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)
Anusandhan Bhawan, C-56/1, Institutional Area, Sector-62, Noida-201307
Phone: 91-120-3063311-14 Website:http://www.cdac.in

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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

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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.cdscoonline.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.

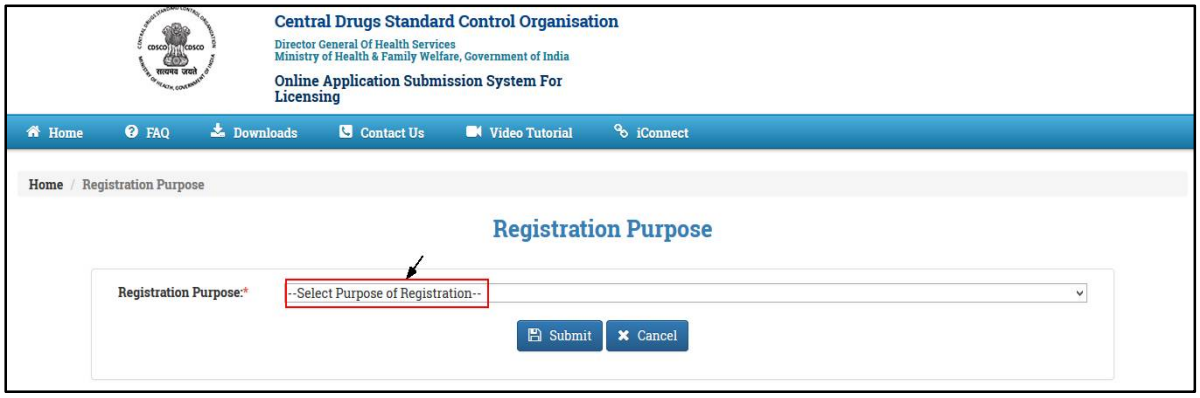


Figure 2 : Screen of Registration Purpose

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.

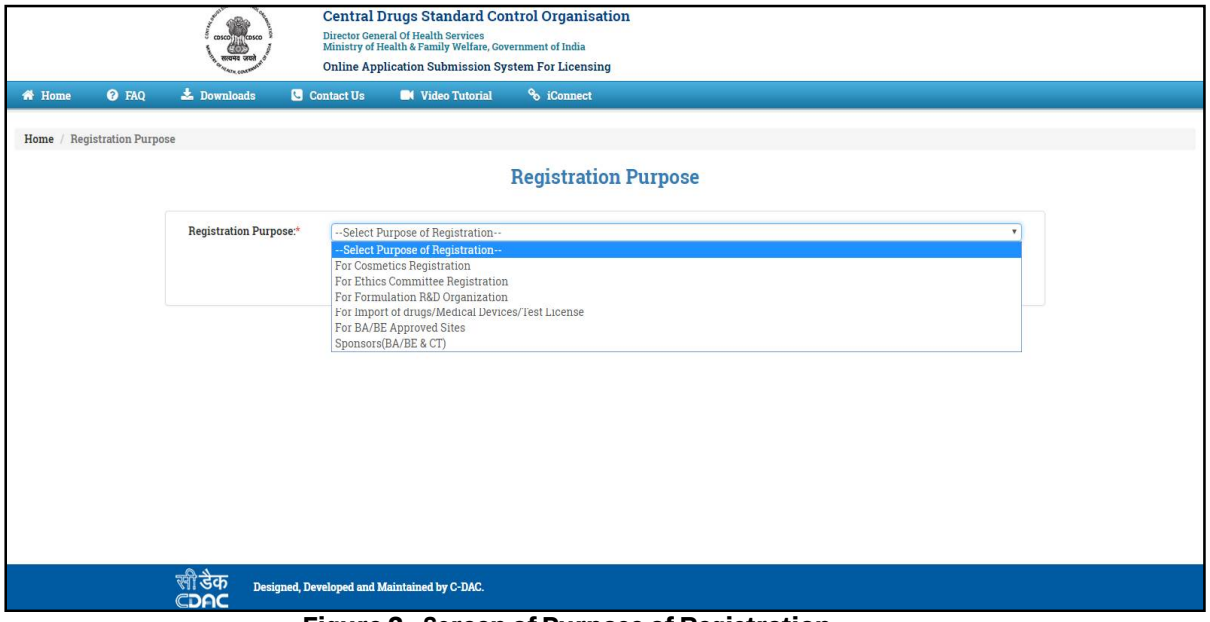


Figure 3 : Screen of Purpose of Registration

- **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

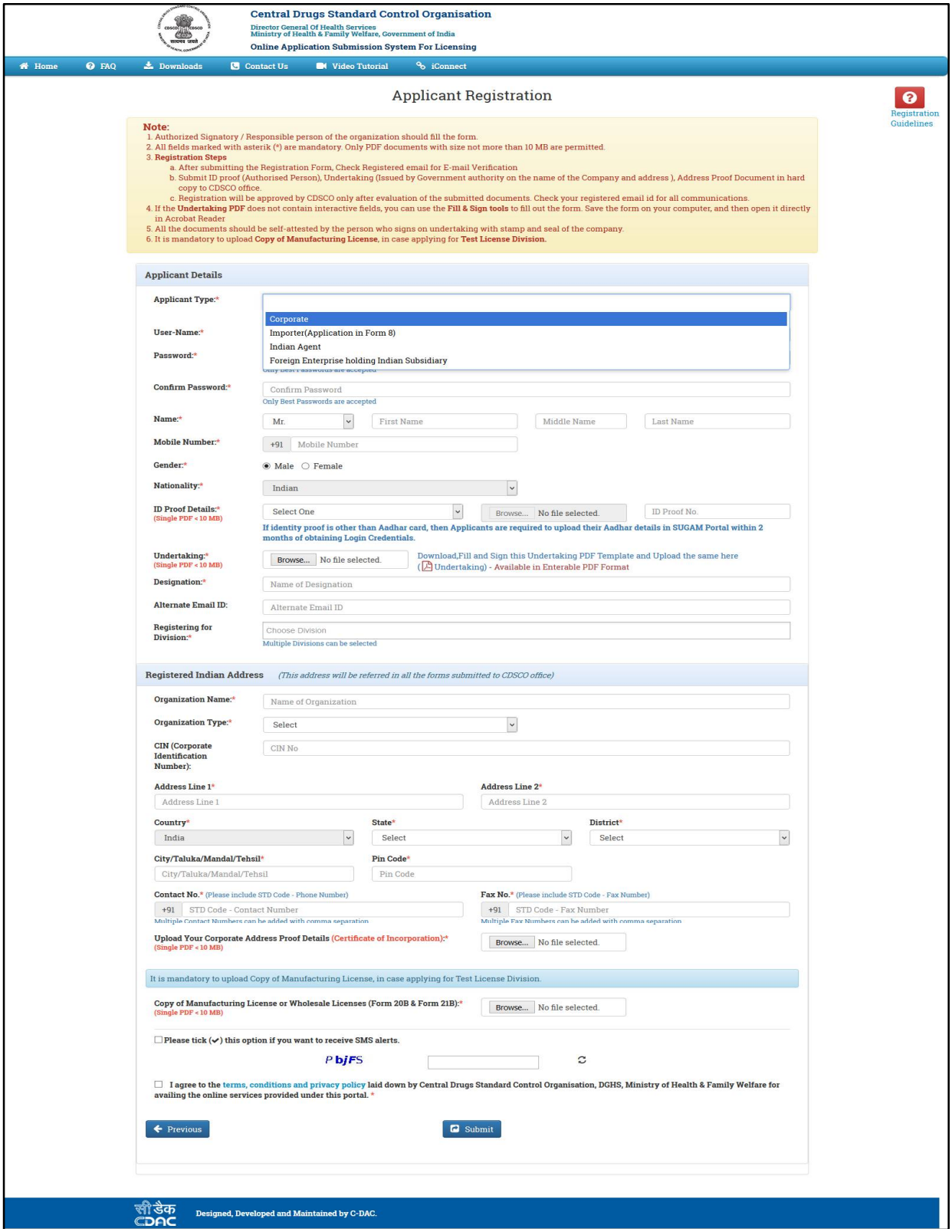


Figure 4 : Registration Form

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.

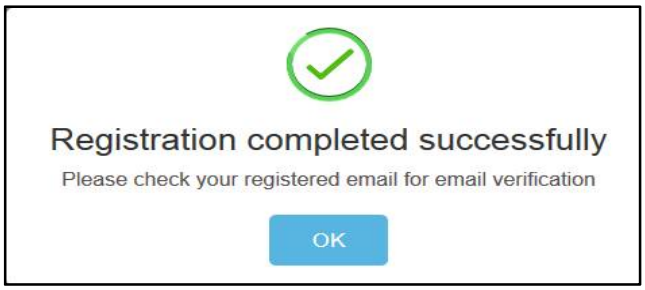


Figure 5 : Screen of Registration Completed Successfully'

- **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.

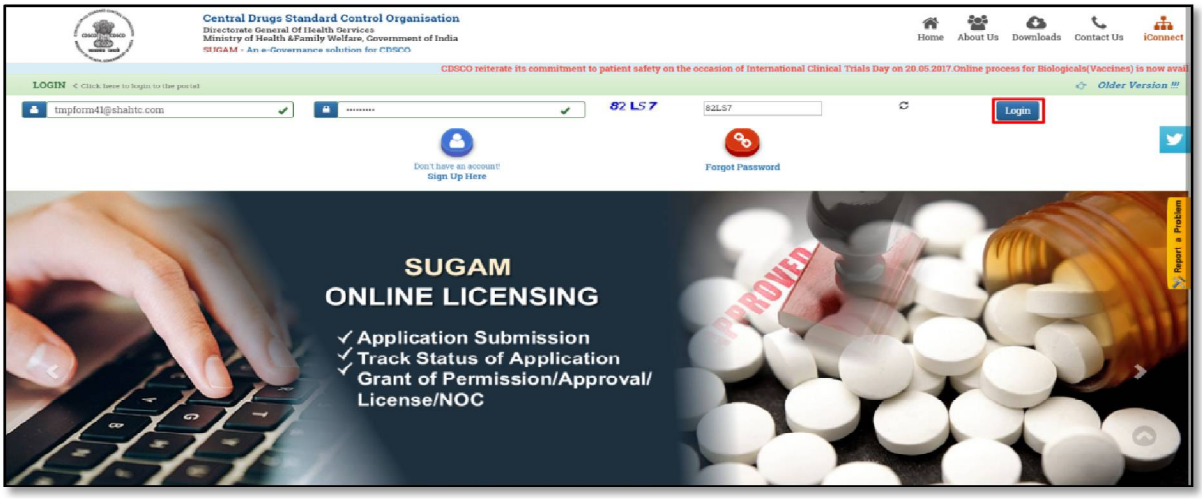


Figure 6 : Login Screen

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.**

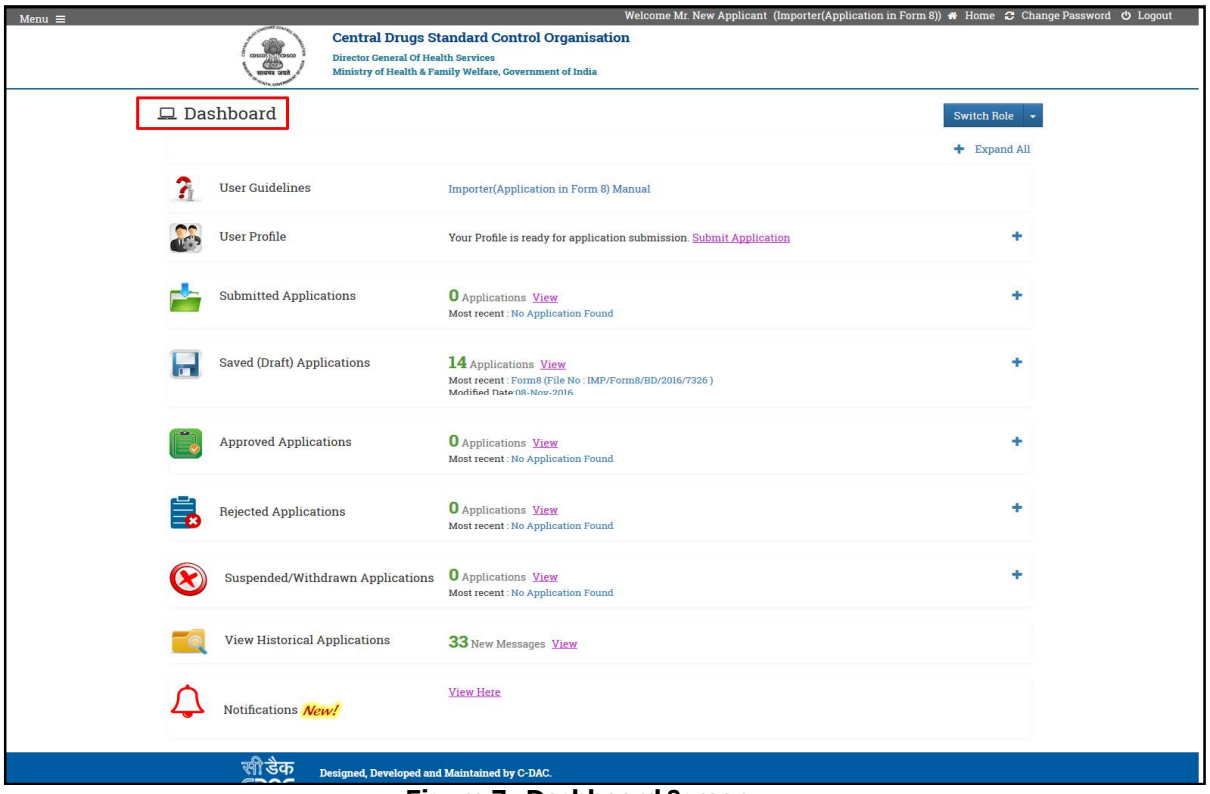


Figure 7 : Dashboard Screen

2.1. Dashboard Options

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

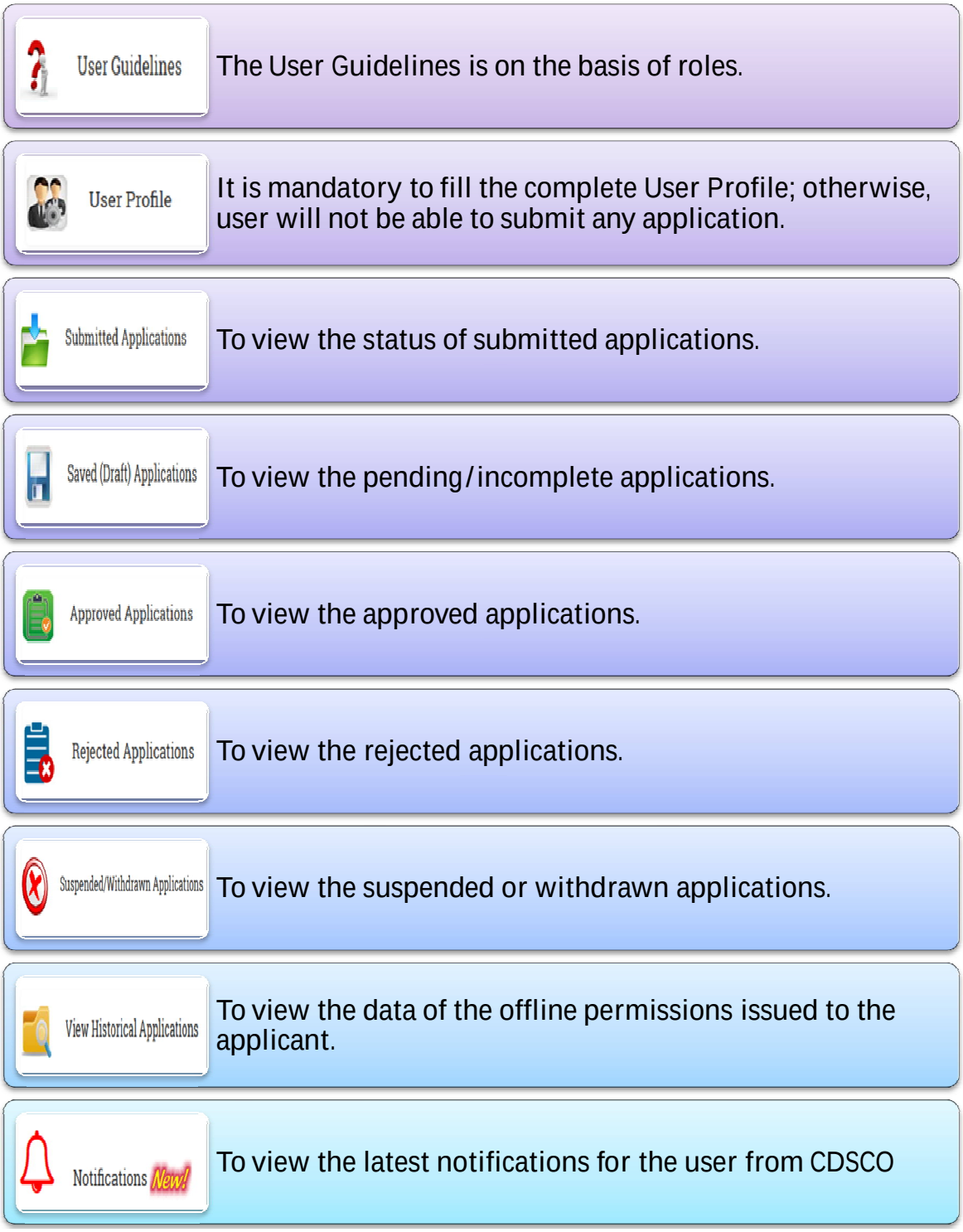


Figure 8 : Dashboard Option (SUGAM Applicants)

2.2. Password Change

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

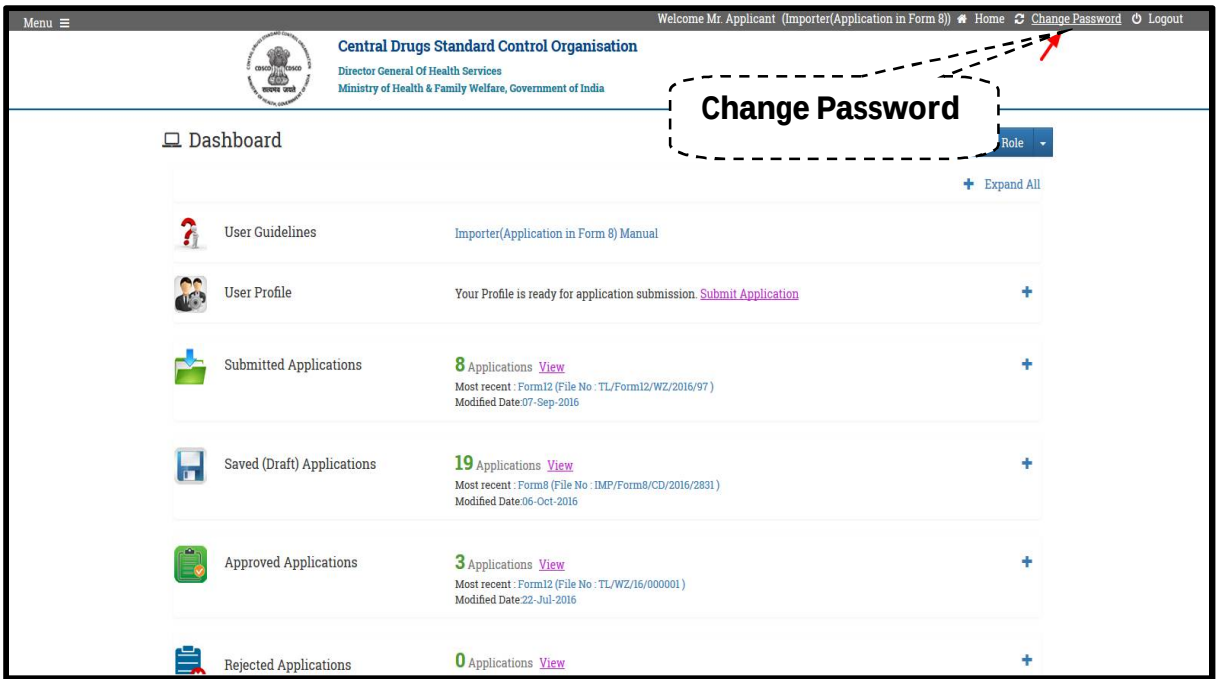


Figure 9 : Screen of Change Password Option

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

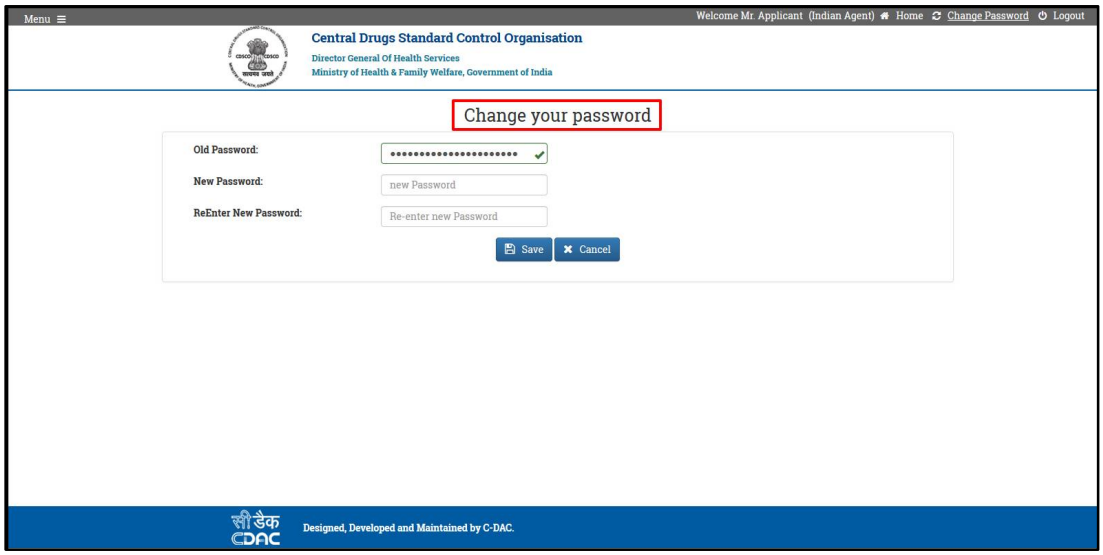


Figure 10 : Screen of change password (Continue)

- 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.**

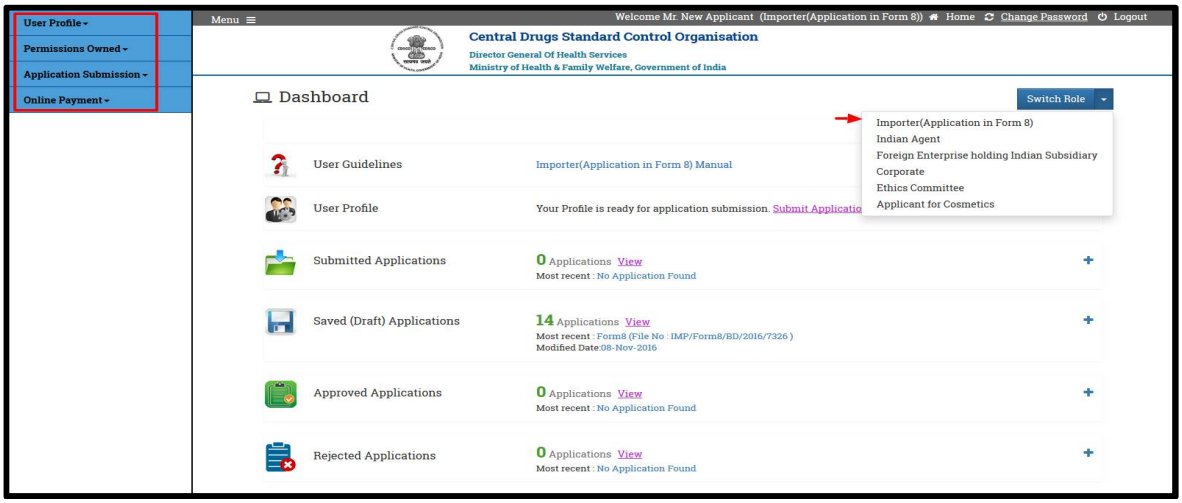


Figure 11 : Switch Role

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.

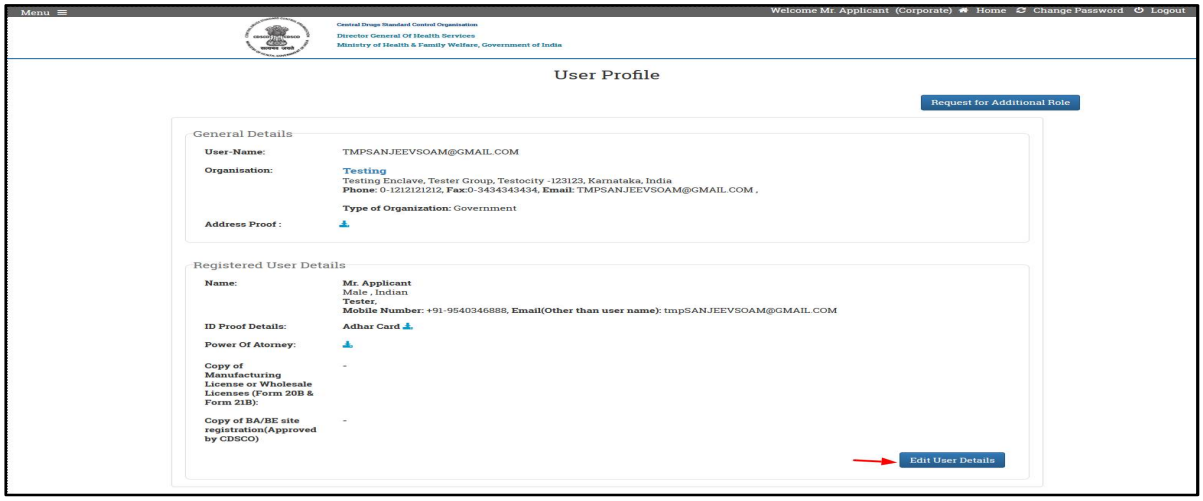


Figure 12 : View Profile

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.**

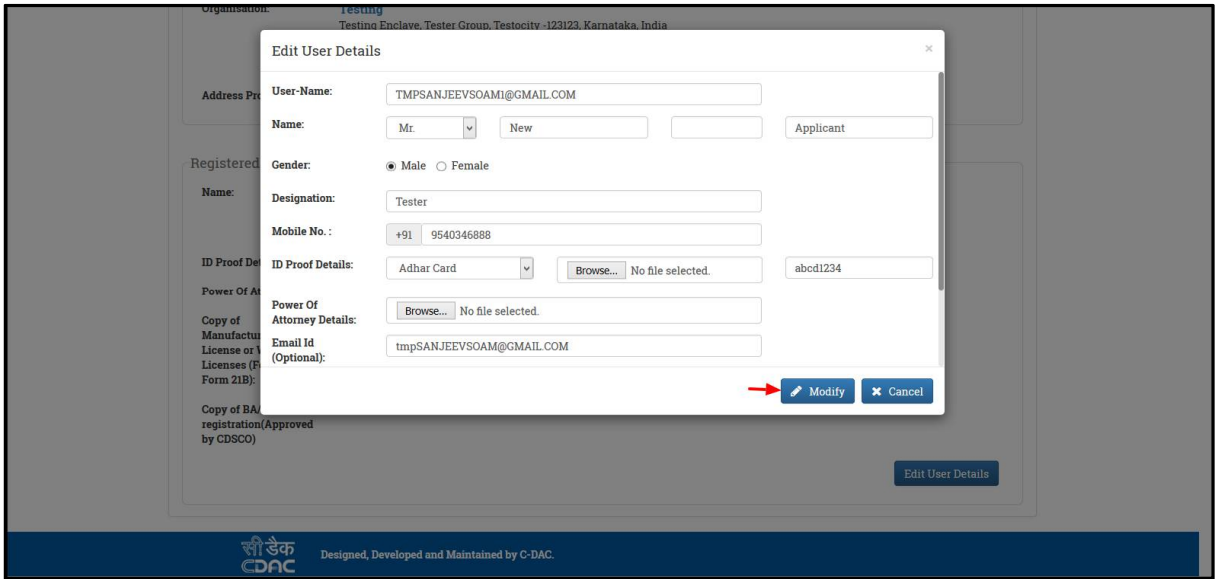


Figure 13 : Screen of Edit User Detail

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.

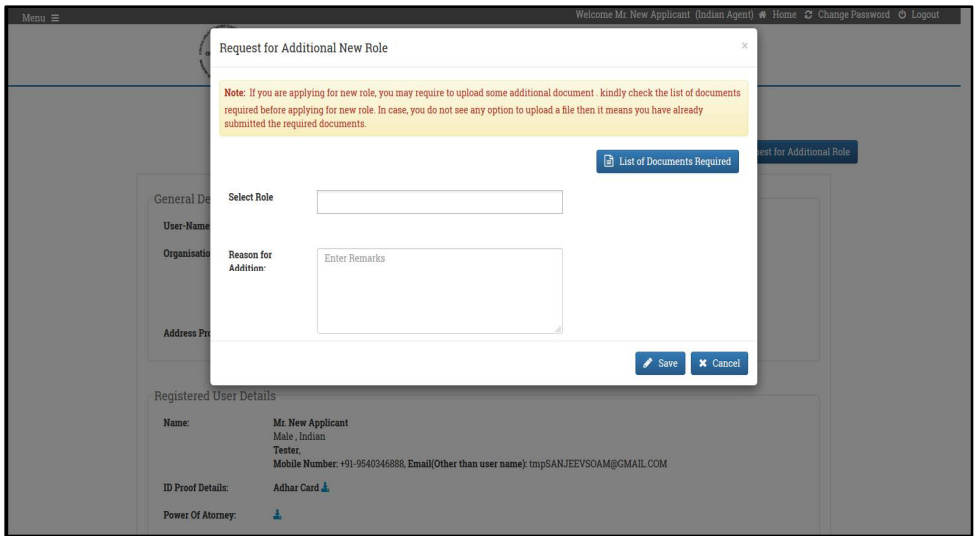


Figure 14 : Screen of Request for Additional New Role

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"**

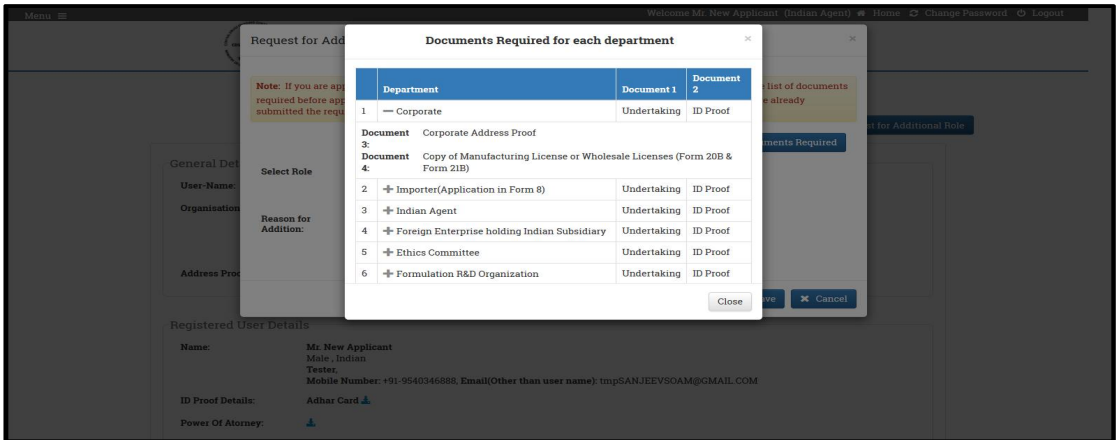


Figure 15 : Screen of List of Documents Required

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.

