BE for Export	Application for BE NOC for Export of new molecule (New Chemical entity) not approved in India but approved in other countries. (Form 44)	Rs 50000/-
20.	BA/BE for Export	Application for BE NOC for Export of New Drugs approved in India within period of 1 year (Form 44)	Rs 25000/-
21.	BA/BE for Export	Application for BE NOC for Export, of New Drugs approved within period of more than 1 year & less than 4 years (Form 44)	Rs 15000/-
22.	BA/BE for Export	Application for BE NOC for Export, of a drug product in modified release form irrespective of their approval status (Form 44)	Rs 15000/-
23.	BA/BE for Export	Application for license to import drugs for the purpose of examination, test & analysis (form 12)	Rs 100 for single drug and additional fee of 50 for each additional drug
24.	Subsequent New Drug	Subsequent new drug application for Import/ manufacturing within one year of its initial approval. (Form 44)	Rs 50000/-
25.	Subsequent New Drug	Any Subsequent new drug application received for import/ manufacturing after one year of the grant of initial approval for the manufacture for sale of the new drug. (Form 44)	Rs 15000/-
26.	Subsequent New Drug	Subsequent new drug application by the same applicant for import and manufacturing that drug,	Rs 15000/-

		whether in modified dosage form or with new claims, is made (Form 44)	
27.	Subsequent New Drug	Application for BE NOC for subsequent new drug (Form 44)	Rs 15000/-
28.	Subsequent New Drug	Application for Licence for examination, test or analysis (Form 12)	Rs 100 for single drug and additional fee of 50 for each additional drug
29.	Subsequent New Drug	Phase II Clinical Trial Permission (Form 44)	Rs 25000/-
30.	Subsequent New Drug	Phase III Clinical Trial Permission (Form 44)	Rs 25000/-
31.	New Drug division	New drug application for Import/manufacturing. (Form 44)	Rs 50000/-
32.	New Drug division	Clinical trial Phase-I application (Form 44)	Rs 50000/-
33.	New Drug division	Clinical trial Phase-II application (Form 44)	Rs 25000/-
34.	New Drug division	Clinical trial Phase-III application (Form 44)	Rs 25000/-
35.	New Drug division	Application for License for examination, test or analysis (Form 12)	Rs 100 for single drug and additional fee of 50 for each additional drug
36.	Fixed Dose Combination	Permission to Import or Manufacture of a New Drug - FDC (Form 44)	Rs 50,000 in case any of the active ingredients is approved for less than one year and Rs 15,000 if all active ingredients are approved in India for more than one year
37.	Fixed Dose Combination	Application for License to import drugs for examination, test or analysis (Form 12)	Rs 100/- for single drug and additional fee of Rs. 50/- for each additional drug
38.	Fixed Dose	Phase II Clinical Trial Permission	Rs 25000/-



	Combination	(Form 44)	
39.	Fixed Dose Combination	Phase III Clinical Trial Permission (Form 44)	Rs 25000/-
40.	Import of New Drugs in small quantities for use in hospital	Import small quantities of new drugs by a Government Hospital or Autonomous Medical Institutions for the treatment of patients (Form 12 AA)	Rs 100/- for single drug and Rs. 50/- for each additional drug
41.	GCT Division	Application to undertake Clinical Trial (Form 44)	Rs 25000/-
42.	GCT Division	Change in CRO/Applicant for Clinical Trial (Form 44)	Rs 25000/-
43.	GCT Division	Application for License to import drugs for examination, test or analysis (Form 12)	Rs 100/- for single drug & additional fee of Rs 50/- for each additional drug

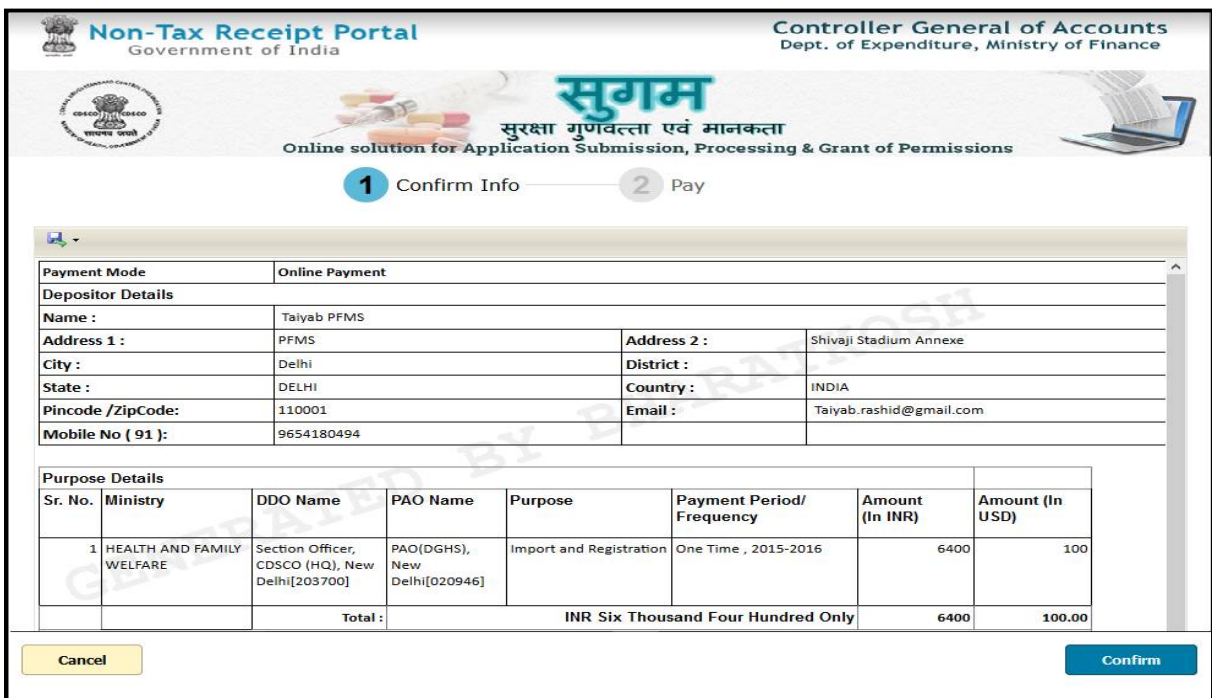
- On Clicking **Submit button** Payment request is forward to Bharatkosh Payment gateway.



Figure 151 : Transfer to BHARTKOSH Payment Gateway

The below page provides the facility to verify the payment details sent to BHARATKOSH payment page. Applicant will be then redirected to BHARATKOSH Online Payment page <https://bharatkosh.gov.in/Bharatkosh/bkepay>

**Please Note:** If payment is required to be made in the USD the actual USD conversion rate is taken from the Reserve Bank of India (RBI).



**Non-Tax Receipt Portal**  
Government of India

**सुगम**  
सुरक्षा गुणवत्ता एवं मानकता  
Online solution for Application Submission, Processing & Grant of Permissions

Controller General of Accounts  
Dept. of Expenditure, Ministry of Finance

1 Confirm Info — 2 Pay

<b>Payment Mode</b>		Online Payment						
<b>Depositor Details</b>								
<b>Name :</b>	Taiyab PFMS							
<b>Address 1 :</b>	PFMS	<b>Address 2 :</b>	Shivaji Stadium Annexe					
<b>City :</b>	Delhi	<b>District :</b>						
<b>State :</b>	DELHI	<b>Country :</b>	INDIA					
<b>Pincode /ZipCode:</b>	110001	<b>Email :</b>	Taiyab.rashid@gmail.com					
<b>Mobile No ( 91 ):</b>	9654180494							
<b>Purpose Details</b>								
Sr. No.	Ministry	DDO Name	PAO Name	Purpose	Payment Period/ Frequency	Amount (In INR)	Amount (In USD)	
1	HEALTH AND FAMILY WELFARE	Section Officer, CDSCO (HQ), New Delhi[203700]	PAO(DGHS), New Delhi[020946]	Import and Registration	One Time , 2015-2016	6400	100	
<b>Total :</b>						INR Six Thousand Four Hundred Only	6400	100.00

Figure 152 : BHARATKOSH Payment View Details

- Once user validates all his details pertaining to the payment and clicks on confirm button, user will be redirected to payment gateway. Clicking on **“Cancel”** will terminate the current transaction and then he will be re-sent to payment status page.
- Payment request processing at SBI ePay payment gateway :At the Payment page, user will click on any of the desired payment channels, these options are displayed on the page as tabs, and users can select either “Net Banking, Debit Card or Credit Card” as depicted in the below figure

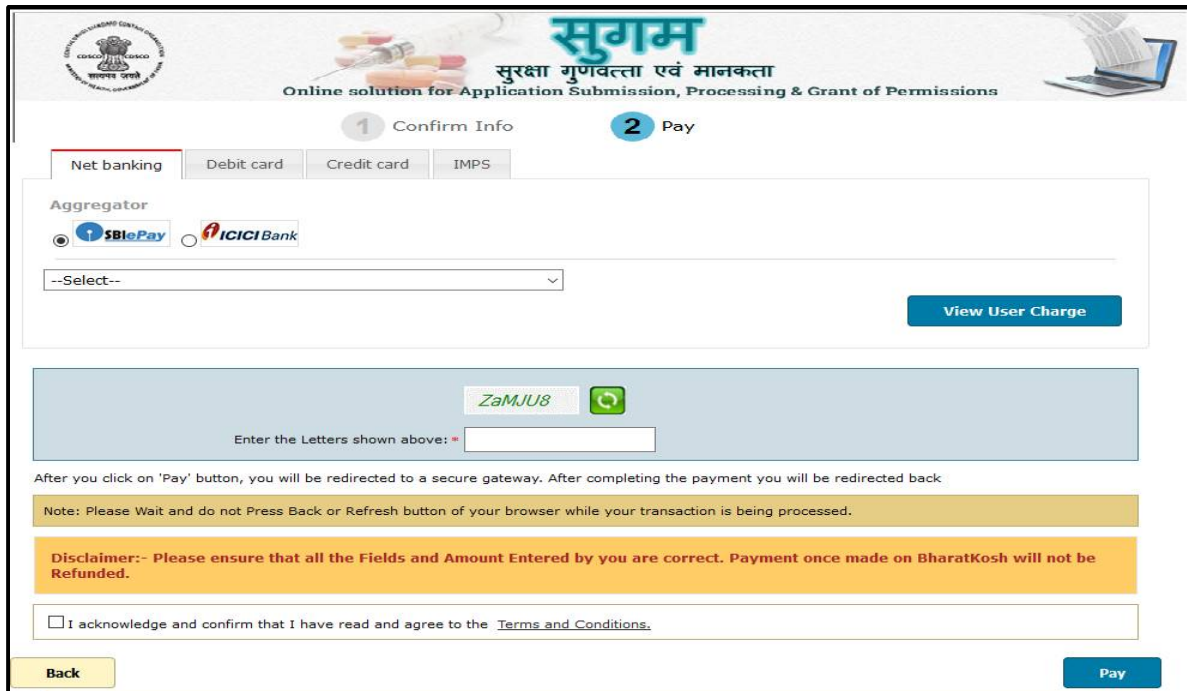


Figure 153 : Payment Gateway

- If User clicks on “Net Banking” tab, user will have an option to select SBI ePay radio button, user will select SBI ePay, all banks mapped with SBI ePay will get populated in “Select your bank” dropdown. User should select his bank of choice from the dropdown list.
- User then types the Word verification as per the words displayed in the image shown at the bottom of this page. User will then click on “Pay” button.
- User will be navigated to the Payment gateway; in this case it will be the login screen of the selected bank.
- User will type his/ her login credentials, enter into the bank’s website and type the amount and click on Pay button.

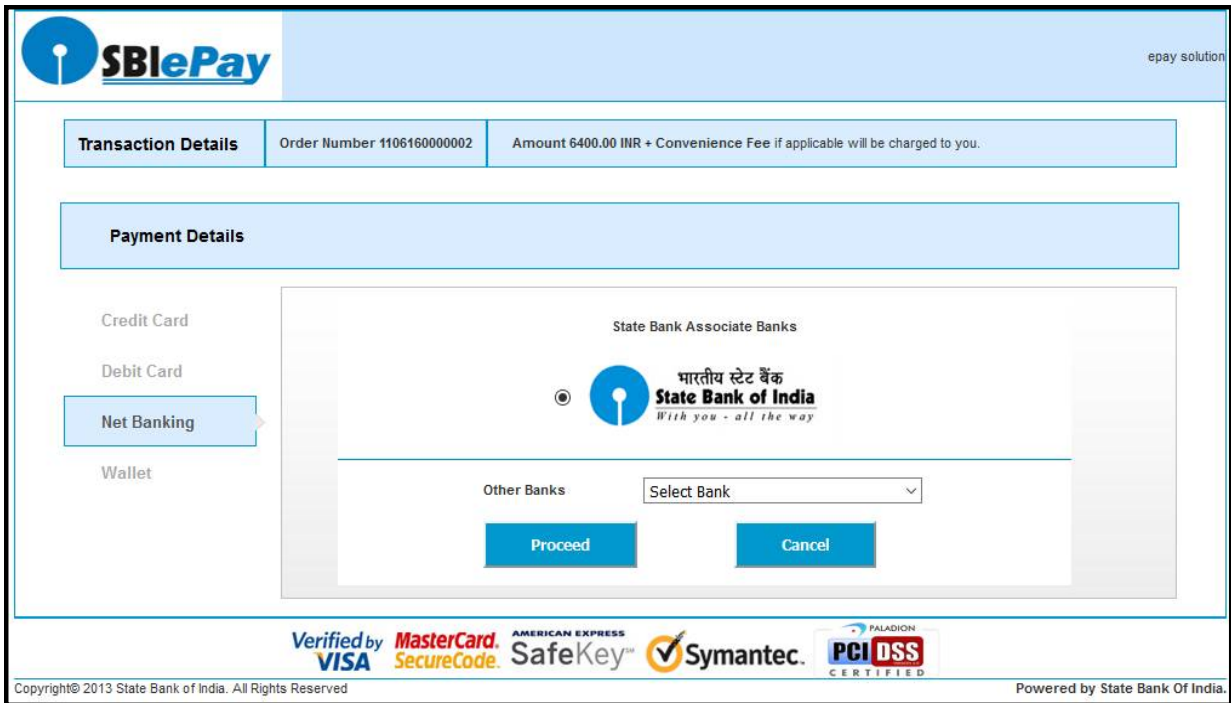


Figure 154 : Screen of SBI ePay

- **Receipt of payment confirmation:** If payment is successfully received by the bank, user will be shown the success page at Bank payment gateway, and then the user will be redirected back to the SUGAM portal at the online payment status page.

<b>SBIePAY Test Bank</b>	
OrderNumber :	1106160000002
Amount :	6400.0
<input type="button" value="Successful"/>	<input type="button" value="Decline"/>

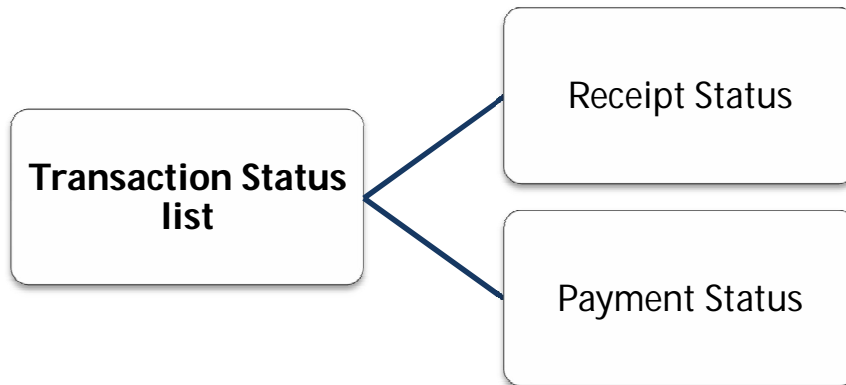
Figure 155 : Receipt of payment confirmation

- **Tracking your Payment Status:** To track your payment status click on the “**Online Payment Status**” menu option.



Figure 156 : Tracking your Payment Status

- **Transaction Status list:** There are two types of status maintained at NTRP (BHARATKOSH).



- **Receipt Status:** - Status of the transaction at Bharat-Kosh before it is being sent to Bank's Payment Gateway.
- **Payment Status:** - Status of the transaction which is received from Bank's Payment gateway i.e. after the transaction has been processed.

- The comprehensive list of all Transaction status maintained at SUGAM is given below:-

**Table 8: Comprehensive list of all Transaction status**

S. No.	Status Type	Status	Status Description
1	Receipt Status	Confirmed	User has clicked on submit button at Payment Info Page At BHARAT KOSH.
2	Receipt Status	Payment Initiated	User submits data from SBI Aggregator Page
3	Receipt Status	Incomplete	User reached on Confirm Info page at BHARAT KOSH and leaves/ clicks Cancel button.
4	Receipt Status	Submitted	User submits data from Confirm Info Page at BHARAT KOSH.
5	Payment Status	SUCCESS	Transaction is completed successfully
6	Payment	FAIL	Transaction failed
7	Status	ABORT	If Aggregator reference number is generated but No Gateway response Or if Aggregator reference number NOT generated and NO response exist.
8	Payment	No records found	No merchant order number present at Aggregator end
9	Status	BOOKED	The customer has not navigated on success page or left the transaction in middle.
10	Payment	REFUND	If the transaction is refunded through either manually refund or DVP refund.
11	Status	PENDING	If maker done the transaction and checker has not authorized the transaction
12	Payment	EXPIRED	If transaction stays in BOOKED condition for 5 days then on 6th day it gets expired.
13	Status	CLOSED	If the transaction is reversed due to discrepancy at issuer Bank
14	Payment	REJECT	If the transaction is reversed due to Risk & Fraud.

- **Step 7: How to get payment e-Challan**
- **GAR 6** -- Once transaction is successful, GAR 6 gets generated at NTRP (BHARATKOSH). User will have to navigate to [bharatkosh.gov.in](http://bharatkosh.gov.in) and click on "track your payment" link, user can login by using OTP method, after logging user can view list of all transactions done through the mobile no., and it will also have the GAR 6 generated for a successful transaction.



**Figure 157 : Payment e-Challan**

- **GAR 7** -When the amount gets credited to PAO's Account and PAO's Bank has sent the scroll for Challan to NTRP, then Challan gets generated at NTRP (Bharatkosh). User can navigate to [bharatkosh.gov.in](http://bharatkosh.gov.in) and click on the link "track your payment" and login using OTP feature and view the Challan generated for the transactions done by him/her.
- **Step 8: How to use online payment Challan which applying to CDSCO.**
- To use the online payment transaction in an application to be submitted to CDSCO, User is required to upload the GAR-7 Challan that is generated at NTRP (BHARATKOSH).
- User has to upload the online generated payment Challan at step 4(Payment) of application submission workflow of SUGAM portal.



# Chapter- 7

## Application for Export NOC





## 7. Application for export NOC

- After choosing the role as “Cooperate” click on “Submit Application” as highlighted in the below **Figure**

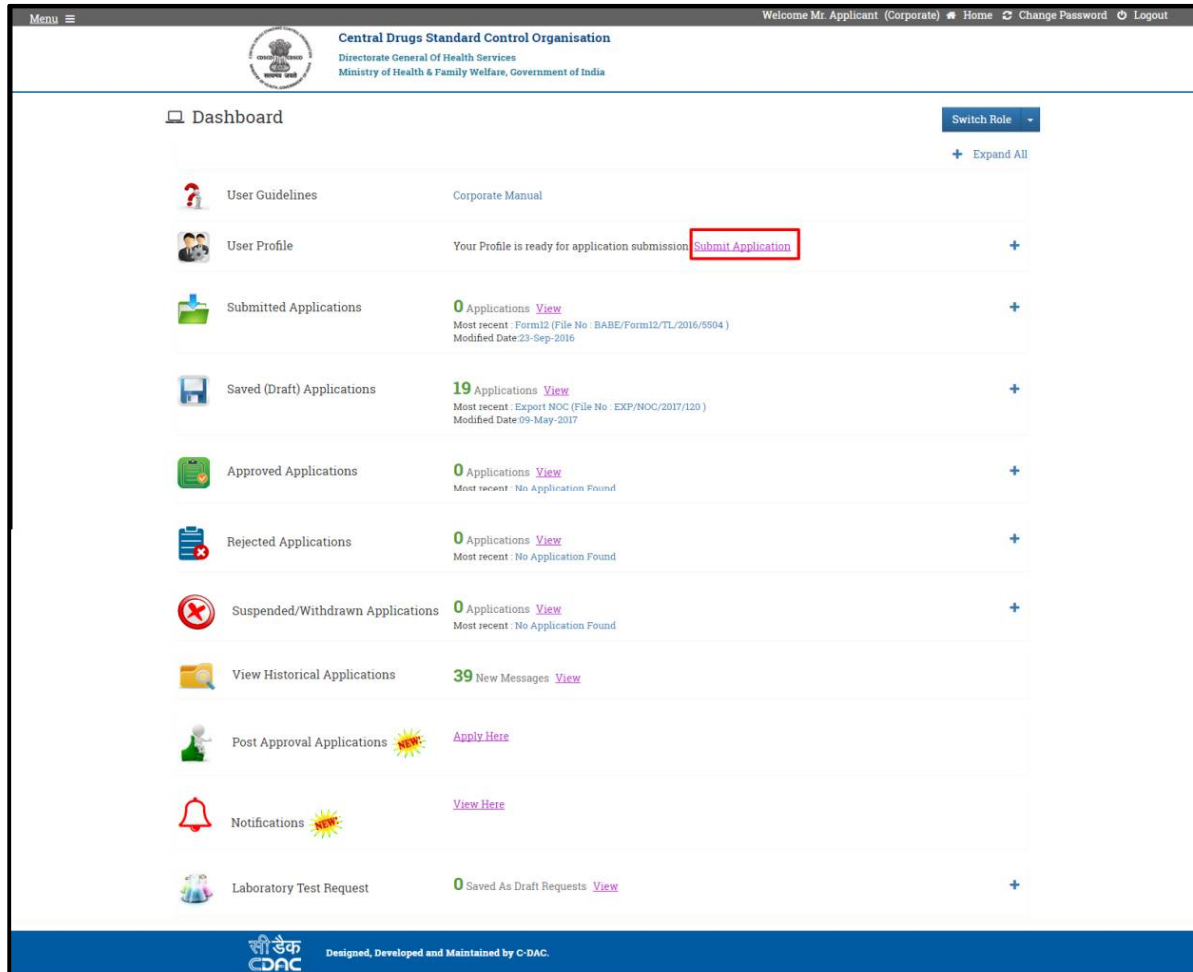


Figure 158 : Application for export NOC

### 7.1 Online Form Submission

- After clicking on “Submit Application” user will be redirected to “Online Form Submission” page.
- Here, user has to select Department as “Zone and Select Form as “NOC”, as shown in below **Figure**.
- Checkbox on terms and condition to move to the next page.

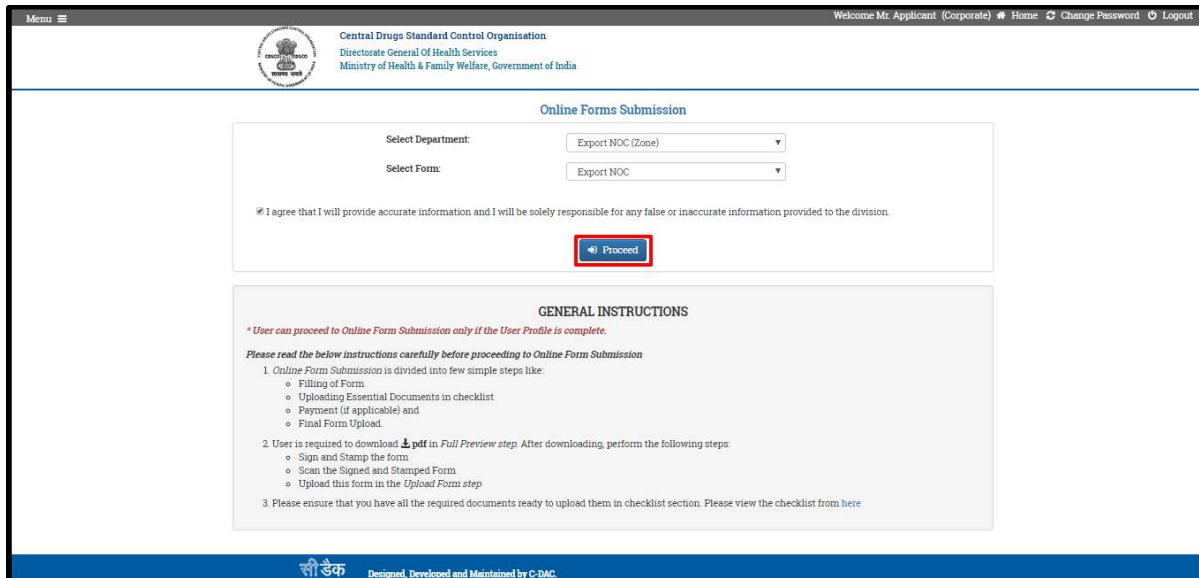


Figure 159 : Online Form Submission

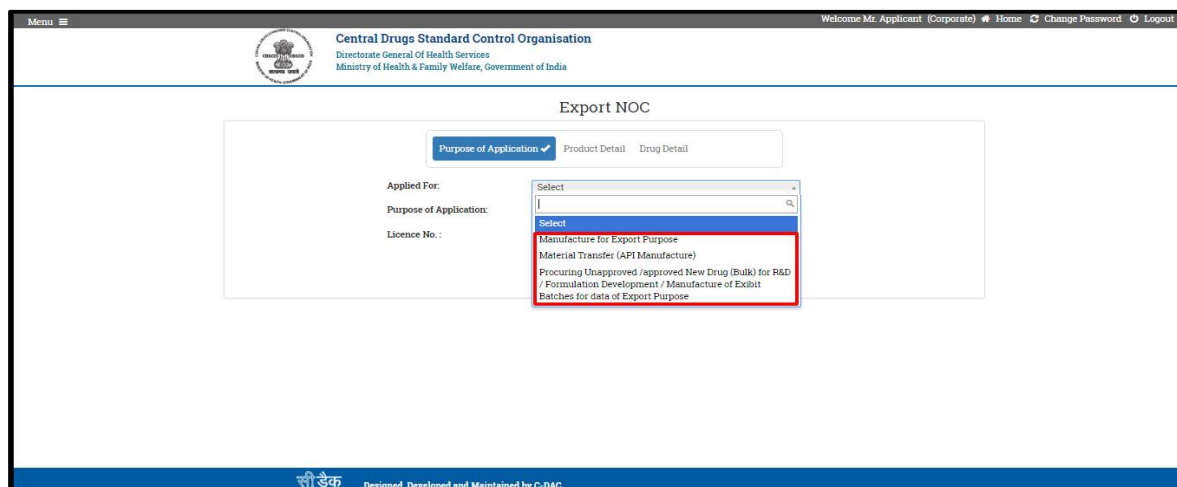
**NOTES:**

- It is mandatory to select “Agree on Terms and Condition” to proceed further.
- Before proceeding further kindly read the ‘**General instructions**’ provided on the same page.
- User can proceed for the online form Submission only if the user profile is complete.

## 7.2 Application Cases

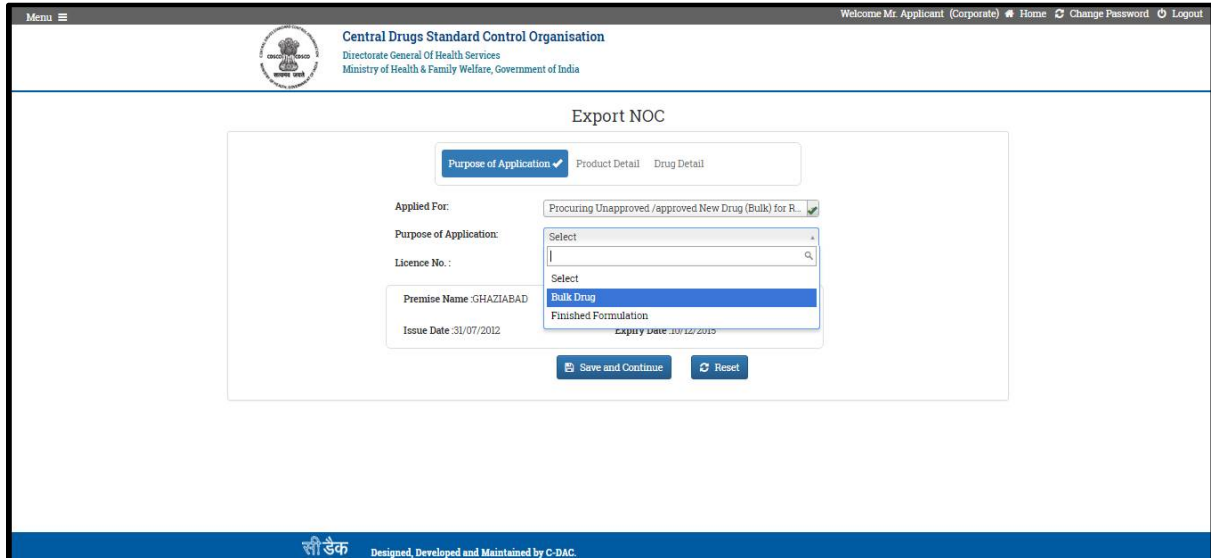
User can apply for one of the following application as highlighted in below **Figure**

- Procuring Unapproved/approved New Drug (Bulk) for R&D/Formulation Development / Manufacture of Exhibit Batches for data of Export Purpose
- Manufacture for Export Purposes.
- Material Transfer (API Manufacture)



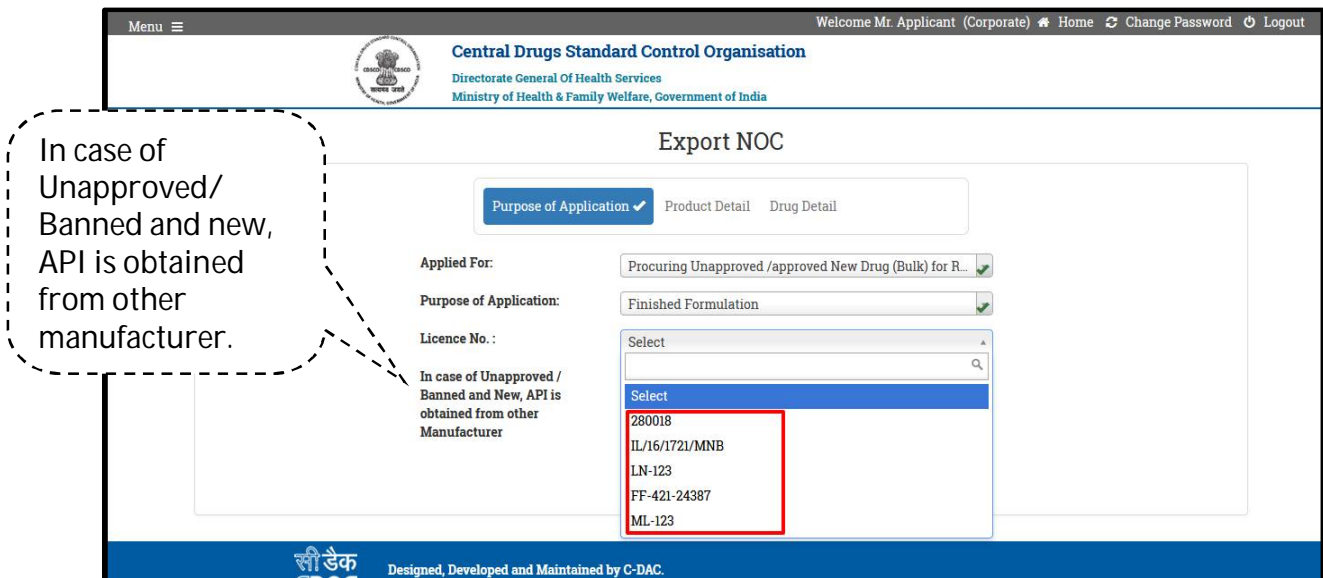
### 7.3 Purpose of Application

- User can choose the Purpose of Application as either **Bulk Drug** or **Finished Formulation** according to his requirement, as shown in **Figure**.



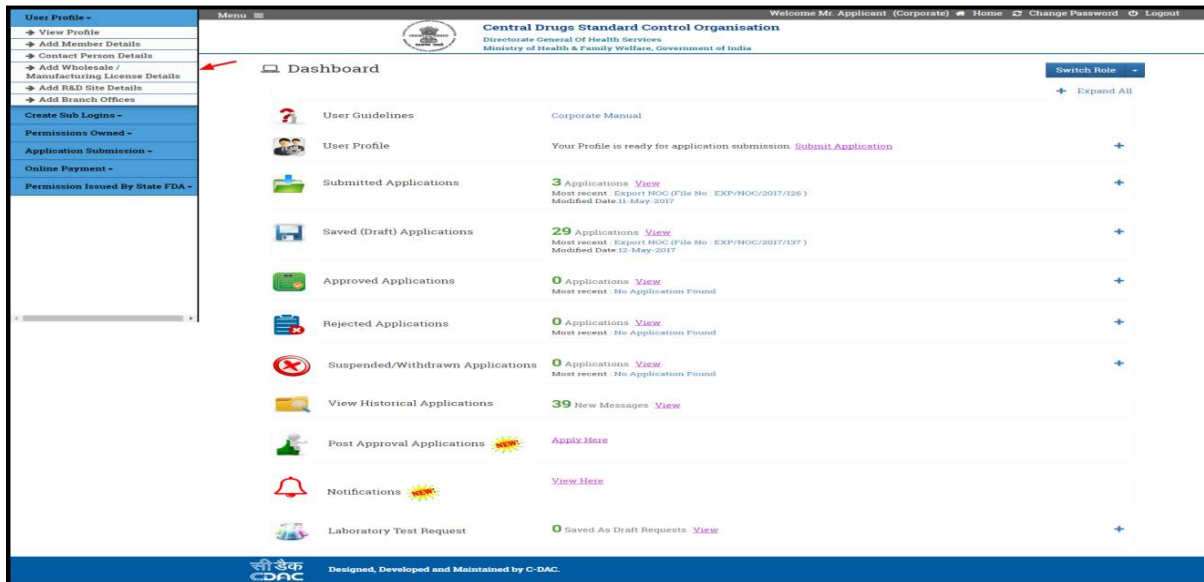
**Figure 160 : Purpose of Application**

- If the user’s license number entry has already been registered in the system then it will be fetched from there and will appear on the drop down menu of the “License No.”, as shown in **Figure**.



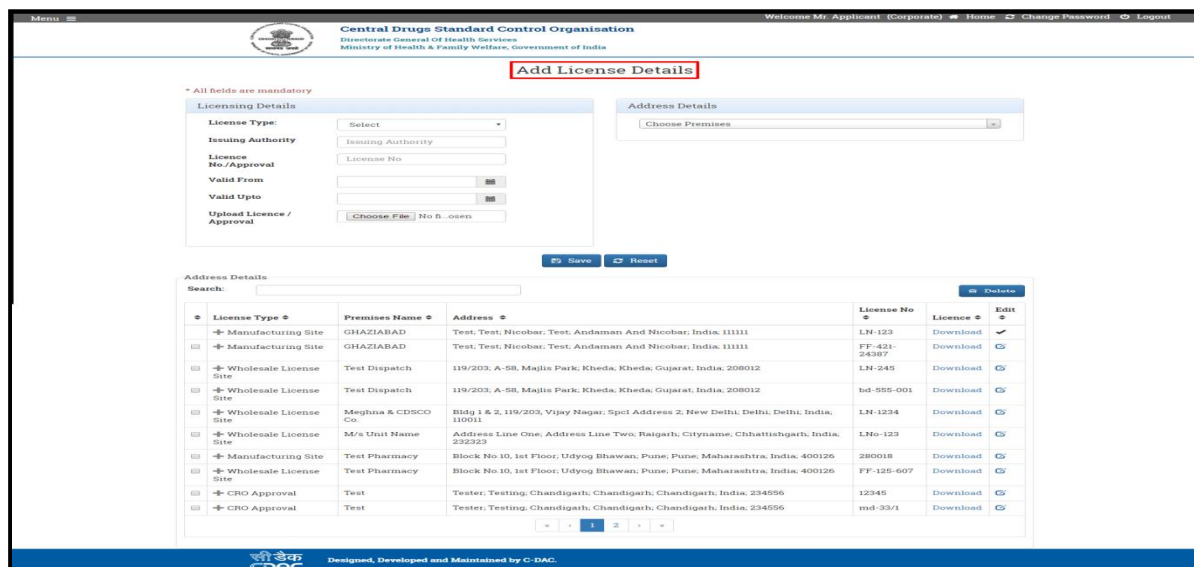
**NOTES:**

- If the user's license number is not registered in the system then the user has to first get it registered on the system and then only he will be able to move further for Online Form Submission.
- For License Registration go to Dashboard homepage, go to the top of menu and select **"Add Wholesale/Manufacturing Licensing Details"** under user profile, as highlighted in the **Figure**.