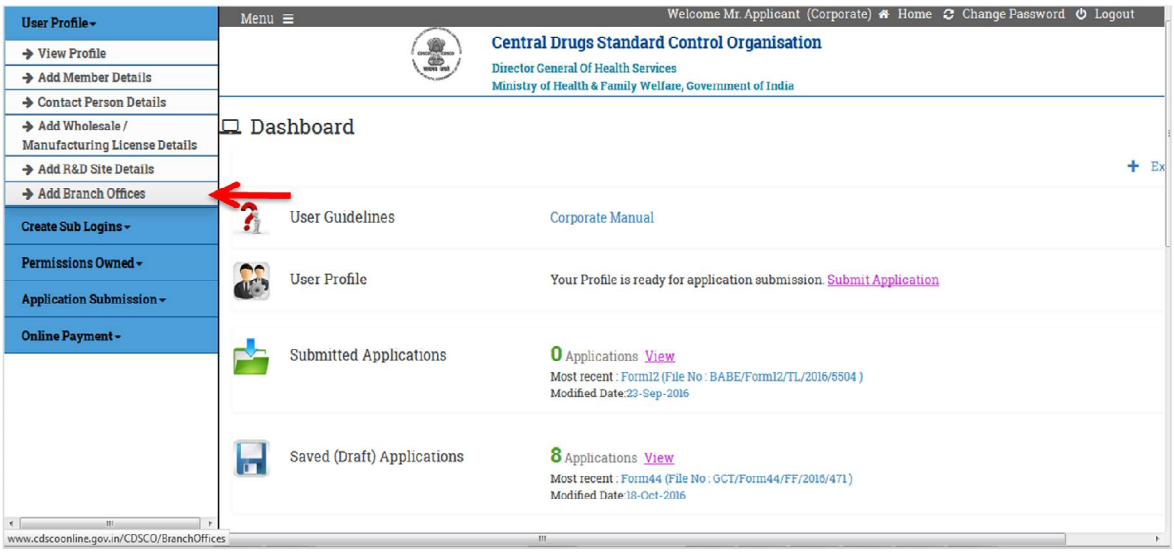


Figure 16 : Adding User Profile Details

➢ Add Member Details

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

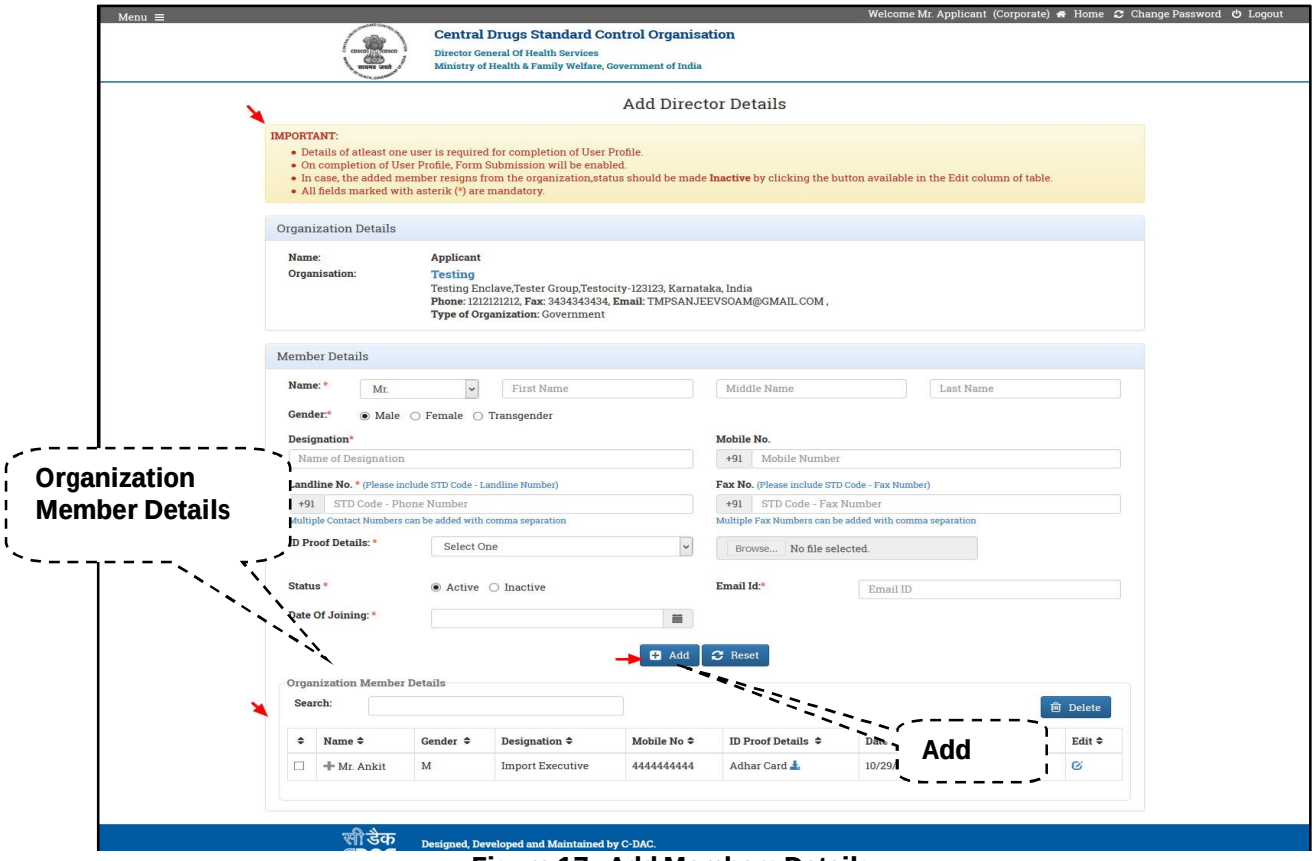


Figure 17 : Add Members Details

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.**

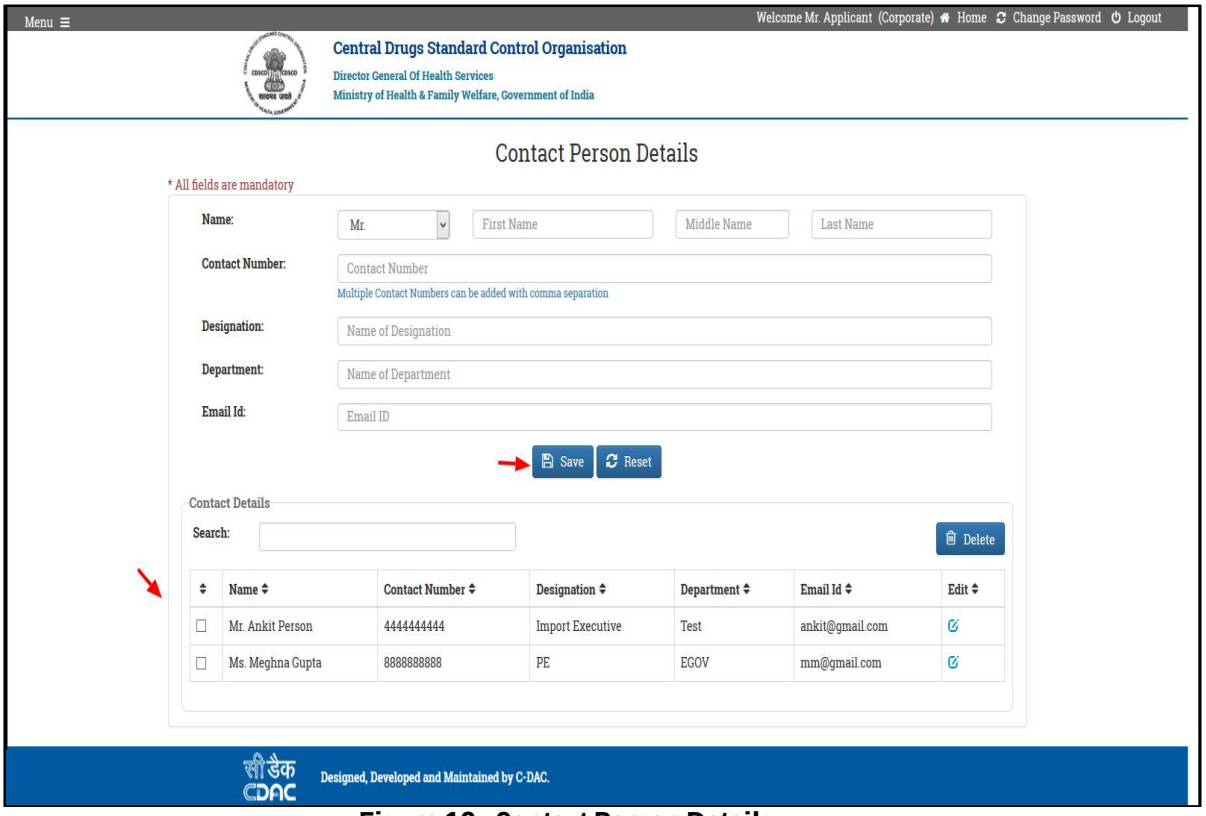


Figure 19 : Contact Person Details

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.**

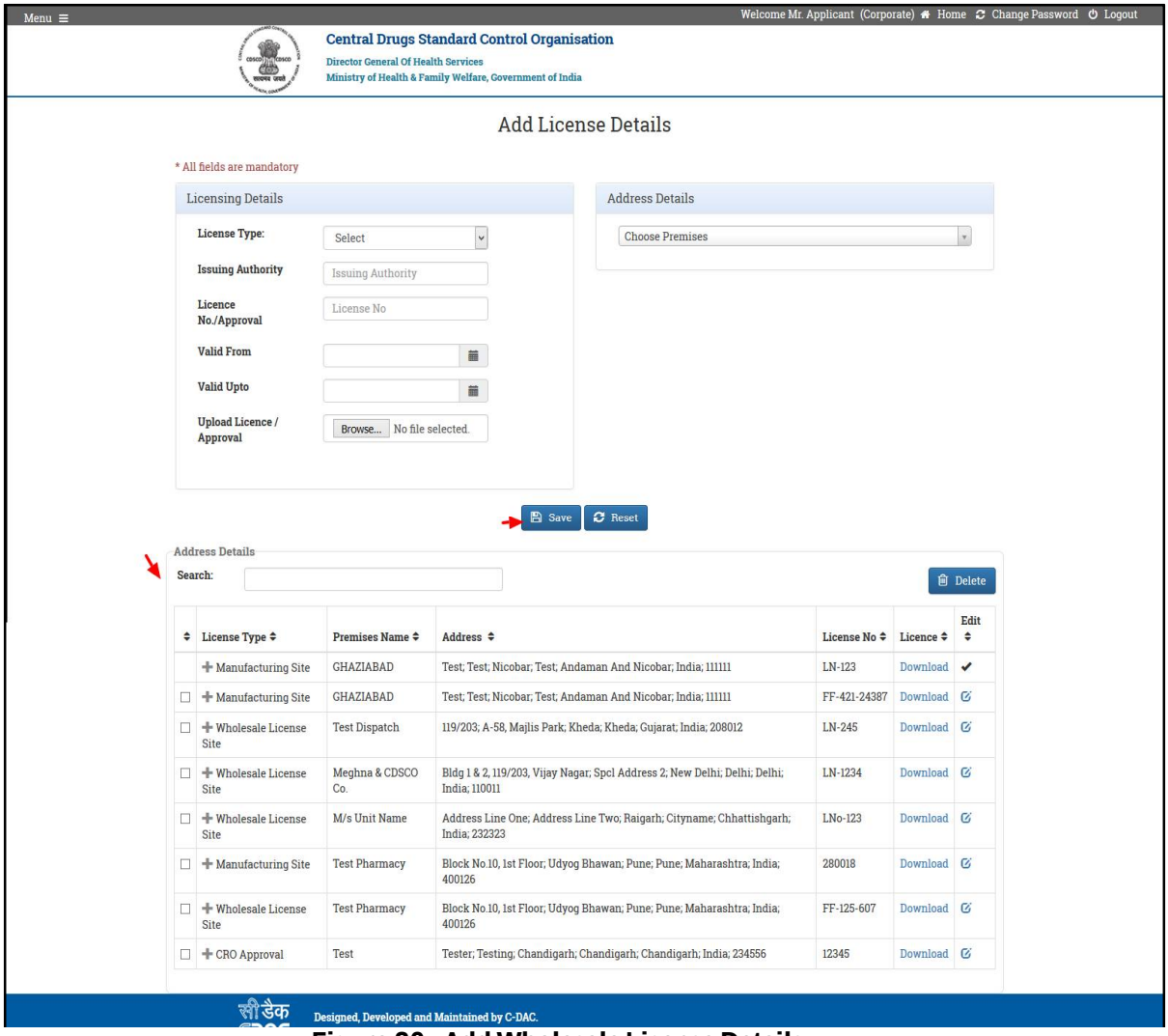


Figure 20 : Add Wholesale License Details

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.**

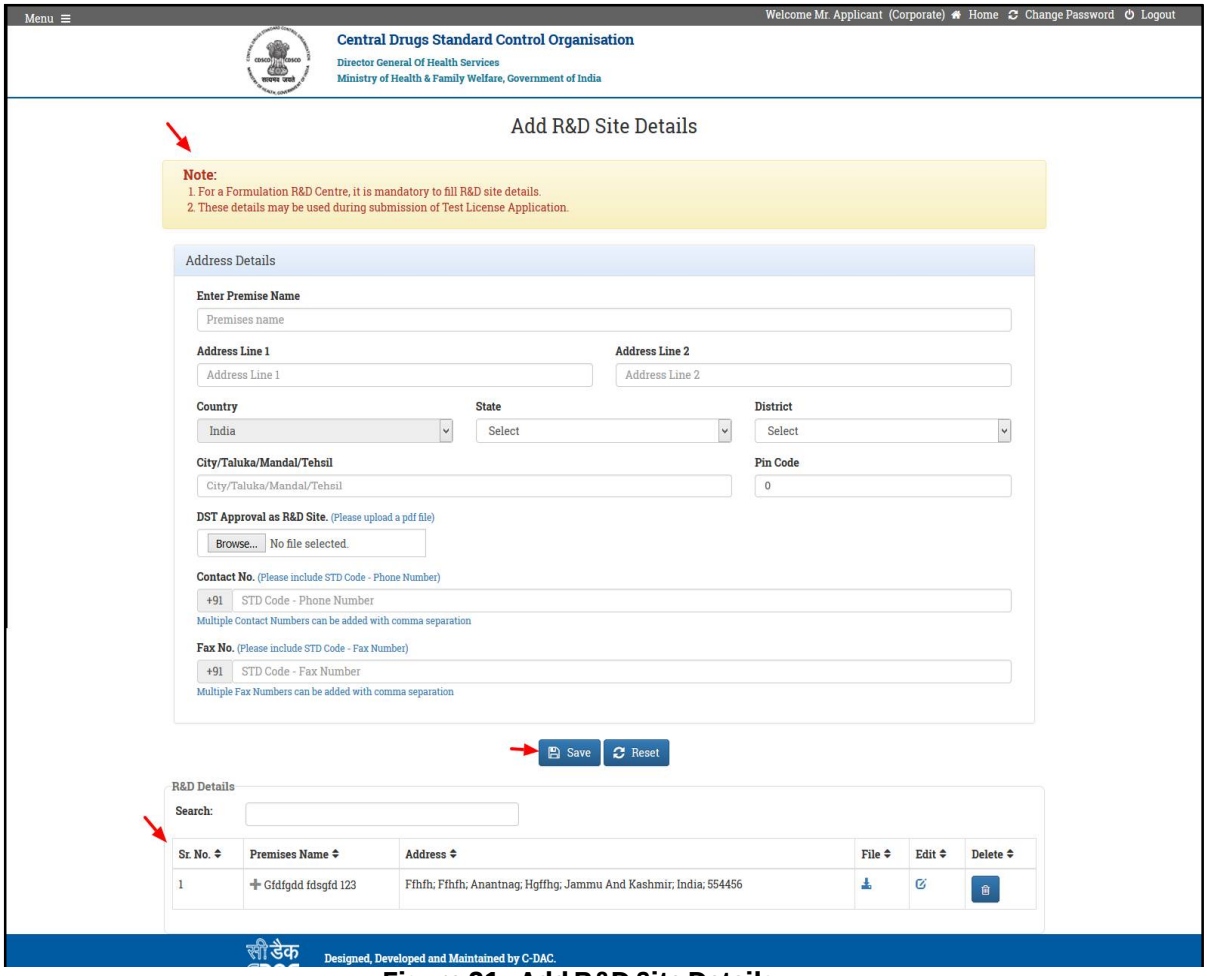


Figure 21 : Add R&D Site Details

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.

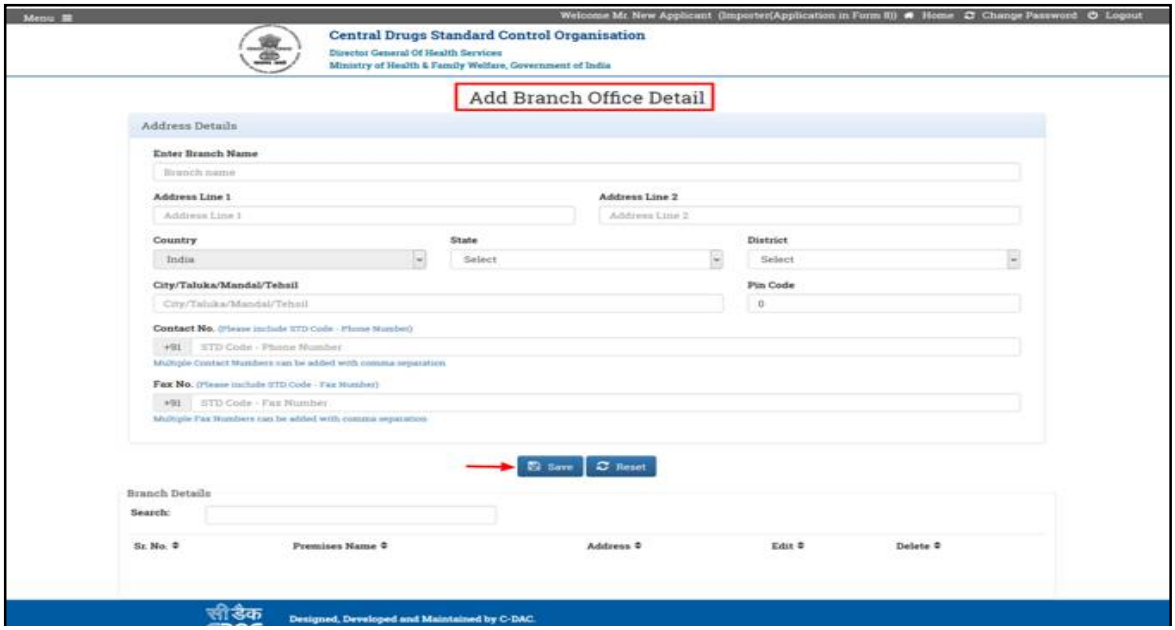


Figure 22 : Add Branch Office Details

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.

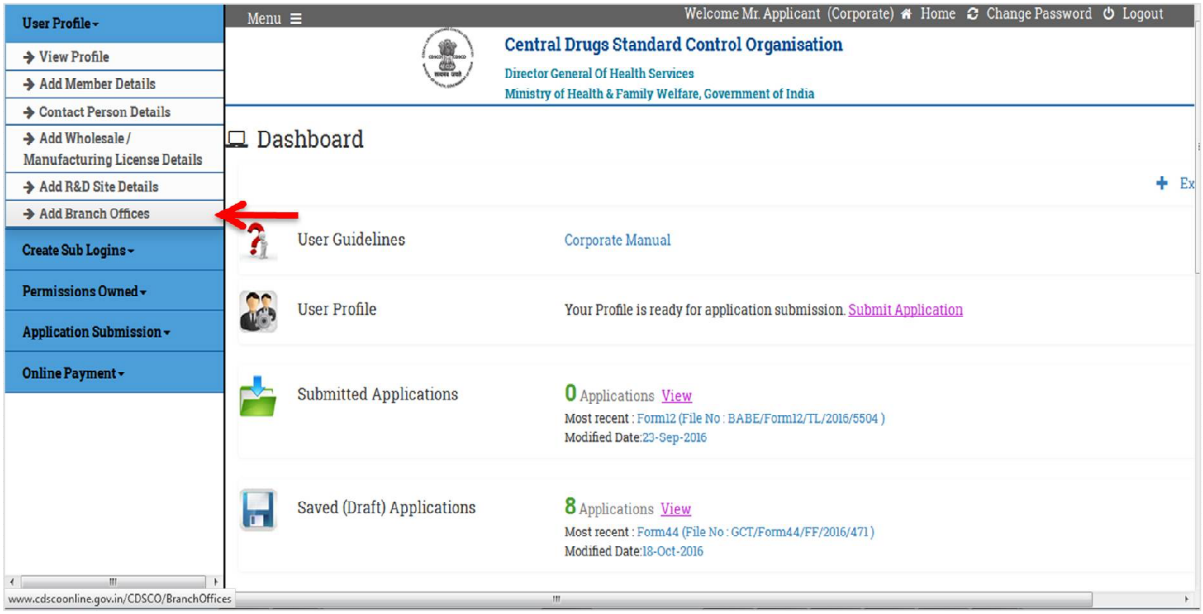


Figure 23 : Option to Add Branch office Details

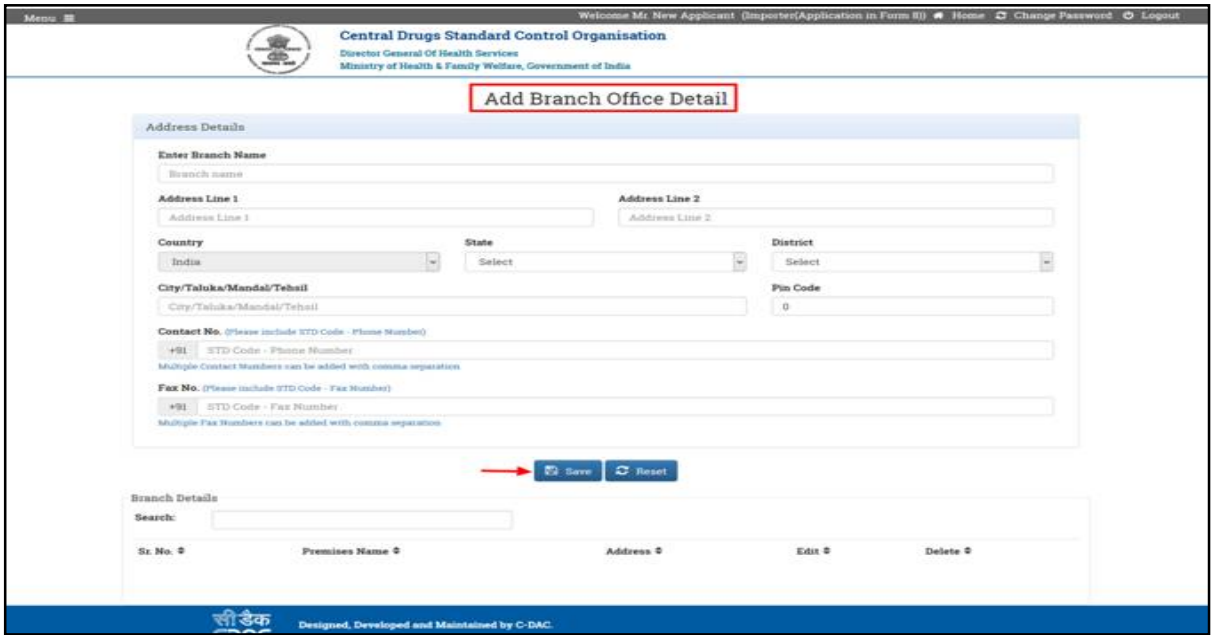


Figure 24 : Add Branch office Details

- 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.**

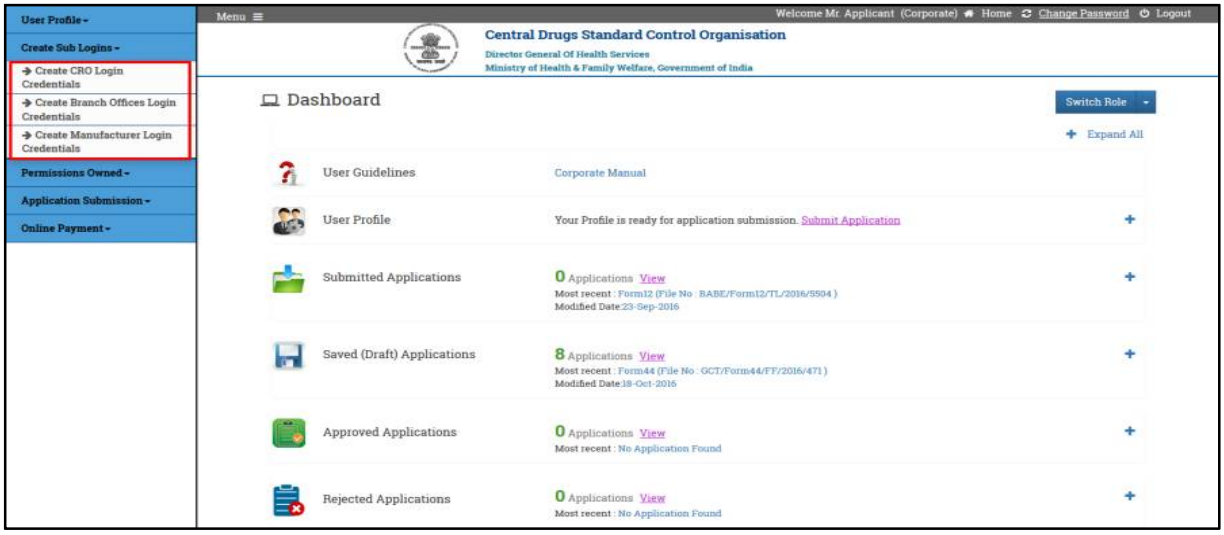


Figure 25 : Option to Create Branch Office Login

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

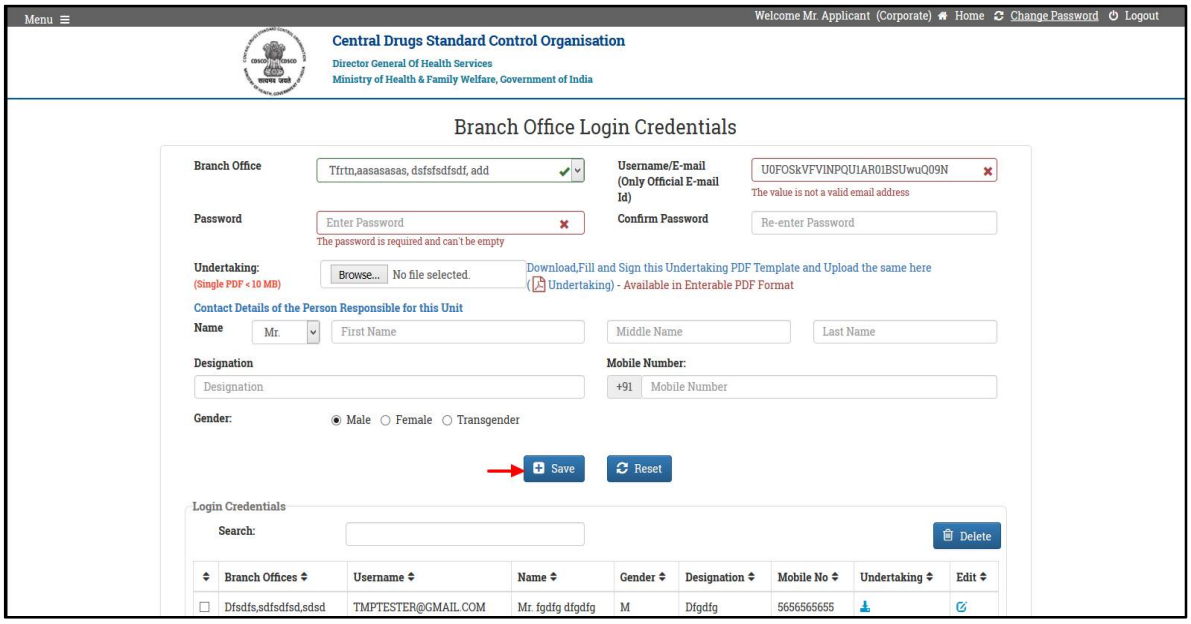


Figure 26 : Screen of Branch Office Login

- 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

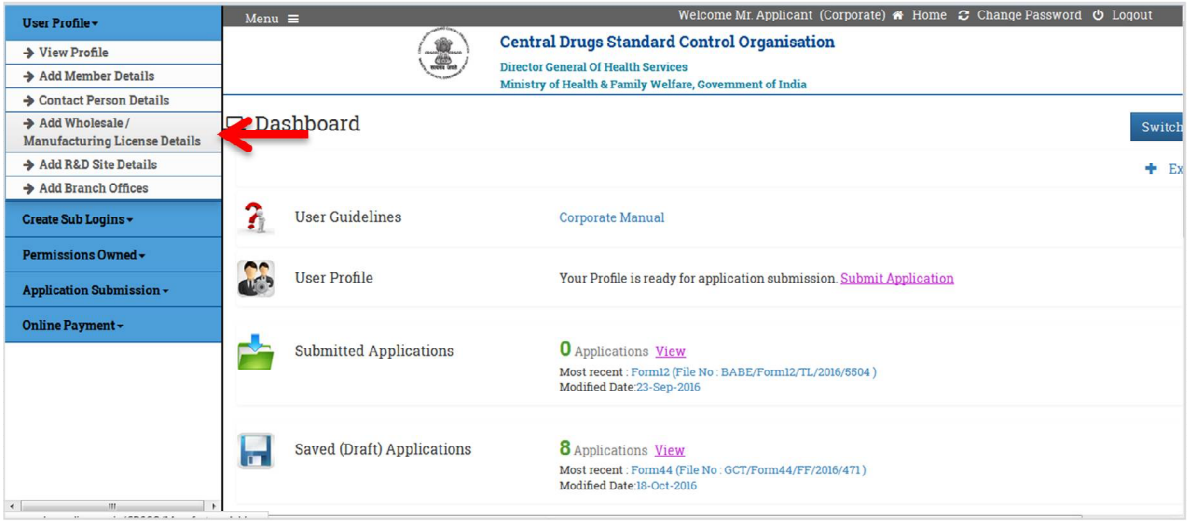


Figure 27 : User Profile - Add Wholesale/Manufacturing License Details

- 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.**

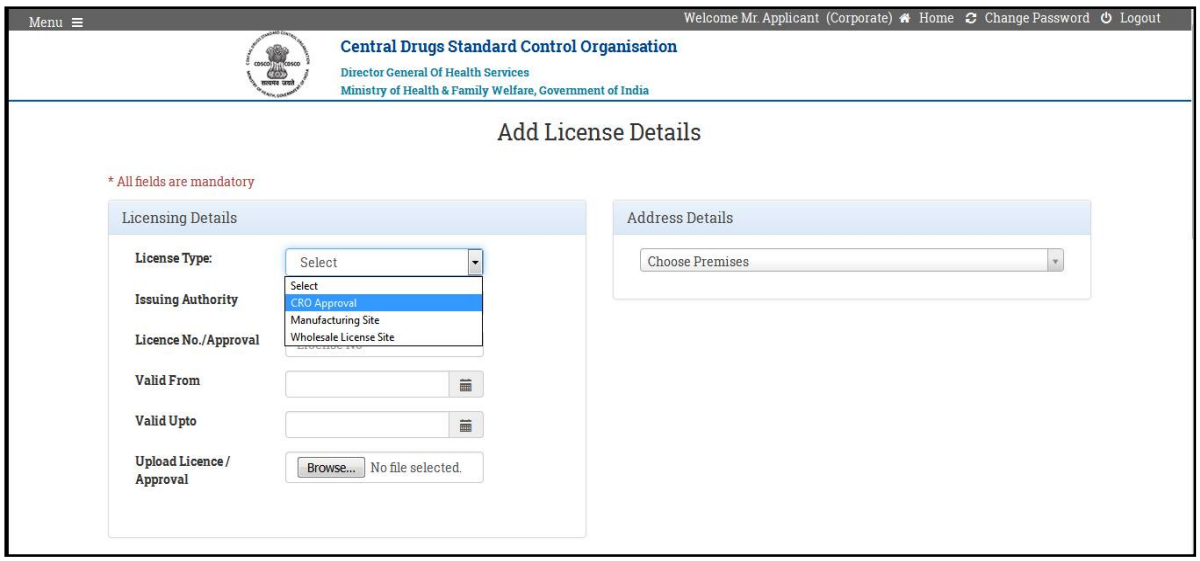


Figure 28 : Add CRO details

- 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.

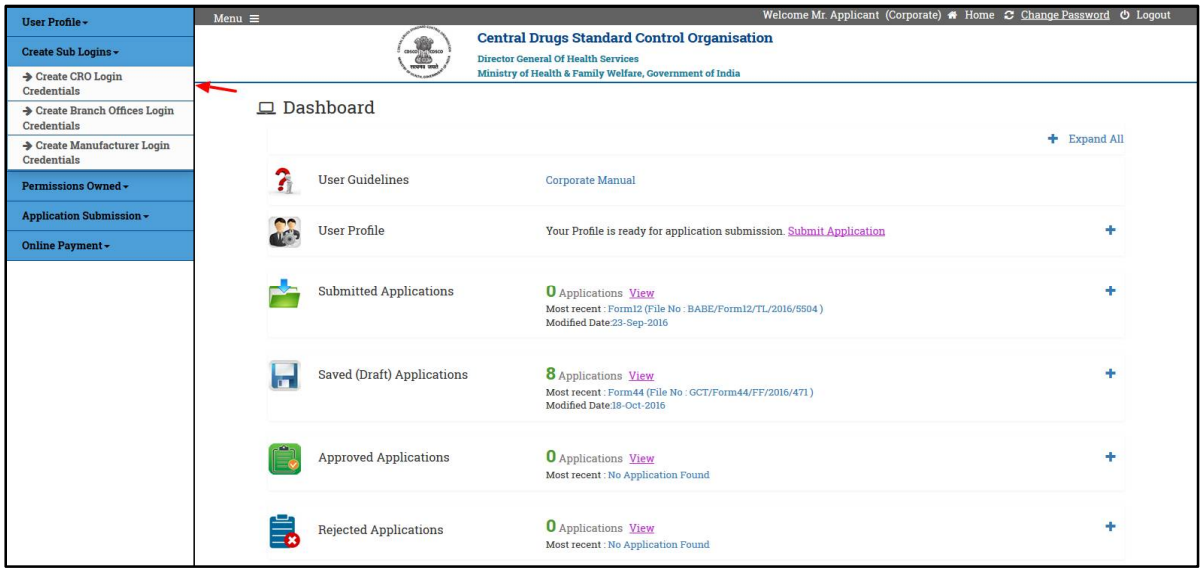


Figure 29 : Create CRO Login

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

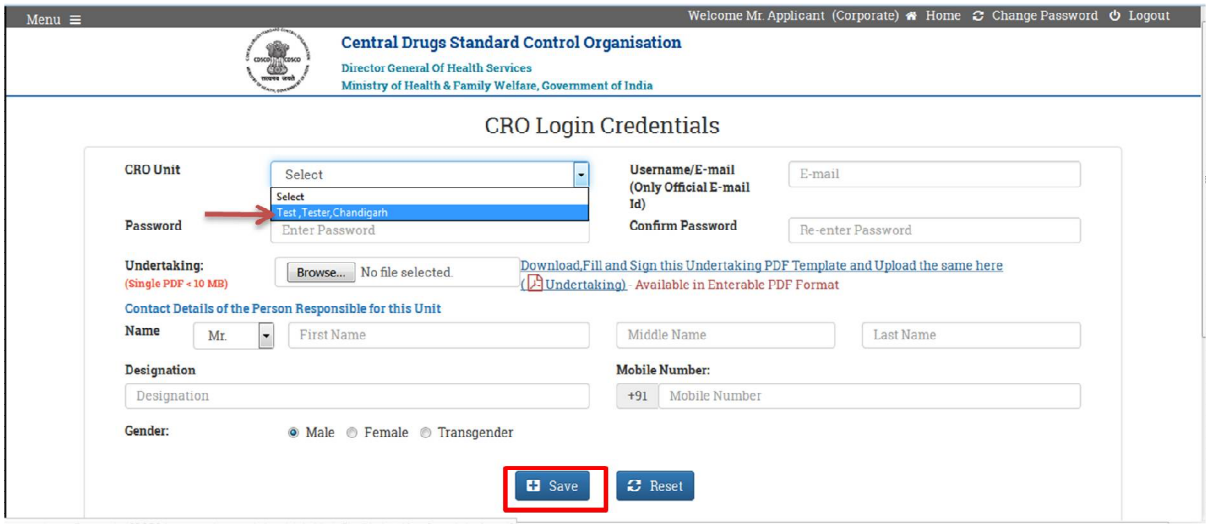


Figure 30 : CRO Login Credential

- 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

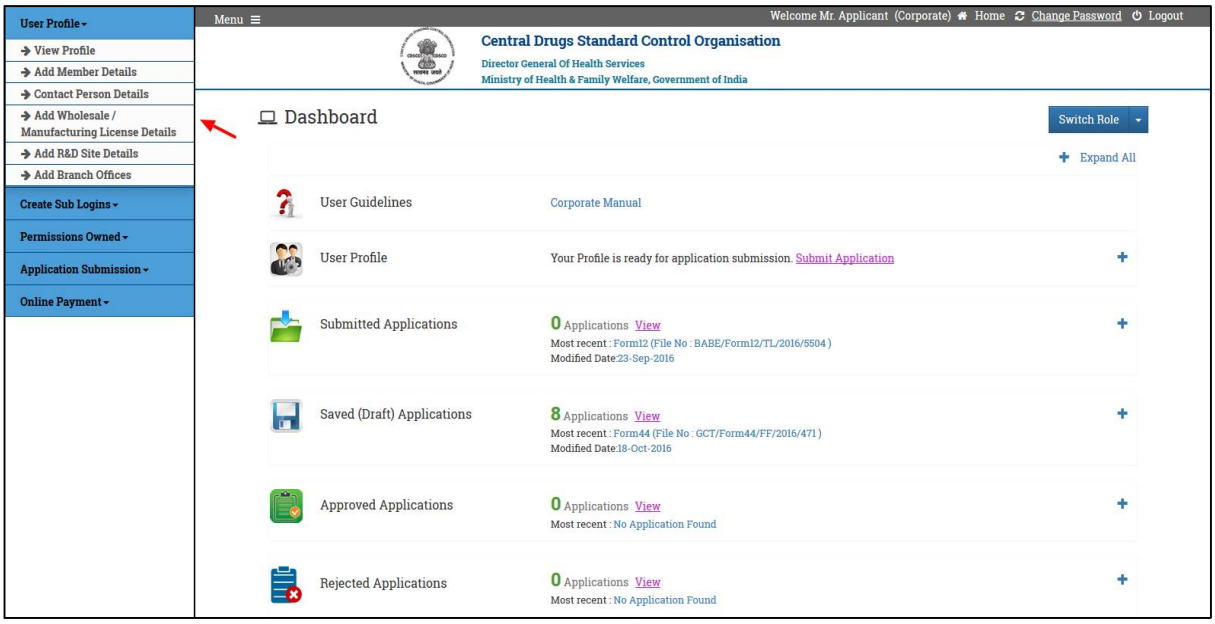


Figure 31 : User Profile - Manufacturer Login

- 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.**

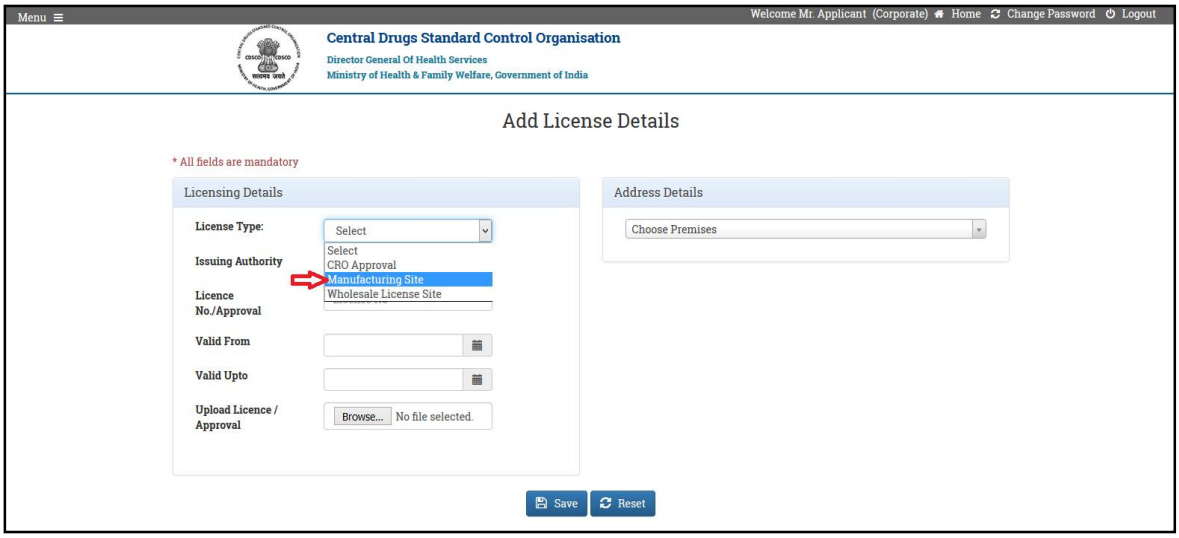


Figure 32 : Manufacturer Login

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.**

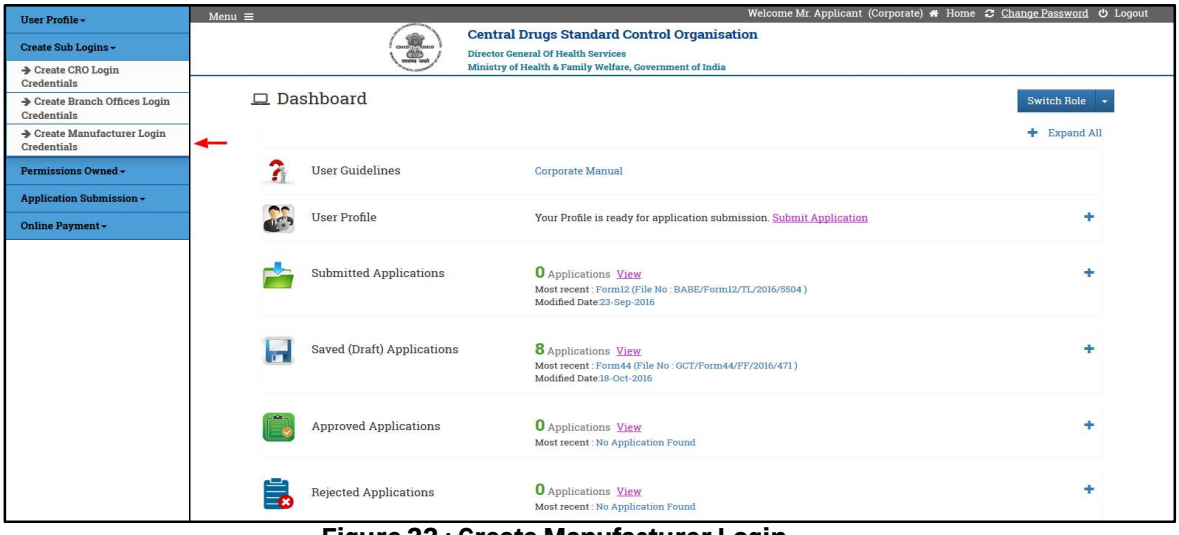


Figure 33 : Create Manufacturer Login

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

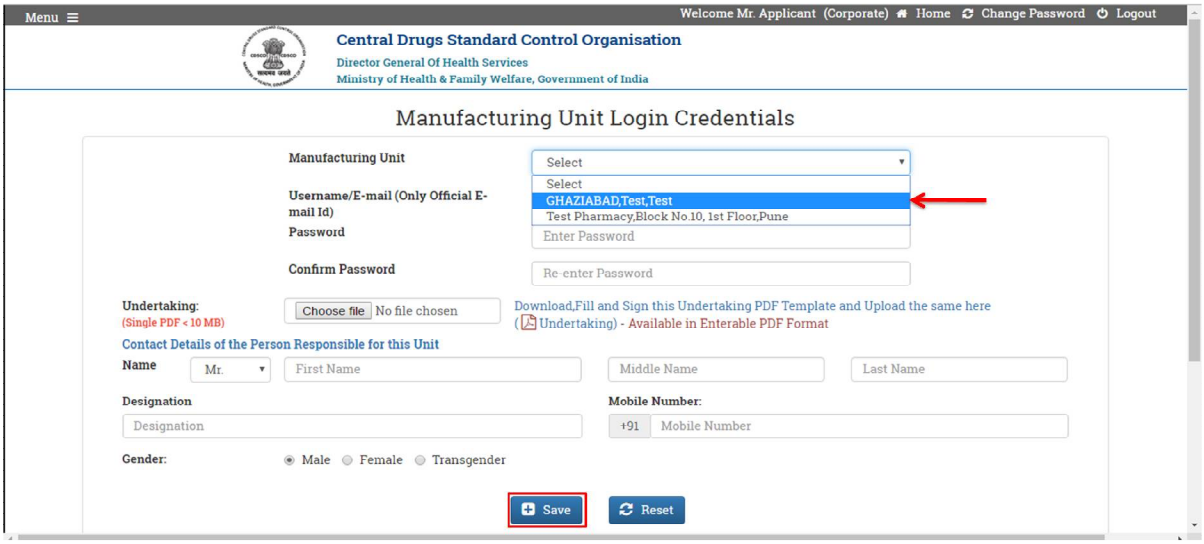


Figure 34 : Manufacturer Login Credentials

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 o Managing Director o Director o CEO o COO o Company Secretary o 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 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
6. I declare that I have authorized Mr/Ms. ..... to access 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 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:

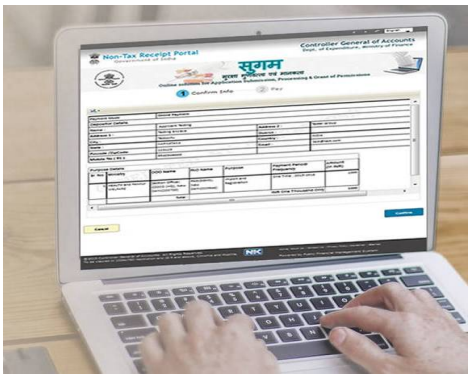
Seal:

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.