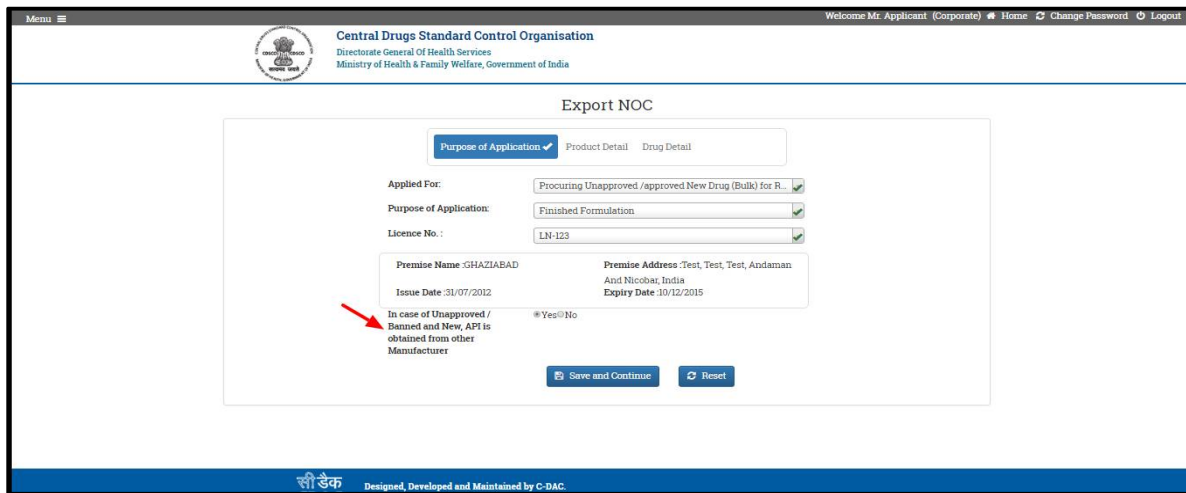
**Figure 161 : Add Wholesale/Manufacturing Licensing Details**

- After selecting **"Add Wholesale/Manufacturing Licensing Details"** a new window will open where user will fill the details to register his/her license number, as shown in **Figure**.



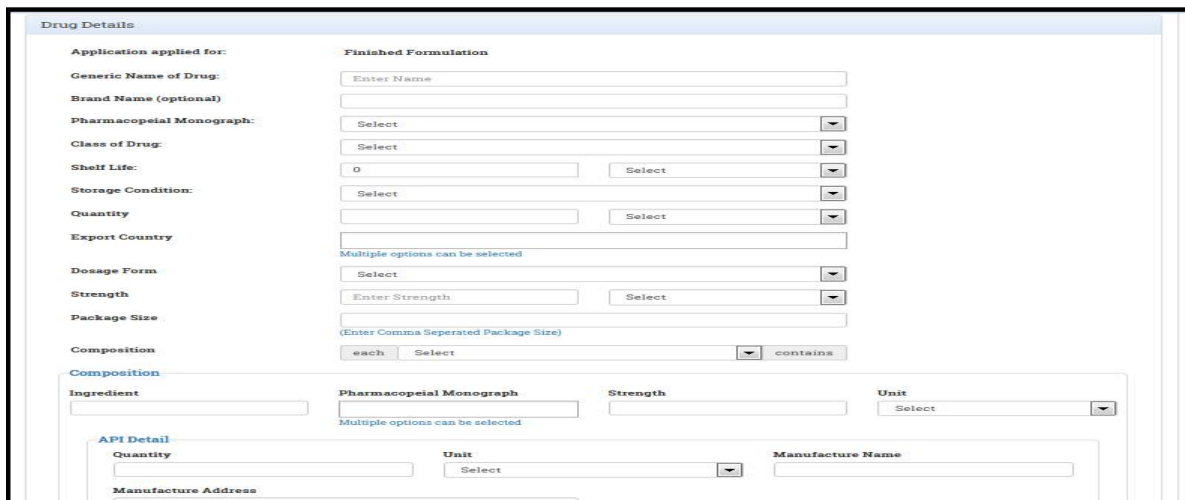
**Figure 162 : Add License details**

- Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exhibit Batches for data of Export Purpose.
- When user select **“Procuring Unapproved /approved New Drug (Bulk) for R&D/Formulation Development / Manufacture of Exhibit Batches for data of Export Purpose”** as the purpose of application then, in case of Unapproved / Banned and New, API is obtained from other Manufacturer, as shown in **Figure**.
- If user need API from other manufacturer click on “Yes” otherwise “No”.
- Click on Save and Continue to move forward or click on Reset button to reset the form.



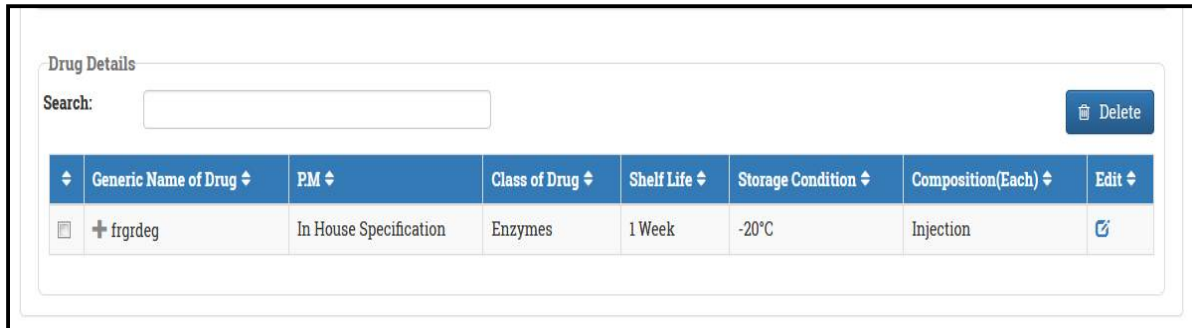
**Figure 163 : Click on Save and Continue**

- After filling the Purpose of Application the form will go to next step i.e. Drug Details, as shown in **Figure**.
- Here the user will fill all the required details and click on “Save” button after completion of the form.



**Figure 164 : Fill all the required details**

- After clicking on save button the entry will be shown in tabular form at the end of the page, as shown in **Figure**.
- User can have more than one entry of drug detail according to his requirement otherwise click on Next button.



Drug Details

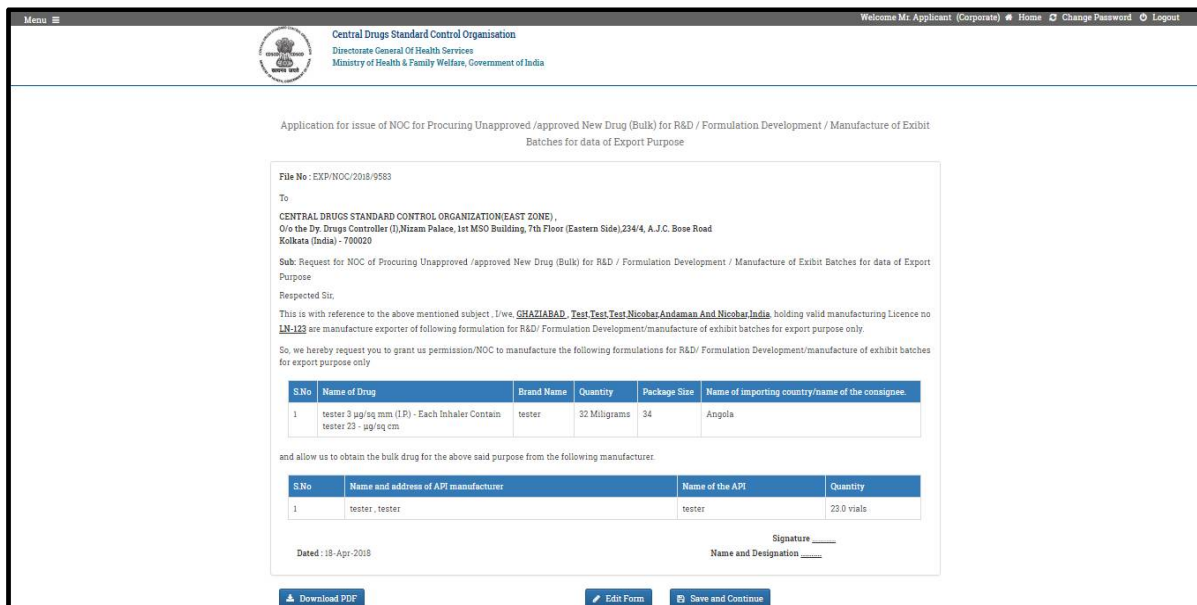
Search:

[Delete](#)

Generic Name of Drug	PM	Class of Drug	Shelf Life	Storage Condition	Composition(Each)	Edit
+ frgrdeg	In House Specification	Enzymes	1 Week	-20°C	Injection	<a href="#">Edit</a>

**Figure 165 : Drug Details**

- At the end user will see the application for issue of NOC for Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exhibit Batches for data of Export Purpose
- Here, the name of the city will be highlighted where manufacturing license is holding, as shown in below **Figure**.
- User can download the PDF form from the button "Download PDF "visible at the left bottom of the page.



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

Application for issue of NOC for Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exhibit Batches for data of Export Purpose

File No : EXP/NOC/2018/9583

To  
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION(EAST ZONE),  
O/o the Dy. Drugs Controller (I),Nizam Palace, 1st MSO Building, 7th Floor (Eastern Side),234/4, A.J.C. Bose Road  
Kolkata (India) - 700029

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

Respected Sir,

This is with reference to the above mentioned subject, I/we, **GHAZIABAD, Test Test Test Nicobar Andaman And Nicobar India**, holding valid manufacturing Licence no **LN-123** are manufacture exporter of following formulation for R&D/ Formulation Development/manufacture of exhibit batches for export purpose only.

So, we hereby request you to grant us permission/NOC to manufacture the following formulations for R&D/ Formulation Development/manufacture of exhibit batches for export purpose only

S.No	Name of Drug	Brand Name	Quantity	Package Size	Name of importing country/name of the consignee.
1	tester 3 µg/sq mm (I.P.) - Each Inhaler Contain tester 23 - µg/sq cm	tester	32 Milligrams	34	Angola

and allow us to obtain the bulk drug for the above said purpose from the following manufacturer:

S.No	Name and address of API manufacturer	Name of the API	Quantity
1	tester, tester	tester	23.0 vials

Signature \_\_\_\_\_  
Name and Designation \_\_\_\_\_

Dated : 18-Apr-2018

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

**Figure 166 : User can download the PDF**

- After clicking on "**Save and continue**" a pop-up will come, as shown in below **Figure**.
- This pop up will ask whether the user wants to proceed to checklist, as after this he won't be able to modify form.

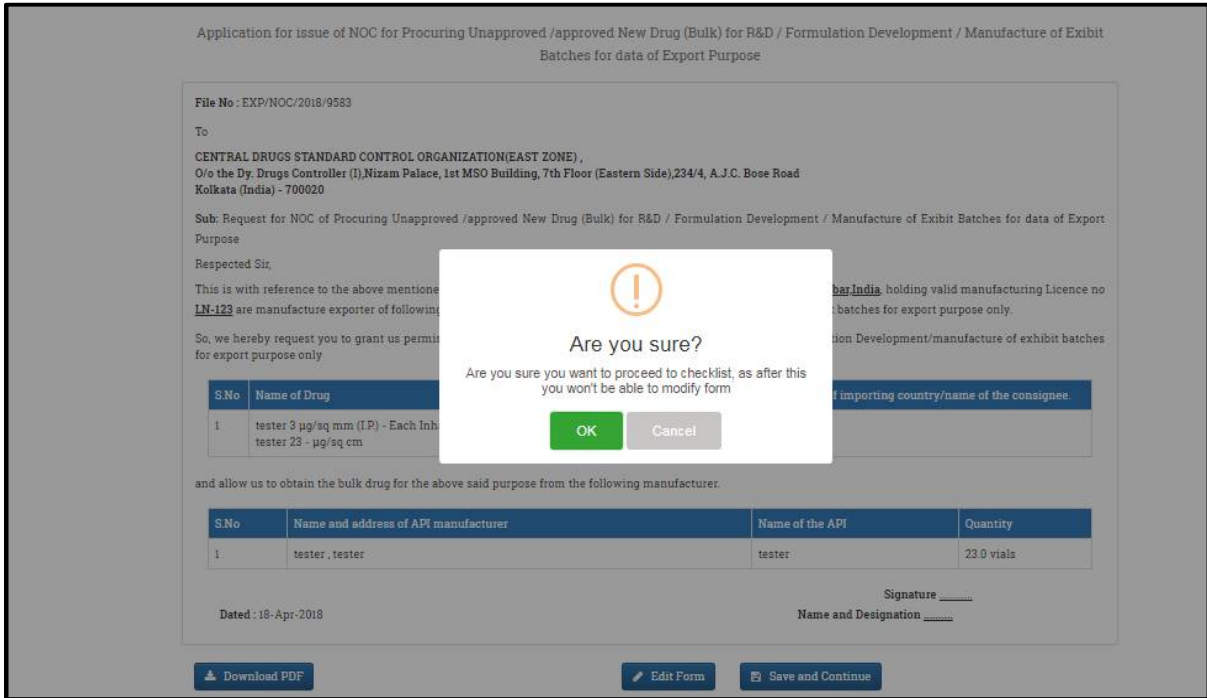


Figure 167 : Confirmation Message – Proceed to checklist

- After clicking on “OK”, a checklist window will open on the screen, as shown in below **Figure**
- Before preceding you must read the “**Note**”, as shown in **Figure**.

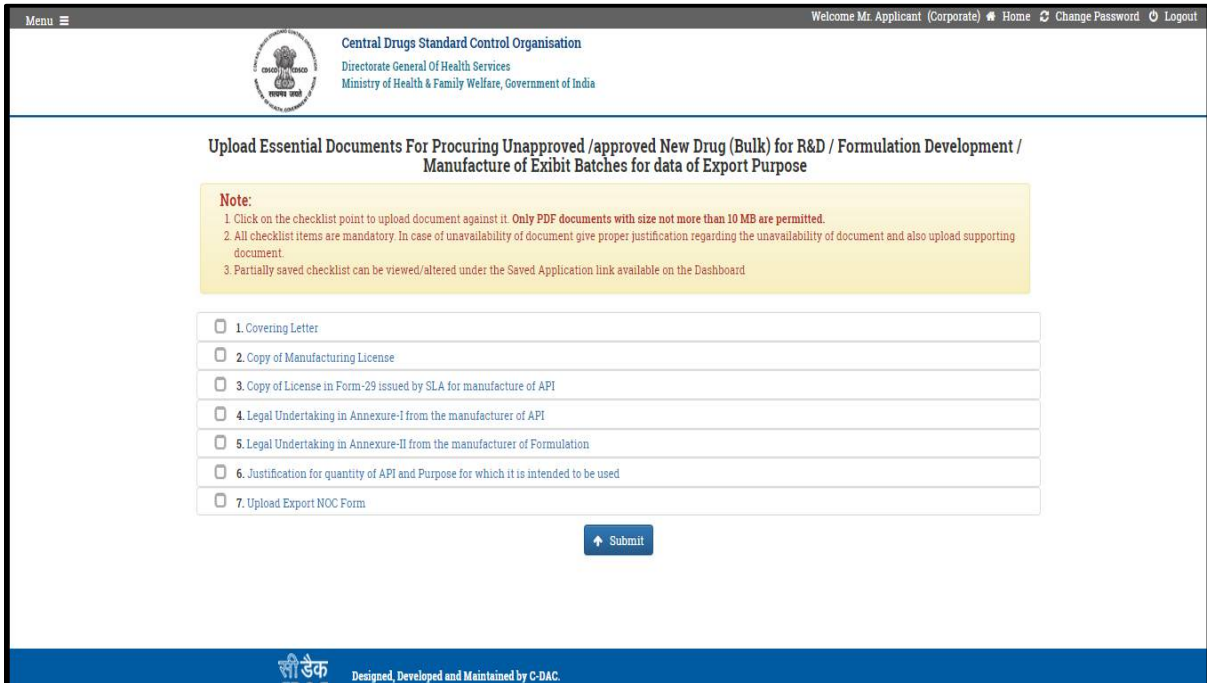
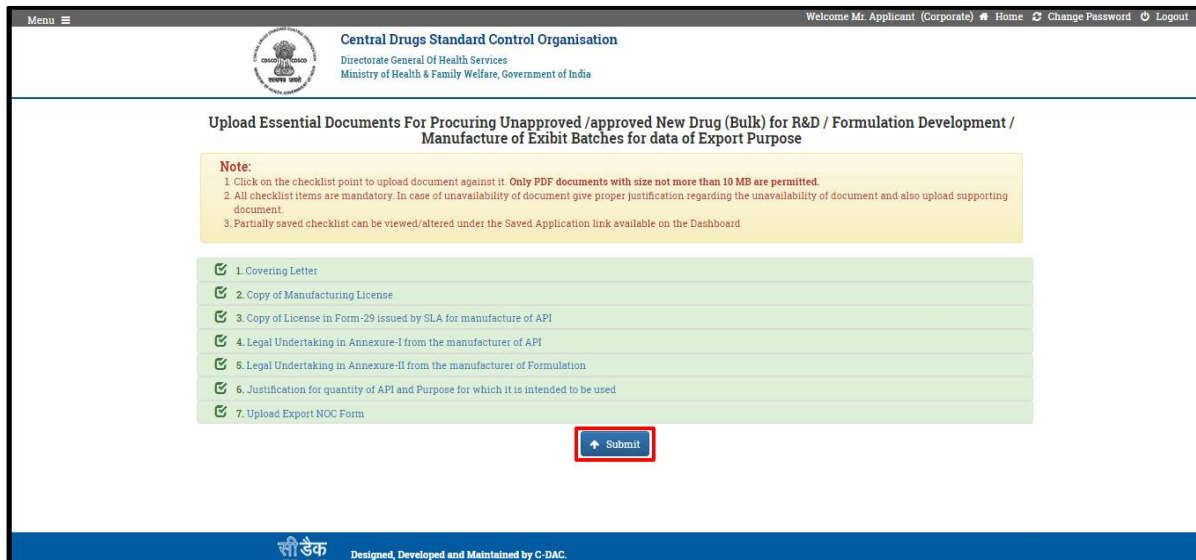