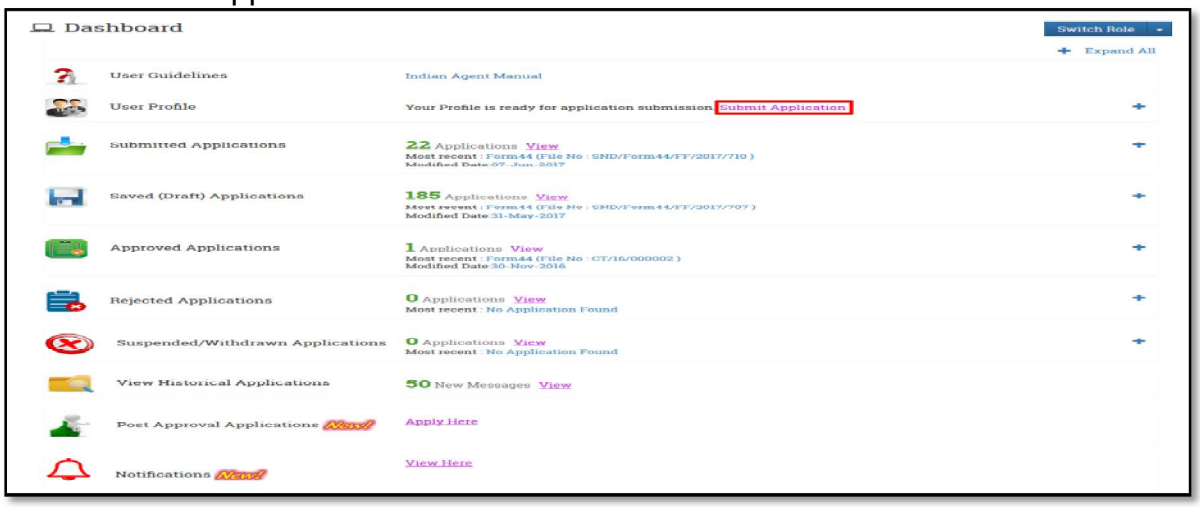


Figure 36 : Form Submission

- 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.

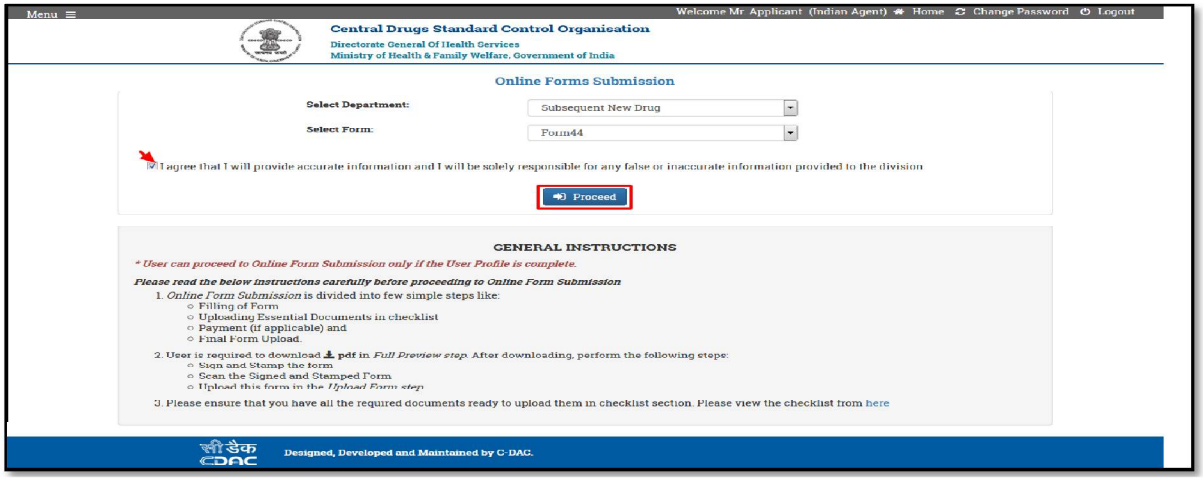


Figure 37 : Screen of after clicking on Submit Button

- 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/STATE FDA	CLAA Processes	Grant & Renewal of Licenses for : • Blood Bank • Anti sera • Stem Cells	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.

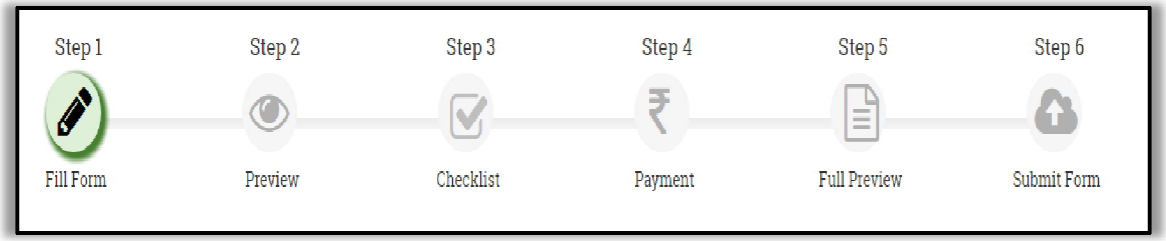


Figure 38 : 6 steps for Submission of form

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 **Import/Marketing Authorization** of Drug Substance
2.	Finished Formulation (FF)	Single Ingredient and Fixed Dose Combination	Permission required for **Import/Marketing Authorization** of Drug Product
3.	Both (BD&FF)	Single Ingredient	Permission required for **Marketing Authorization of Drug Product as well as for its Drug substance**
4.	Both (BD&FF)	Fixed Dose Combination	Permission required for **Marketing Authorization of Drug Product as well as for one or more of its Drug substance**

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	**CASE 1: Permission for FF** One of the ingredients of the FF which is a New Drug should have status: 'Application filed by other company simultaneously'. **CASE 2 (BOTH): Permission for FF and one or more of the ingredients which are New Drug** 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
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	**CASE 1: Permission for FF** One of the ingredients of the FF which is a IND should have status: 'Application filed by other company simultaneously'. **CASE 2 (BOTH): Permission for FF and one or more of the ingredients which are IND** 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

						permission applicant needs to file separate Application to SND division
3.	**Biological**	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.	**SND**	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.	**FDC**	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.	**BA/BE for Export**	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.	**Global Clinical Trial**	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.

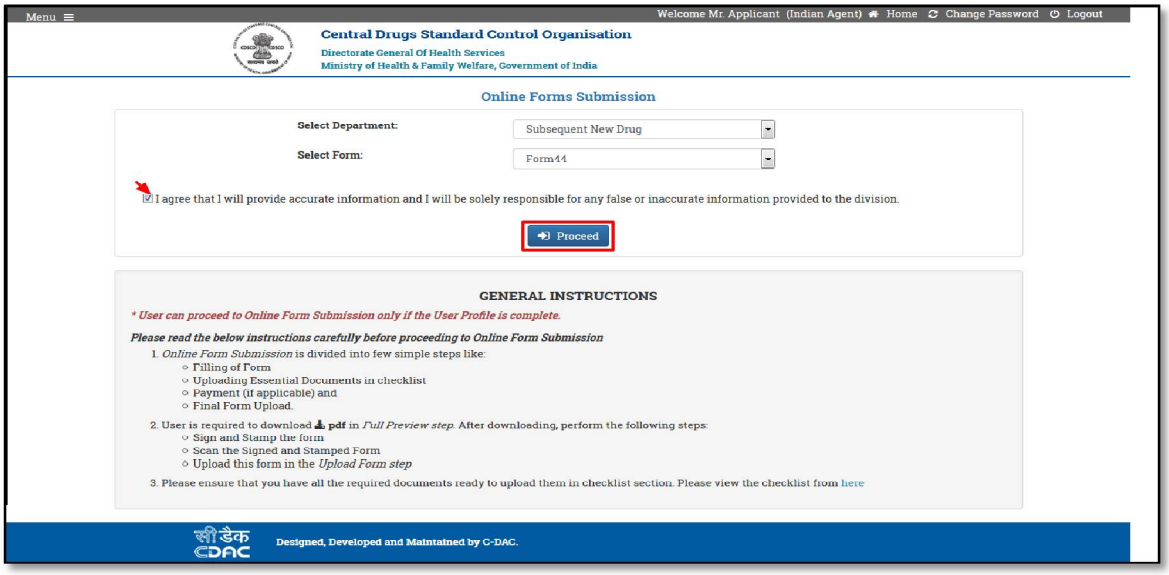


Figure 39 : Select Division -- Select the Form 44

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

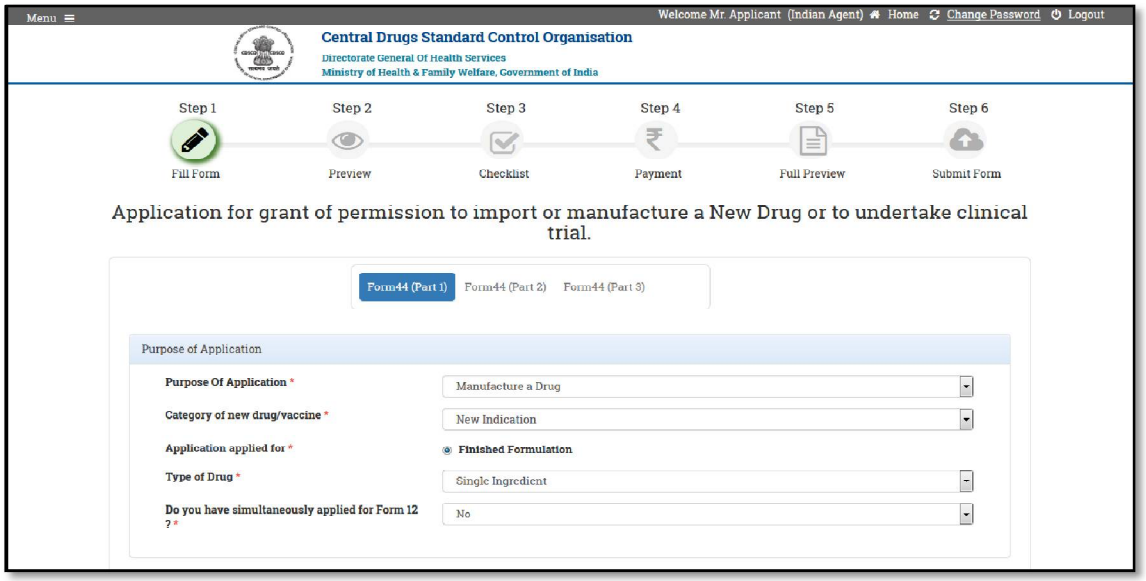


Figure 40 : Application Details

- **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

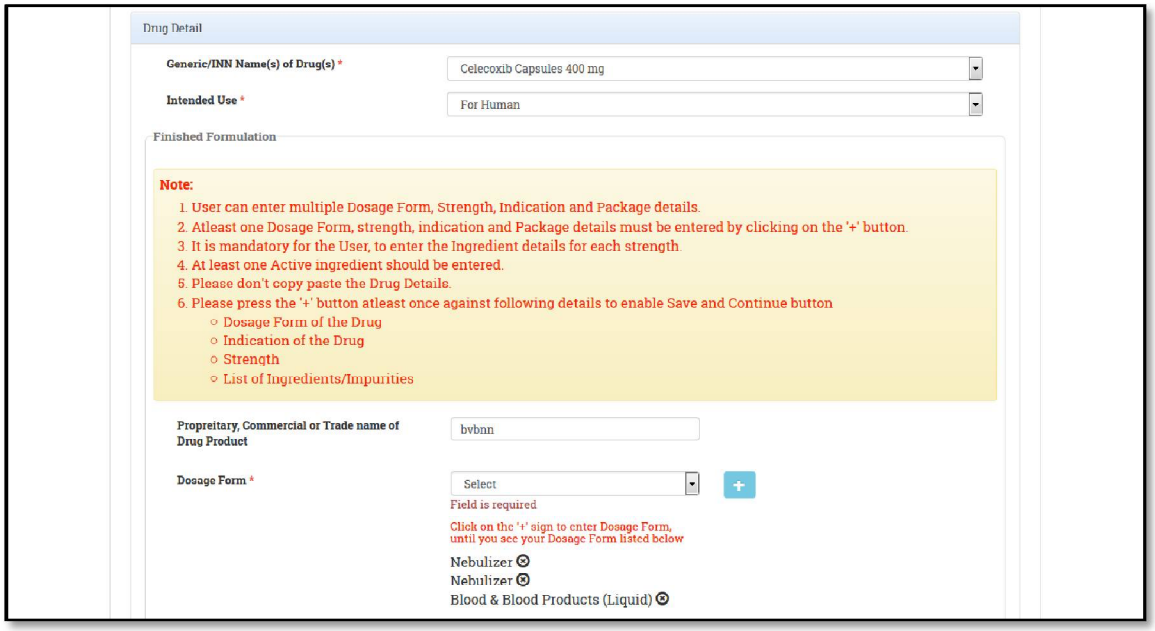


Figure 41 : Drug Details

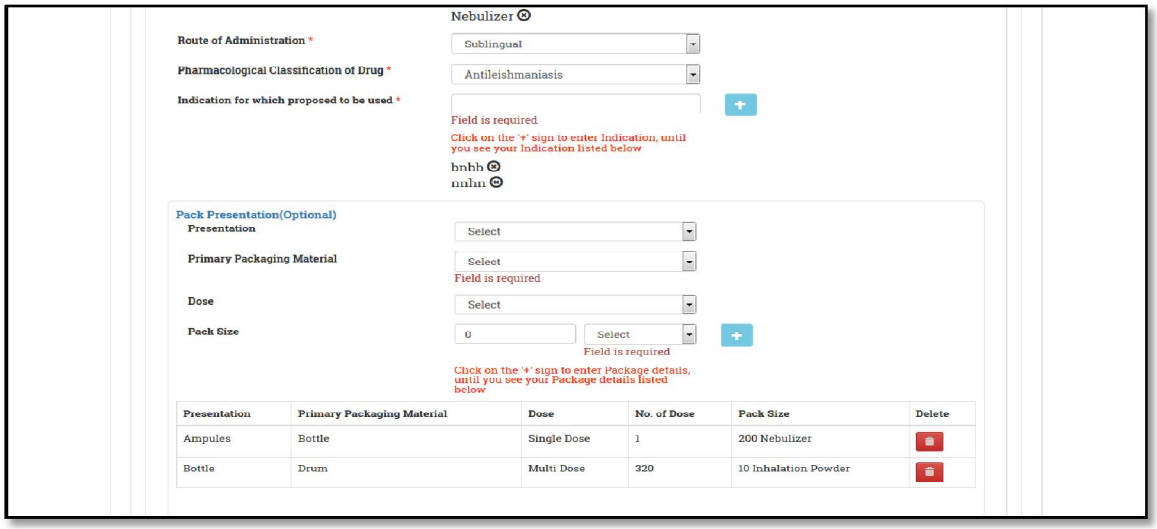


Figure 42 : Drug Details (Continue)

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.

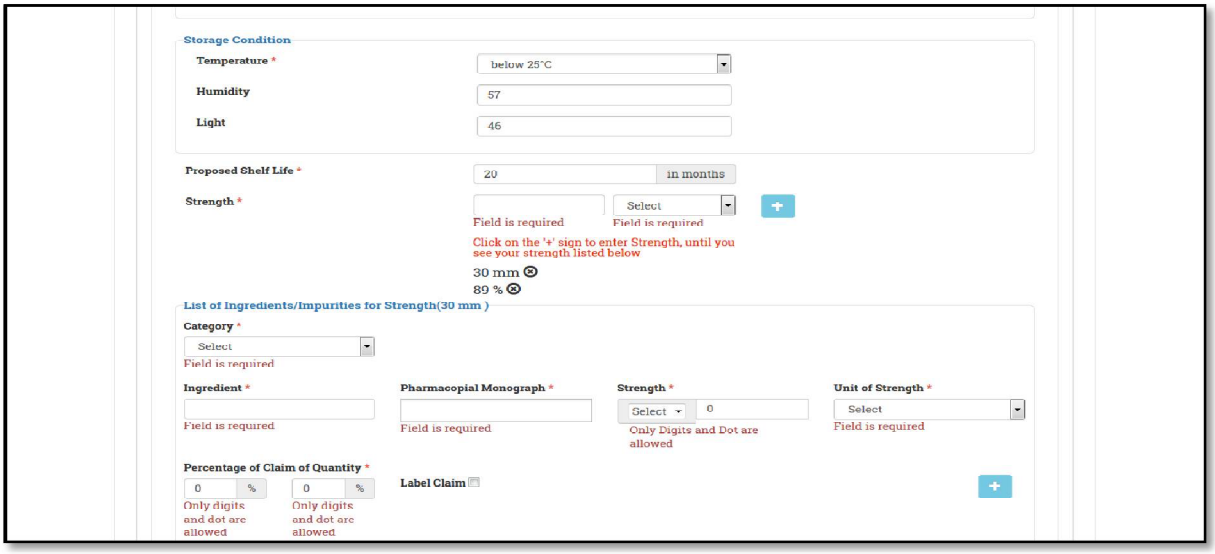


Figure 43 : Storage Condition & List of Ingredients

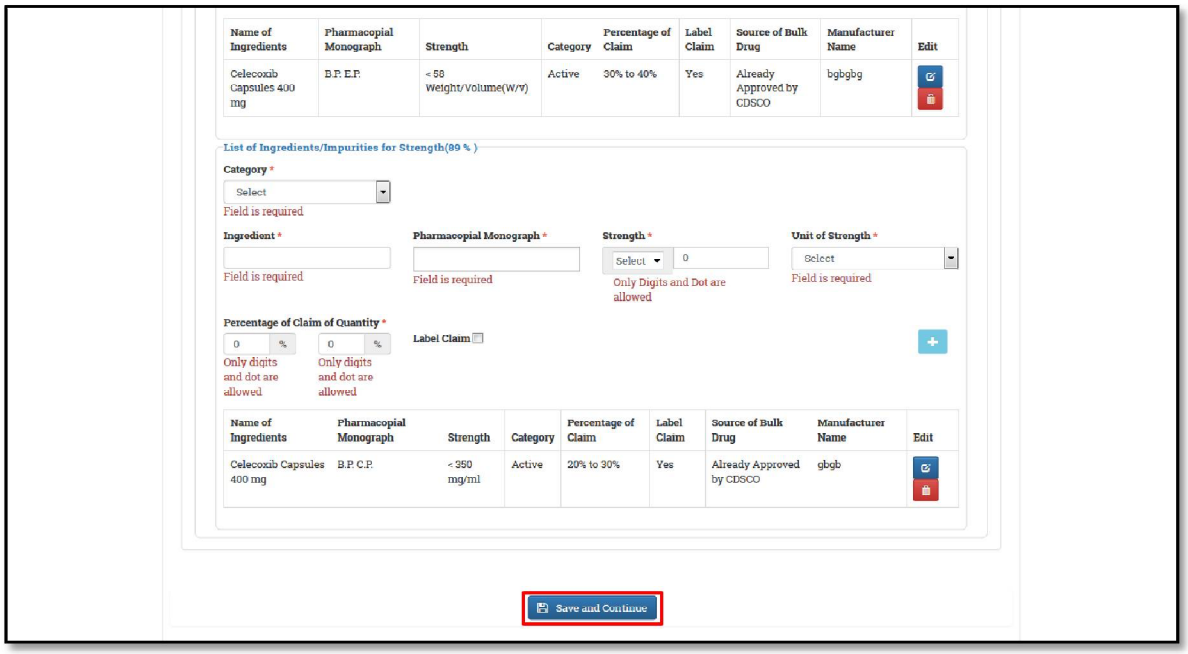


Figure 44 : Click on Save and Continue button

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

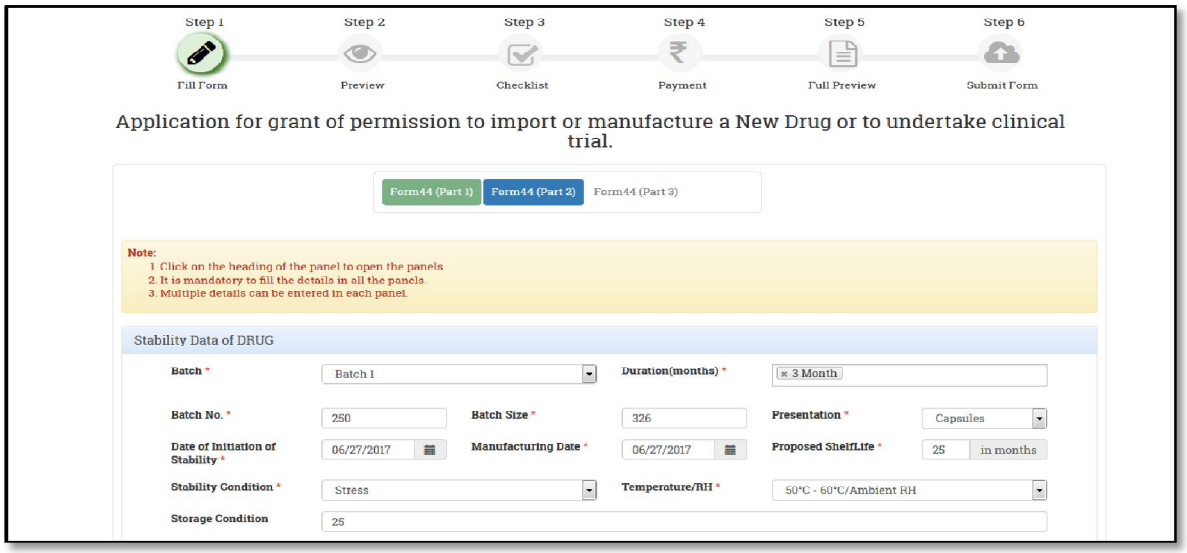


Figure 45 : Drug Stability Details

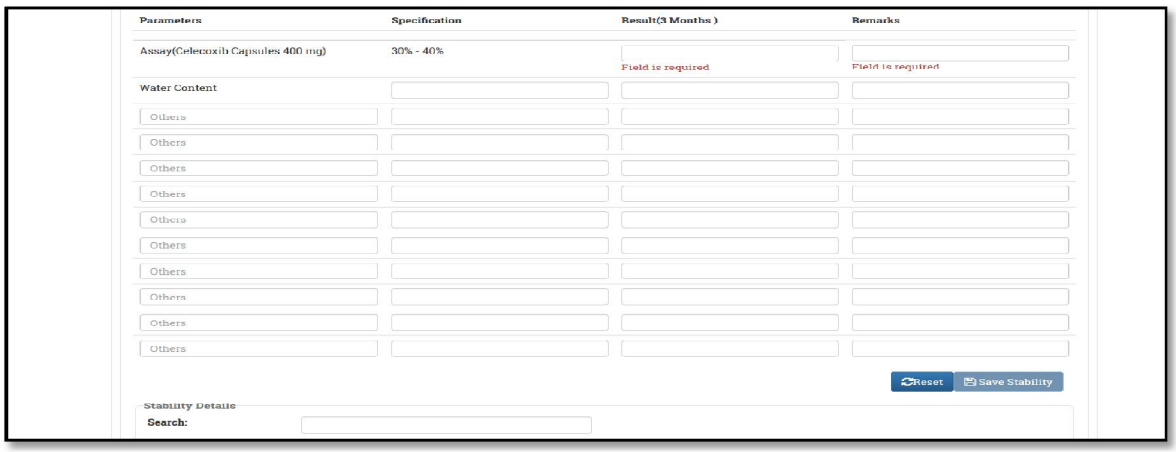


Figure 46 : Fill Drug Stability Details

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 :

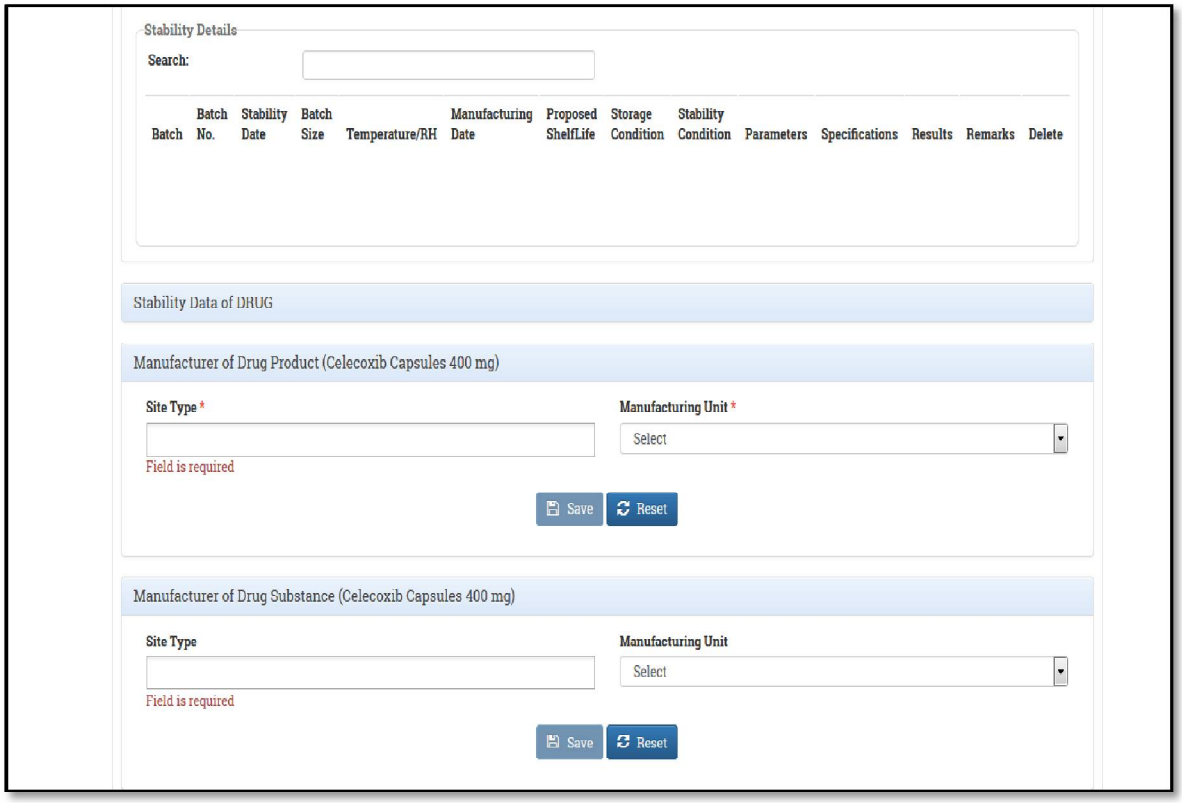


Figure 47 : Manufacturer & Site Details

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

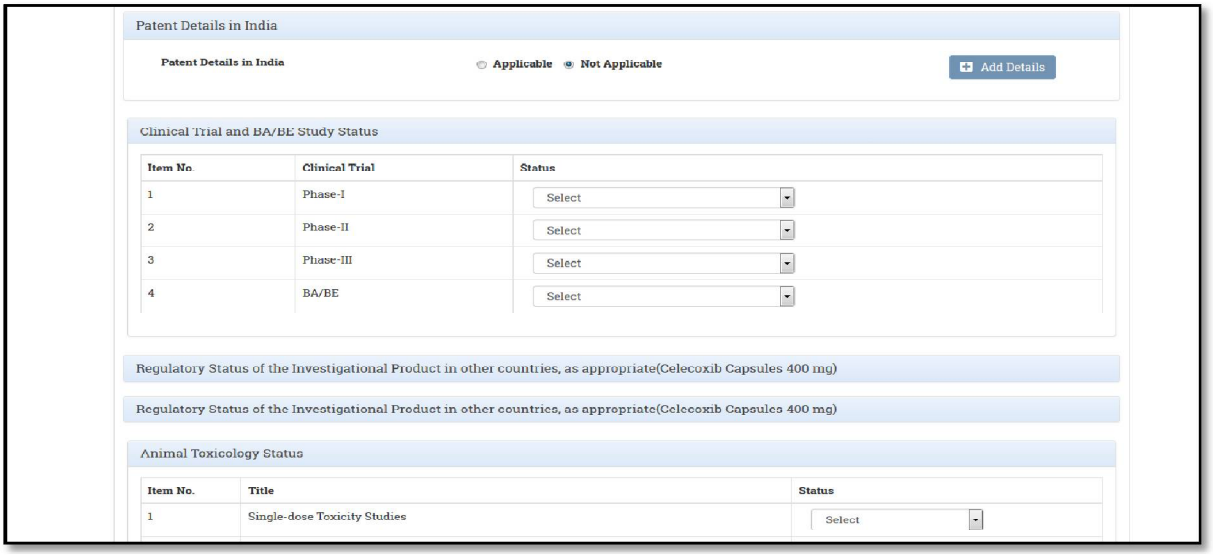


Figure 48 : Patent, Regulatory Status, CT & BA/BE Study Details

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:

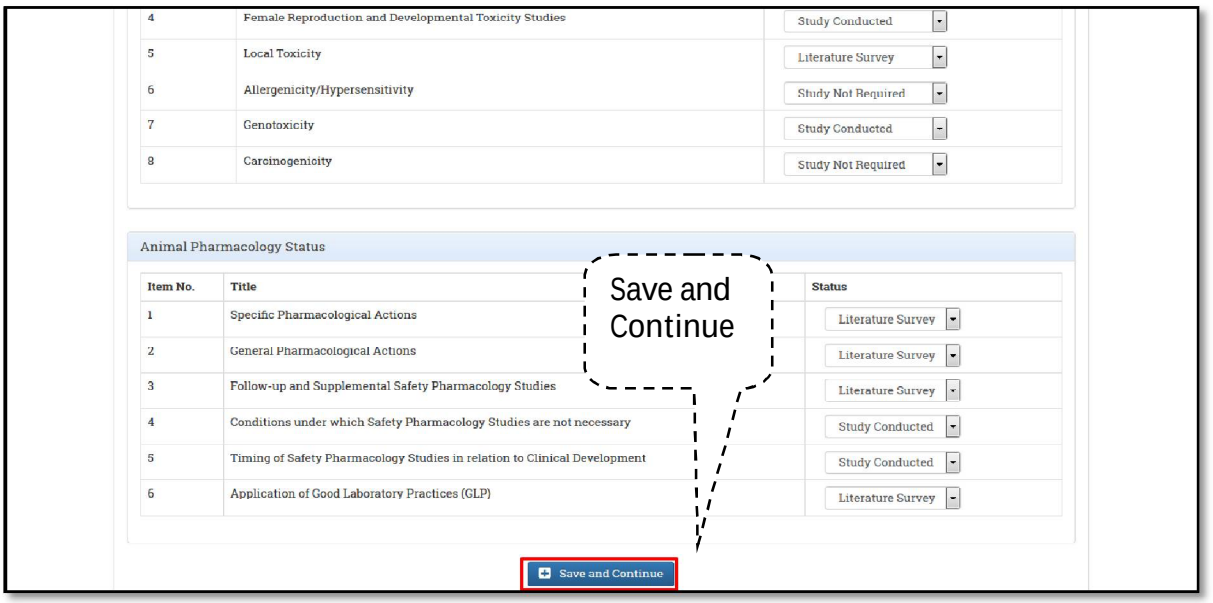


Figure 49 : Click on Save and Continue Button

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.