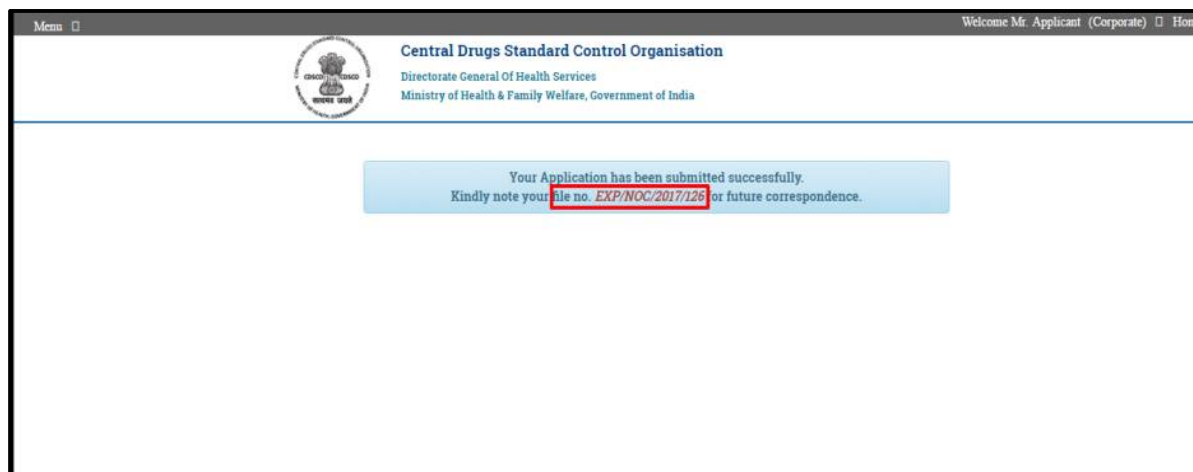
Figure 168 : Before proceeding read the “Note”,

- Click on the checklist point to upload document against it. PDF document size should not more than 100MB.
- All checklist items are mandatory.
- Partially saved checklist can be viewed /altered under the Saved Application link available on the Dashboard.
- After completion of all the documents in checklist the window will appear in green, as shown **Figure**
- Now click on **“Save”** button to further proceed, as show in **Figure**.



**Figure 169 : “Save” button to further proceed**

- After uploading all the documents a new window will appear with the text “Application has been submitted successfully.” As shown in **Figure**.



**Figure 170 : Message Shown -- Application has been submitted successfully**



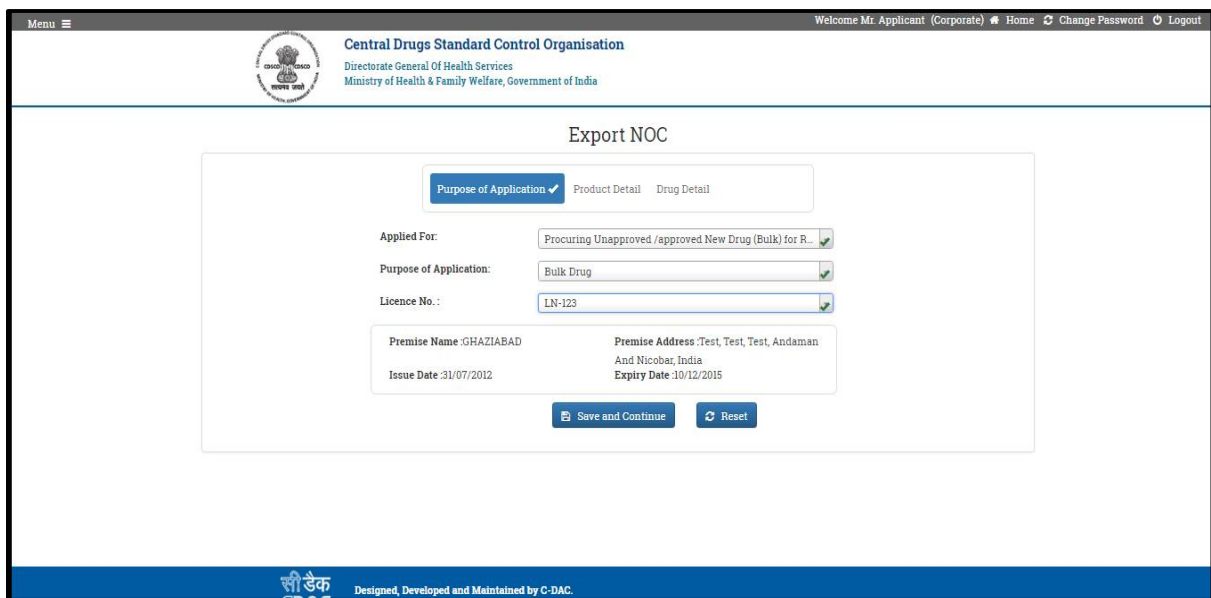
**NOTE:** Future correspondence is on the basis of our generated **File No.**

**Elaboration of File No. generated through system, as below –**

- NOC – meant for - This File Number generated for ‘No Objection Certificate’
- 2017 – Meant for the current year.
- 126 - Stands for serial number generated through system.

### 7.4 Bulk Drug

- When user selects “**Procuring Unapproved /approved New Drug (Bulk) for R&D / Formulation Development / Manufacture of Exhibit Batches for data of Export Purpose**” and “**Bulk Drug**” as the purpose of application then directly click on Save and Continue button to move forward, as shown in **Figure**.



**Figure 171 : Bulk Drug**

- After filling the Purpose of Application the form will go to next step i.e. Drug Detail, as shown in **Figure**.
- Here the user will fill all the required details and click on “Save” button after the completion of the form.

Figure 172 : after the completion of Form Click on Save button

**NOTE:**

- Further steps are same as mentioned above.



### 7.5 Manufacture for Export Purposes

- When user apply for “Manufacture for Export Purpose” in Purpose of Application as “Bulk Drug” or “Finished Formulation” then form looks like as shown in **Figure**.
- After completing form click on “Save and Continue” to go to next step.

Figure 173 : Manufacture for Export Purposes

- In Purchase Order Detail Form, purchase can be issued either by “**Trader**” or “**Buyer**”, as shown in **Figure**.
- If user selects “**Trader**”, then he has to fill the details of Buyer and Trader respectively.
- Else, if user selects “**Buyer**” then, he has to only fill Buyer Details.

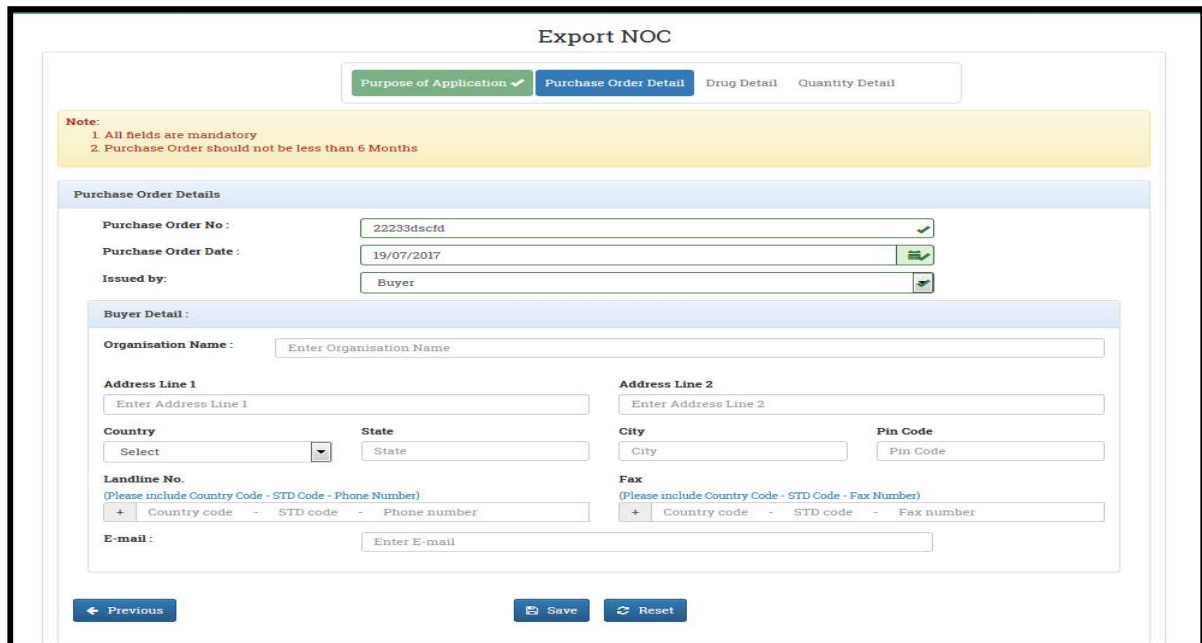


Figure 174 : Fill Buyer and Trader Details

- In next form user will fill the drug details as shown in **Figure**.

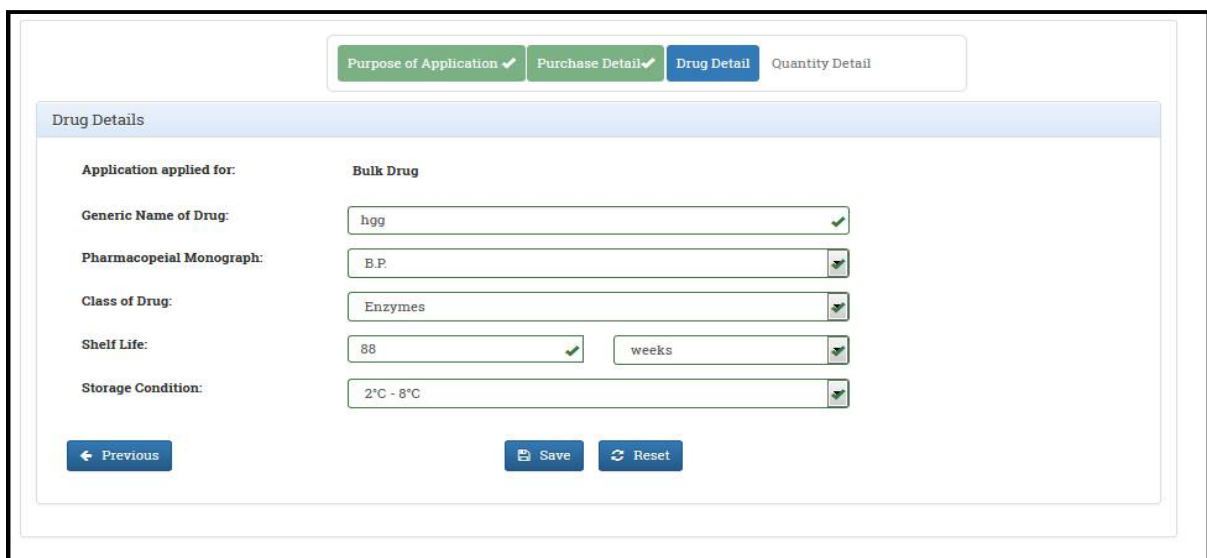
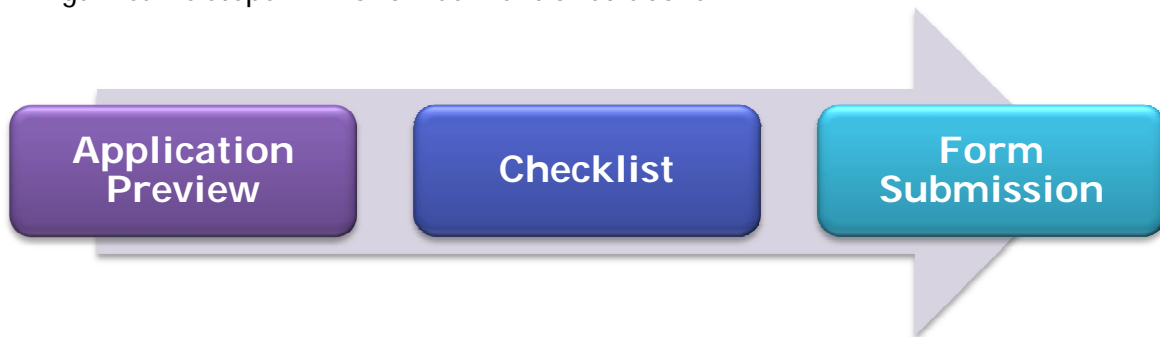


Figure 175 : User will fill the drug details

- After filling the Drug Detail the user will move to next step i.e. to Quantity Detail, as shown in **Figure**.

Figure 176 : Quantity Detail

- Again same steps will follow as mentioned above.

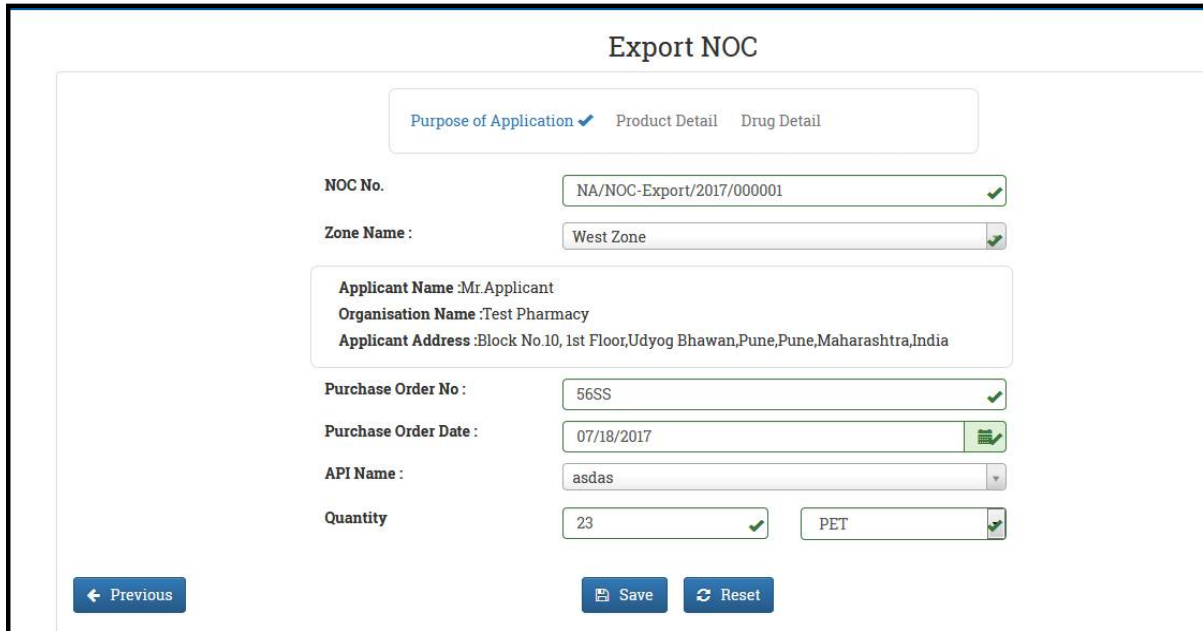


## 7.6 Material Transfer (API Manufacture)

- When user applies for Material Transfer then, in the Purpose of Application he can apply only for "Bulk Drug", as shown in **Figure**.
- After completing the form click on "Save and Continue" so as to go to next step.

Figure 177 : Material Transfer (API Manufacture)

- In this section user will fill the “NOC No.” and “Zones Name” as shown in **Figure**.
- User can add multiple zone names as per his requirement.



**Figure 178 : Fill the “NOC No.” and “Zones Name”**

- After this same steps as above mentioned will be repeated.





# Chapter- 8

## Serious Adverse Events Reporting



## 8. Serious Adverse Event Reporting

A Serious Adverse Event (SAE) is defined as any adverse drug event (experience) occurring at any dose that in the opinion of either the investigator or sponsor results in any of the following outcomes:

- Death
- Life-threatening adverse drug experience
- Inpatient hospitalization or prolongation of existing hospitalization (for > 24 hours)
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- Congenital anomaly/birth defect
- Important Medical Event (IME) that may not result in death, be life threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon medical judgment, it may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

It is important to remember that all SAEs are adverse events, but not all adverse events are SAEs

A “Life Threatening Adverse Drug Experience” defined as

Any adverse experience that places the subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred, or it is suspected that the use or continued use of the product would result in the patient’s death.

“Congenital Anomaly” defined as

Exposure to a medical product prior to conception or during pregnancy resulting in an adverse outcome in the child.

### ➤ **General SAE Reporting Policy**

A Serious Adverse Event report must be submitted on any event which meets the reporting criteria specified in the relevant protocol. These criteria vary depending on factors such as whether an investigational new drug (IND) has been given, the grade of the adverse event, whether or not the event resulted in hospitalization/prolongation of hospitalization, whether the event is expected or unexpected, and/or the attribution of the event to protocol treatment.

### ➤ **Timeframe for initial SAE reports submission**

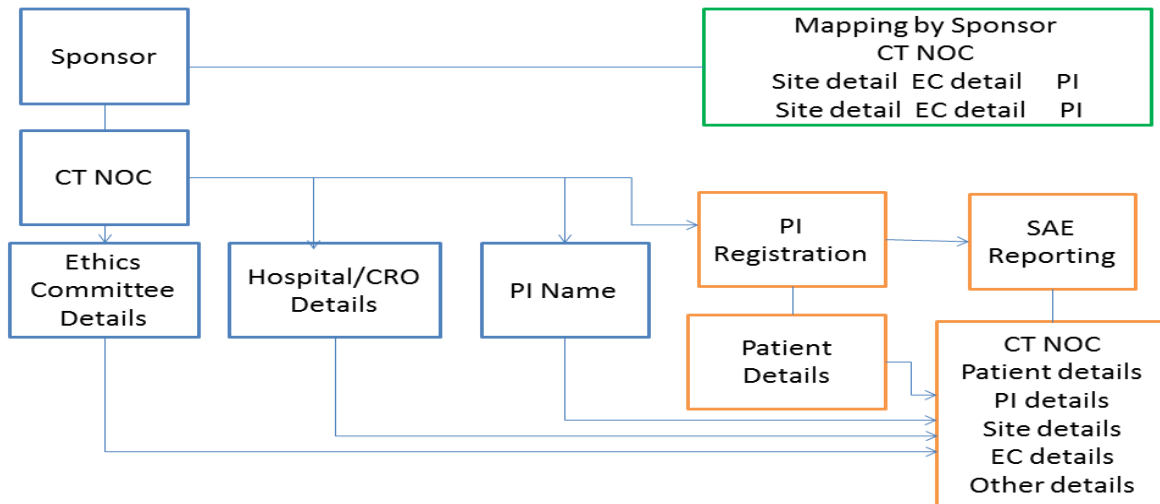
SAEs have to be reported immediately within 24 hours of the Site Principal Investigator (PI) becoming aware of the event. PI has to send initial and follow up SAEs reports to the Trial Sponsor and Site Ethics Committees (EC) within 14 days of SAE reporting. After receipt of 14<sup>th</sup> day SAEs reports from investigator, the EC have to send the 30<sup>th</sup> day SAEs reports to the Trial Sponsor.

➤ **Recipients of SAEs reports**

Site Principal Investigators (PI), who confirmed that SAEs occurred in their trial, are required to report the SAEs to CDSCO and also to their Trial Sponsor and Ethics Committees. There are chains of communication that are specific to each trial but, since not all investigators are required to send SAEs reports to their Trial Sponsor. After receipt of SAEs reports, the Sponsor must notify CDSCO and all other participating Ethics Committees and Site Investigators (i.e., all investigators to whom the sponsor is providing drug) of potential serious risks, from clinical trials or any other source, as soon as possible. Timely reporting of Serious Adverse Events (SAEs) should be tightly monitored by CDSCO. Such reporting is not merely a legal requirement, but a necessity for safe patient care.

**8.1 Workflow for Online SAE Reporting**

**CT SAE Reporting/Monitoring**



**Figure 179 : Workflow for SAE Reporting**

- For any clinical trial, Sponsor is responsible person and has all the information. After receiving the CT-NOC from CDSCO and trial registration in the Clinical Trials Registry-India (CTRI), it is the responsibility of the Sponsor to start and monitor the clinical trial in all the participating sites.
- Before reporting of Serious Adverse Events there are some mandatory steps to be followed to build-up the database and for proper linking of data.
  - Add Site Investigator
  - Site Investigator Mapping
  - Initiate Clinical Trial
  - SAE Reported

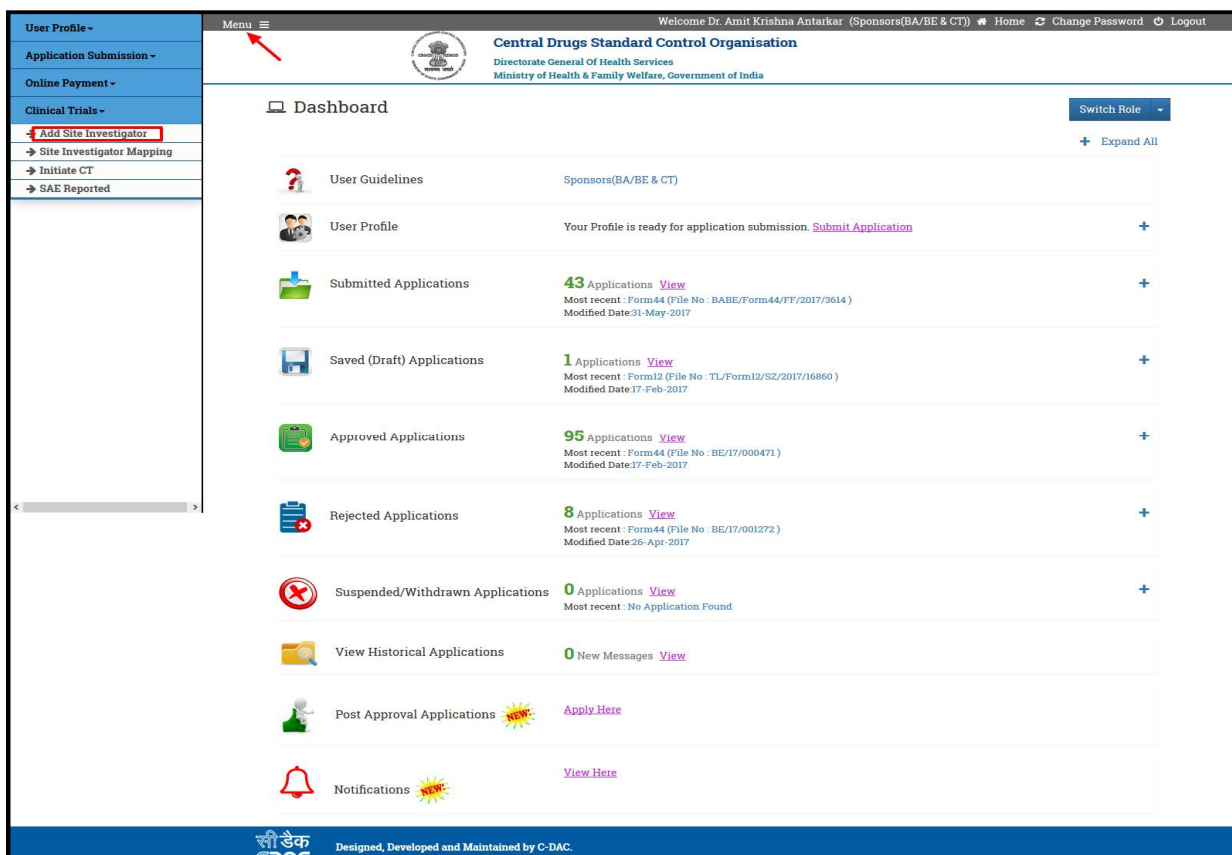


To accomplish above steps the Sponsor may login into the SUGAM portal and then click on CLINICAL TRIALS tab under MENU from his dashboard.

➤ **Step 1: Add Site Principal Investigator**


As the Sponsor/Applicant, when receives CT NOC, it only contains details of trail sites (i.e. Hospital), Ethics committee and PI name (but not PI details and each PI has to register themselves in the portal to report SAE).

After login into the portal click on "Add Site Investigator" tab under "Clinical Trials" in Menu as shown in below figure.



**Figure 180 : Add Site Principal Investigator**

After that a new window will open as shown in below figure. Applicant has to enter the Investigator's basic details and click on "Submit" button. He must add all the investigators mentioned in the CT-NOC for which trial is going to start.



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

## Site Investigator Registration

**User-Name:\***  ✓

**Name:\***   ✓  ✓  ✓

**Mobile Number:\***  ✓

**Gender:\***  Male  Female  Transgender

**Nationality:\***  ✓

**ID Proof Details:\***  ✓ [Download\(hrAADHAR RC.pdf\)](#)  
(Single PDF < 10 MB) [Remove](#)

**Aadhar Card Number:\***

**MCI Registration Number:\***  ✓

**Upload Resume / CV:\*** [Download\(Office Timing Circular.pdf\)](#)  
[Remove](#)

**Email Id(Other then user name):\***  ✓

[↑ Submit](#)

**Site Investigator Details**

**Search:**

User Name ⇅	Investigator Name ⇅	MCI Registration Number ⇅	Added by Sponsor ⇅	Delete ⇅
+ abc@mail.in	Mr. Aa Bb Cc	6789	Ms. Laxmi Sharma	<input type="button" value="🗑"/>
+ test@gmail.com	Mr. Aaa Klkk	23333434sdd	Ms. Nipa Raju Doshi	<input type="button" value="🗑"/>
+ Test@yopmail.com	Mr. Aaaaa Maurya	frgrt	Mr. Parveen Jain	<input type="button" value="🗑"/>
+ MUNEESHGARG@mail.in	Dr. MUNEESH Kr Garg	10021	Ms. Laxmi Sharma	<input type="button" value="🗑"/>
+ neetu.pi@yopmail.com	Ms. Neetu Sss Maurya	100321	Mr. Parveen Jain	<input type="button" value="🗑"/>
+ SITEINVESTIGATOR@CDSCO.IN	Mr. Principal Investigator	1470	Mr. Parveen Jain	<input type="button" value="🗑"/>

**Figure 181 : Screen of Site Investigator Registration**

- On clicking Submit button, an e-mail link will be send to Investigator for conforming and creating his login credentials. Once the investigator clicks the e-mail link a window will open as shown in below figure.

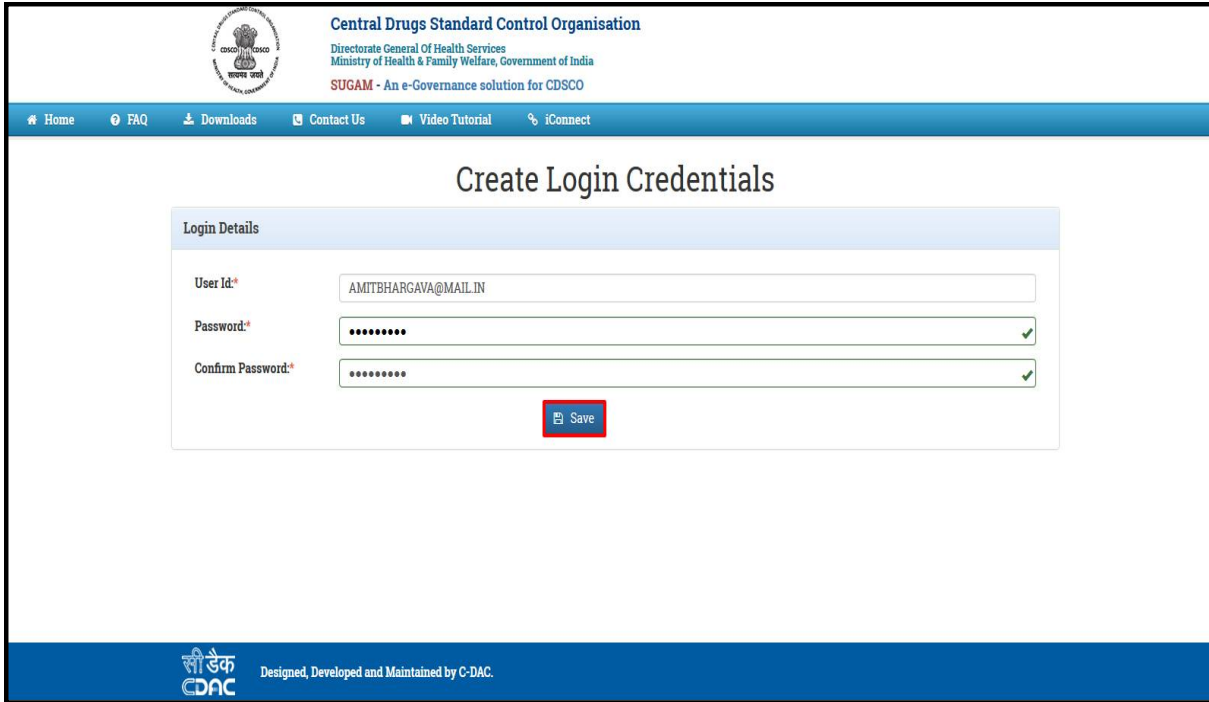


Figure 182 : Screen of Create Login Credential

- The User Id is auto fetched (i.e. same as entered by applicant/sponsor), investigator needs to enter only Password and Confirm Password. After clicking on “Save” button a message will pop-up as shown in below figure.

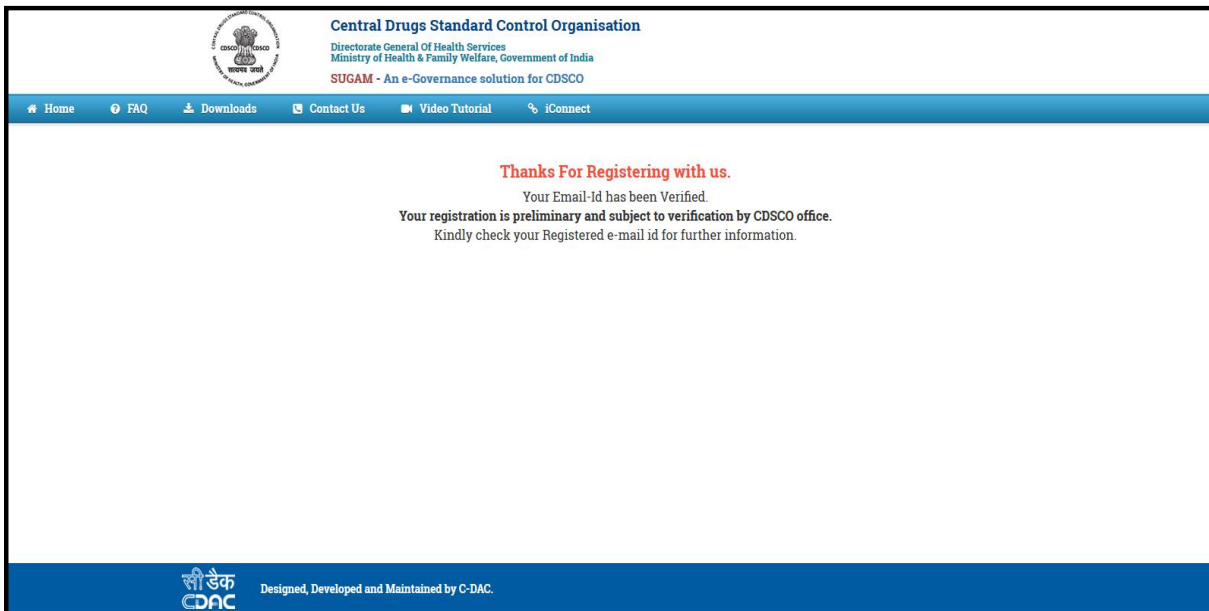


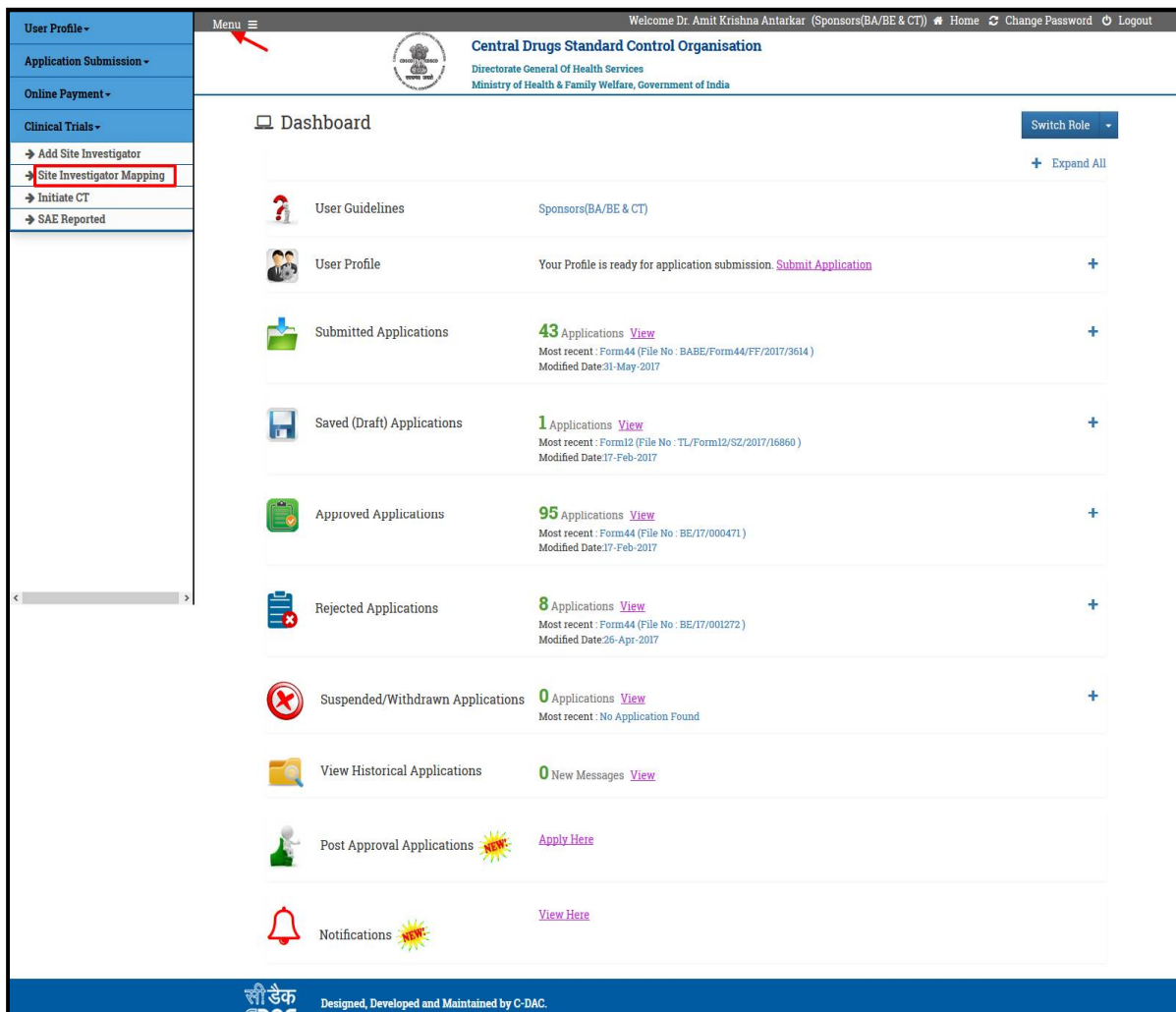
Figure 183 : Popup Message -- Thank you for Registering with us

- Once the login credentials of Investigators are created meanwhile they must login into the SUGAM portal, complete their user profile and send request for Approval of User Profile.