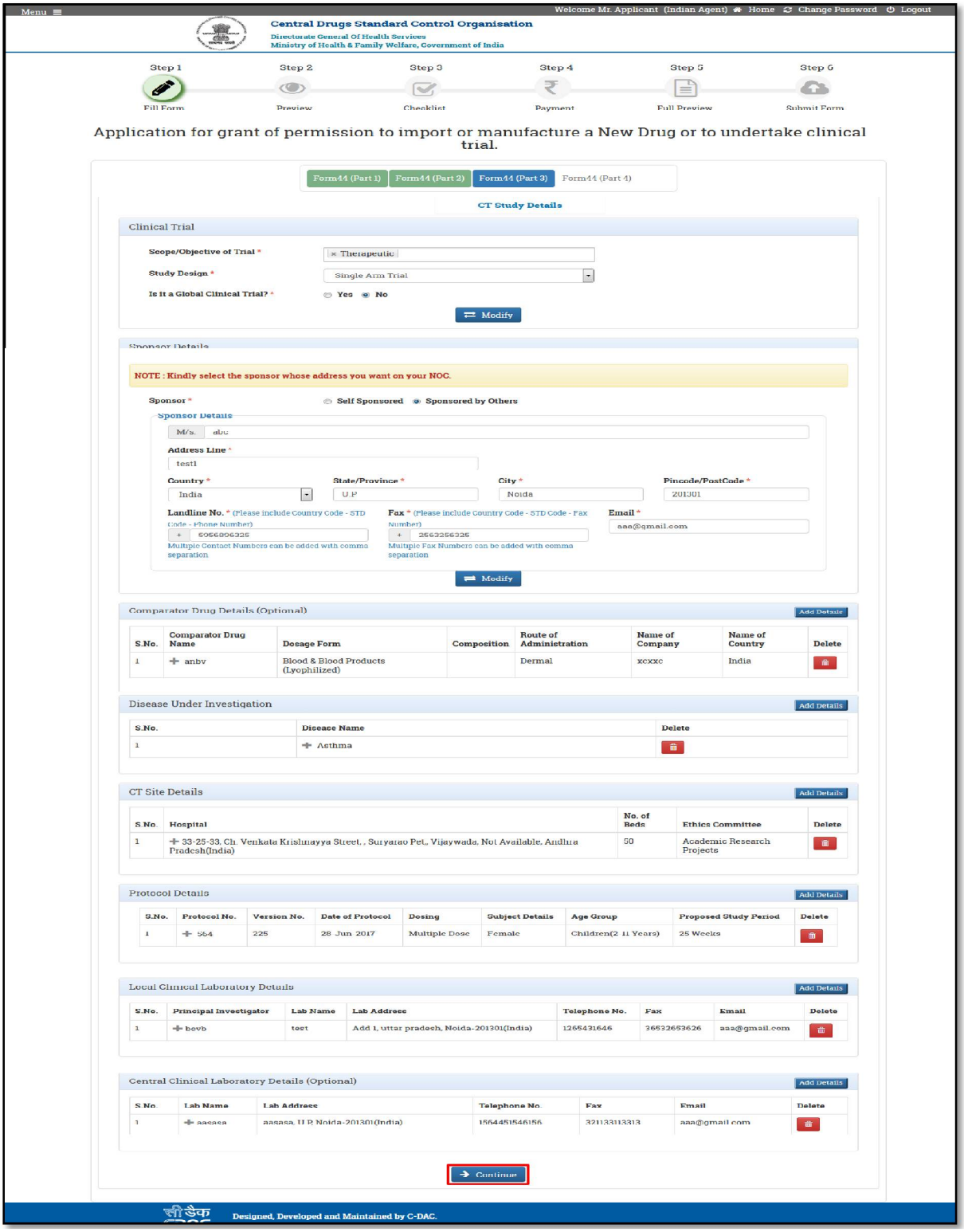


Figure 50 : Clinical Trial Details

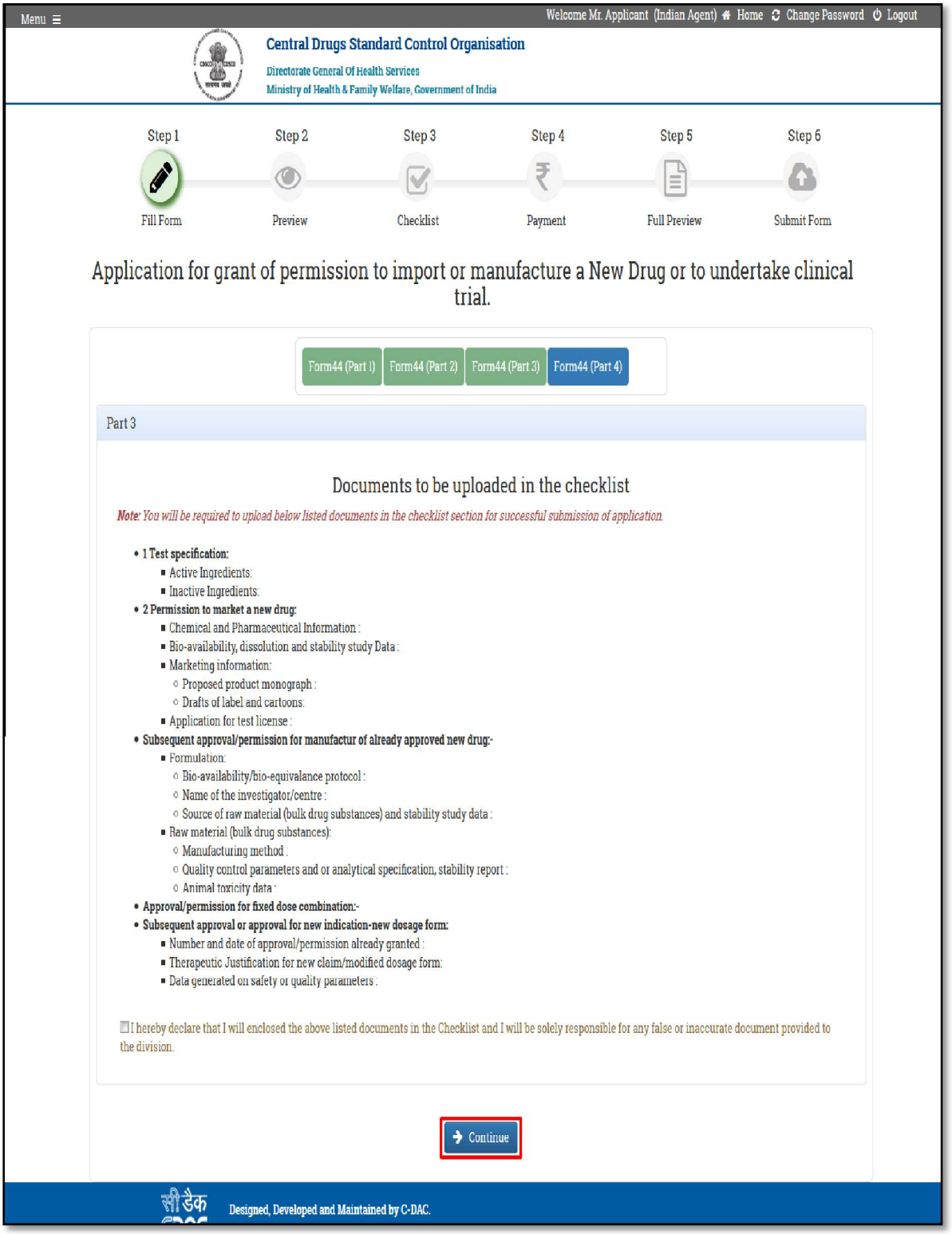


Figure 51 : Undertaking for checklist documents

- **First Preview of the Form 44**

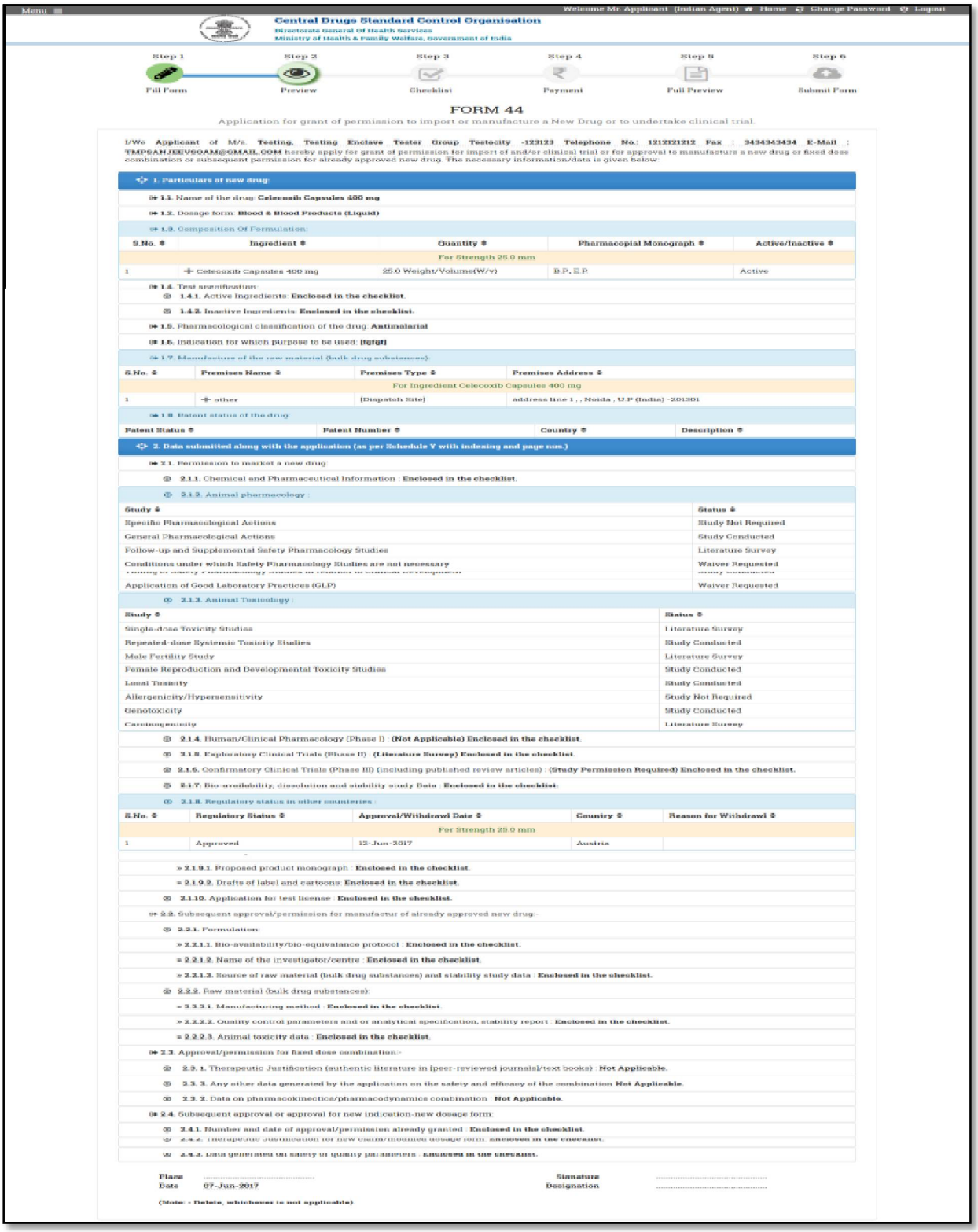


Figure 52 : First Preview of the Form 44

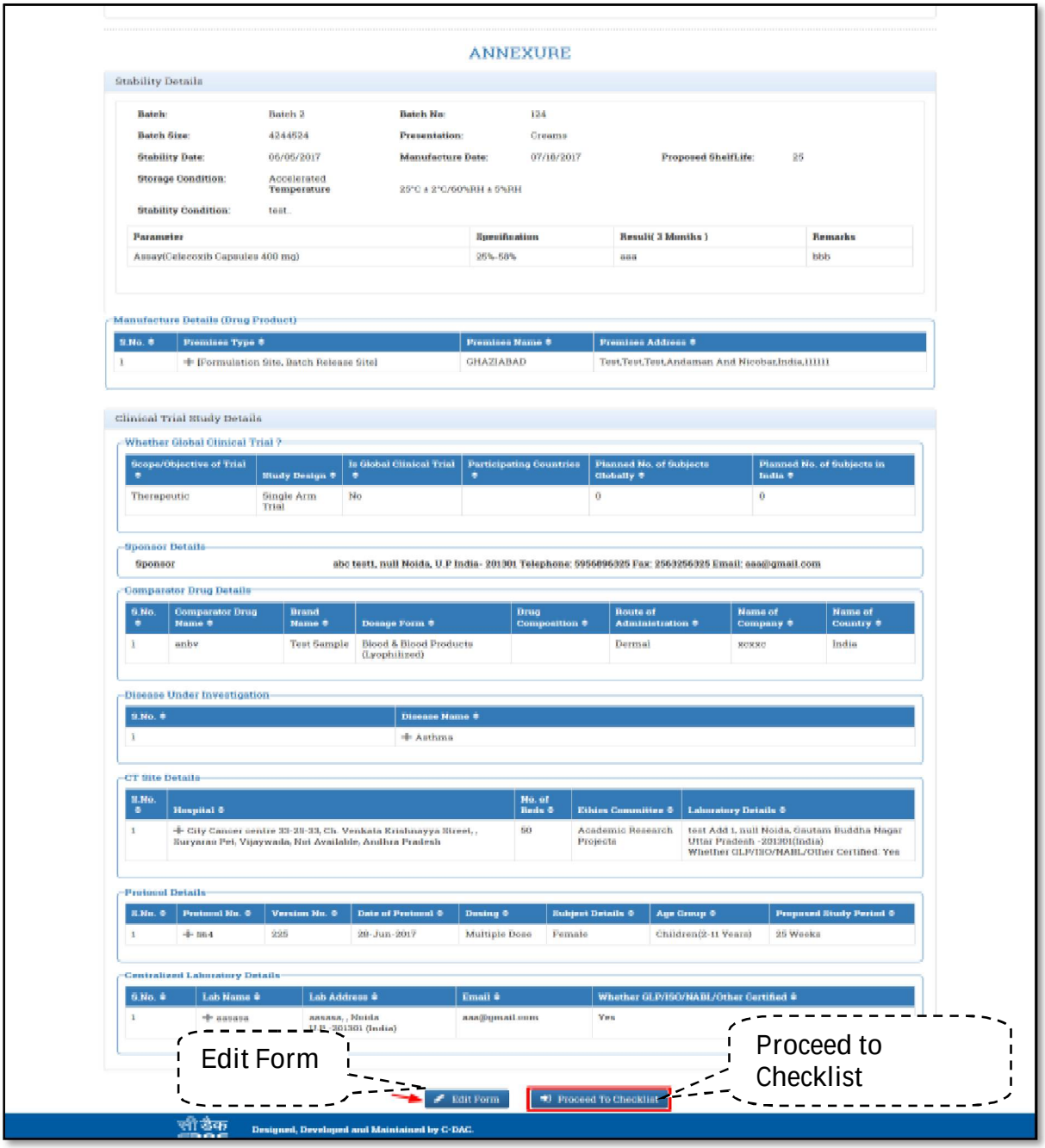


Figure 53 : First Preview of the Form 44 (Continue)

- Confirmation alert to proceed to checklist

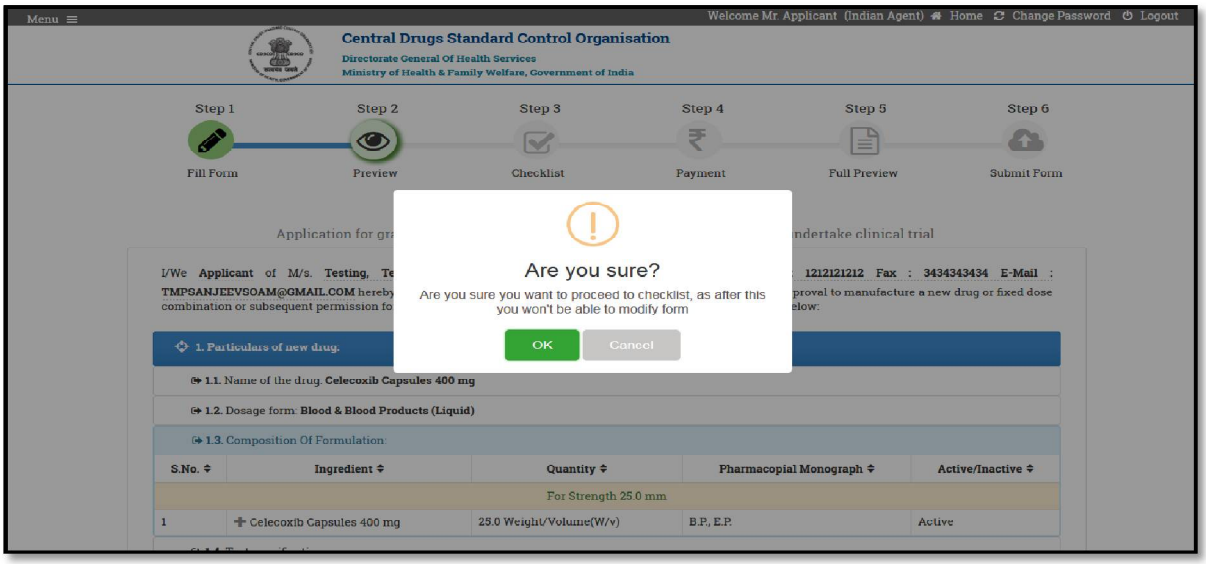


Figure 54 : Popup Message: Confirmation alert to Proceed to Checklist

- **Checklist to upload the documents**

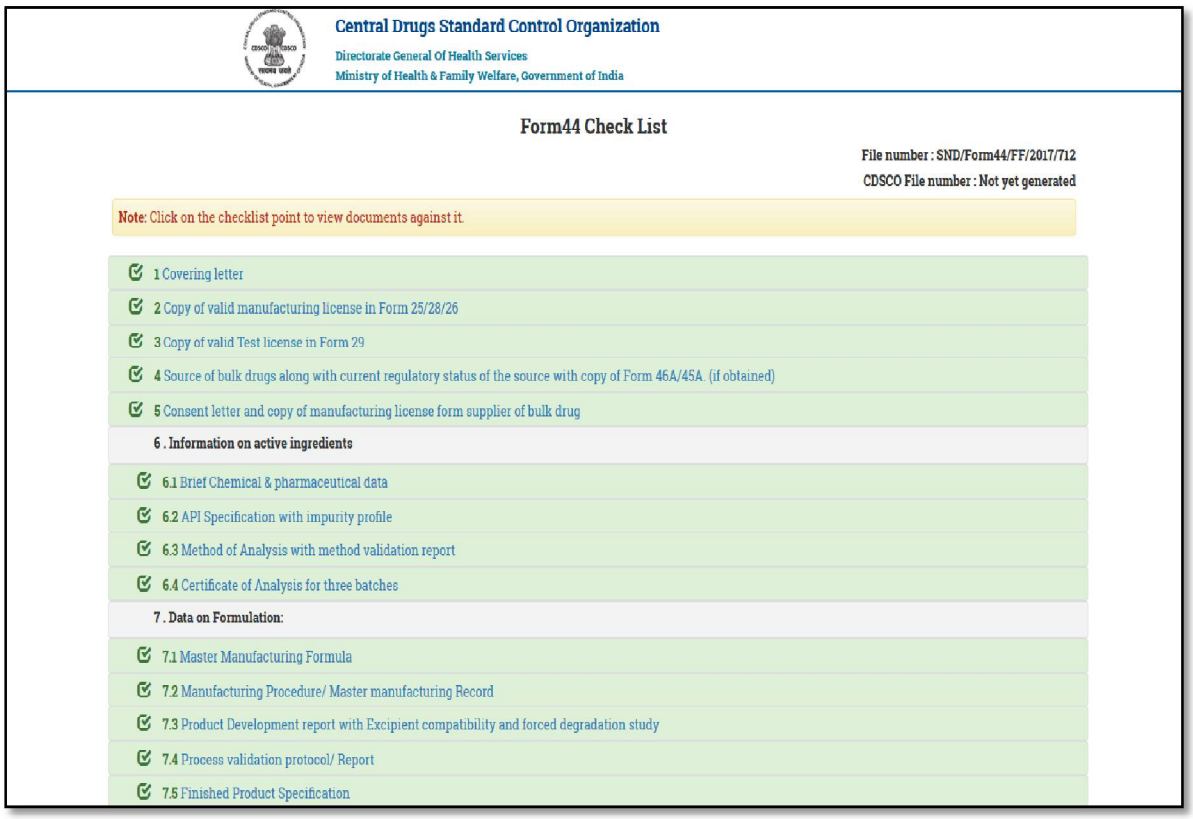


Figure 55 : Checklist to upload the documents

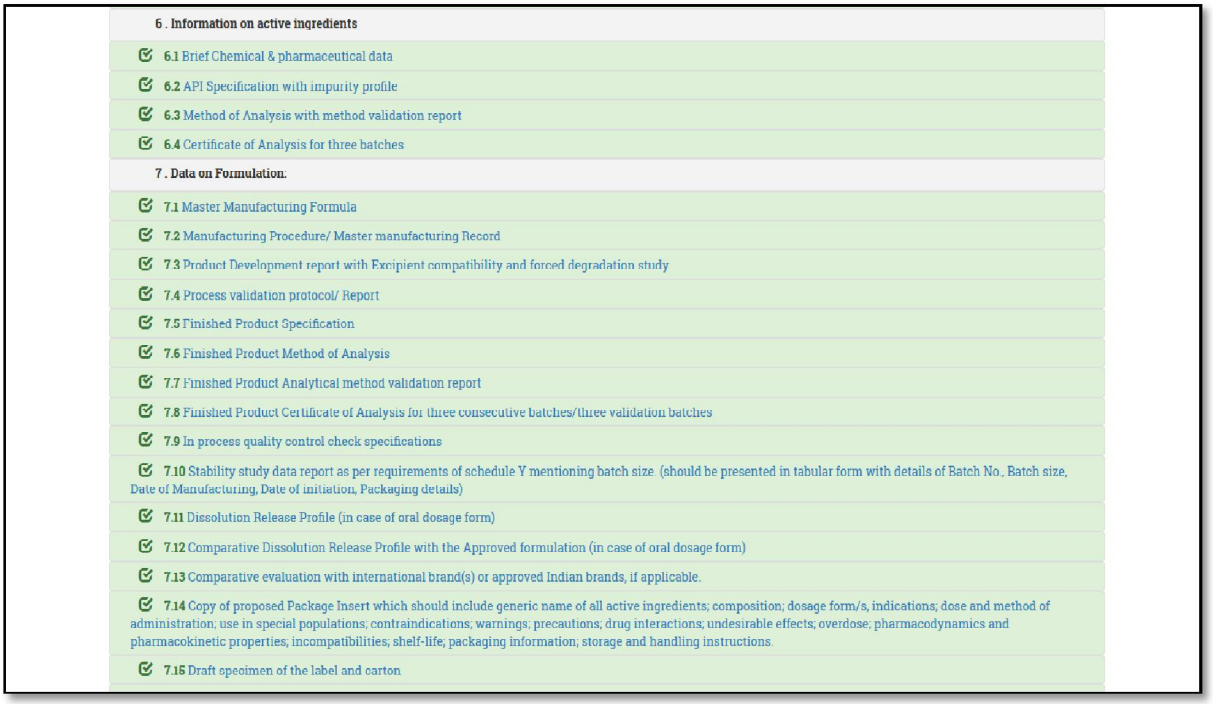


Figure 56 : Checklist to upload the documents (Continue)

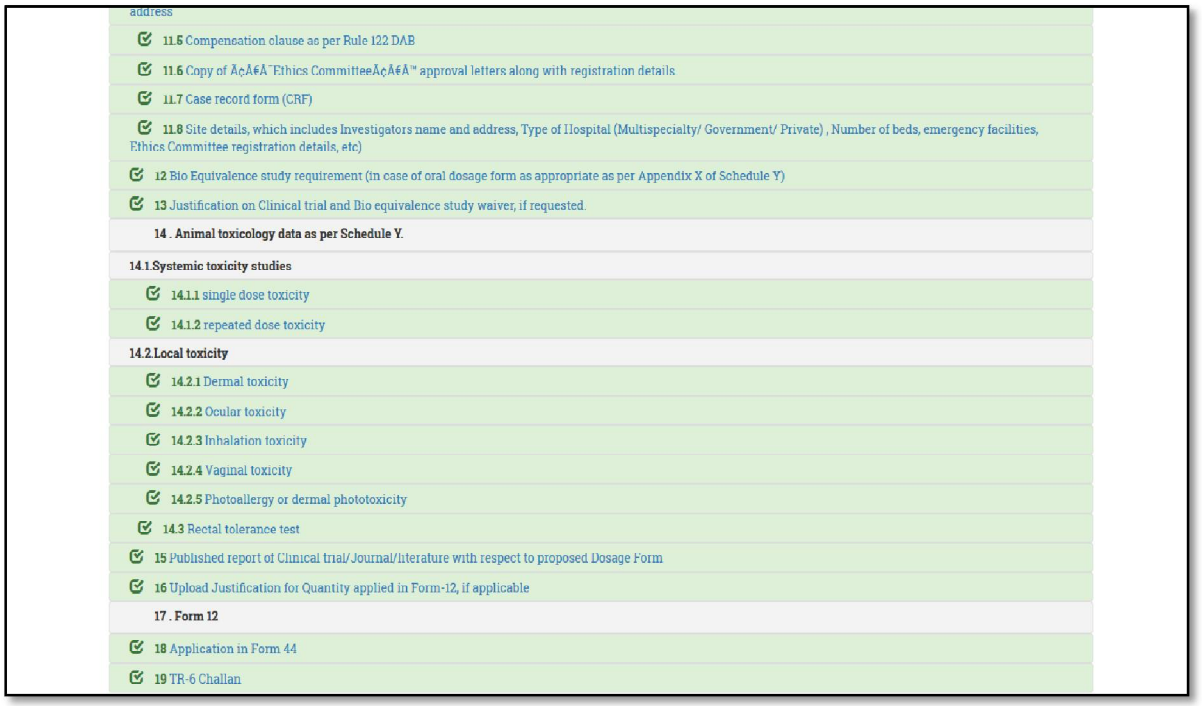


Figure 57 : Checklist to upload the documents (Continue)

- **Payment for the form**

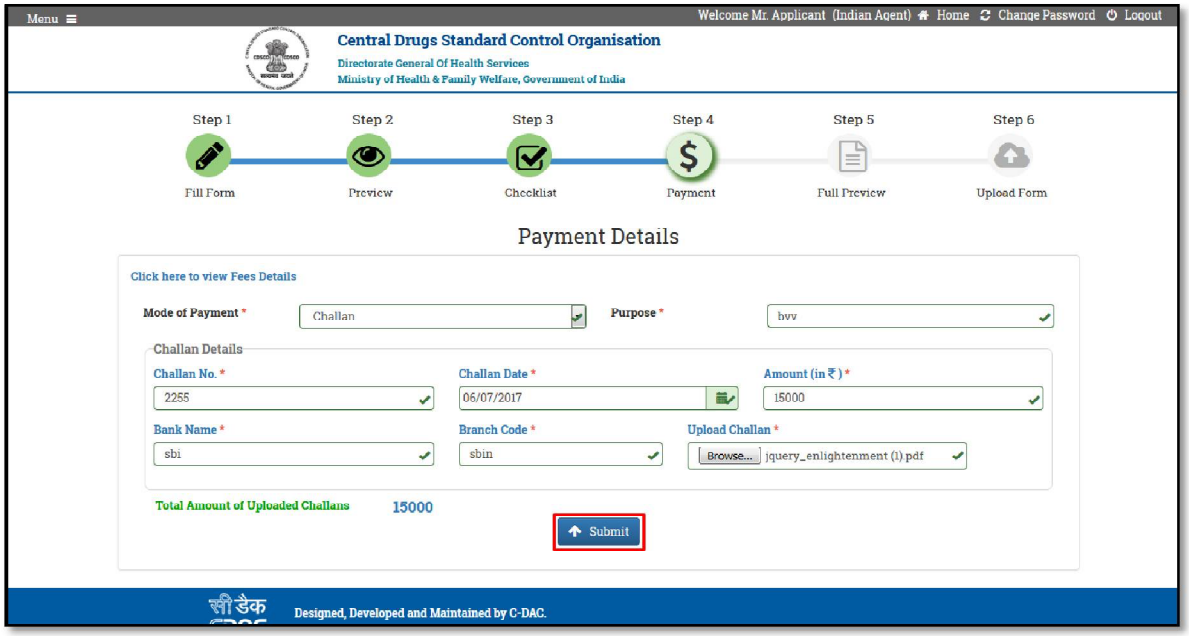


Figure 58 : Payment for the form

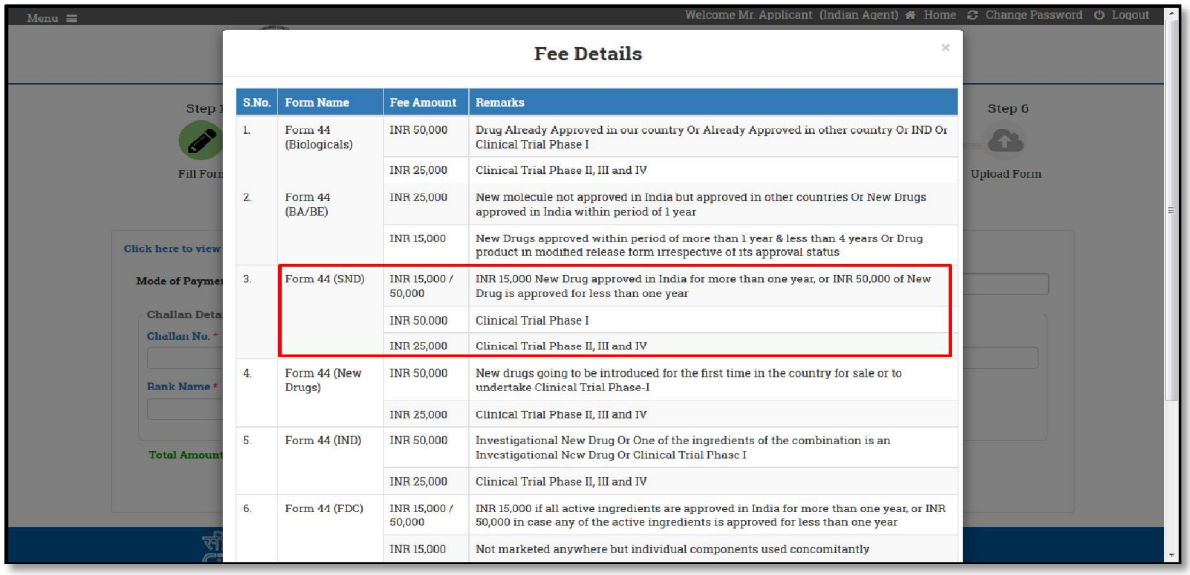


Figure 59 : Screen of Fee Details

- **Final preview of the form with download option**

Figure 60 : Final preview of the form with download option

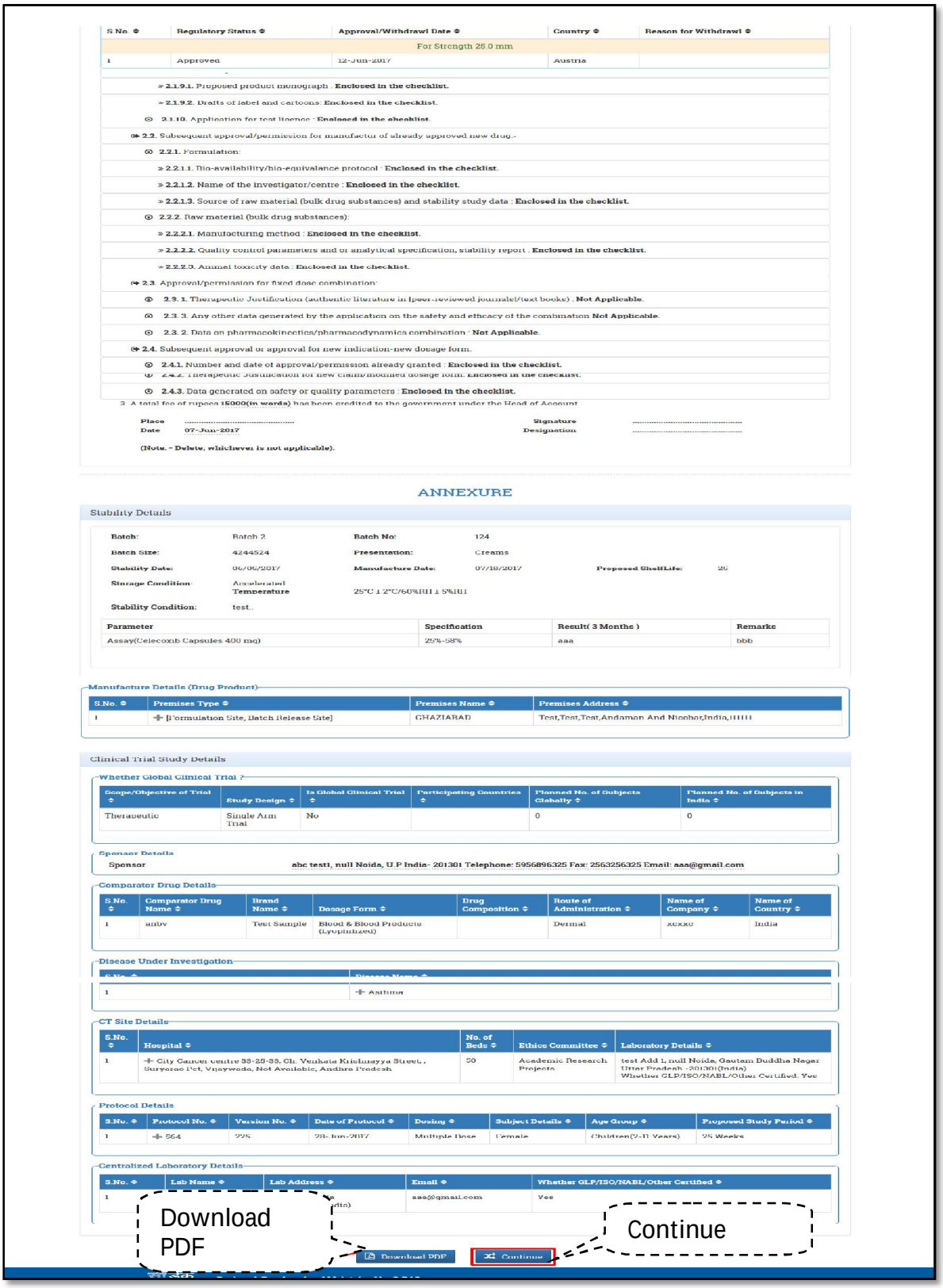


Figure 61 : Final preview of the form with download option (Continue)

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

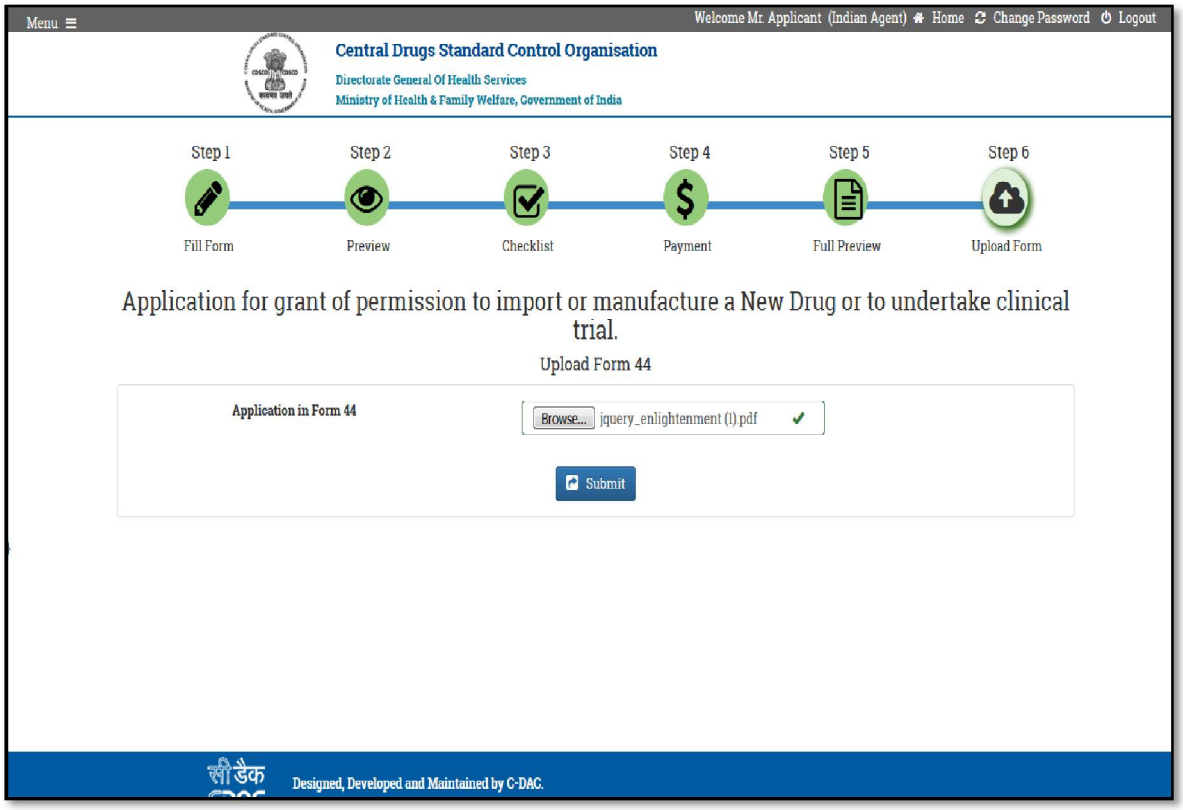


Figure 62 : Uploading & Submitting Form44

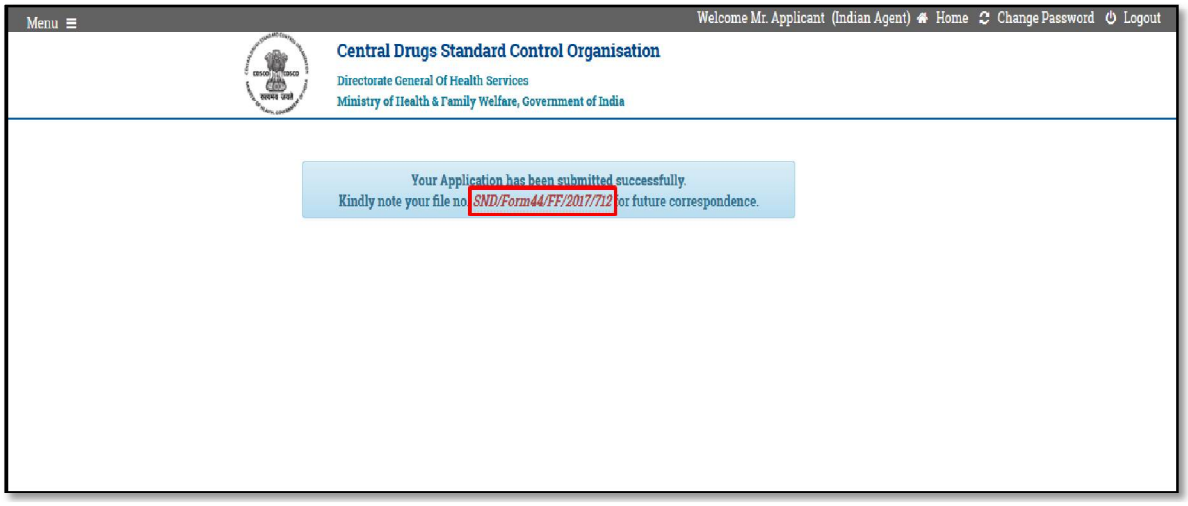


Figure 63 : Application Submitted Successfully

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:

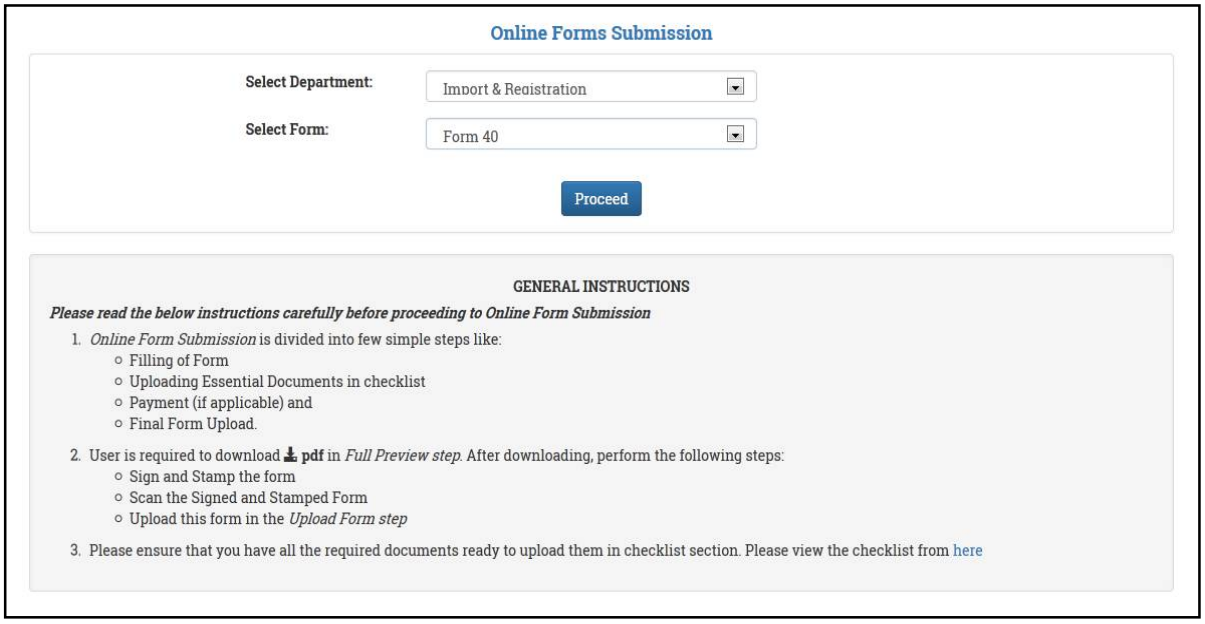


Figure 64 : Application for Grant of Registration Certificate (RC)

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**

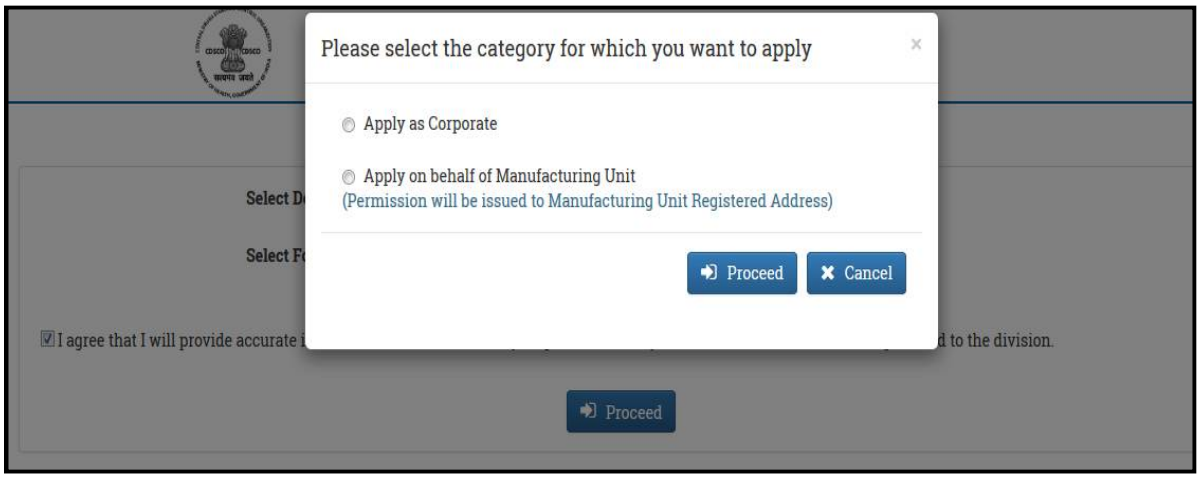


Figure 65 : Confirmation Message: Proceed

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.

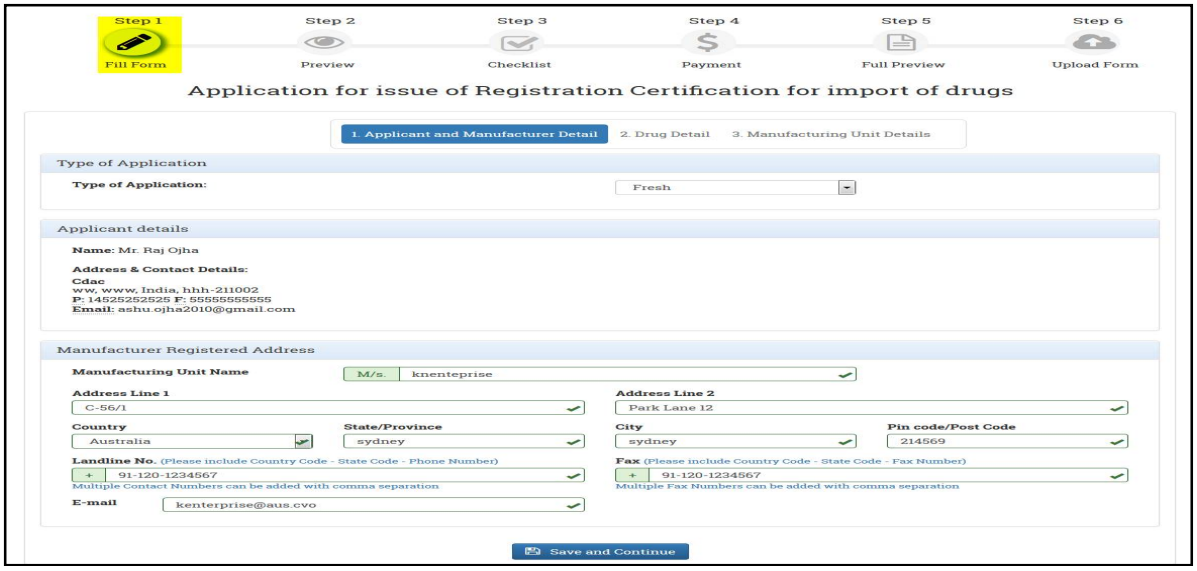


Figure 66 : Applicant & Manufacturer details

- **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

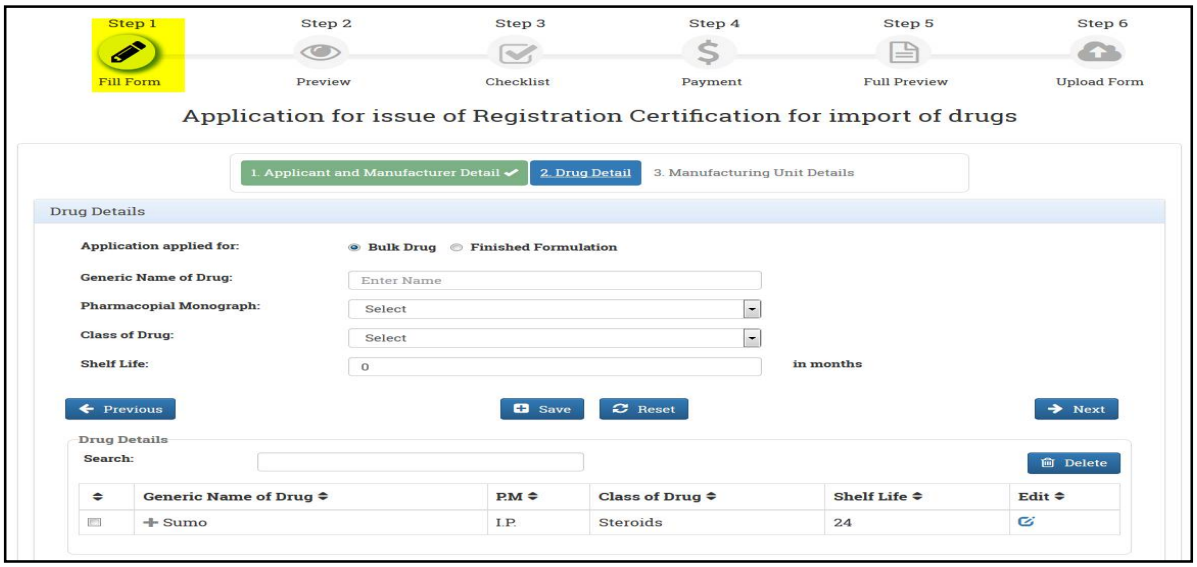


Figure 67 : Drug details

- 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.

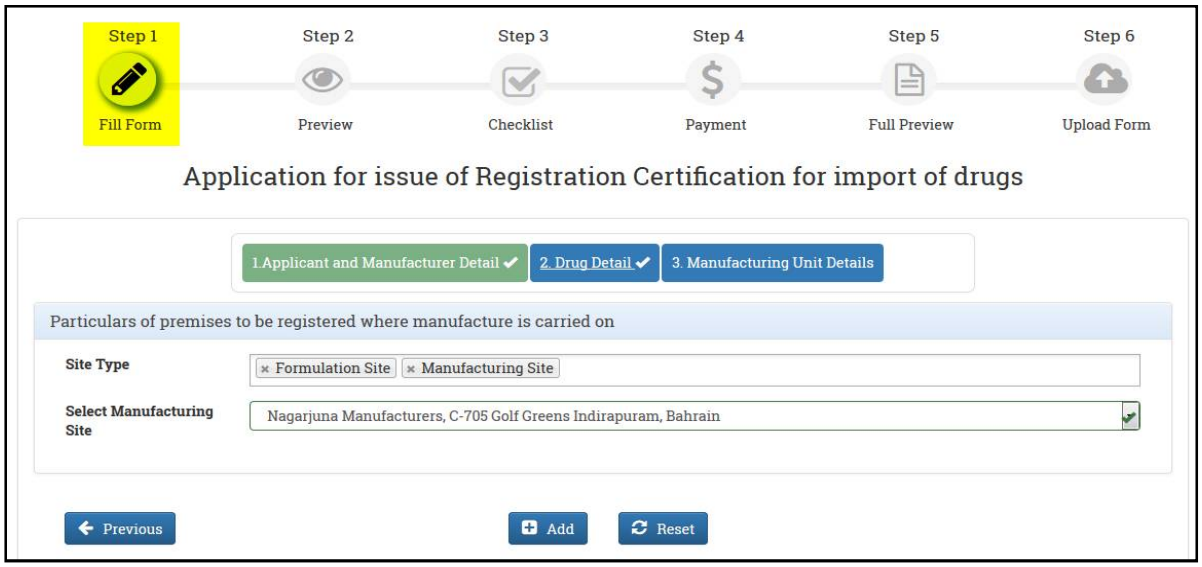


Figure 68 : Manufacturing Site details

- **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.

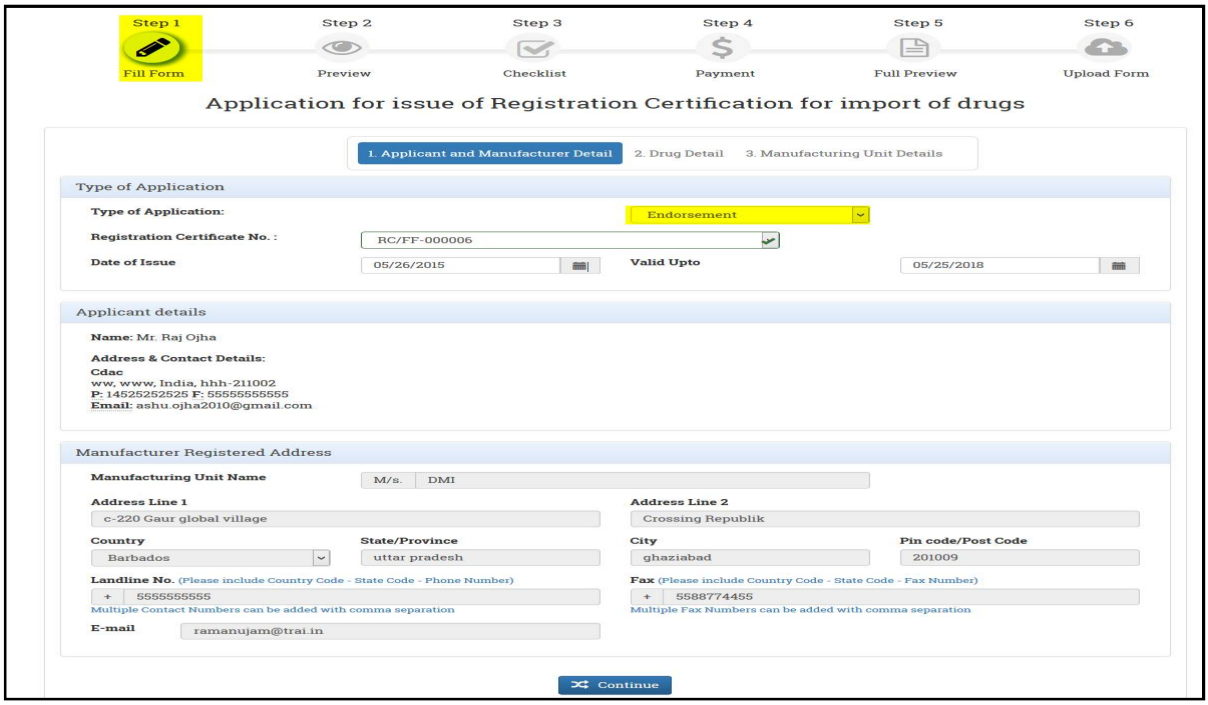


Figure 69 : Type of Application- Endorsement

- 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.

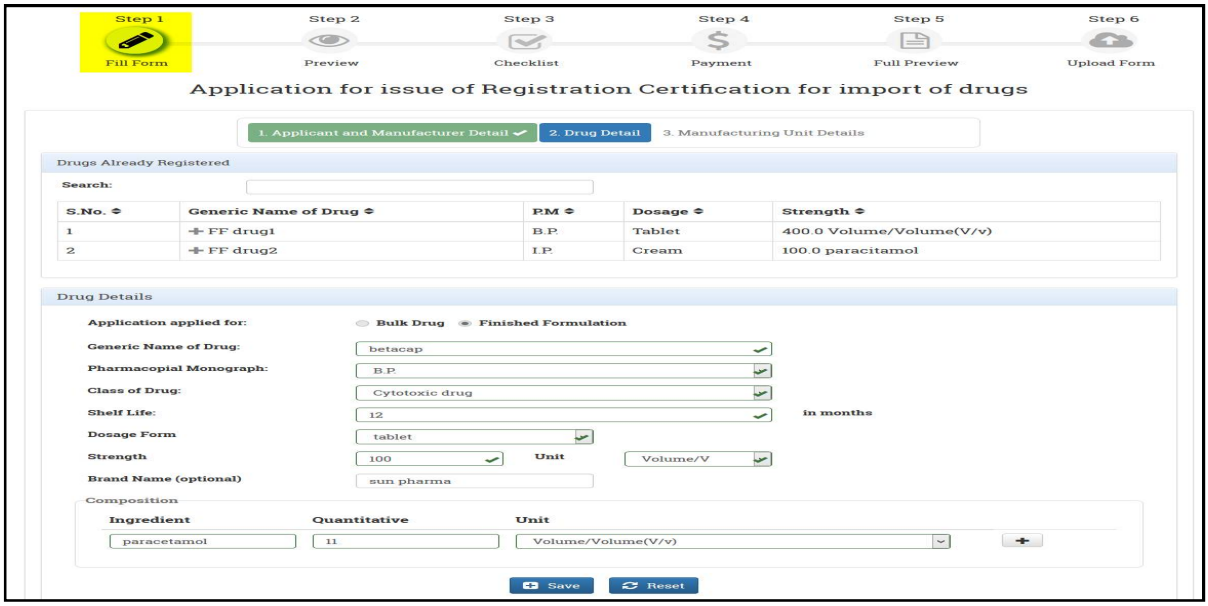


Figure 70 : Update the data of the additional drugs

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

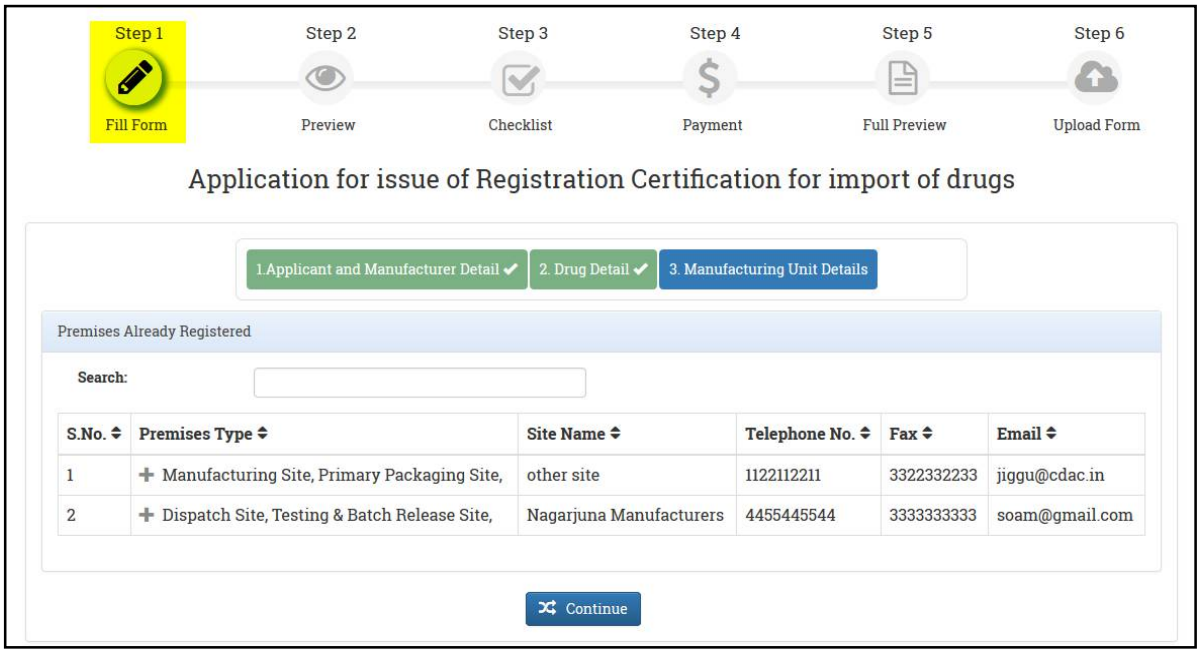


Figure 71 : Screen of after clicking on save button

➢ **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.

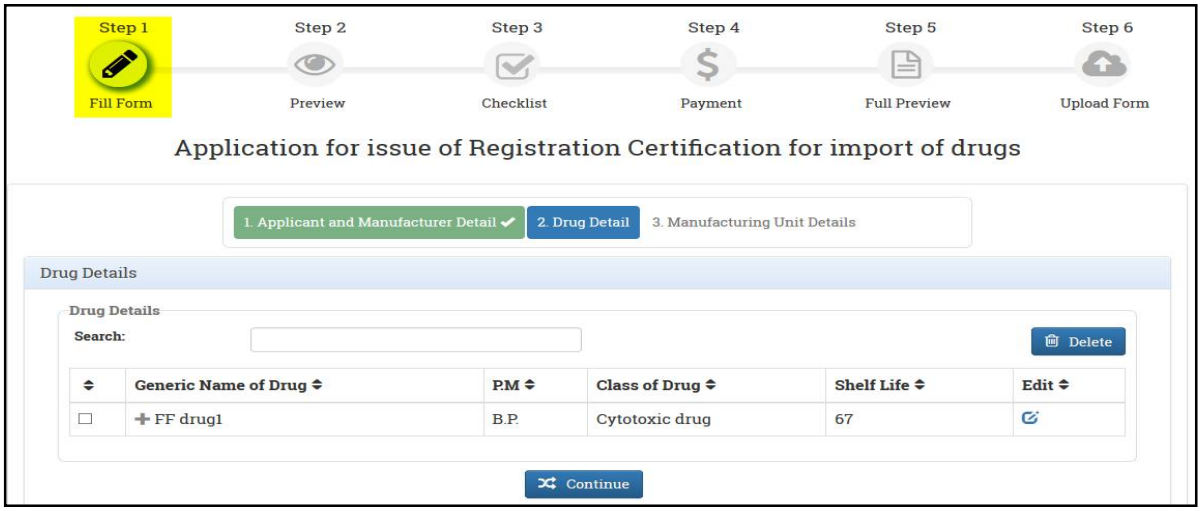


Figure 72 : Type of Application: - Re-registration

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

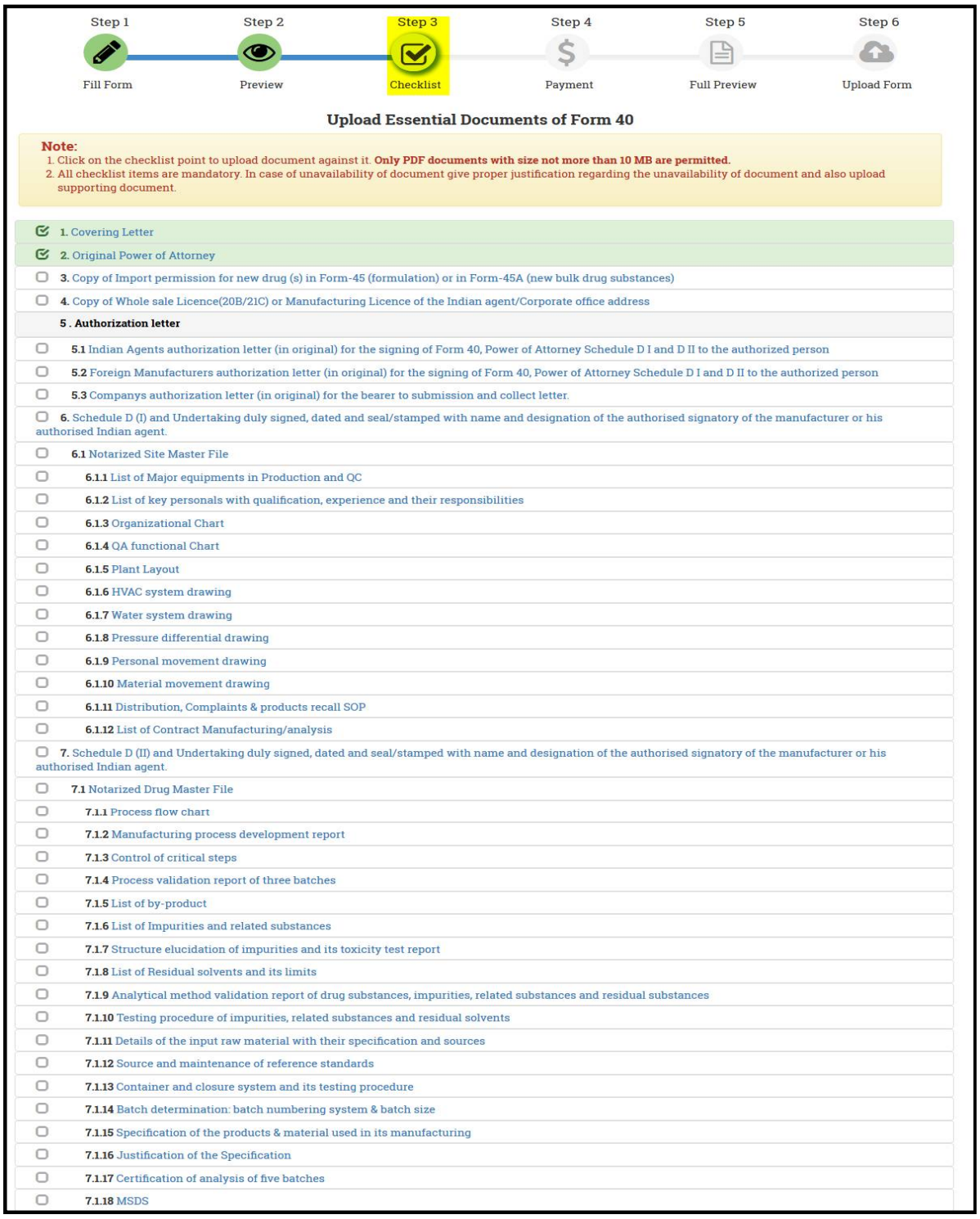


Figure 73 : Screen of Upload Essential Documents of Form 40

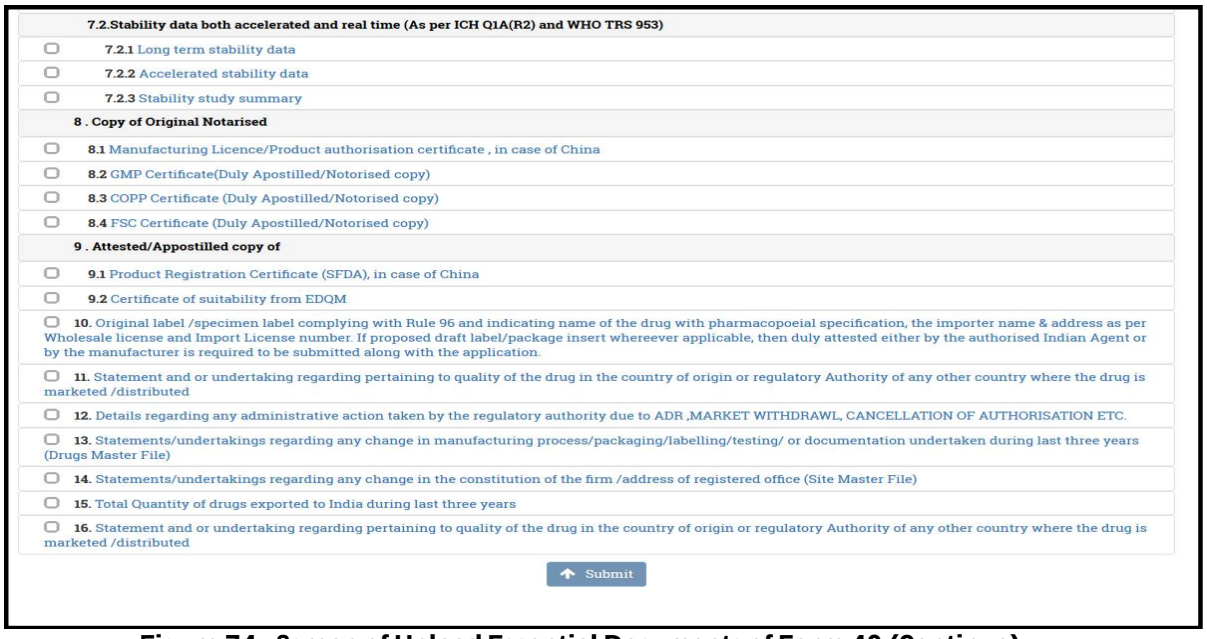


Figure 74 : Screen of Upload Essential Documents of Form 40 (Continue)

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

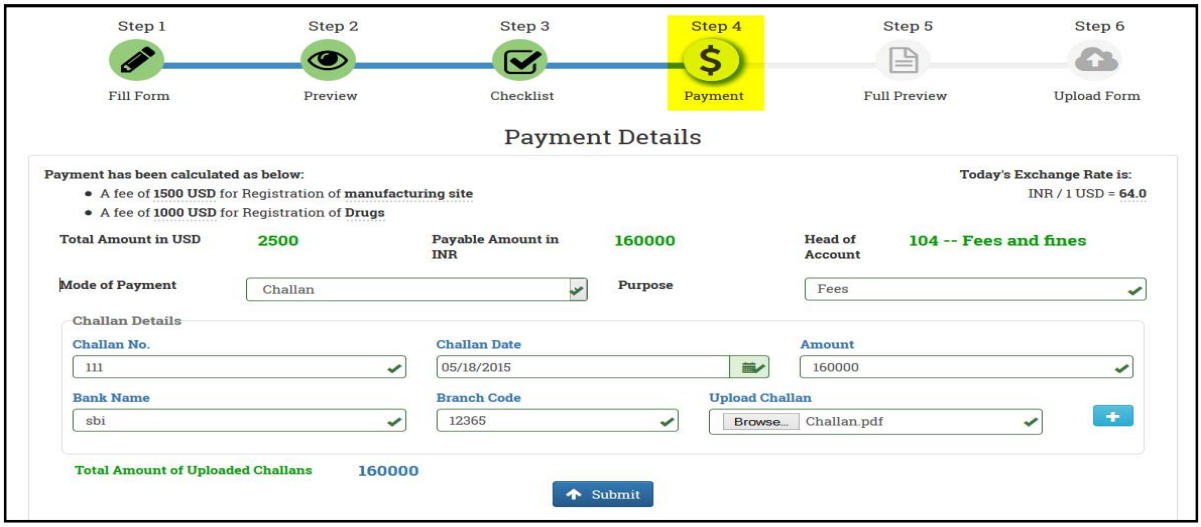


Figure 75 : Payment Details

- 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.

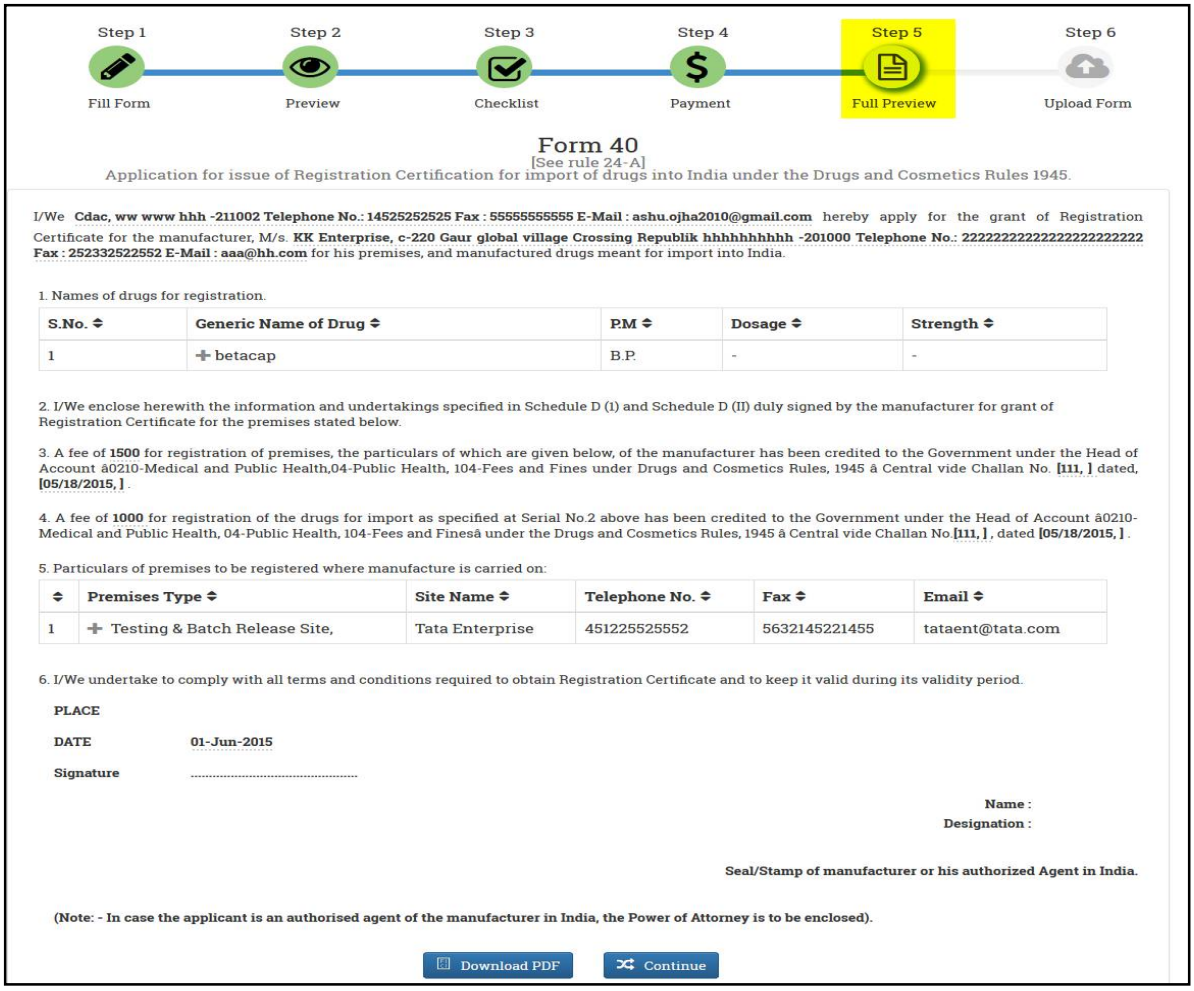


Figure 76 : Final preview of the filled form in legal form40

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

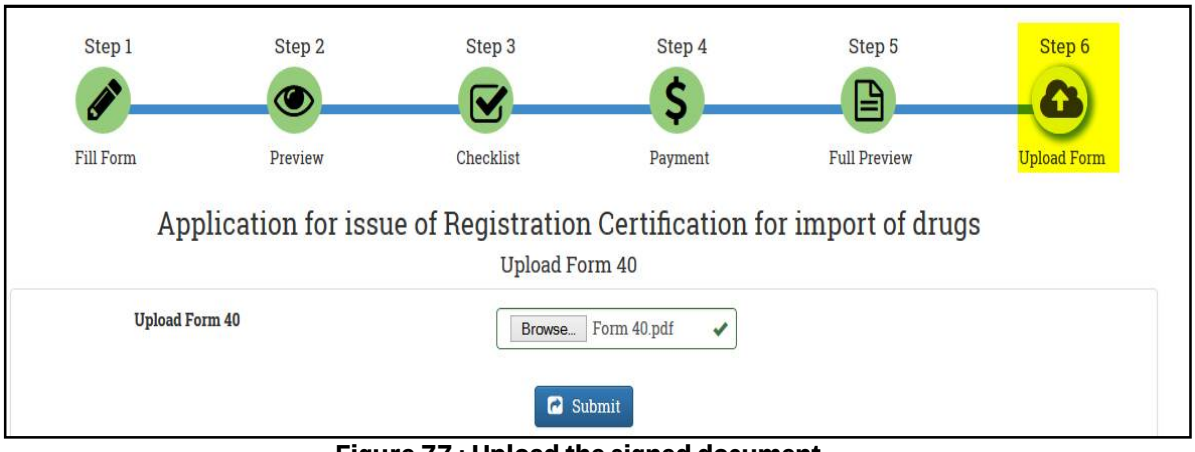


Figure 77 : Upload the signed document

- 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.**

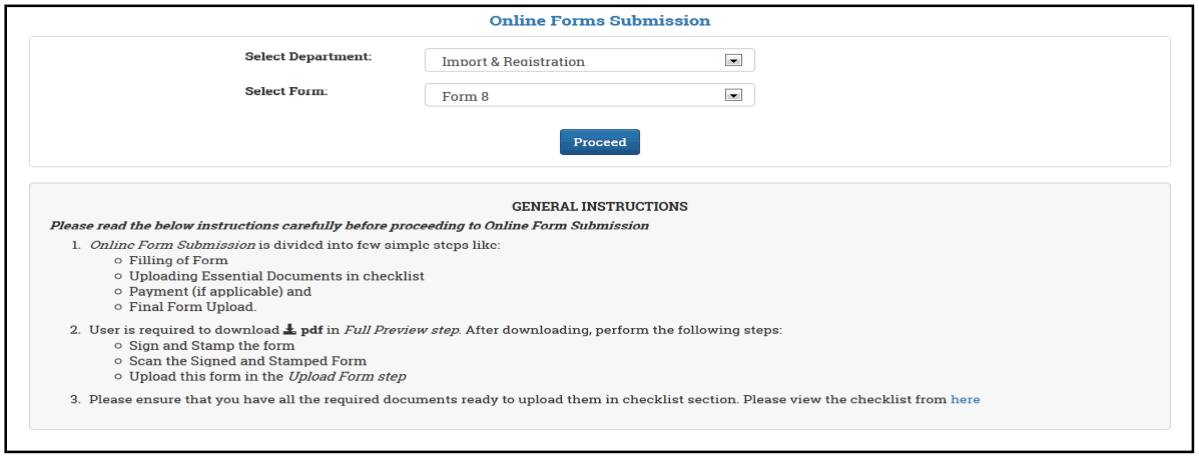


Figure 79 : Application for Grant of Import License

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

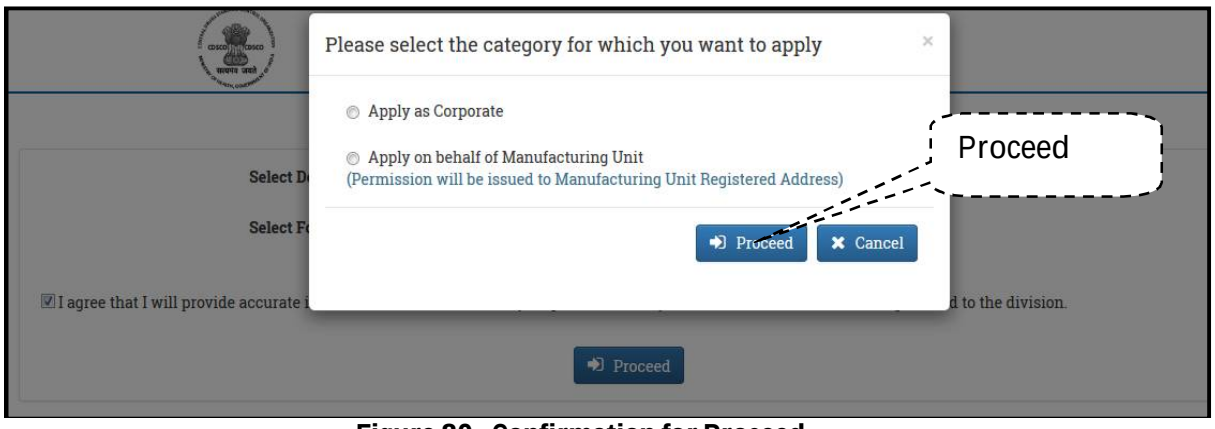


Figure 80 : Confirmation for Proceed

- 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 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.