➤ **Step 2: Site Investigator Mapping**


After approval of Investigator’s User Profile, Applicant/Sponsor will map them with the trial Site/Hospital from his dashboard.

Click on “*Site Investigator Mapping*” tab under “*Clinical Trials*” in Menu as shown in below figure.



**Figure 184 : Site Investigator Mapping**

- After that a new window will open as shown in below figure. Applicant/Sponsor has to select the BE/CT application, a list of sites mentioned in the CT-NOC will get displayed just select the site investigator from drop down and check the checkbox (as highlighted) and click on “*Save*” button.



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

### Application Investigator Mapping Form

**NOTE :**

- If you are **unable to find Site Investigator name in dropdown list** then inform the respective PI to kindly register on SUGAM portal <https://cdscoonline.gov.in/CDSCO/homepage>
- After saving the data, kindly inform the respective PIs to login on SUGAM portal and enter the data of patients enrolled for Clinical Trial.

\* All fields are mandatory

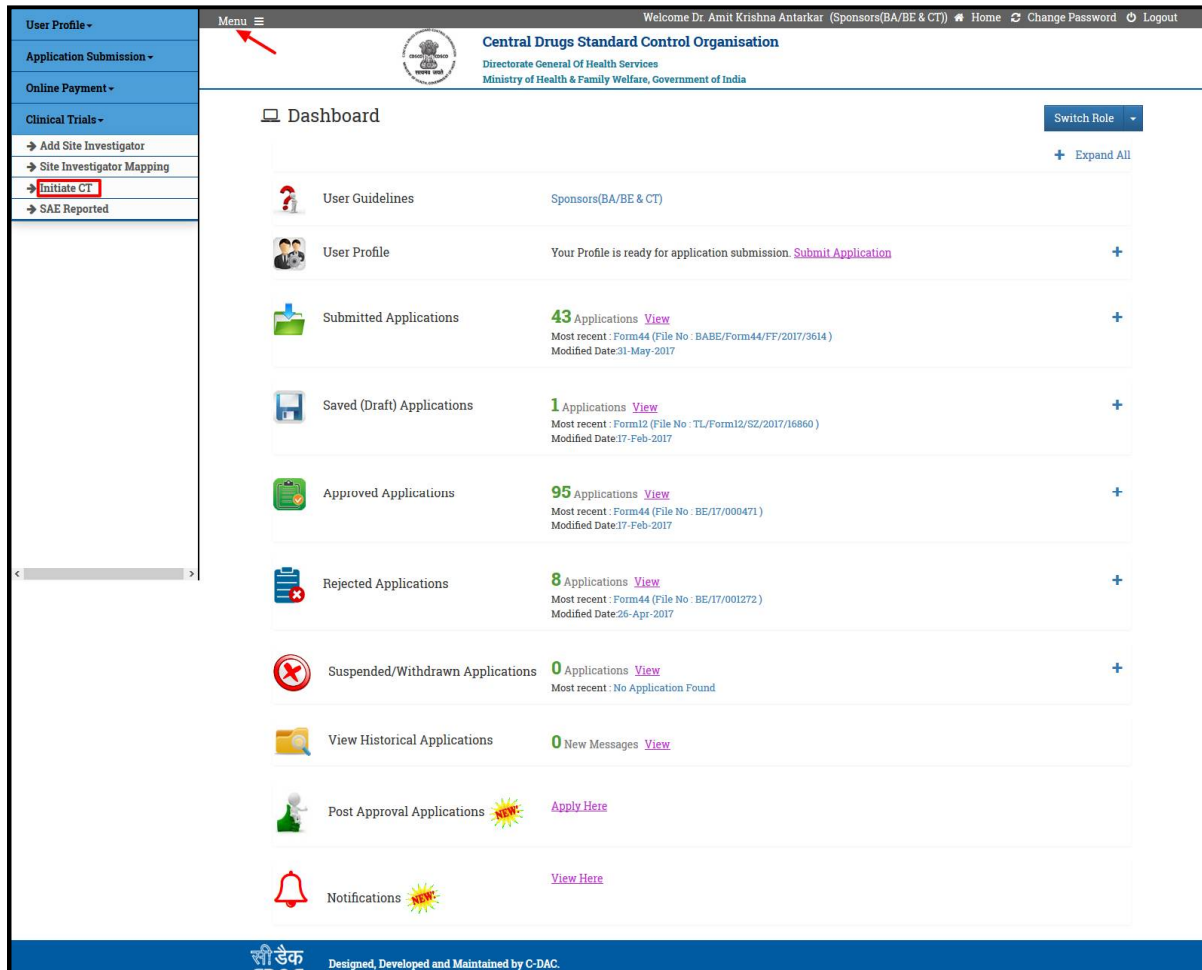
Select BE / CT Application: \*

**CT Site Mapping Details**

☐	Site	Proposed Site Investigator	Select Site Investigator
<input checked="" type="checkbox"/>	+ All India Institute of Medical Sciences Ethics Committee, All India Institute of Medical Sciences, Room No. 102, 1st Floor, Old O.T. Block, Ansari Nagar, , New Delhi, Not Available, Delhi	Name: Dr Shalimar	<input type="text" value="TEST@YOPMAIL.COM"/>
<input checked="" type="checkbox"/>	+ Government Medical College Dept of Pharmacology , Govt Medical College, Nagpur, Not Available, Maharashtra	Name: Dr Sudhir Gupta	<input type="text" value="SITEINVESTIGATOR@CDSCO.IN"/>
<input checked="" type="checkbox"/>	+ S.M.S. Medical College and Attached Hospitals, Jaipur First Floor, Dhanvantri OPD Block, S.M.S. Hospital, J.L.N. Marg, Jaipur, Not Available, Rajasthan	Name: Dr Sandeep Nijhawan	<input type="text" value="Select"/>
<input type="checkbox"/>	+ SR Kalla Memorial Gastro and General Hospital 78, Dhuleshwar Garden, Behind HSBC Bank, sardar Patel Marg C-Scheme, Jaipur, Not Available, Rajasthan	Name: Dr Ramesh Roop Rai	<input type="text" value="AMITBHARGAVA@MAIL.IN"/> <input type="text" value="MUNEESHGARG@MAIL.IN"/>
<input type="checkbox"/>	+ Global Hospital Ethics Committee, Global Hospital situated at Room No.: 214, Global Hospital, Dr. E Borges Road, Hospital Avenue, Opp. Shirodakar High School, Parel, , Mumbai, Not Available, Maharashtra	Name: Dr Samir Shah	<input type="text" value="NEETU.PI@YOPMAIL.COM"/> <input type="text" value="SITEINVESTIGATOR@CDSCO.IN"/> <input type="text" value="TEST@YOPMAIL.COM"/>
<input type="checkbox"/>	+ Institutional Ethics committee Global Hospitals B-1-1070/1 TO 4, LAKDIKAPUL , Hyderabad, Not Available, Telangana	Name: Dr Dharmesh Kapoor	<input type="text" value="Select"/>
<input type="checkbox"/>	+ VGM Hospital institutional ethics committee VGM Hospital No-2100, Trichy Road , Coimbatore, Not Available, Tamil Nadu	Name: Dr V G Mohan Prasad	<input type="text" value="Select"/>
<input type="checkbox"/>	+ Deccan college of medical sciences and allied Hospitals P.O., Kanchanbagh, DMRL 'X' Road, Santosh Nagar, , Hyderabad, Not Available, Telangana	Name: Dr Mohd Aejaz Habeeb	<input type="text" value="Select"/>
<input type="checkbox"/>	+ Ethics Committee Midas Multispeciality Hospital Ethics Committee Midas Multispeciality Hospital Pvt.Ltd situated at Midas Maharashtra, Nagpur, Not Available, Maharashtra	Name: Dr Shrikant Mukewar	<input type="text" value="Select"/>
<input type="checkbox"/>	+ Sir Ganga Ram Hospital Ethics Committee Room No 1496. IV Floor , Old Building , Old Rajinder Nagar, New Delhi, Not Available, Delhi	Name: Dr Anil Arora	<input type="text" value="Select"/>

Figure 185 : Application Investigator Mapping Form

- **Step 3: Initiate Clinical Trial:** Once the Site Investigator mapping is done for any BE /CT application the applicant/sponsor can initiate the trial.
- Click on “*Initiate CT*” tab under “*Clinical Trials*” in Menu as shown in below figure.



**Figure 186 : Initiate Clinical Trial**

- After that a new window will open as shown in below figure. Applicant/Sponsor has to select the BE/CT application enter the CTRI Registration No. and click on “*Save*” button.

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

### To Initiate Clinical Trial

*\* All fields are mandatory*

Select BE / CT Application: \*

CRTI Registration No: \*

[Save](#)

Details:

Search:

Sr.No. ↕	CRTI No. ↕	CDSCO File No. ↕
1	CRTI/2017/123	CT/17/000013

Figure 187 : To Initiate Clinical Trial

➤ **Step 4: SAE Reported**

After the initiation of the clinical trial SAE occurring at any trial site can be reported either by investigator or sponsor or ethics committee involved in that particular clinical trial.

An applicant/sponsor can view the list of all reported SAEs for that just Click on "SAE Reported" tab under "Clinical Trials" in Menu as shown in below figure.

User Profile -

Application Submission -

Online Payment -

Clinical Trials -

- ➔ Add Site Investigator
- ➔ Site Investigator Mapping
- ➔ Initiate CT
- ➔ **SAE Reported**

Welcome Dr. Amit Krishna Antarkar (Sponsors(BA/BE & CT)) | Home | Change Password | Logout

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

Dashboard Switch Role

Menu
Expand All

- User Guidelines Sponsors(BA/BE & CT)
- User Profile Your Profile is ready for application submission. [Submit Application](#)
- Submitted Applications 43 Applications [View](#)

Most recent : Form44 (File No : BAE/Form44/FF/2017/3614)  
Modified Date:31-May-2017
- Saved (Draft) Applications 1 Applications [View](#)

Most recent : Form12 (File No : TL/Form12/SZ/2017/16860)  
Modified Date:17-Feb-2017
- Approved Applications 95 Applications [View](#)

Most recent : Form44 (File No : BE/17/000471)  
Modified Date:17-Feb-2017
- Rejected Applications 8 Applications [View](#)

Most recent : Form44 (File No : BE/17/001272)  
Modified Date:26-Apr-2017
- Suspended/Withdrawn Applications 0 Applications [View](#)

Most recent : No Application Found
- View Historical Applications 0 New Messages [View](#)
- Post Approval Applications [Apply Here](#)
- Notifications [View Here](#)




Figure 188 : SAE Reported

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- After that a new window will open as shown in below figure. Applicant/Sponsor can view or report SAEs by clicking on options available under actions button (as highlighted).

**List of Severe Adverse Effects Reported by Site Investigator**

Search:

BE or CT NOC No. ▾	CTRI Registration No. ▾	SAE Terminology ▾	SAE Type ▾	Sponsor's created Subject Id ▾	Status ▾	Action ▾
+ BE/16/000194	CTRI/2016/11/94	Fasting	Non-Death	ALK/20017/583	14th Day SAE Report Submitted	
+ BE/16/000194	CTRI/2016/11/94	terminology	Non-Death	2016/54/145	24 Hour SAE Report Submitted	
+ CT/2017/000013	CTRI/2017/11/91	sea seeefge	Death	2016/54/145	24 Hour SAE Report Submitted	

14th day Due Analysis Reporting

View SAE Report(24 Hour) Preview

**Figure 189 : List of Severe Adverse Effects Reported by site Investigator**

## 8.2 Online forms of SAE Reporting

To report serious adverse events (SAE) there are three types of forms.

- SAE Reporting (24 hour Report)
- SAE Reporting (14<sup>th</sup> Day Due Analysis Report)
- SAE Reporting (30<sup>th</sup> Day Report)

While SAE reporting all the data (Sponsor/CRO details, Ethics committee details, Hospital/Site details, PI details) will be fetched automatically based on BE/CT NOC number and rest details will be entered depending on the form.

- **SAE Reporting (24 Hours)** : Investigator will fill the *SAE Reporting* form with the following details:
  - **Administrative Information**
    - SAE report of Death or non-death(**to be filled**)
    - Sponsor/CRO details (Auto fetch from CT NOC)
    - Clinical Site details(Auto fetch from CT NOC)
    - Investigators details (from PI registration)
    - Ethics Committee details(Auto fetch from CT NOC)
  - **Clinical Study/BE Study details**
    - Study title & Protocol No.(Auto fetch from CT NOC)



- **Patient/Subject details**
  - Unique Identifier (Initials/Subject No) **(to be filled)**
  - Gender **(to be filled)**
  - Date of birth and age at the time of SAE **(to be filled)**
  - Weight & Height **(to be filled)**
  
- **SAE(s) Details**
  - SAE(s) Term **(to be filled)**
  - Start date of SAE **(to be filled)**
  - Stop date of SAE **(to be filled)**
  - Appendix XI **(Upload)**

**SAE Reporting**  
(24 Hour)  
(To be Filled and Signed by Investigator & Sponsors/CROs)

**Patient/Subject Details**

Select Patient	<input type="text" value="ALK/20017/582"/>		
Unique Identifier (Initials/Subject No.)	VB/ALK/20017/582	Gender	Male
		Date of Birth	02-Aug-2003
Weight(in Kg):	45.65	Height(in cms):	152.6

**Administrative Information**

**Sponsor/CRO Details**

Name: M/s. Cipla Limited

Address: Cipla Ltd, Cipla House, Peninsula Business Park Ganpatrao Kadam Marg, Lower Parel, Mumbai Lower Parel Maharashtra (India) - 400013

Mobile No. : 022-24826000, 011-43563648, 011-43563647

Landline No. :

Email ID. : LAXMI.SHARMA@CIPLA.COM

**Clinical Site Details**

Name: M/s. Sitec Labs Pvt. Ltd

Address: M/s. Sitec Labs Pvt. Ltd, Pee-Dee Info Tech, Plot No. Gen.40, TTC, MIDC, Behind Millenium Business Park, Near Nelco Bus Stop, Mahape, Mumbai City, Maharashtra- 400710

Contact No. :

Email ID. :

**Investigator Details**

Name : Dr. MUNEEESH Kr Garg

Site Address:

Email ID. : muneesh@mail.in

Figure 190 : SAE (s) Reporting

### Ethics Committee Details

Name of the Ethics Committee:	Ethos Ethics Committee
EC Registration No. provided by CDSCO:	ECR/139/Indt/MH/2013
Address:	Ethos Ethics Committee ,2, Ashiv Apartment, Sector-5, Opp.Kopar, Khairne Rly Stn Kopar Khairne, Navi Mumbai (India) - 400709
Contact No. :	
Email ID. :	

### Clinical Study/BE Study Details

Study Title:	A randomized, open label, 3-treatment, 4-period, 4-sequence, single dose, crossover, partial replicate, bioequivalence study between the two test products Ibrutinib 140 mg capsule (Cipla Ltd., India) and the reference product, Imbruvica (Ibrutinib) 140 mg capsule (Janssen Biotech, Inc., USA) in healthy adult human subjects under fasting conditions.
Protocol No.:	16-08-156

### Clinical Study/BE Study Details

Study Title:	A randomized, open label, 3-treatment, 4-period, 4-sequence, single dose, crossover, partial replicate, bioequivalence study between the two test products Ibrutinib 140 mg capsule (Cipla Ltd., India) and the reference product, Imbruvica (Ibrutinib) 140 mg capsule (Janssen Biotech, Inc., USA) in healthy adult human subjects under fed conditions.
Protocol No.:	16-08-157

### SAE(s) Details

SAE report of Death or other than Death  Death  Non Death

SAE(s) Terminology

Start Date of SAE(s)   Stop Date of SAE(s)

Appendix XI (24 hr. Report submitted) [Download](#)  
 Please Tick To Change File  
(Single Pdf File < 10 MB)

Brief description of the SAE including medical management given an outcome

Figure 191 : SAE (s) Reporting (Continue)

➤ **SAE Reporting (14<sup>th</sup> Day Due Analysis Report)**

After 24 hour SAE reporting is submitted, investigator may proceed to fill the Due Analysis Report. This form is divided into several parts. After filling Part 1, the data in rest form parts may be filled at the convenience of the investigator. A report may be submitted only after all the parts of the form are completed. Before clicking the SUBMIT button Investigator may check the filled data from preview page.