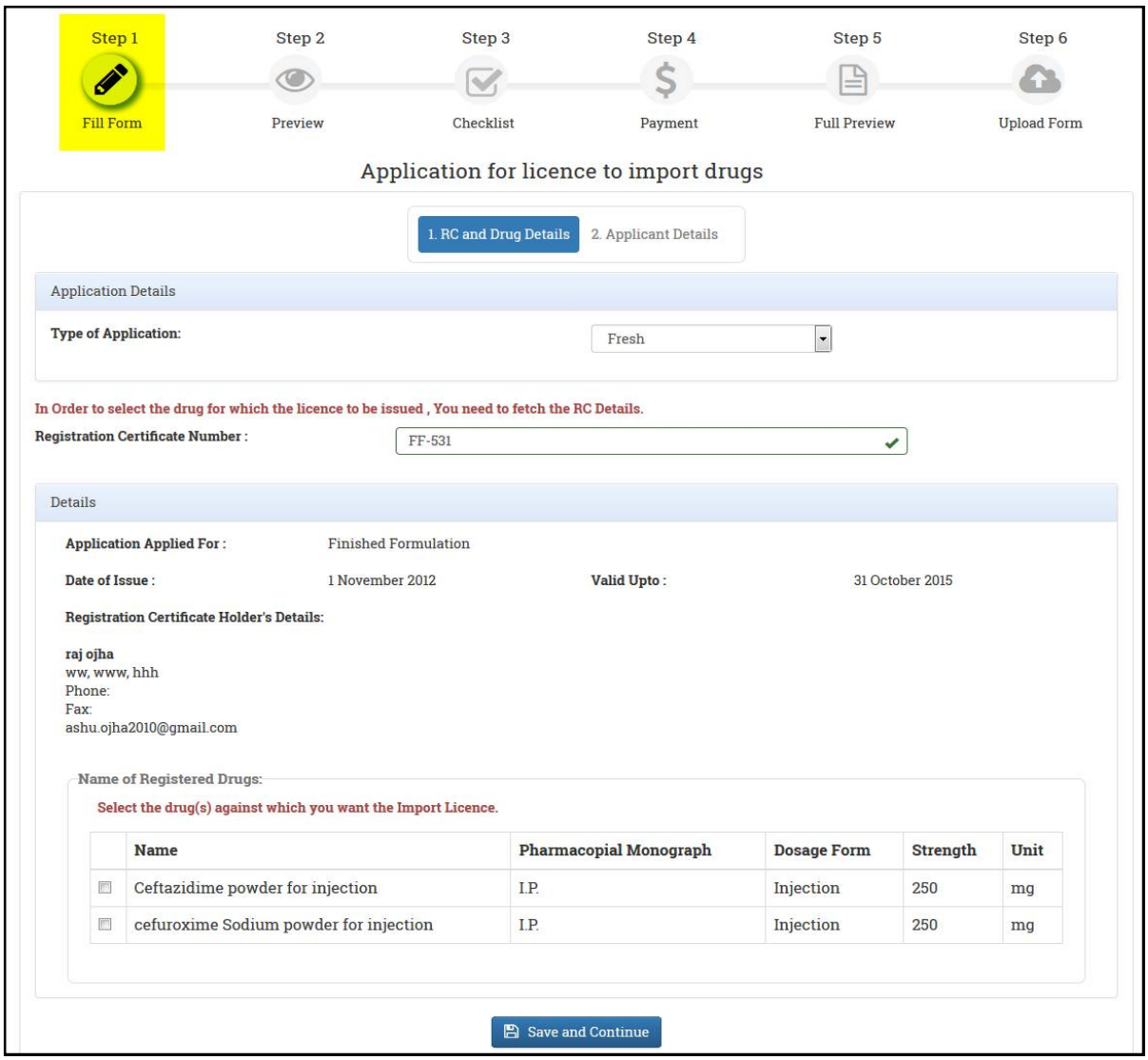


Figure 81 : Type of application: Fresh

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

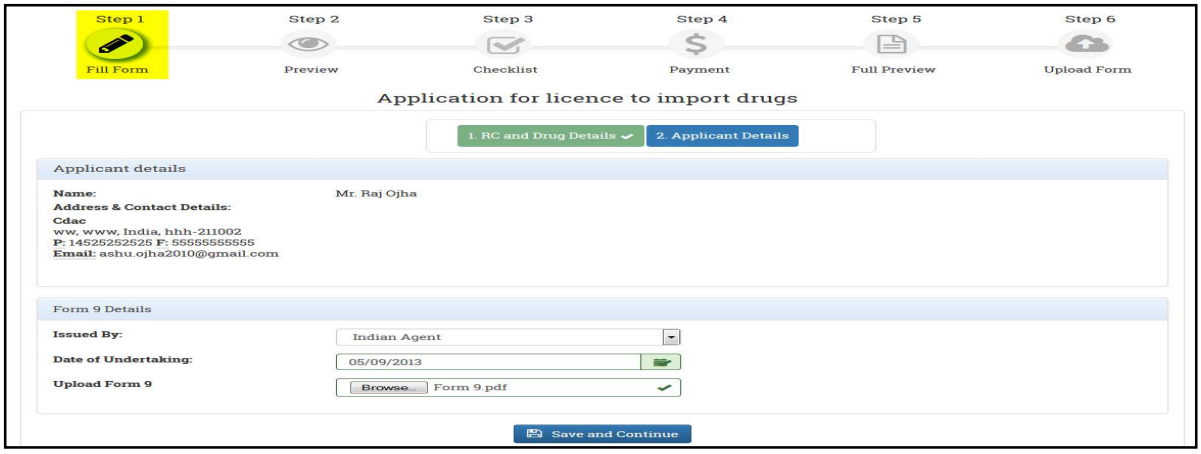


Figure 82 : Upload Form 9

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

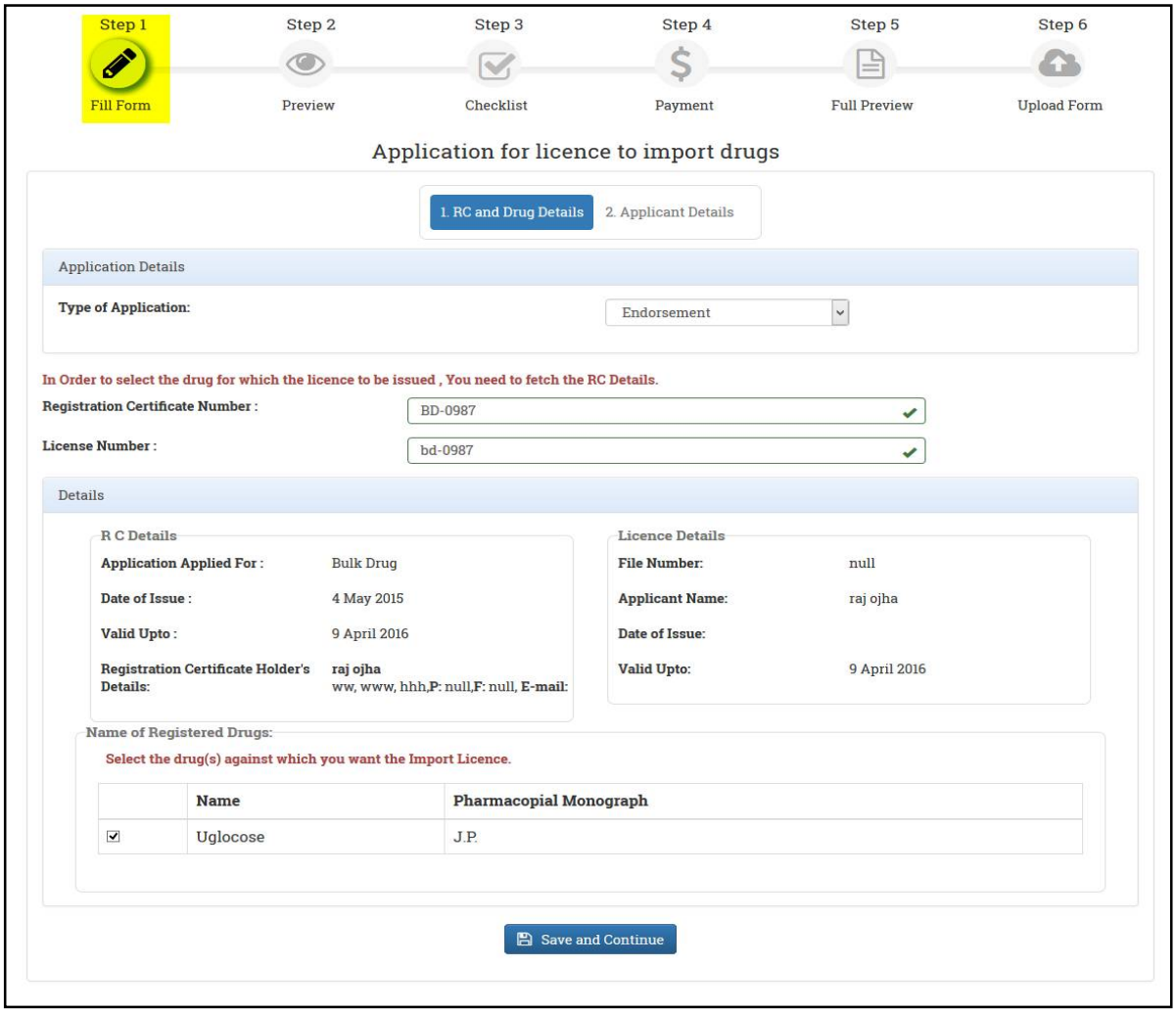


Figure 83 : Type of application: Endorsement

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

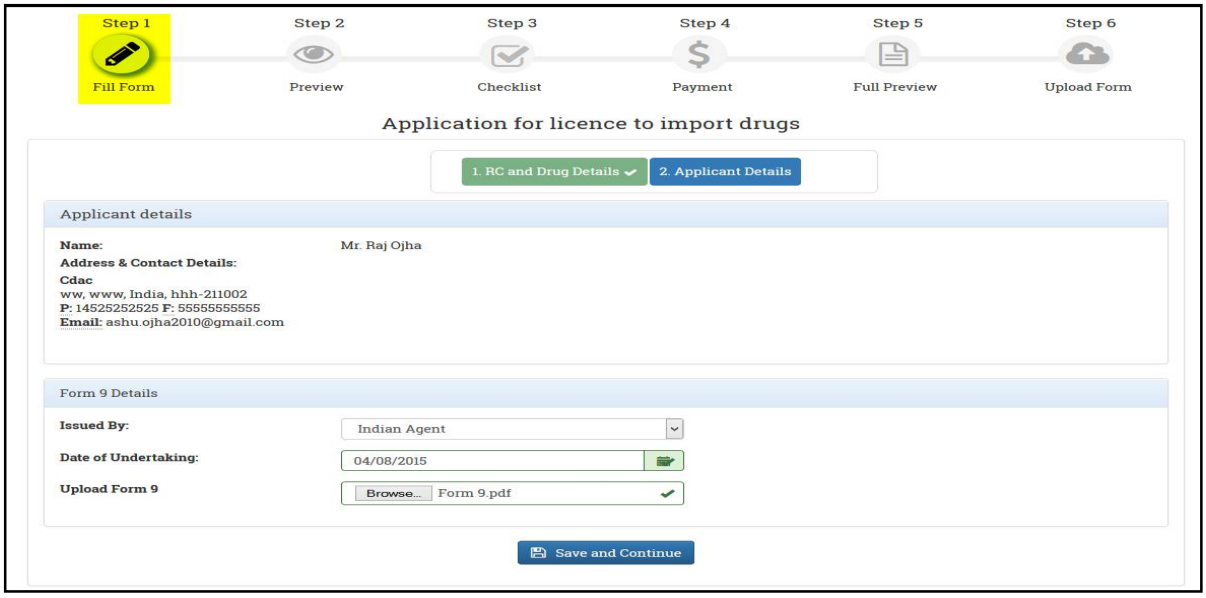


Figure 84 : For Endorsement: Enter License Number

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.

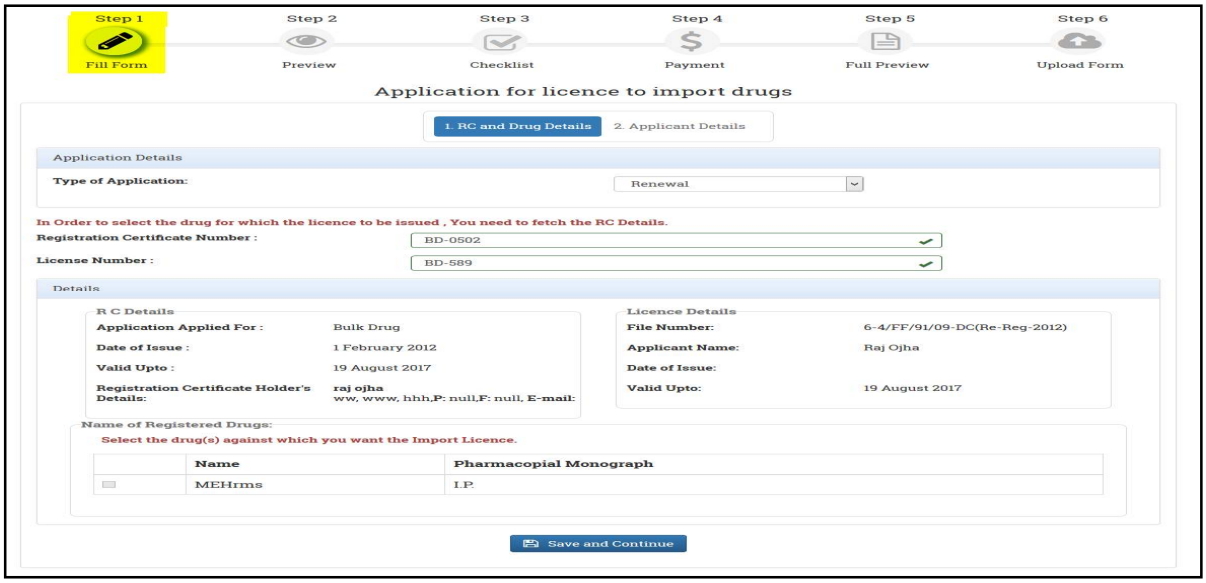


Figure 85 : Type of application: Re-registrations

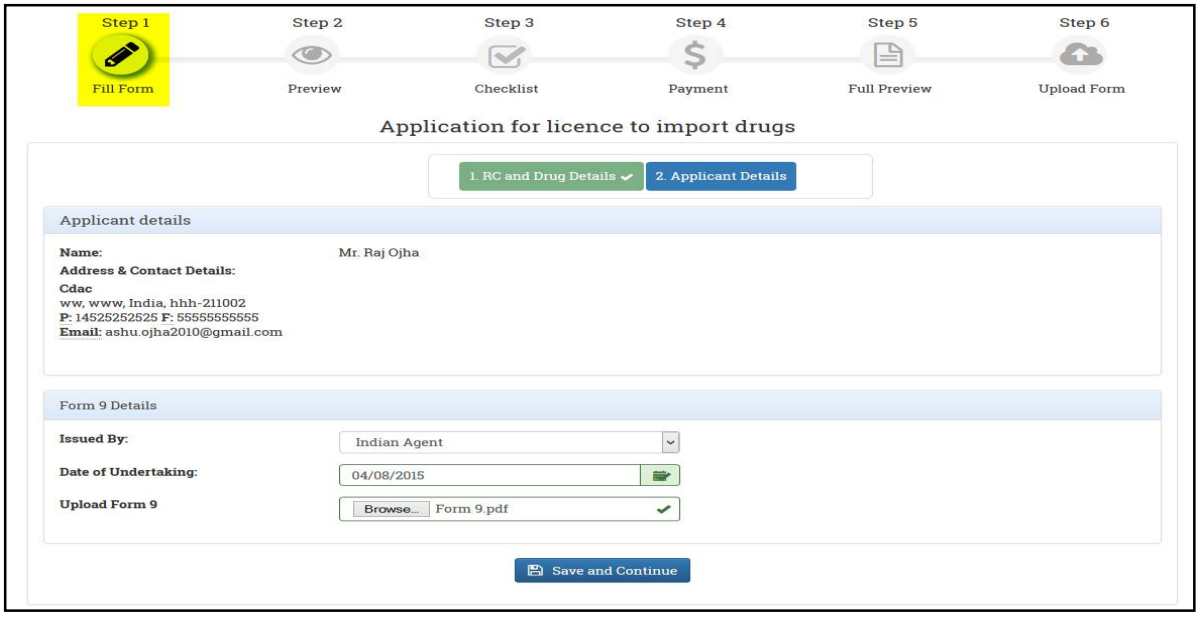


Figure 86 : for Endorsement – enter License Number

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.**

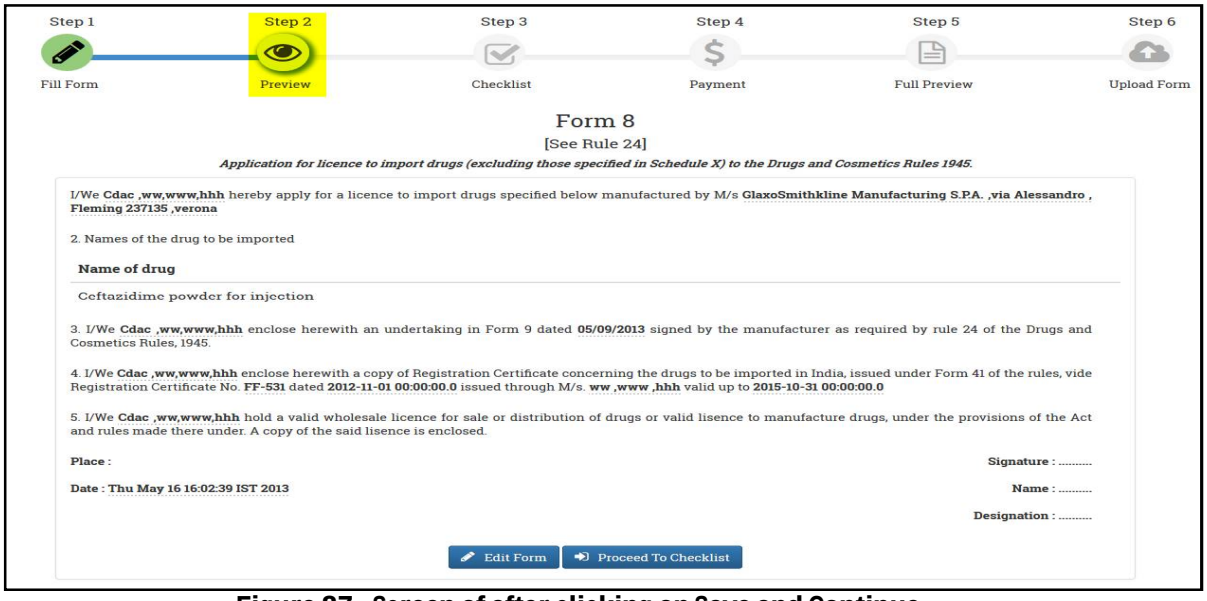


Figure 87 : Screen of after clicking on Save and Continue

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.**

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.

Figure 89 : Upload Certificate

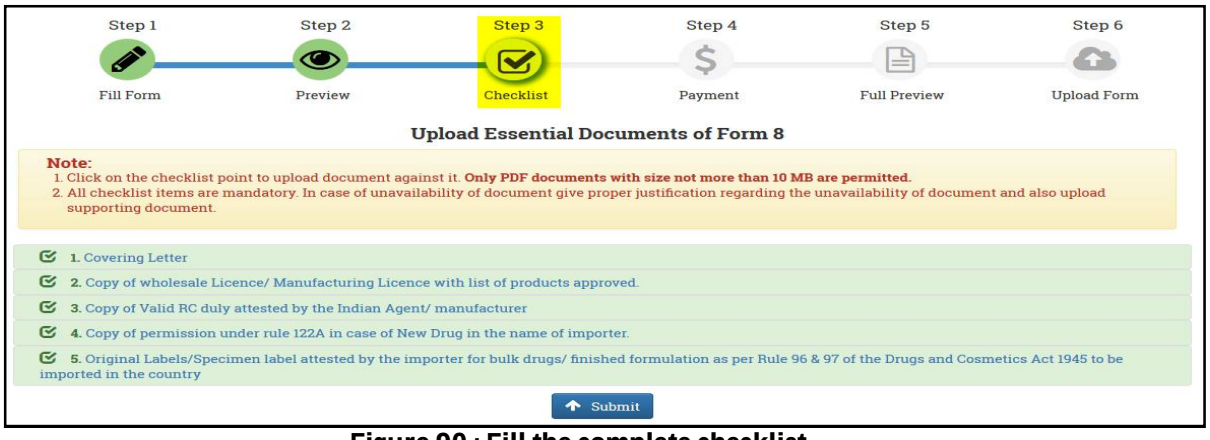


Figure 90 : Fill the complete checklist

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

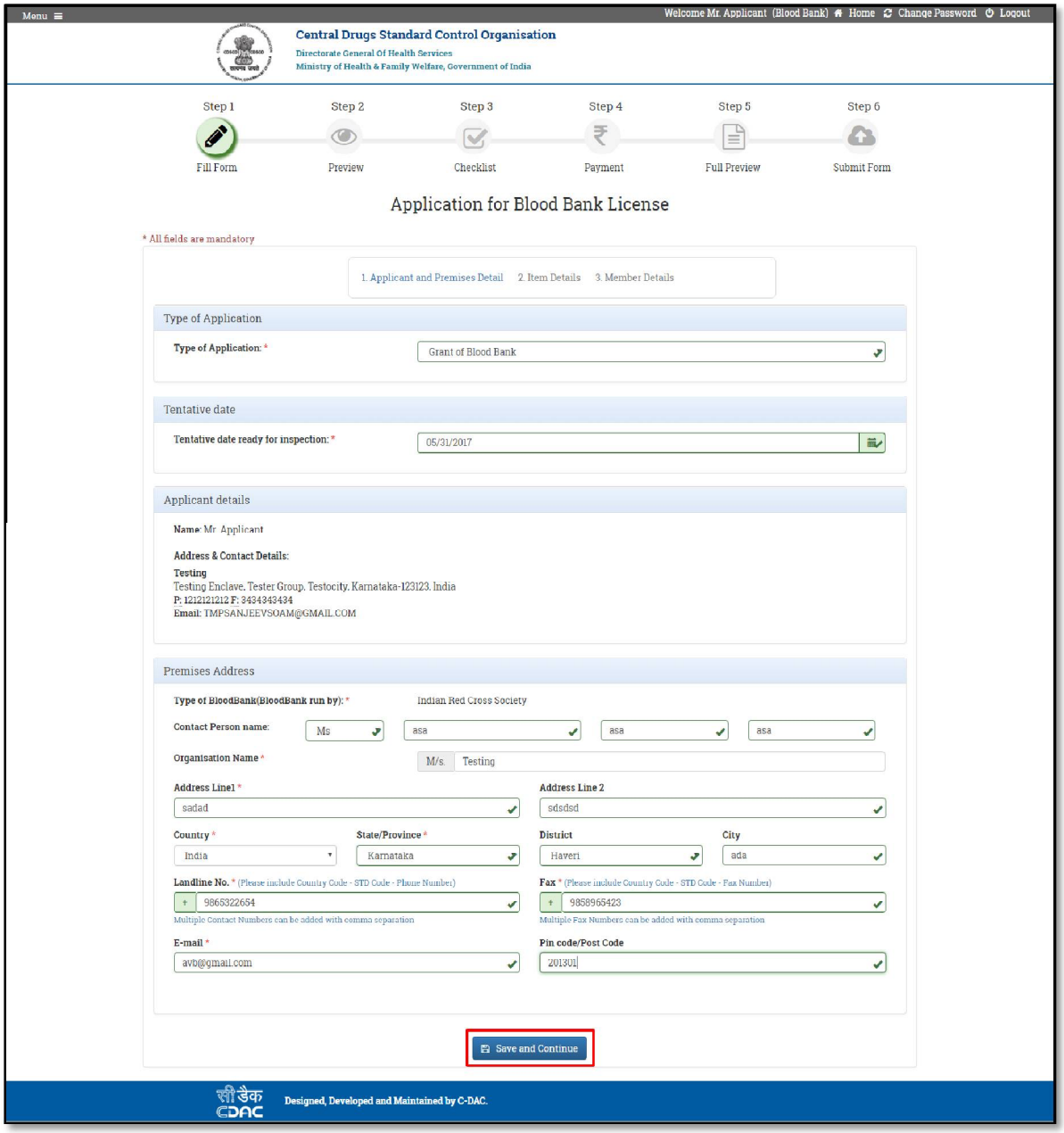


Figure 91 : Application for Blood Bank License

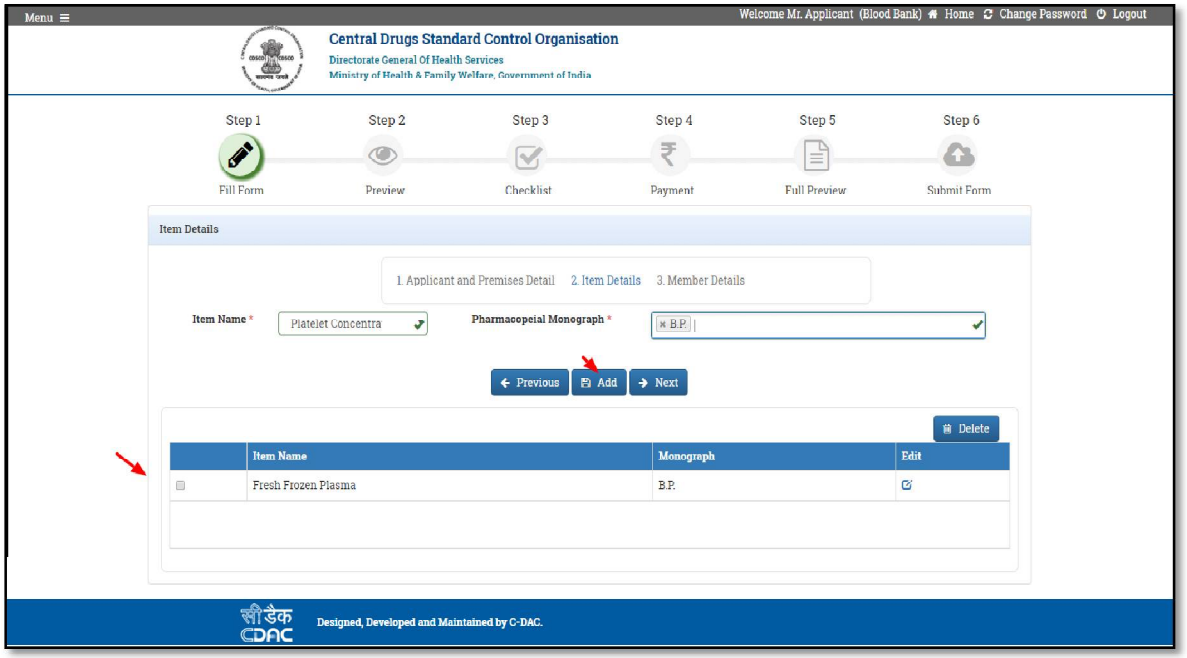


Figure 92 : Application for Blood Bank License (Add Button)

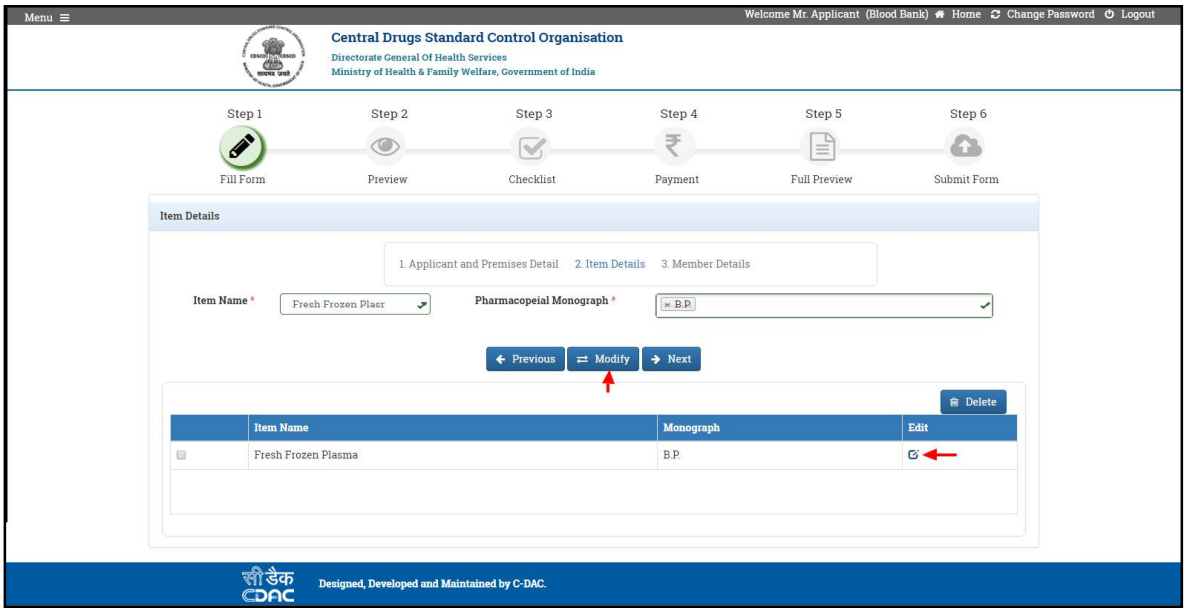


Figure 93 : Application for Blood Bank License (Modify)

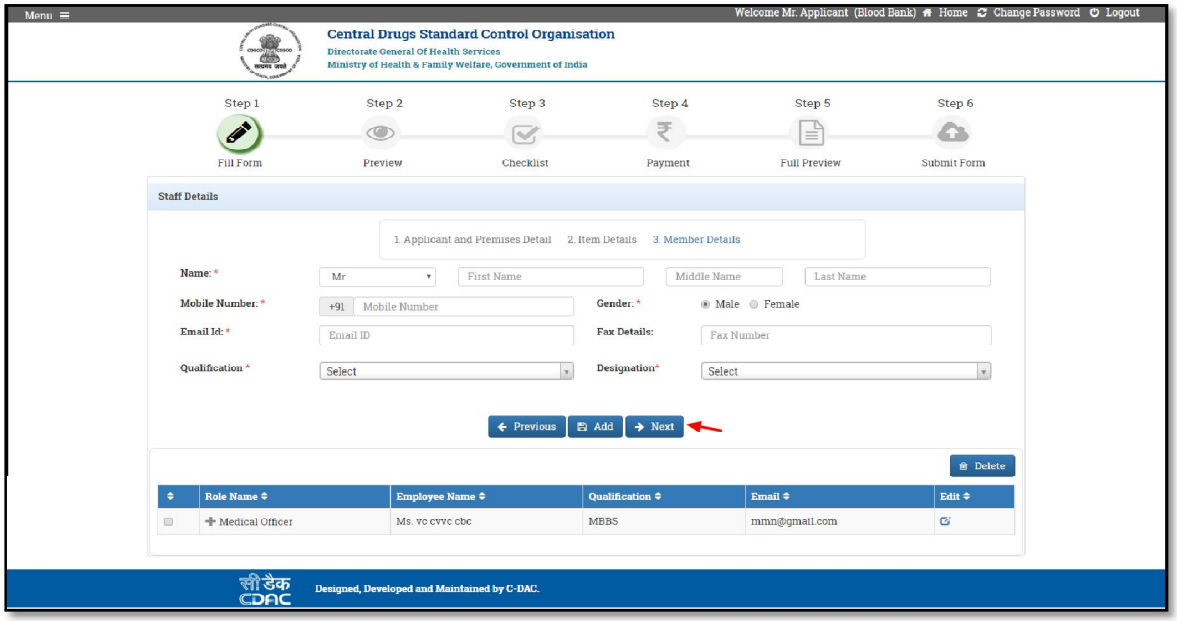


Figure 94 : Next button to Click for Next Step

- First Preview of the form

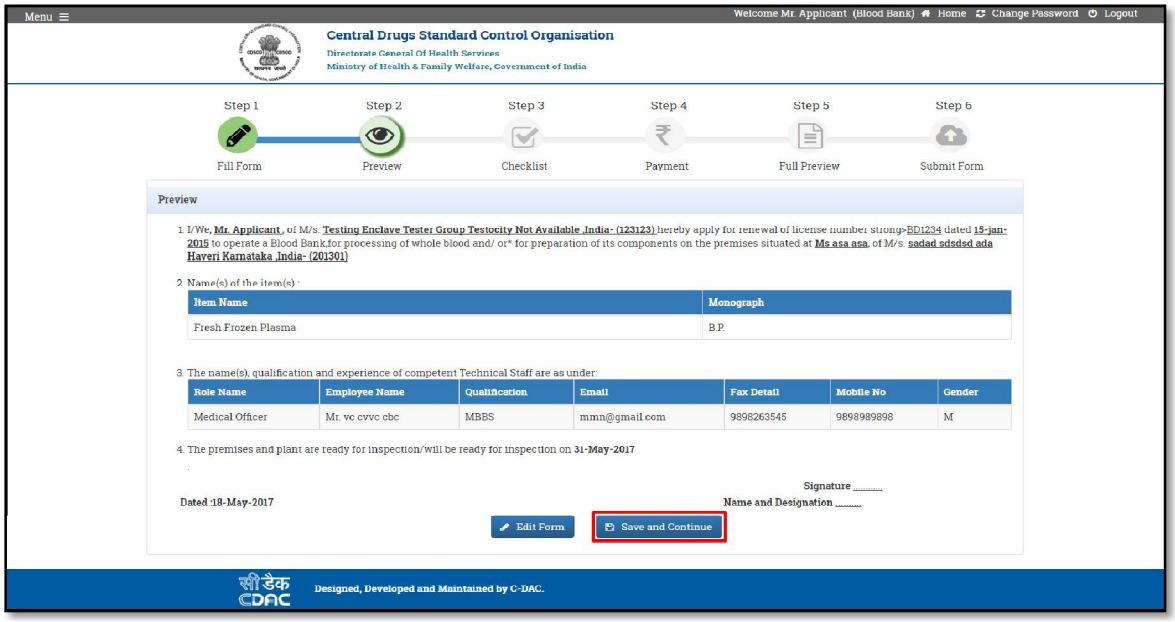


Figure 95 : First Preview of the form

- Confirmation alert to proceed to checklist.

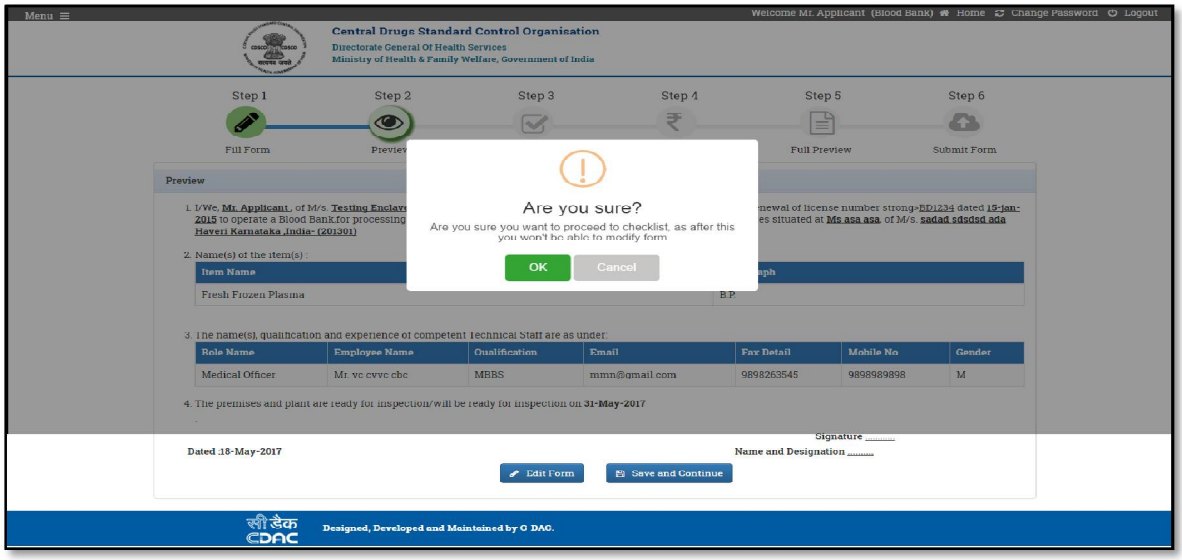


Figure 96 : Confirmation alert to proceed to checklist

- Checklist to upload the documents

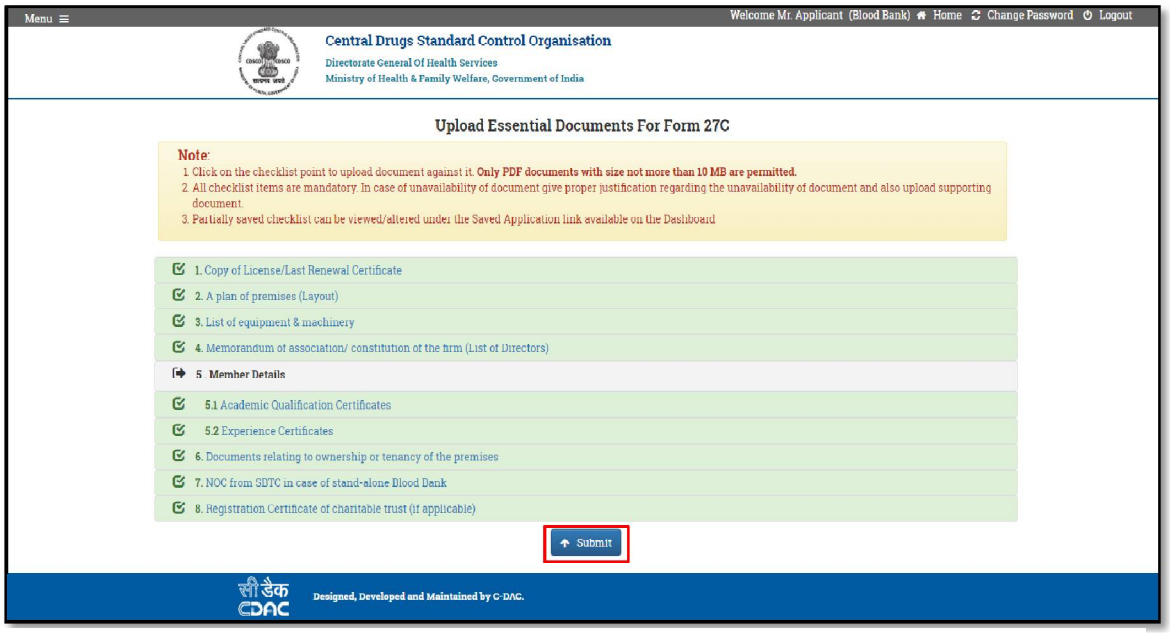


Figure 97 : Checklist to upload the documents

- Payment for the form

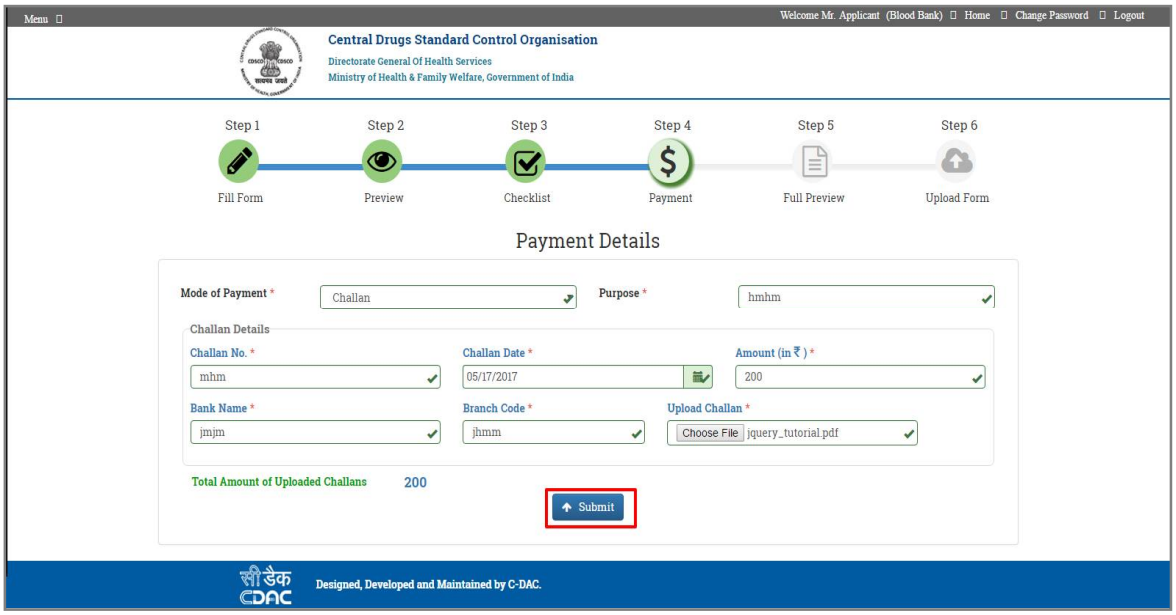


Figure 98 : Payment for the form

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

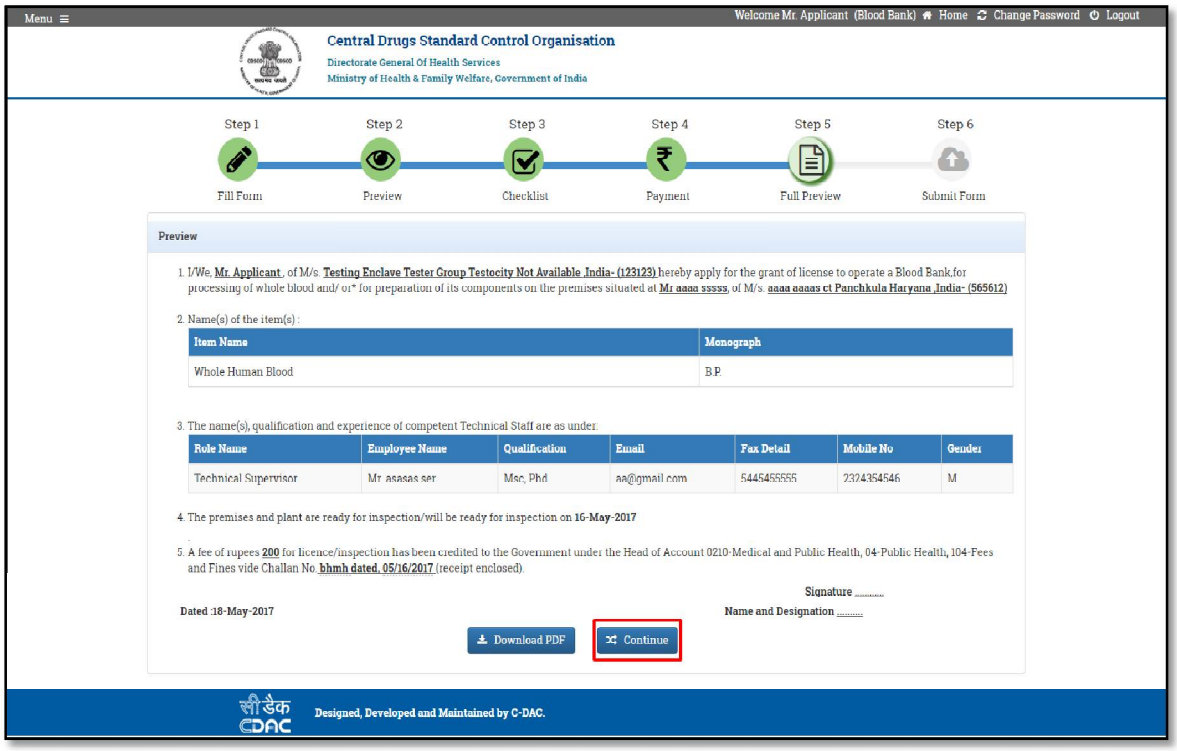


Figure 99 : Final Preview of the Legal Form

- Upload the signed system generated form for final submission:

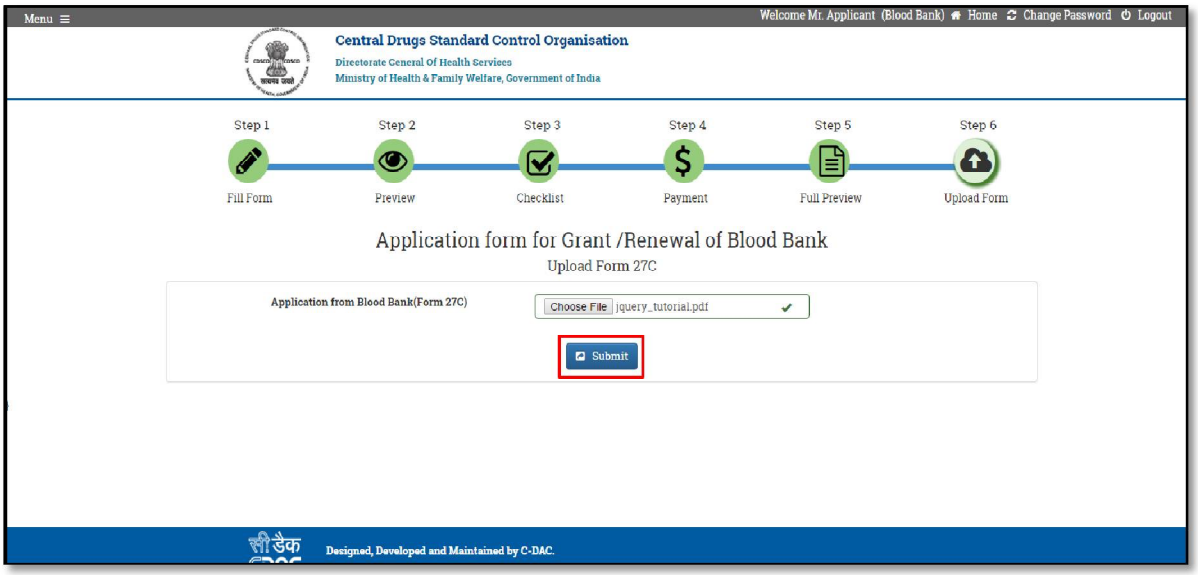


Figure 100 : Generated form for final submission

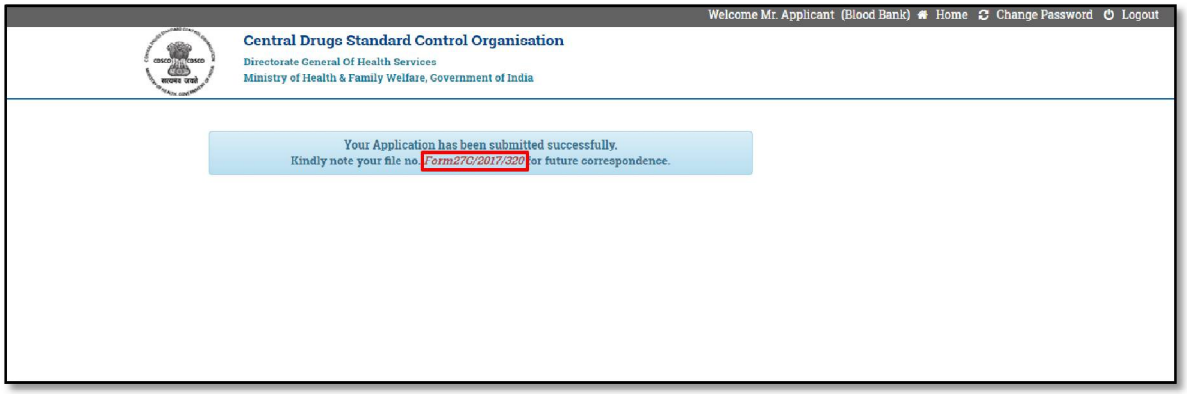


Figure 101 : Application has been submitted successfully

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:

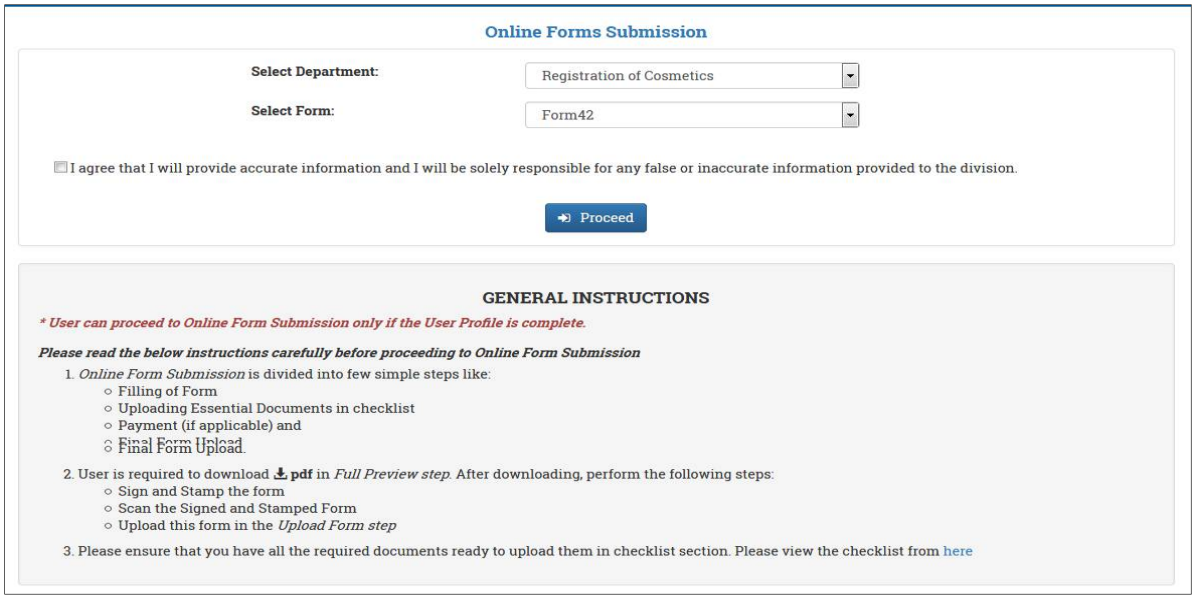


Figure 102 : Cosmetic Registration

- 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.

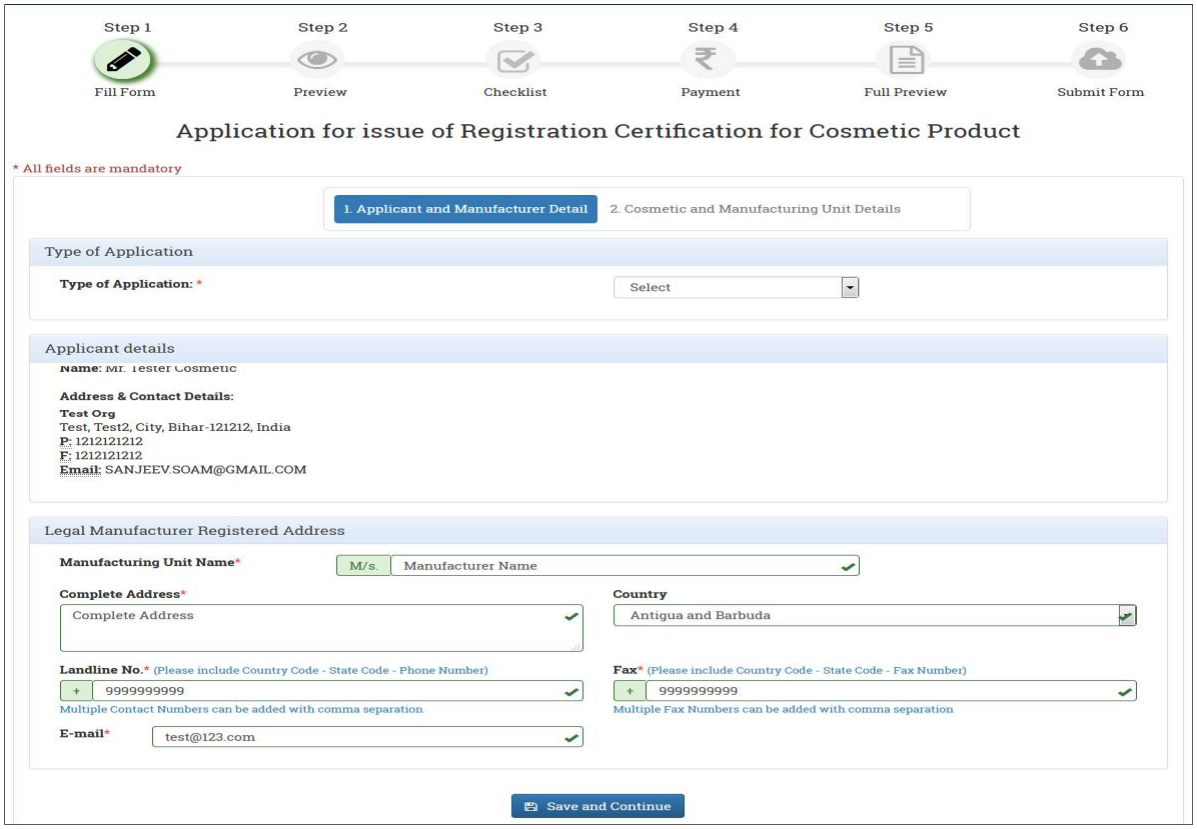


Figure 103 : Applicant & Manufacturer details

- **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

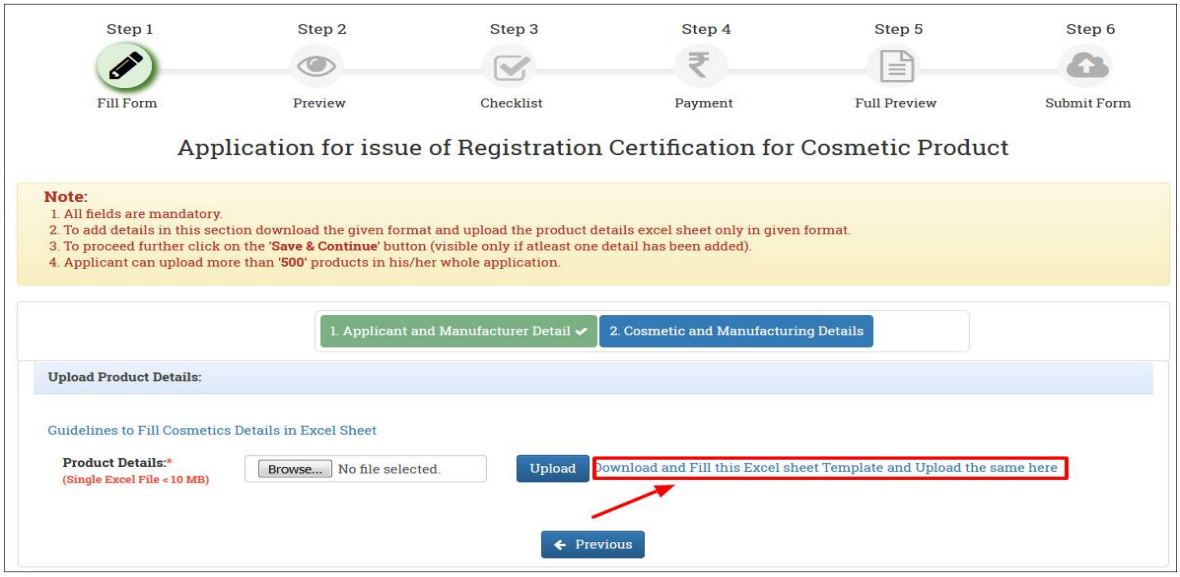


Figure 104 : Cosmetics and Manufacturing Site details

- Browse the filled excel sheet and click on upload.

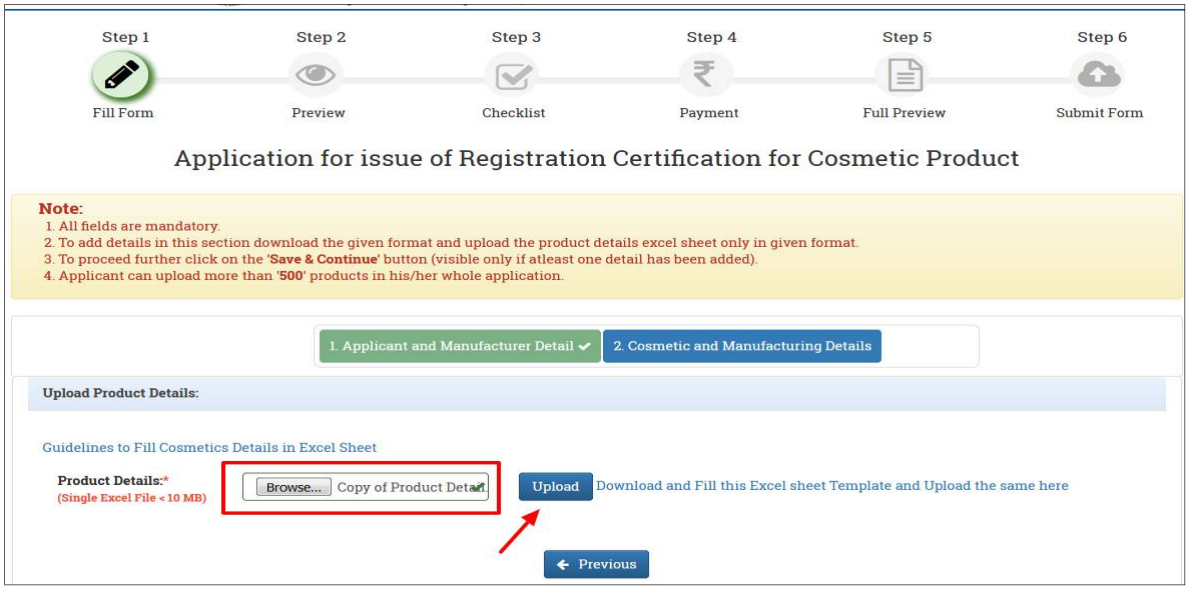


Figure 105 : Upload Excel Sheet

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

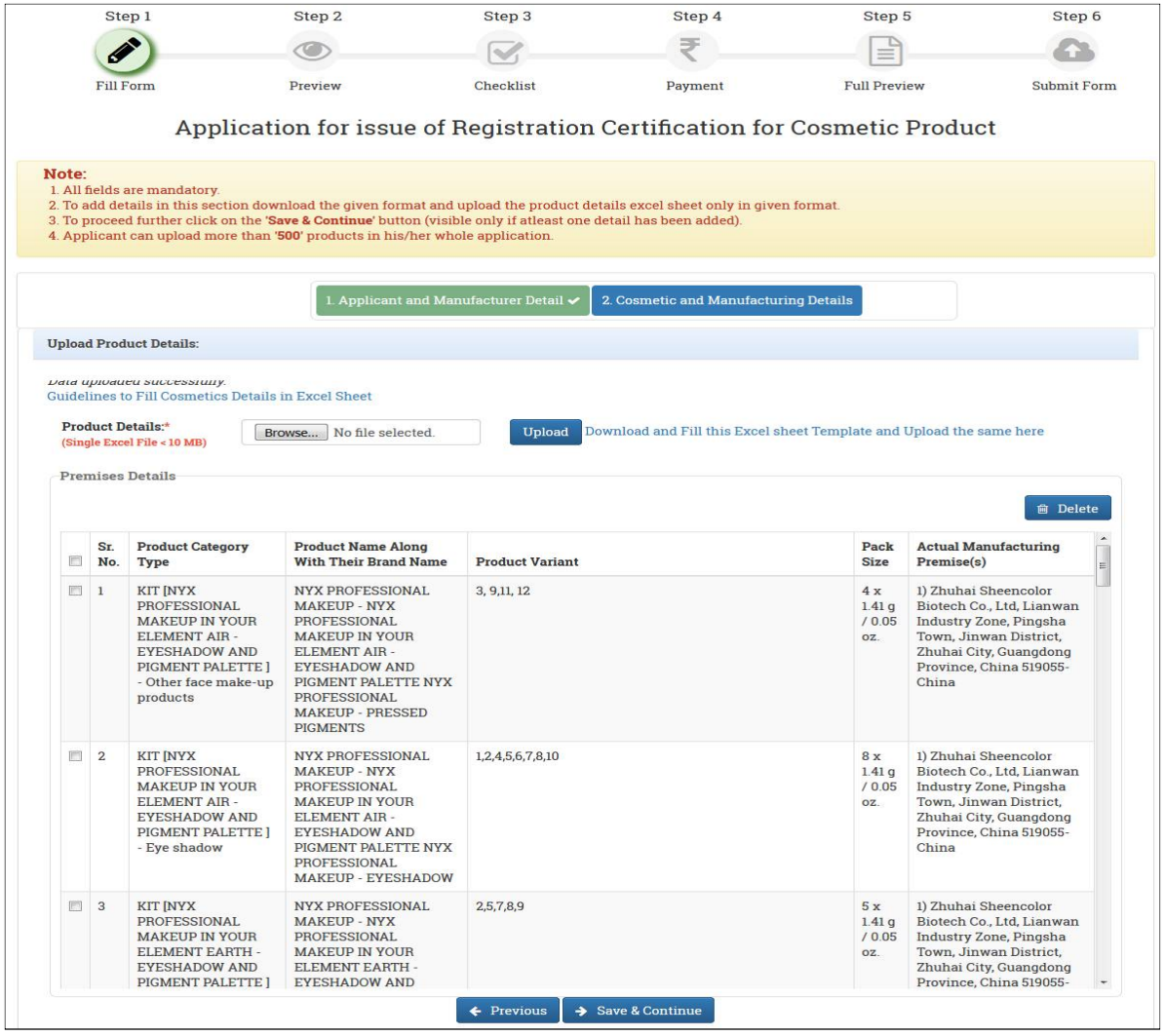


Figure 106 : Upload the data and visible to the user

- **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.

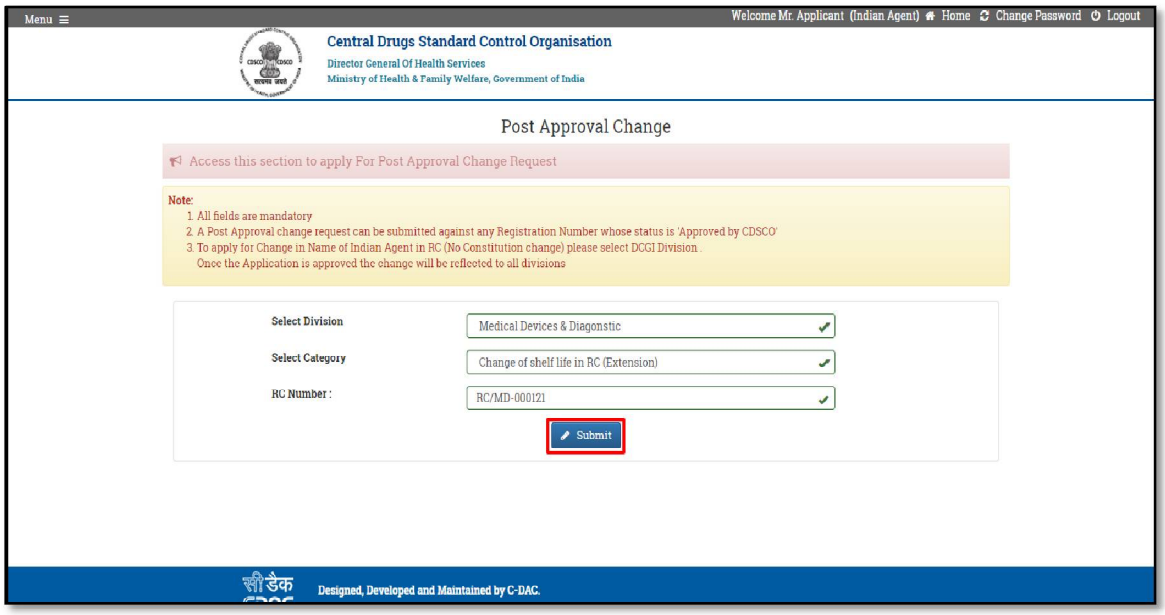


Figure 107 : Change of shelf life in RC Extension

- 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.

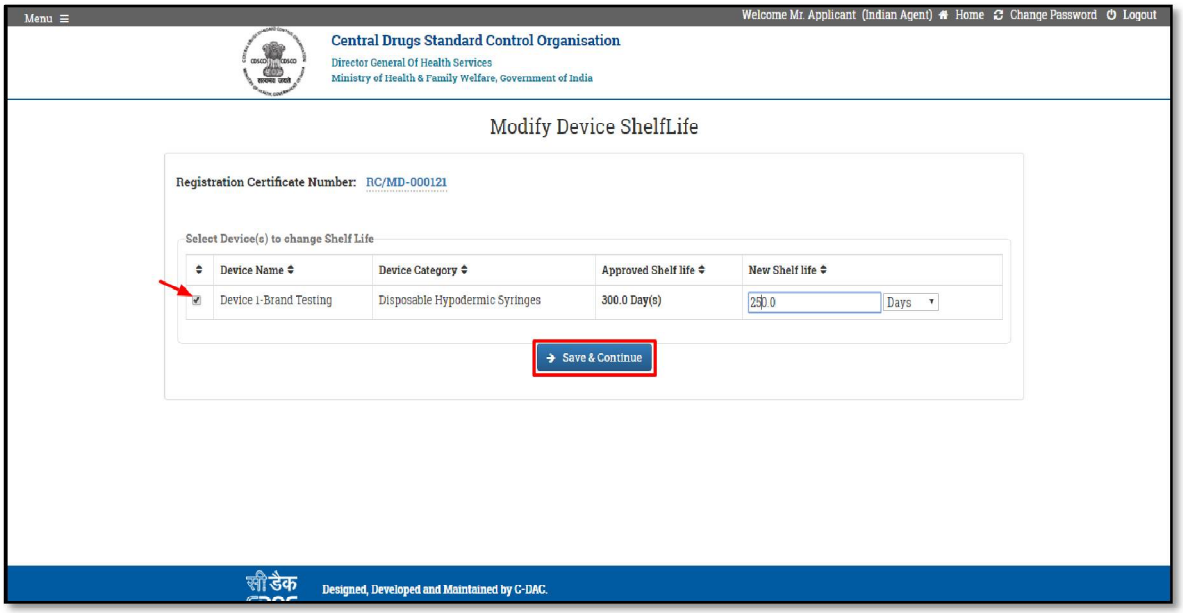


Figure 108 : Screen of Modify Device Shelf Life

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

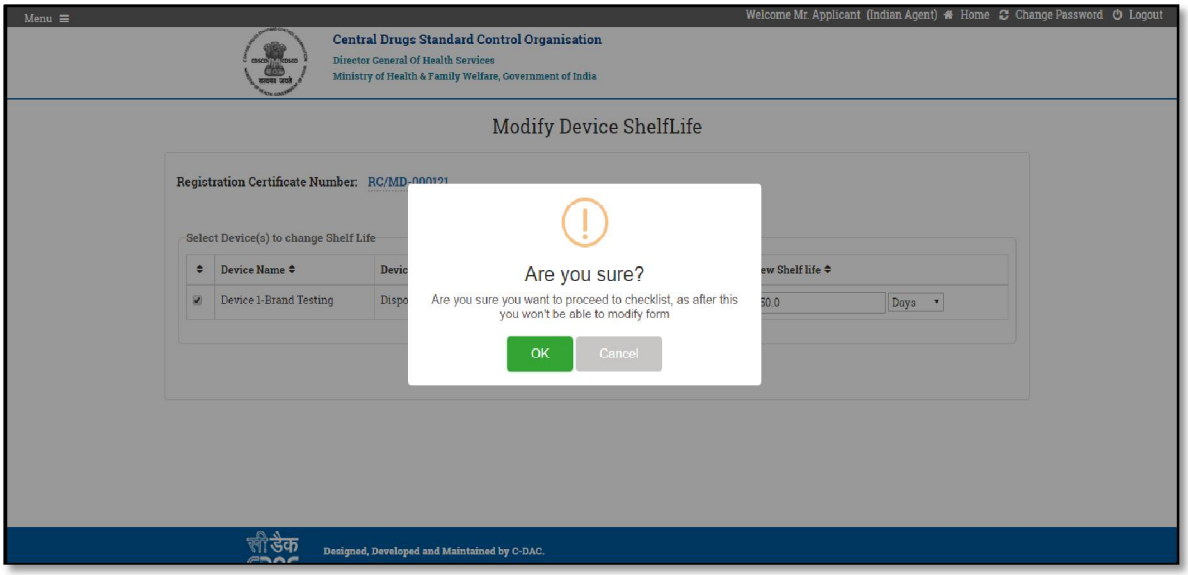


Figure 109 : Popup Message: Proceed to Checklist

- Checklist of documents to be uploaded for the case.

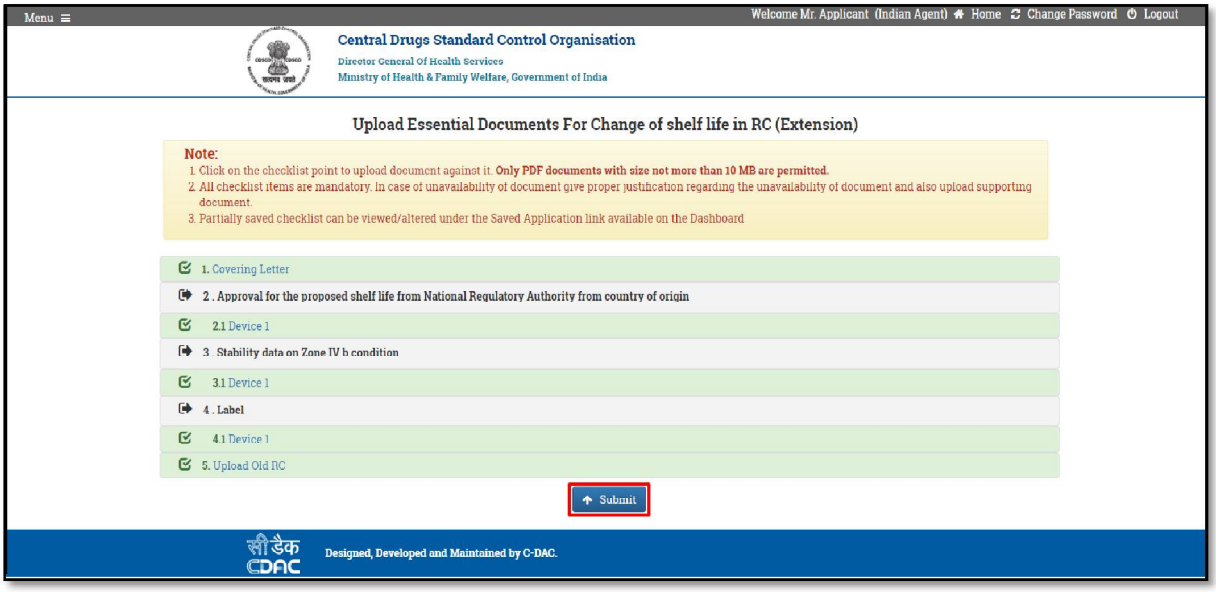


Figure 110 : Checklist of documents to be uploaded

- Preview of the change you have applied for

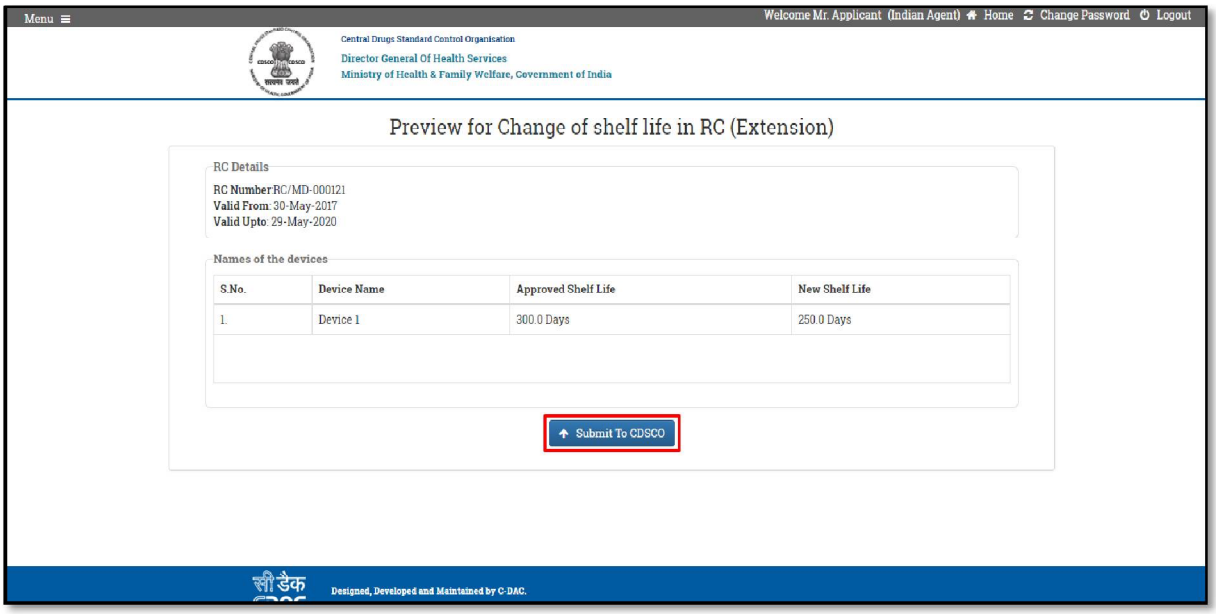


Figure 111 : Preview for change of shelf life

- File number generated after the application is submitted.

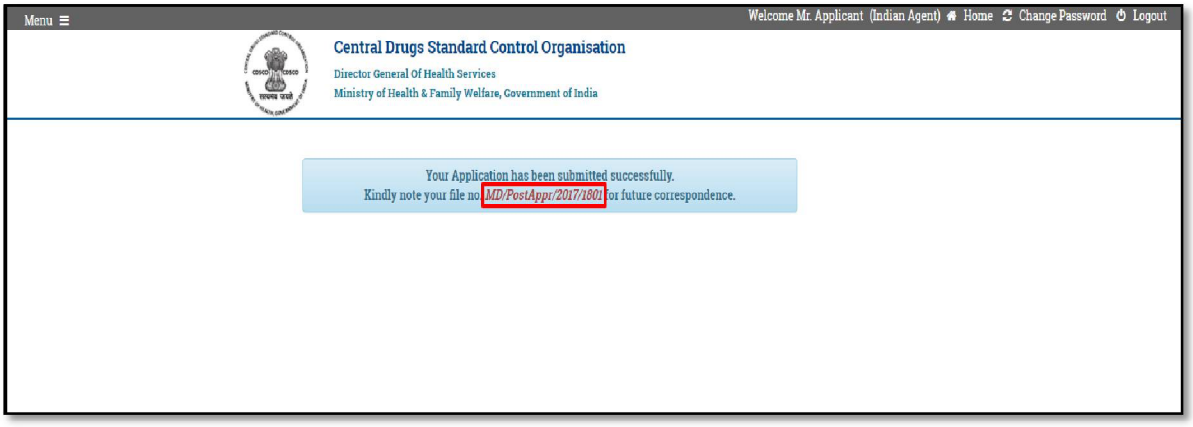


Figure 112 : Application has been submitted successfully

- **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.