Investigator will fill the *SAE Reporting* form with the following details:

➤ **Administrative Information**

- SAE report of Death or other than death **(to be filled)**
- Type of Report **(to be filled)**
- Sponsor/CRO details (Auto fetch from CT NOC)
- Clinical Site details (Auto fetch from CT NOC)
- Investigators details (Auto fetch from PI registration)
- Ethics Committee details (Auto fetch from CT NOC)

➤ **Clinical Study/BE Study details**

- Study title & Protocol No. (Auto fetch from CT NOC)

➤ **Patient/Subject details**

- Unique Identifier (Initials/Subject No) (Auto fetch from 24 hour report)
- Gender (Auto fetch from 24 hour report)
- Date of birth and age at the time of SAE (Auto fetch from 24 hour report)
- Weight & Height (Auto fetch from 24 hour report)
- Previous disease/medical history **(to be filled)**

➤ **SAE(s) Details**

- SAE(s) Term (Auto fetch from 24 hour report)
- SAE Management Setting **(to be filled)**
- Start date of SAE (Auto fetch from 24 hour report)
- Stop date of SAE (Auto fetch from 24 hour report)
- Re challenge/De challenge Details **(to be filled)**

- Investigational/Suspected drug(s)/Device Details (to be filled)
- Any concomitant Drug(s) taken by the subject/patient. (Exclude those used for treating SAE) (to be filled)
- SAE Management (to be filled)
- Baseline Lab Investigation Details (At the time of screening) (to be filled)
- Details of Lab Investigation done (On and before Onset of SAE) (to be filled)
- SAE case narrative and Due analysis/Causality of the SAE (to be filled)

### Due Analysis Report

**Note:**

1. All forms are mandatory to fill.
2. Below forms should be filled sequentially.

Click the below links to fill the details

- Steps to fill SAE Reporting Form
  1. Administrative Information
  2. Patient/subject Details
  3. SAE(s) Details.
  4. Investigational/Suspected drug(s)/Device Details
  5. Any concomitant Drug(s) taken by the subject/patient.(Exclude those used for treating SAE)
  6. SAE Management
  7. Baseline Lab Investigation Details (At the time of screening)
  8. Details of Lab Investigation done (On and before Onset of SAE)
  9. SAE case narrative and Due analysis/Causality of the SAE
- SAE Reporting 14th Day Form Preview

Figure 192 : Due Analysis Report

### Due Analysis Report

(To be filled by Investigators/Sponsors/CROs)  
(14th day report, Initial and Subsequent Follow-Up)

<b>Administrative Information</b>	
SAE report of Death or other than Death *	<input type="radio"/> Death <input checked="" type="radio"/> Non Death
Type of Report *	Follow up No. <input type="text" value="3"/>
CT/BE Permission No. (Copy to be attached)	BE/16/000194 <b>dated</b>
CTRI Registration No.	CTRI/2016/11/94
<b>Sponsor/CRO Details</b>	
Name:	M/s. Cipla Limited
Address:	Cipla Ltd, Cipla House, Peninsula Business Park Ganpatrao Kadam Marg, Lower Parel, Mumbai Lower Parel Maharashtra (India) - 400013
Mobile No. :	022-24826000, 011-43563648, 011-43563647
Landline No. :	-----
<b>Clinical Site Details</b>	
Name:	M/s. Sitec Labs Pvt. Ltd
Address:	M/s. Sitec Labs Pvt. Ltd, Pee-Dee Info Tech, Plot No. Gen.40, TTC, MIDC, Behind Millenium Business Park, Near Nelco Bus Stop, Mahape, Mumbai City, Maharashtra- 400710
Contact No. :	
Email ID :	
<b>Investigator Details</b>	
Name :	Dr. MUNEEESH Kr Garg
Site Address:	
Email ID :	muneesh@mail.in
<b>Ethics Committee Details</b>	
Name of the Ethics Committee:	Ethos Ethics Committee
EC Registration No. provided by CDSCO:	ECR/139/Indt/MH/2013
Contact No. :	
Email ID :	
<b>Clinical Study/BE Study Details</b>	
Study Title:	A randomized, open label, 3-treatment, 4-period, 4-sequence, single dose, crossover, partial replicate, bioequivalence study between the two test products Ibrutinib 140 mg capsule (Cipla Ltd., India) and the reference product, Imbruvica (Ibrutinib) 140 mg capsule (Janssen Biotech, Inc., USA) in healthy adult human subjects under fasting conditions.
Protocol No.:	16-08-156
<b>Clinical Study/BE Study Details</b>	
Study Title:	A randomized, open label, 3-treatment, 4-period, 4-sequence, single dose, crossover, partial replicate, bioequivalence study between the two test products Ibrutinib 140 mg capsule (Cipla Ltd., India) and the reference product, Imbruvica (Ibrutinib) 140 mg capsule (Janssen Biotech, Inc., USA) in healthy adult human subjects under fed conditions.
Protocol No.:	16-08-157
Study Status *	<input type="radio"/> Ongoing <input checked="" type="radio"/> Completed
Is subject/patient Continued or Withdrawn from the Study *	<input type="radio"/> Continued <input checked="" type="radio"/> Withdrawn
<input type="button" value="Previous"/> <input type="button" value="Save"/> <input type="button" value="Reset"/>	

Figure 193 : Due Analysis Report (Continue)

### Due Analysis Report

(To be filled by Investigators/Sponsors/CROs)  
(14th day report, Initial and Subsequent Follow-Up)

**Patient/Subject Details**

**Patient Unique Identifier (Initials/ Subject No.)** EE/2016/54/145  
**Gender** Male      **Date of Birth**      **Age at the time of SAE** in Yrs  
**Weight (in Kg)** 69.04      **Height (in cms)** 168.0

**Disease Condition/Diagnosis**       **Since (Year)(YYYY)**       **Duration (Years/Months)**

← Previous
+ Save
↻ Reset

Relevant previous Disease/Medical History

↕	Disease Condition/Diagnosis ↕	Since (Year) ↕	Duration (Years/Months) ↕	Delete ↕
+				-

Figure 194 : Due Analysis Report (Continue)

### SAE Details

**Fill SAE Details**

**SAE(s) Term(s) \***

**SAE Management Setting:**       **Date of Awareness of SAE by the Site Personnel(s):**

**Start Date of SAE(s):** 06/12/2017      **Stop Date of SAE(s):** 06/30/2017

**4.6. Re challenge/De challenge Details**

**(a) Did Reaction abate after discontinuation or dose reduction?**       **(b) Did reaction re-appear after re-introduction of the drug?**

**4.7. How was drug regimen altered in response to the event?**

**4.8. Outcome of the Event at the time of the Report dated**       **Please Select**

← Previous
+ Save
↻ Reset

Figure 195 : Screen of SAE Details

### Investigational/Suspected drug(s)/Device Details

*\* All fields are mandatory*

Fill the following details

Generic Name: *	Ibrutinib	Strength: *	140	Units: *	Weight/weight(W/w)
Dosing Frequency: *	2 times a day <input checked="" type="checkbox"/>	Route Administration: *	Oral	Indication for use: *	for the treatment of patients with mantle cell lymphoma who have received atleast one prior therapy, for the treatment of patients with chronic lymphocytic leukemia, for the treatment of patients with chronic lymphocytic leukemia with 17p deletion, for the treatment of patients with Waldenstroms macroglobulinemia
Start Date: *	04/04/2017 <input type="text"/>	Stop Date: *	05/10/2017 <input type="text"/>		
Therapy Duration: *	1 month <input type="text"/>	Suspected: *	Yes <input checked="" type="checkbox"/>		
5.1. Date of Last dose taken prior to the SAE *	05/09/2017 <input type="text"/>	5.2. Whether Study regimen altered in response to the SAE? *	No <input checked="" type="checkbox"/>		

Suspected Drug Details

Search:

Generic Name	Dosing Frequency	Start Date	Stop Date	Therapy Duration	Suspected	Date of Last Dose	Study regimen altered	Edit
<input type="checkbox"/> + Ibrutinib	0							<input checked="" type="checkbox"/>

Figure 196 : Investigational / Suspected Drug (s) Device Details

### Concomitant Drug Details

*\* All fields are mandatory*

Fill the following details

Any Concomitant Drug(s) taken by the subject/patient.(Exclude those used for treating SAE)

Generic Name: *	Generic Name	Strength: *	0	Units: *	Select
Dosing Frequency: *		Route Administration: *	Select	Indication for use: *	
Start Date: *	<input type="text"/>	Stop Date: *	<input type="text"/>		
Therapy Duration: *		Suspected: *	Select		

Figure 197 : Concomitant Drug Details

### SAE Management

*\* All fields are mandatory*

Fill the following details

7.1. Date of Hospitalization (Admission Date)

7.2. Date of Discharge

Provide the copy of Discharge Summary/autopsy report (where application)/verbal autopsy/antecedent events prior to the death or injury

---

7.3. Details about Drugs/treatment used in SAE Management

Generic Name: \*  Strength: \*  Units: \*

Dosing Frequency: \*  Route Administration: \*  Indication for use: \*

Start Date: \*  Stop Date: \*

Figure 198 : SAE Management

### Due Analysis Report

(To be filled by Investigators/Sponsors/CROs)  
(14th day report, Initial and Subsequent Follow-Up)

Baseline Lab Investigation Details (At time of screening)

**Lab Test Details**

Test Name \*  Test Date \*

Test Results \*  Normal Values \*

Classification/Remarks (Clinical Impressions) \*

Lab Test Details						
Test Name	Test Date	Test Results	Normal Values	Classification/Remarks (Clinical Impressions)	Delete	Edit
↕	↕	↕	↕	↕	↕	↕

Figure 199 : Due Analysis Report -- Lab Test Details

### Due Analysis Report

(To be filled by Investigators/Sponsors/CROs)  
(14th day report, Initial and Subsequent Follow-Up)

Due analysis/Causality of the SAE

---

**SAE case narration**

SAE case narrative should cover following points. \*

1. Date of Screening and Date of Randomization
2. Disease status if any at the time of entry/randomization to the study
3. Date of first dose of study drug, concomitant medications etc.
4. Lab tests reports / values before enrollment
5. Detailed description of the SAE and lab investigations reports at the time of the SAE
6. Medical management of the SAE
7. Possible causes of the event

---

**Analysis**

Pre-Existing/underlying Disease (Specify the disease condition) \*

Due to Study drug (Specify the drugs related to SAE with reasoning) \*

Due to Concomitant medication (Specify the details) \*

Protocol Violation (Specify) \*

Medical Mismanagement (Specify) \*

Others (eg. Accident, New or current illness) (Specify) \*

Possible cause of Death (in case of death) (Specify) \*

Re-challenge/De-challenge Information (Specify) \*

---

**Assessment**

SAE Assessment by Investigator with Reasoning for Relatedness/Un Relatedness as per criteria under Appendix XII (5) of Schedule Y. \*

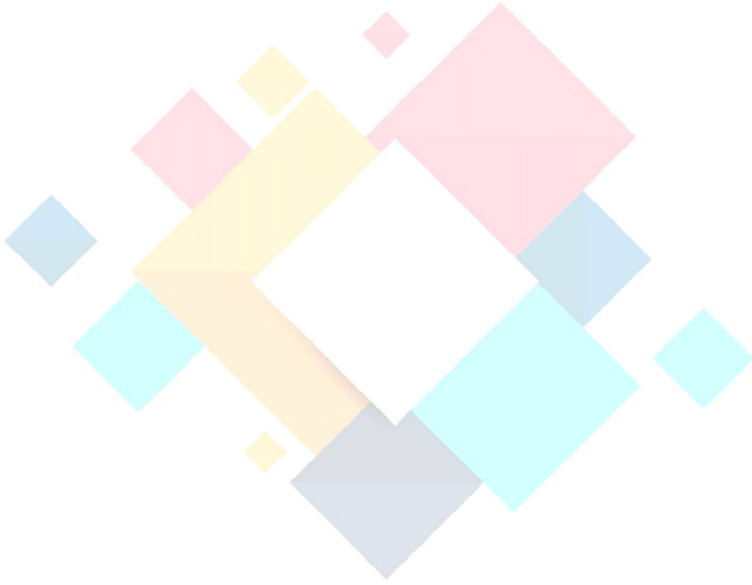
SAE Assessment by Sponsor/CRO with Reasoning for Relatedness/Un Relatedness as per criteria under Appendix XII (5) of Schedule Y. \*

← Previous
Save
Reset

Figure 200 : Due Analysis Report -- SAE Case Narration

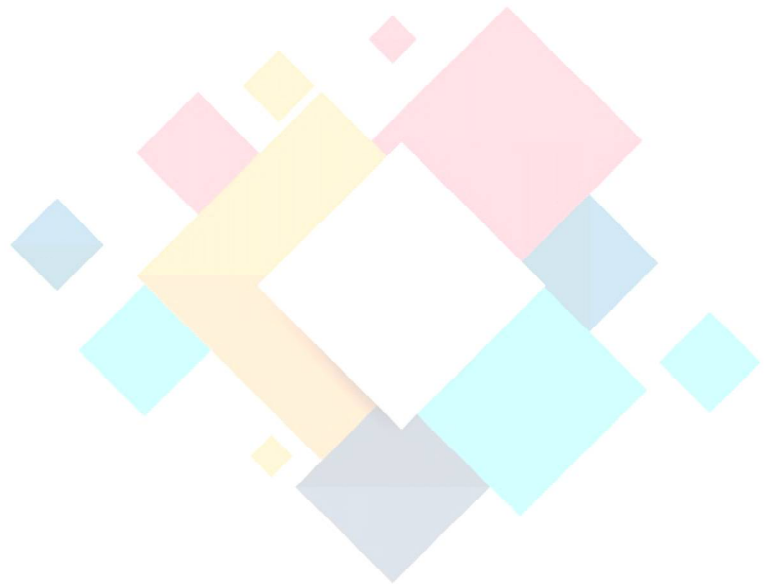
- **SAE reporting (30<sup>th</sup> Day Report):** After 14<sup>th</sup> day SAE reporting is submitted by investigator, the ethics committee may proceed to fill 30<sup>th</sup> day SAE Report. This form is similar to 24 hour report.





## **Chapter- 9**

# **Application for Import of Non-Registered Drugs in India (Personal License)**



## 9. How to Apply for Personal License

Application for Import of drugs in small quantity for personal use is applied online on SUGAM portal in Form12A. This is to enable Government to citizens (G2C) services by CDSCO through SUGAM. To apply for personal user need not get registered on SUGAM portal. This facility is available for general public on the homepage of the portal as shown below:

- Open link "www.cdsoonline.gov.in" and then click on "**Import Drugs for Personal Use**" (highlighted) to apply for import of non-registered drugs in India, as shown in Figure.

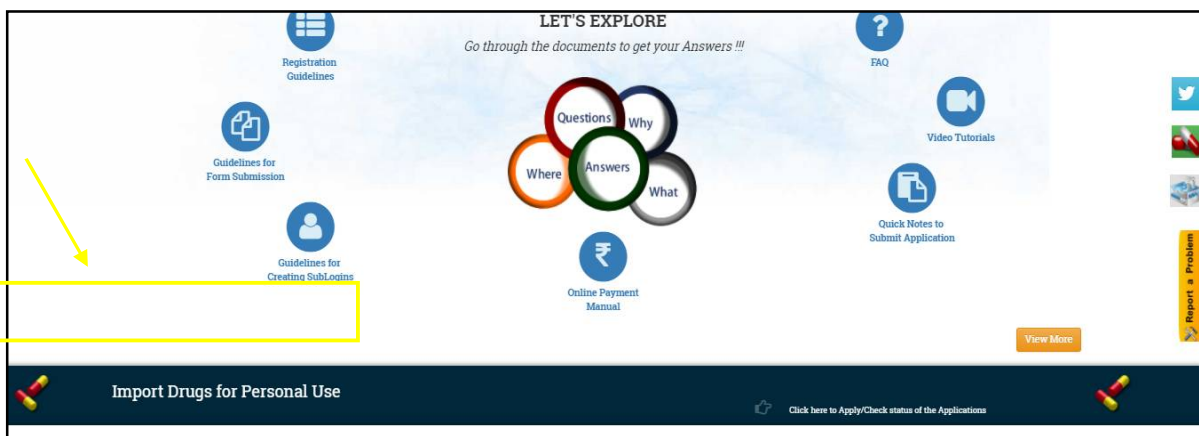
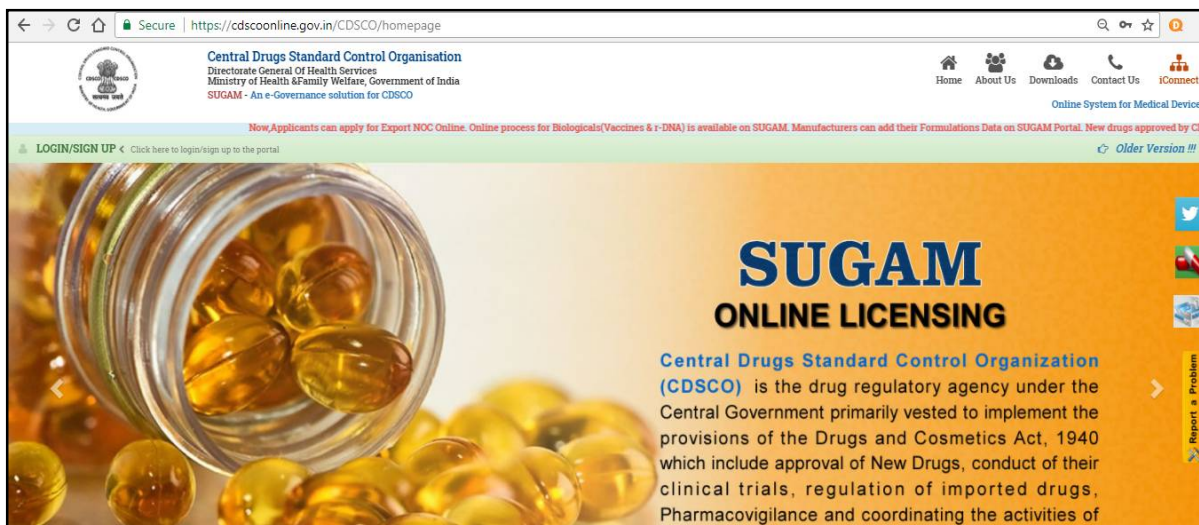


Figure 201 : Apply for Personal License

- After clicking on "**Import Drugs for Personal Use**" link on the portal, a new window will open, as shown in Figure.
- User can either apply for **Form 12A Application** or User can check his **Application Status**.
- **Part 1: Form 12A Application**

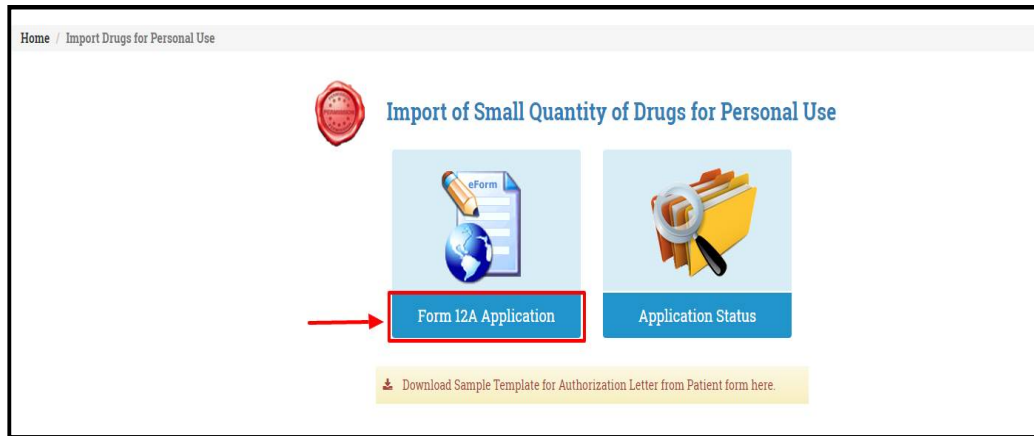


Figure 202 : Import of Small Quantity of Drug for Personal Use

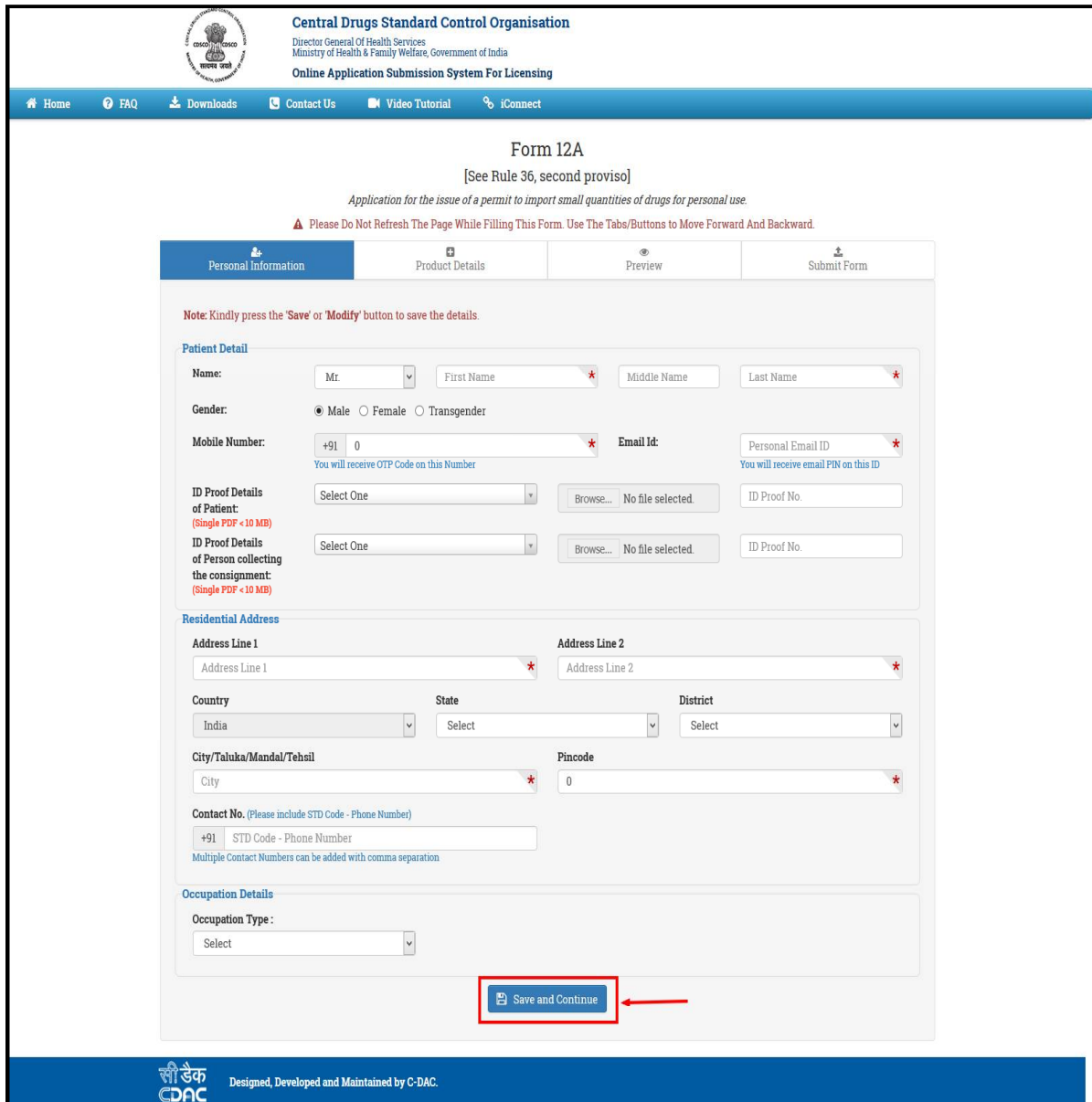
**Note:**

- User has to click on the **“Form 12A Application”** as shown in Figure.
- After clicking on **“Form 12A Application”** link on the portal, a new window will open, as shown in **Figure**.

Figure 203 : Form 12A Application

**Note:** These form contents four steps for “Application for the issue of a permit to import small quantities of drugs for personal use”.

➤ **Step 1: Personal Information**



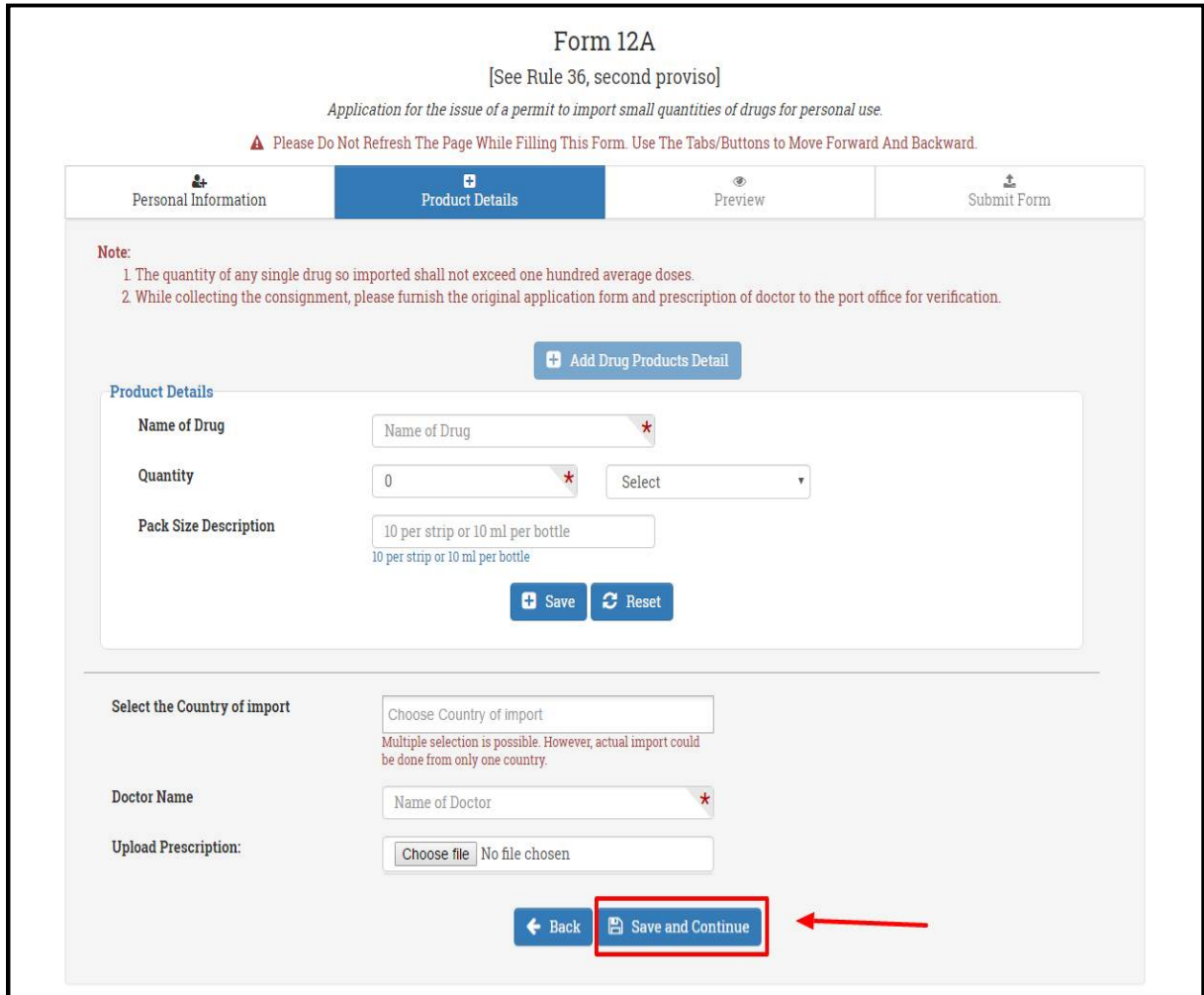
**Figure 204 : Personal Information**

**Note:**

- User must upload necessary documents like **ID Proof Details of Patient** and **ID Proof Details of Person Collecting the Consignment**.
- After filling up the entire details user must click on **Save and Continue** on the form as Highlighted in **figure**.

- After clicking on **Save and Continue** on the form, Step 2 of the application (Product Details) will open as shown in **figure**.

➤ **Step 2: Product Details**



**Form 12A**  
[See Rule 36, second proviso]  
*Application for the issue of a permit to import small quantities of drugs for personal use.*

⚠ Please Do Not Refresh The Page While Filling This Form. Use The Tabs/Buttons to Move Forward And Backward.

Personal Information    **Product Details**    Preview    Submit Form

**Note:**  
1. The quantity of any single drug so imported shall not exceed one hundred average doses.  
2. While collecting the consignment, please furnish the original application form and prescription of doctor to the port office for verification.

+ Add Drug Products Detail

**Product Details**

Name of Drug:  \*

Quantity:  \*   

Pack Size Description:   
10 per strip or 10 ml per bottle

+ Save    ↻ Reset

---

Select the Country of import:   
Multiple selection is possible. However, actual import could be done from only one country.

Doctor Name:  \*

Upload Prescription:

← Back    **Save and Continue** ←

**Figure 205 : Product Details**

- **Note:** User must fill all the details on Product details page as shown in Figure, and then click on **Save and Continue (Highlighted)** to move to the next step of the application / Form.

➤ Step 3: Preview

### Form 12A

[See Rule 36, second proviso]

*Application for the issue of a permit to import small quantities of drugs for personal use.*

⚠ Please Do Not Refresh The Page While Filling This Form. Use The Tabs/Buttons to Move Forward And Backward.

Personal Information	Product Details	Preview	Submit Form
----------------------	-----------------	---------	-------------

**Note:**

1. It is mandatory to submit system generated Form 12A.
2. Click 'Download Form12A' Button available at the bottom of this page to download system generated Form.
3. Sign the Downloaded Form and upload it back into the system after scanning in the 'Submit Form' step.

### Form 12A

[See Rule 36, second proviso]

*Application for the issue of a permit to import small quantities of drugs for personal use.*

I Ankit Kumar Chaudhary resident of C-DAC(Anusandhan Bhawan), C-56/1, Inst. Area, Sector-62,, NOIDA, Uttar Pradesh -201307 by occupation In Government Service hereby apply for a permit to import the drugs specified below for personal use from Belgium

I attach a prescription from a registered medical practitioner in regard to the need for the said drugs.

S.No. ↕	Names of Drugs ↕	Quantity which may be imported ↕
1	Drug1	2 Eye Drops,10 ml per bottle

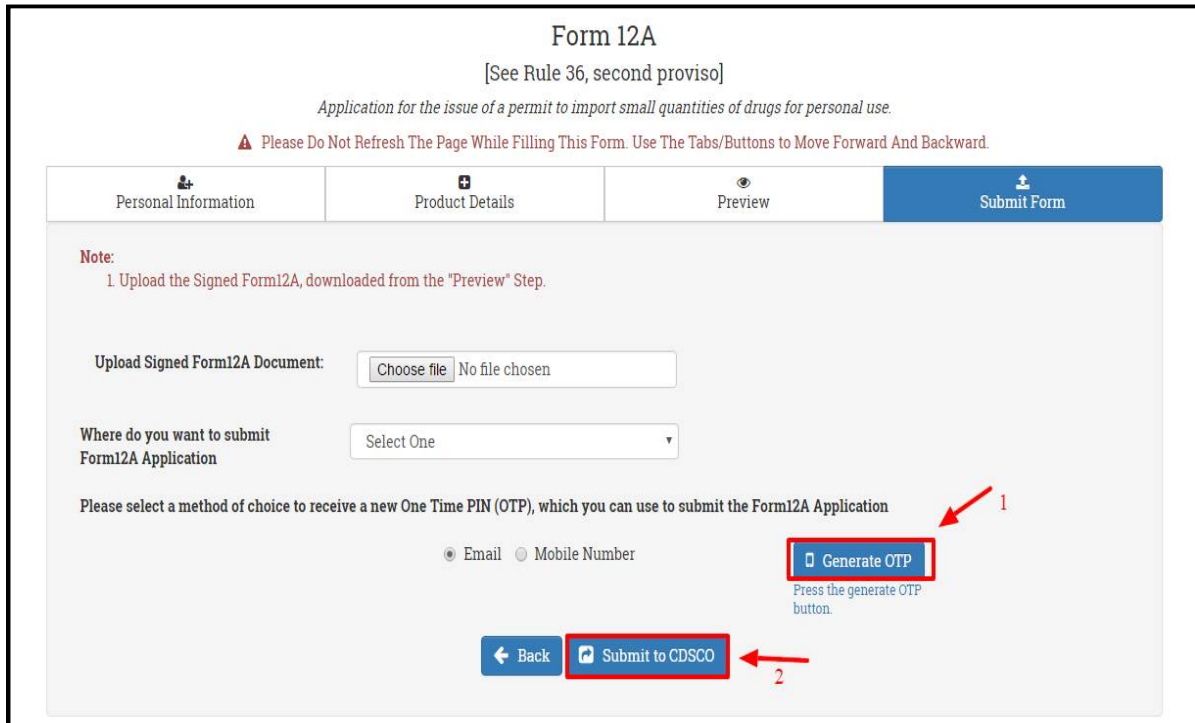
DATE 04-Nov-2016 1 2 Signature \_\_\_\_\_

← Back
↓ Download Form12A
↻ Save And Continue

Figure 206 : Preview Form 12A

**Note:** User must **Download Form12A** (highlighted Arrow 1) and fill the form. Then user must click on **Save and Continue** to move to next step for **Submit Form** as shown in figure.

➤ **Step 4: Submit Form**



**Figure 207 : Submit Form**

**Note:**

- User must upload Signed Form12A Document and all the necessary details.
- Then user must choose the method of receiving One Time Pin (OTP) to complete the process, user can choose either **Email** or **Mobile Number** for generating OTP and then click on **Generate OTP (highlighted)** as shown in figure.
- After entering the received OTP, user must click on **Submit to CDSCO (highlighted)** for submit the application to CDSCO as shown in figure.
- After Submitting the Application to CDSCO, user will be assigned a **file no.** for the application as shown in below figure.

**Application has been submitted successfully.**

Your Application Number is 'PL/F12A/HQ/2016/XXX'

Kindly check your Registered e-mail id for further information.

**Figure 208 : Application Number**

**Note:**

- Using this File no. user can track the status of his/her application.
- Here **HQ** in the Application Number reference for **CDSCO HQ**.

- EZ (East Zone) references to AIR PORT OFFICE KOLKATA,
- SZ (South Zone) references to CUSTOM HOUSE COCHIN,
- WZ (West Zone) references to PORT OFFICE AHMEDABAD,
- SZ (South Zone) references to PORT OFFICE CHENNAI,
- NZ (North Zone) references to PORT OFFICE DELHI (IGI Airport),
- WZ (West Zone) references to PORT OFFICE GOA,
- SZ (South Zone) references to PORT OFFICE HYDERABAD,
- EZ (East Zone) references to PORT OFFICE KOLKATA,
- WZ (West Zone) references to PORT OFFICE MUMBAI,
- WZ (West Zone) references to PORT OFFICE NAVI MUMBAI,
- SZ (South Zone) references to SEA PORT OFFICE CHENNAI

➤ **Check your Application Status**

- For tracking the status of the application, users have to click on “**Application Status**” link on the portal, as shown in **Figure**.



**Figure 209 : Check your Application Status**

- After clicking on “**Application Status**” link on the portal, a new window will open, as shown in **Figure**.



### Form 12A Application Status

Enter File No.  ✓  
File No. is case sensitive

Please select a method of choice to receive a new One Time PIN (OTP), which you can use to check Form12A Application Status

Email 
  Mobile Number

←  
Press the generate OTP button.

**Figure 210 : Form 12A Application Status**

**Note:**

- User must enter correct file no. to search the status of his application and then choose either **Email** or **Mobile Number** to generate OTP to find the status of the application.
- After clicking on Generate OTP (highlighted) in **figure**, user must enter received OTP on his phone to view status of his application as shown in **figure**.

### Form 12A Application Status

Enter File No.  ✓  
File No. is case sensitive

Enter Mobile OTP  ✓  
Enter the OTP Code you have received on your Mobile No.

Sending the Mobile OTP may take 5-15 minutes. Press the Resend button, in case OTP is not received

S.No. ↓	Applicant Name ↓	Drug Details ↓	Submission Date ↓	Issue Date ↓	Applicant ID proof ↓	Prescription ↓	Form12A ↓	Status ↓
1	Mr. AnkitKumarChaudhary	{2 Drug2 Eye Drops 10 per strip or 10 ml per bottle}	04-11-2016	----	↓	↓	↓	Submitted To CDSCO

**Figure 211 : View Status of Application**

- User can check the Status of application by clicking onto the Status given, as shown in figure, and user can also download "Id proof of Person collecting the consignment".

S.No. ↓	Applicant Name ↓	Drug Details ↓	Submission Date ↓	Issue Date ↓	Applicant ID proof ↓	Prescription ↓	Form12A ↓	Status ↓
1	Mr. AnkitKumarChaudhary	{2 Drug2 Eye Drops 10 per strip or 10 ml per bottle}	04-11-2016	----	↓	↓	↓	Submitted To CDSCO
Permission Number:		----						
Email ID:		chaudharyankit3@gmail.com						
Mobile:		7830960649						
Import Country:		Australia						
Doctor Name:		Doctor						
Form12B:		----						
ID proof of Person collecting the consignment:		↓ ←						
Residence Contact:		7830960649						
Residence Address:		C-DAC(Anusandhan Bhawan),C-56/1, Inst. Area, Sector-62,NOIDA,Uttar Pradesh ,India						
Occupation Type:		In Government Service						
Organization:		CDAC						
Designation:		PA						
Organization Address:		C-DAC(Anusandhan Bhawan),C-56/1, Inst. Area, Sector-62,NOIDA,Uttar Pradesh,India						
Reason of Approval/Rejection:		----						

**Figure 212 : Check the Status of application**

**Note:** On clicking “Download Sample Template for Authorization Letter from Patient form here.” link open the Template for Authorization letter from Patient “for import of medicine on Patient behalf along with specimen signature”.



Figure 213 : Clicking on “Download Sample Template for Authorization Letter from Patient form here”

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