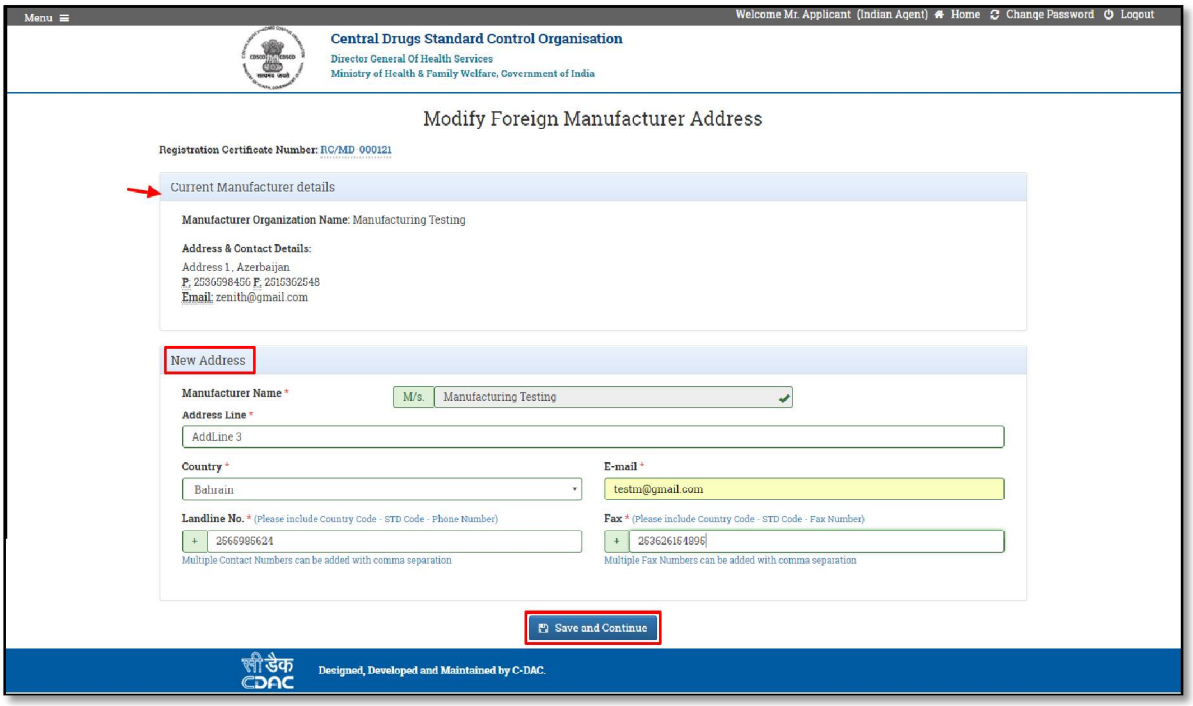


Figure 113 : Enter the Details of the New Address

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

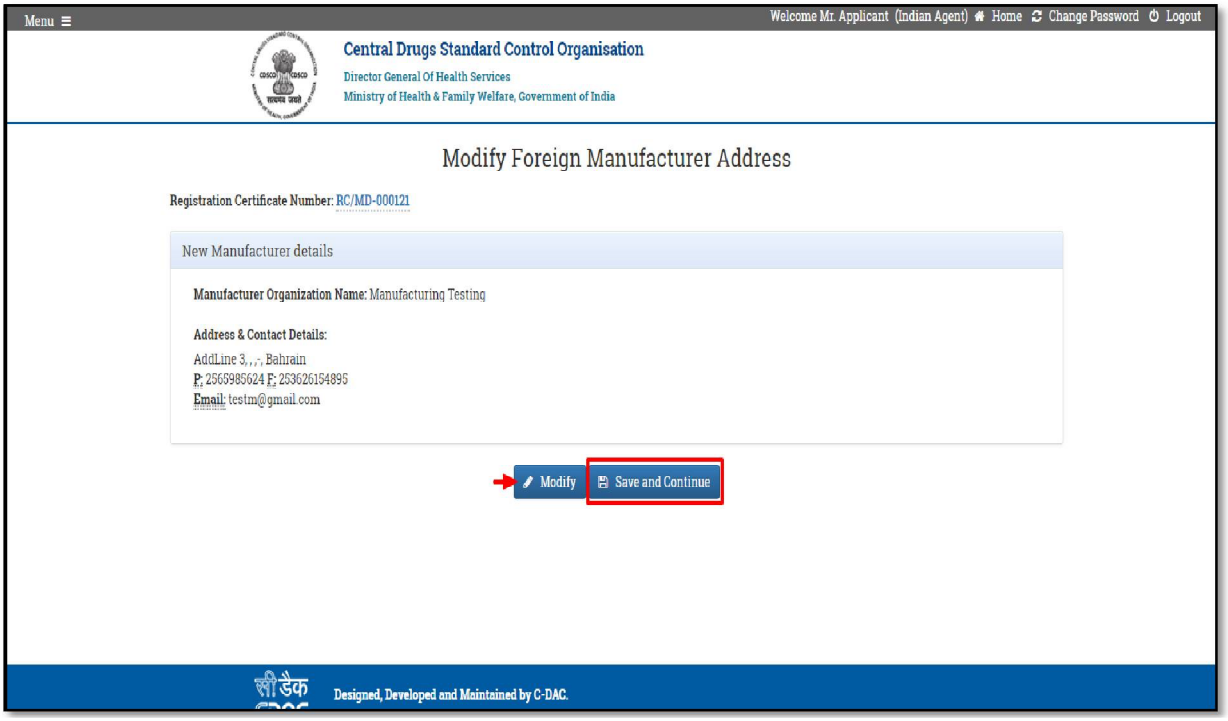


Figure 114 : Modify foreign Manufacturer Address

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

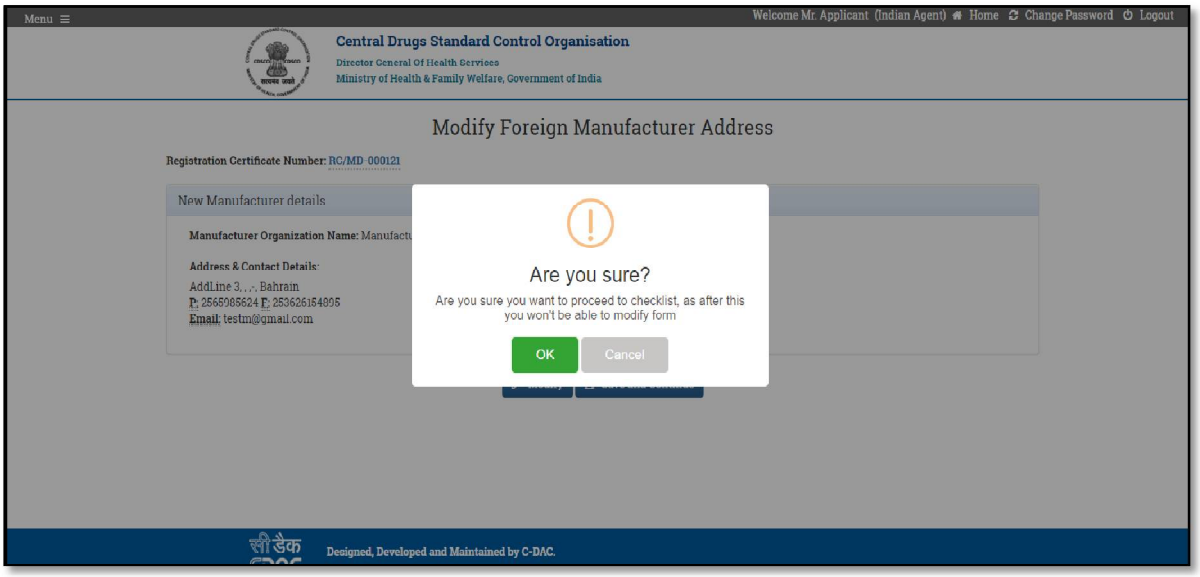


Figure 115 : Popup Message -- Proceed to Checklist

- Checklist of the documents to be uploaded for this case

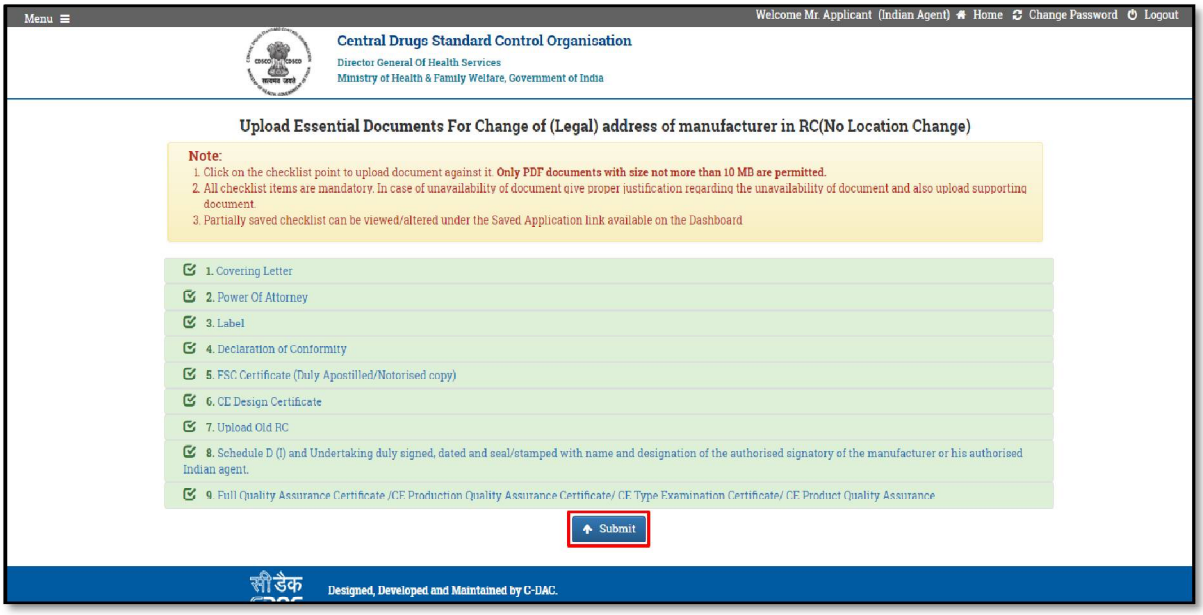


Figure 116 : Checklist of the Documents

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

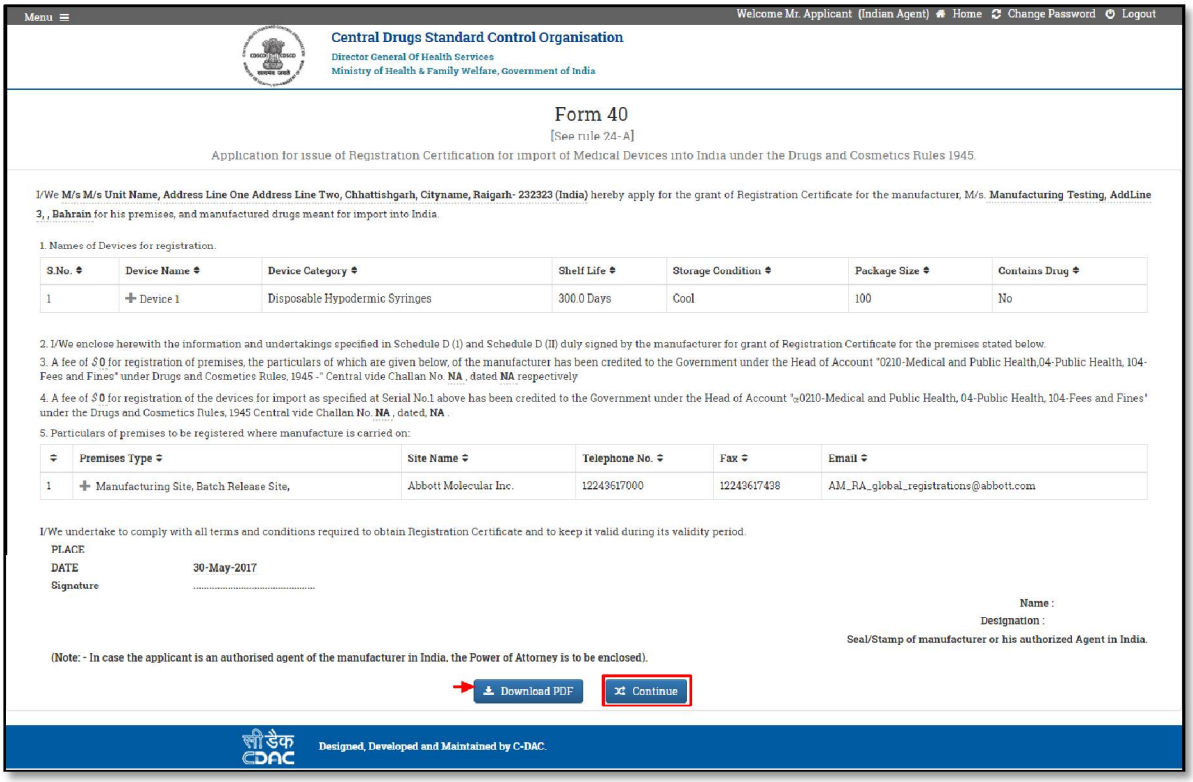


Figure 117 : Preview of Form 40

- Upload the signed legal form.

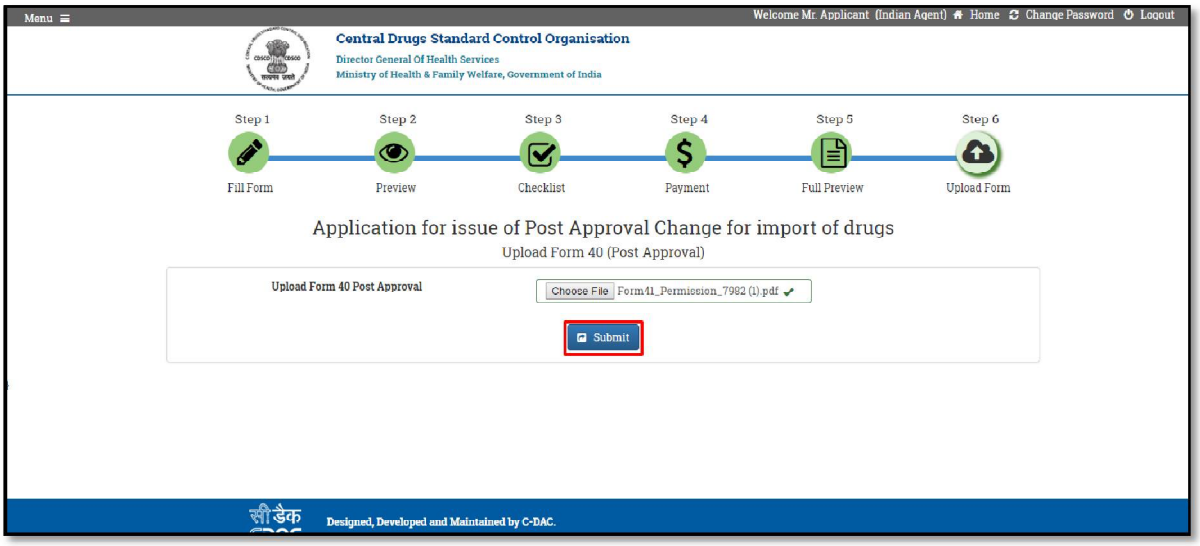


Figure 118 : Screen of Upload the signed legal form

- File number is generated after submission of the application.

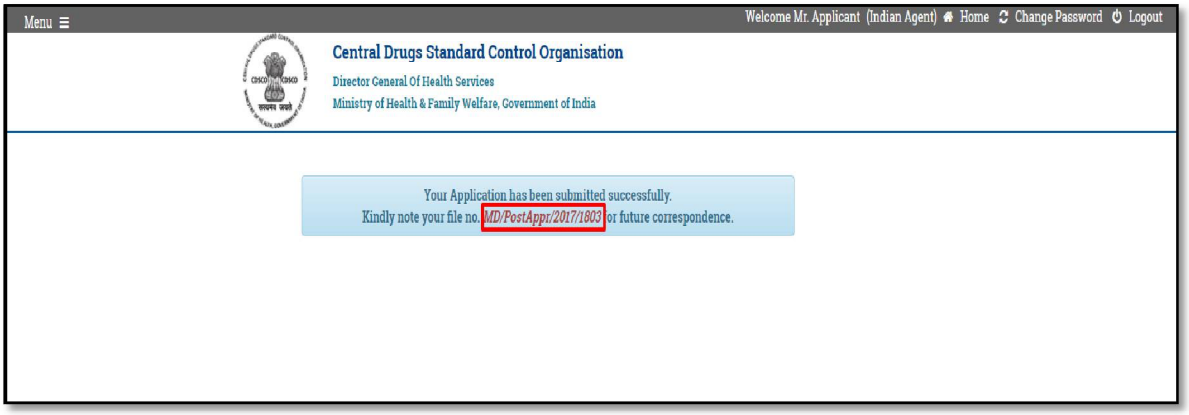


Figure 119 : File number is generated

- **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.

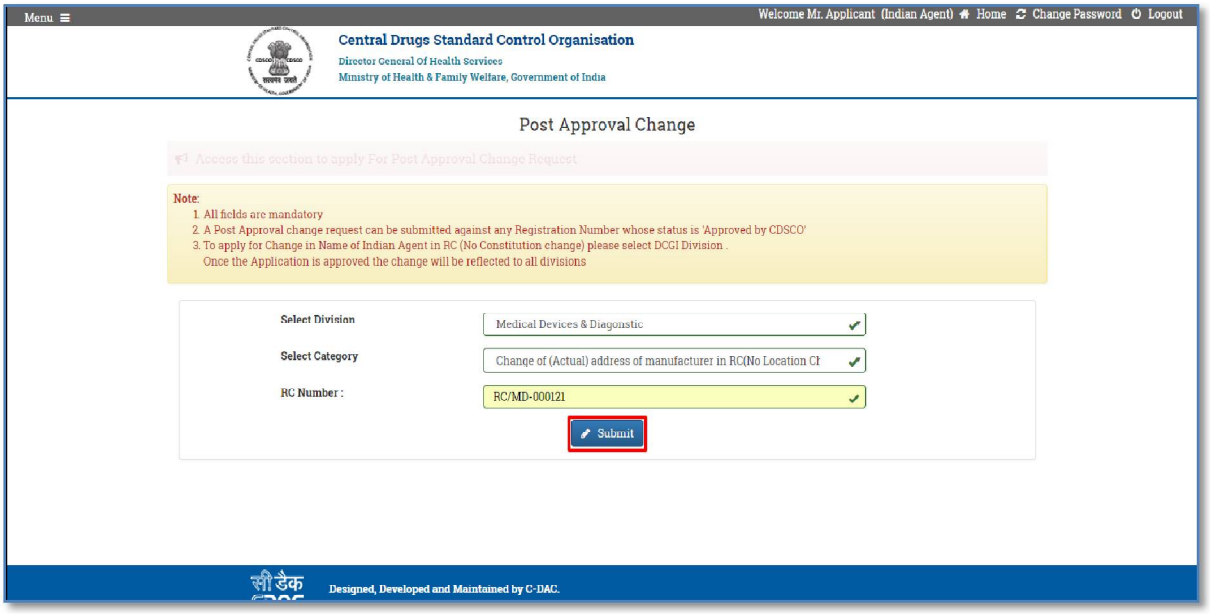


Figure 120 : Screen of Post Approval Changes

- 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.

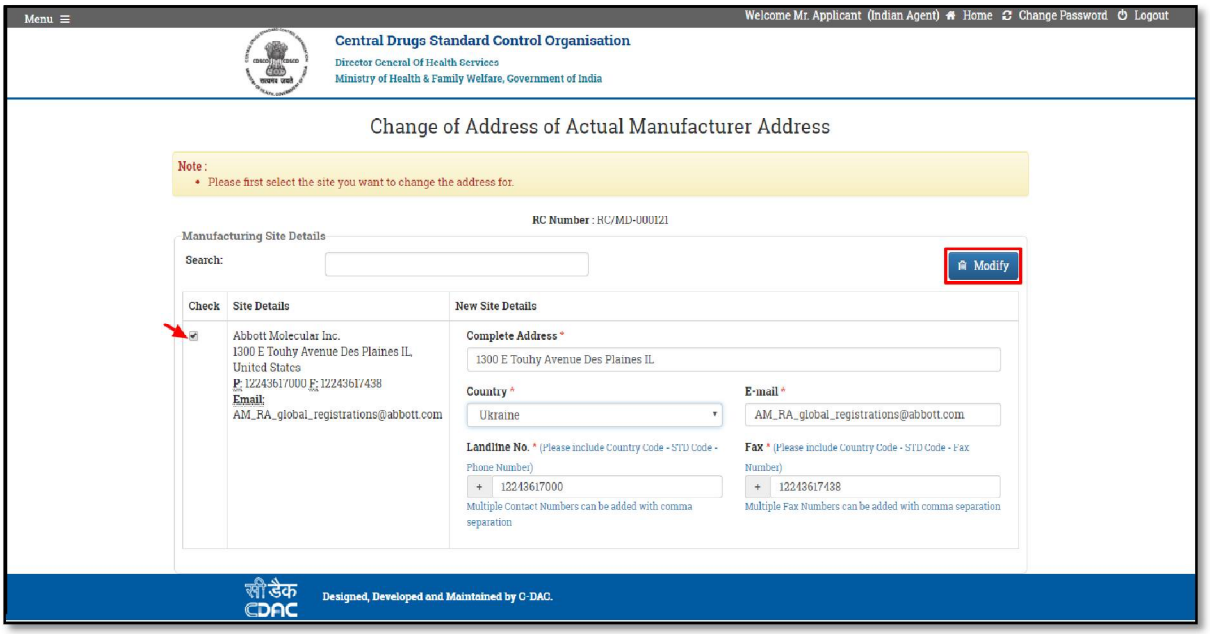


Figure 121 : Enter the details of the new Address

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

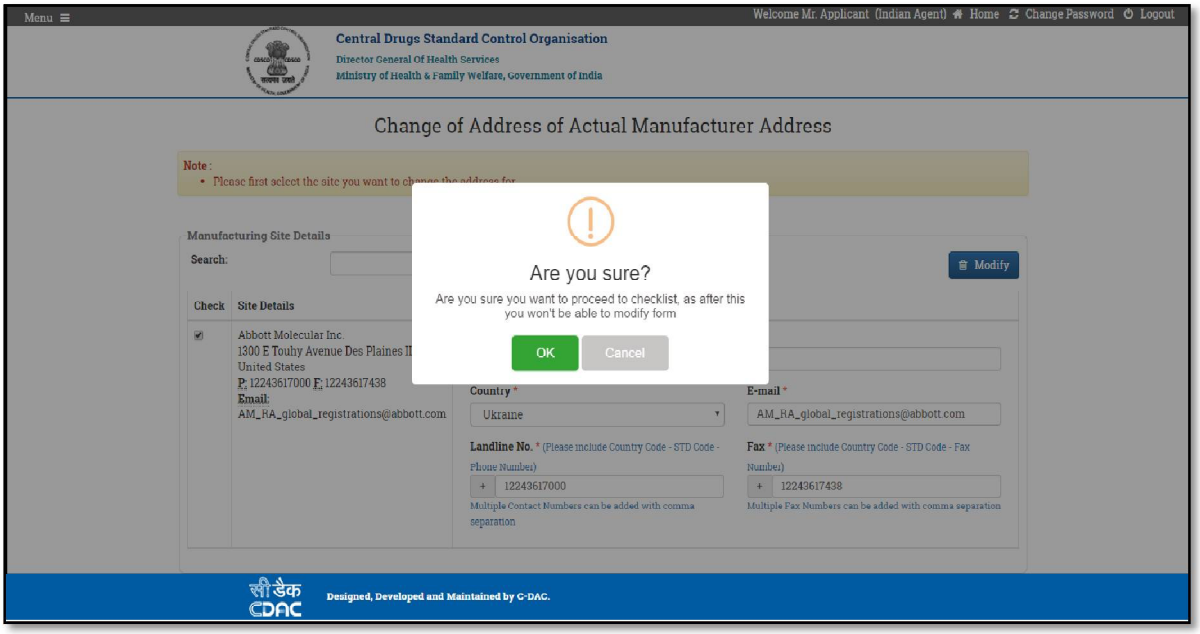


Figure 122 : Popup Message -- Proceed to Checklist

- Checklist of documents to be uploaded for the case.

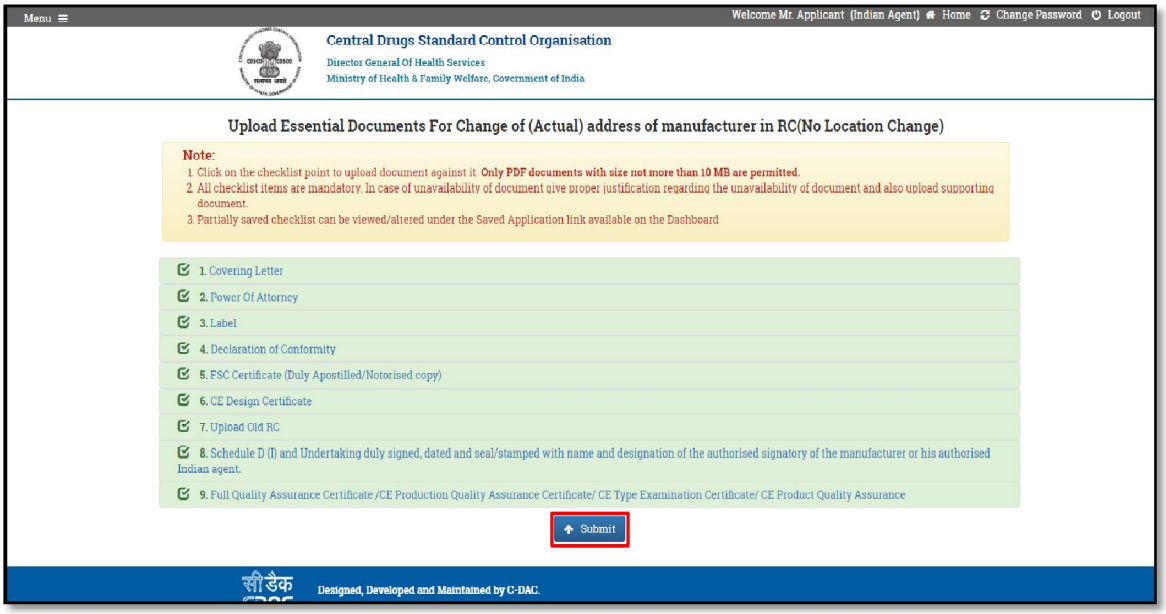


Figure 123 : Upload Essential Documents for Changes

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

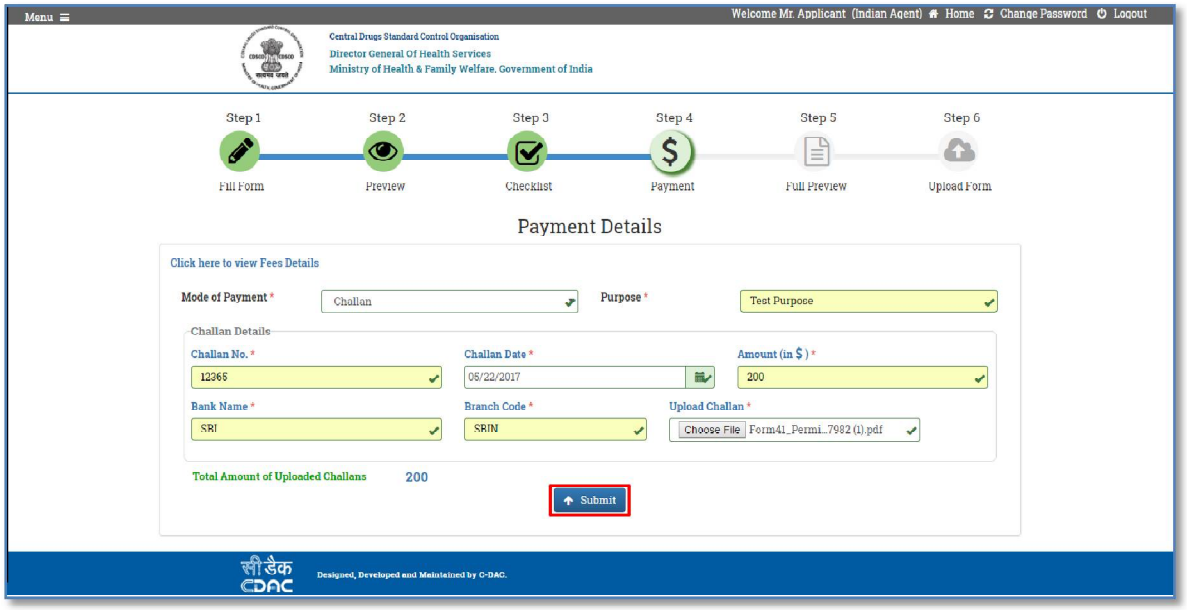


Figure 124 : Screen of Payment Details

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

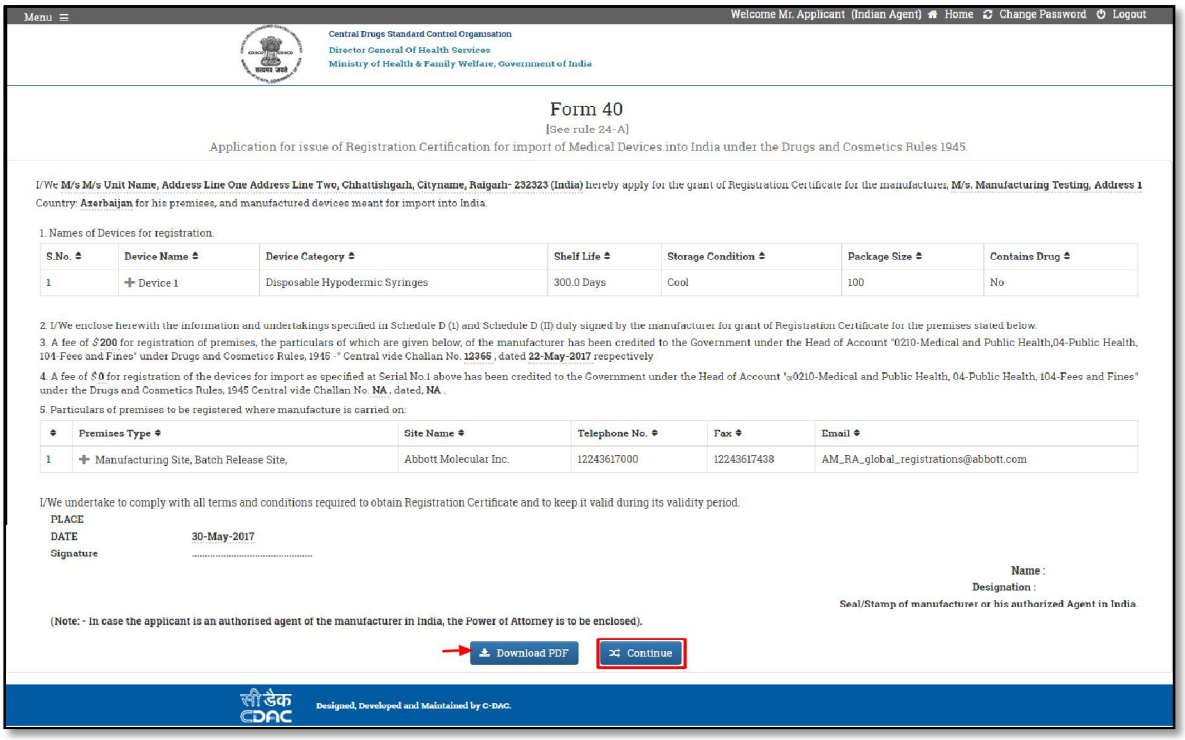


Figure 125 : Download the system generated Form 40

- Upload the signed Legal form

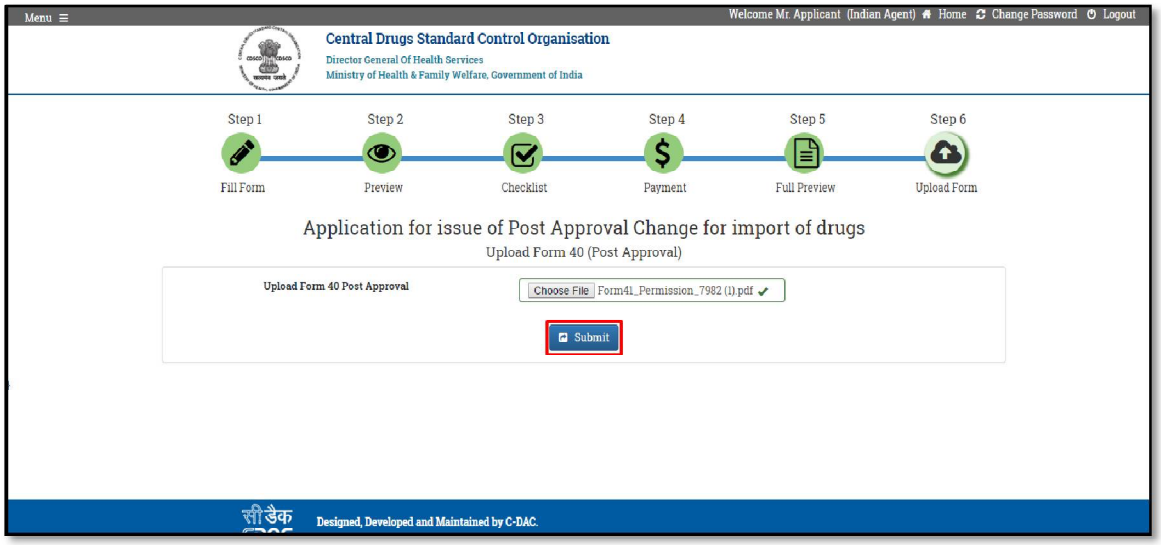


Figure 126 : Upload the signed Legal form

- File number is generated after submission of the application

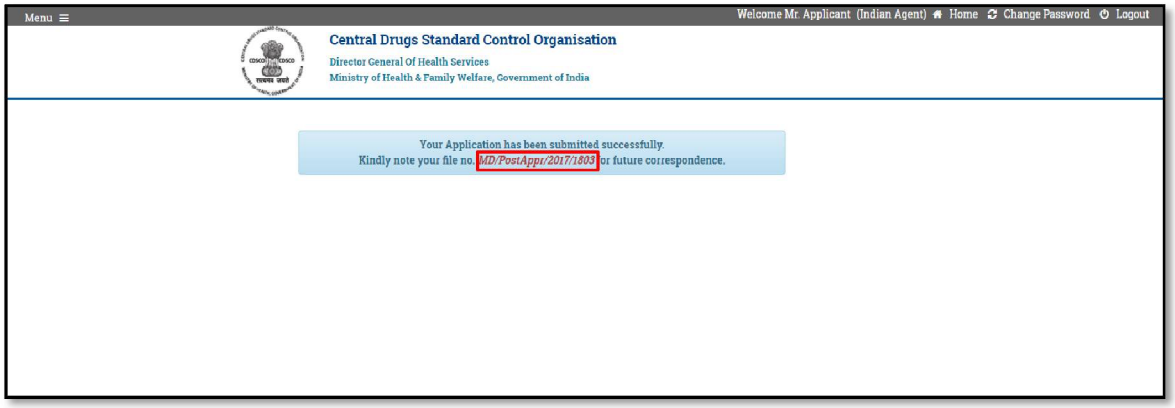


Figure 127 : File number is generated

- 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.

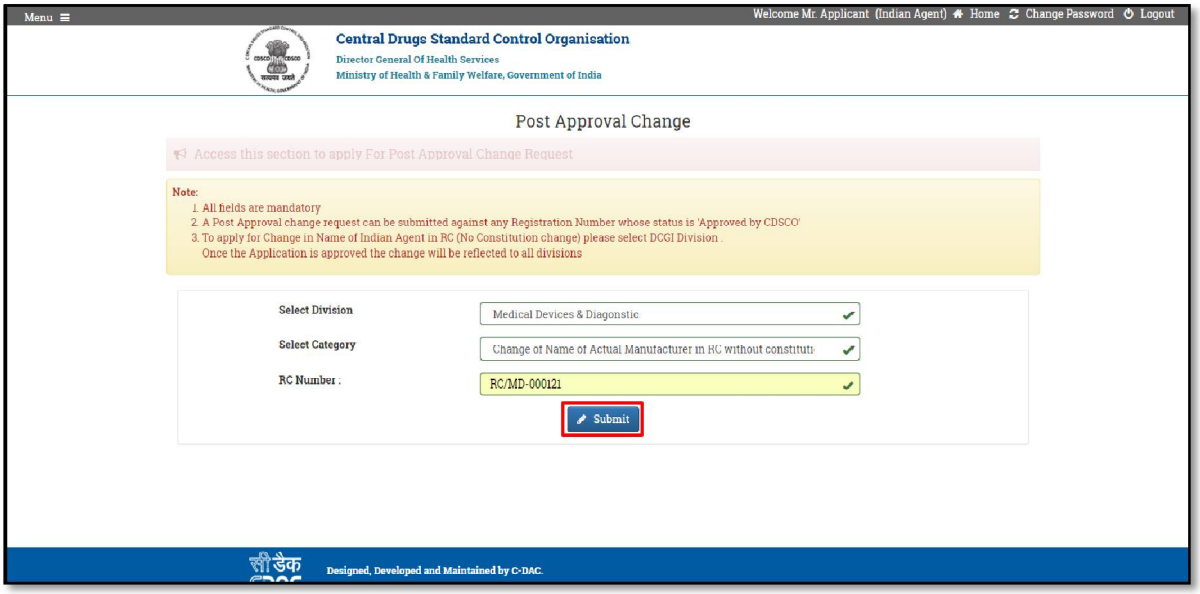


Figure 128 : Change the name of legal manufacturer of an Approved RC

- 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.

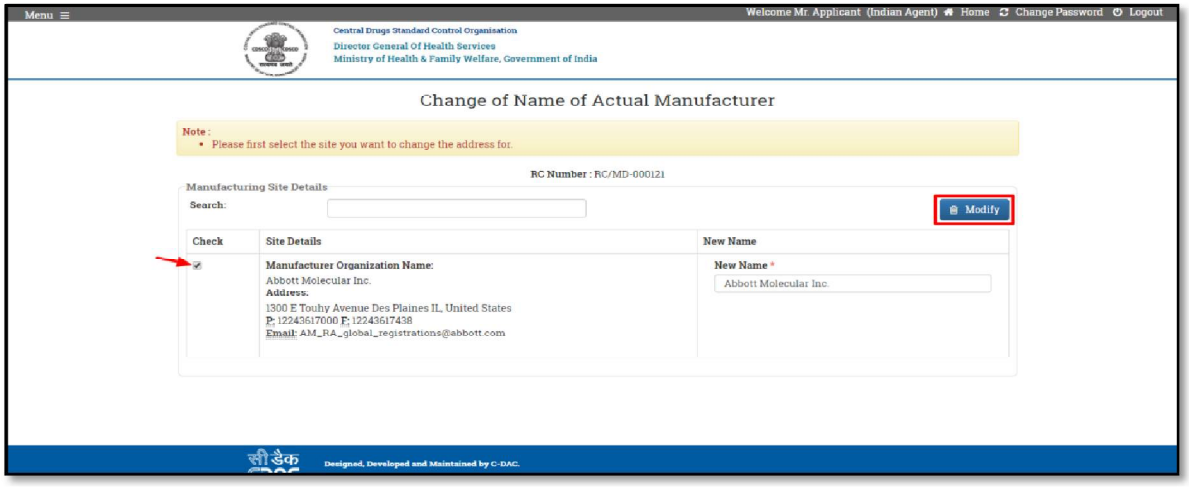


Figure 129 : Check the checkbox againest the address

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

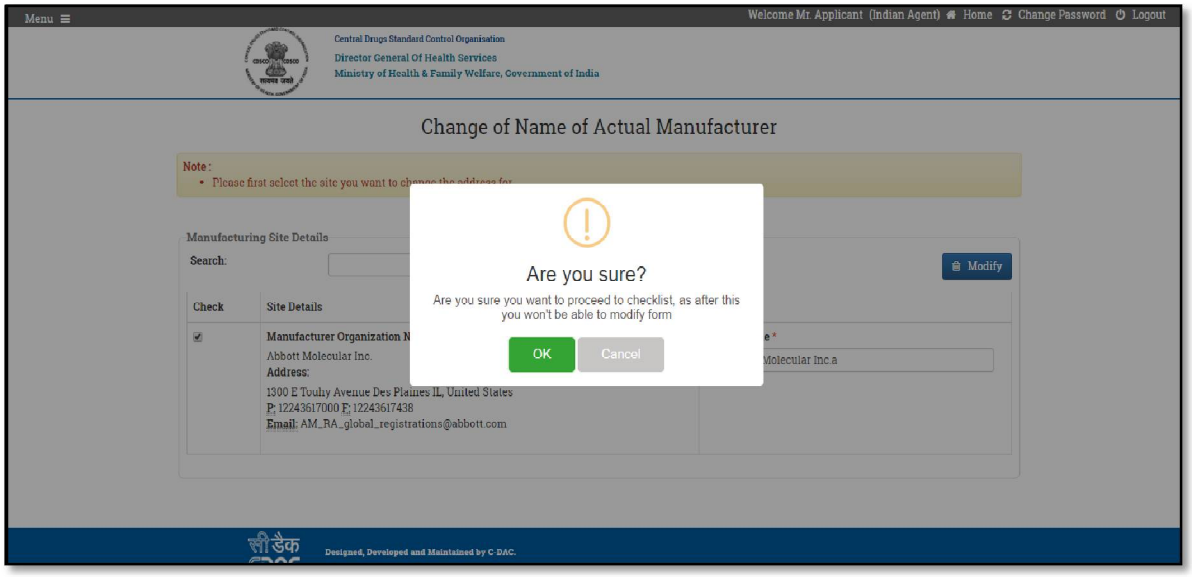


Figure 130 : Popup Message – for confirmation of Proceed to checklist

- Checklist of documents to be uploaded for this case.

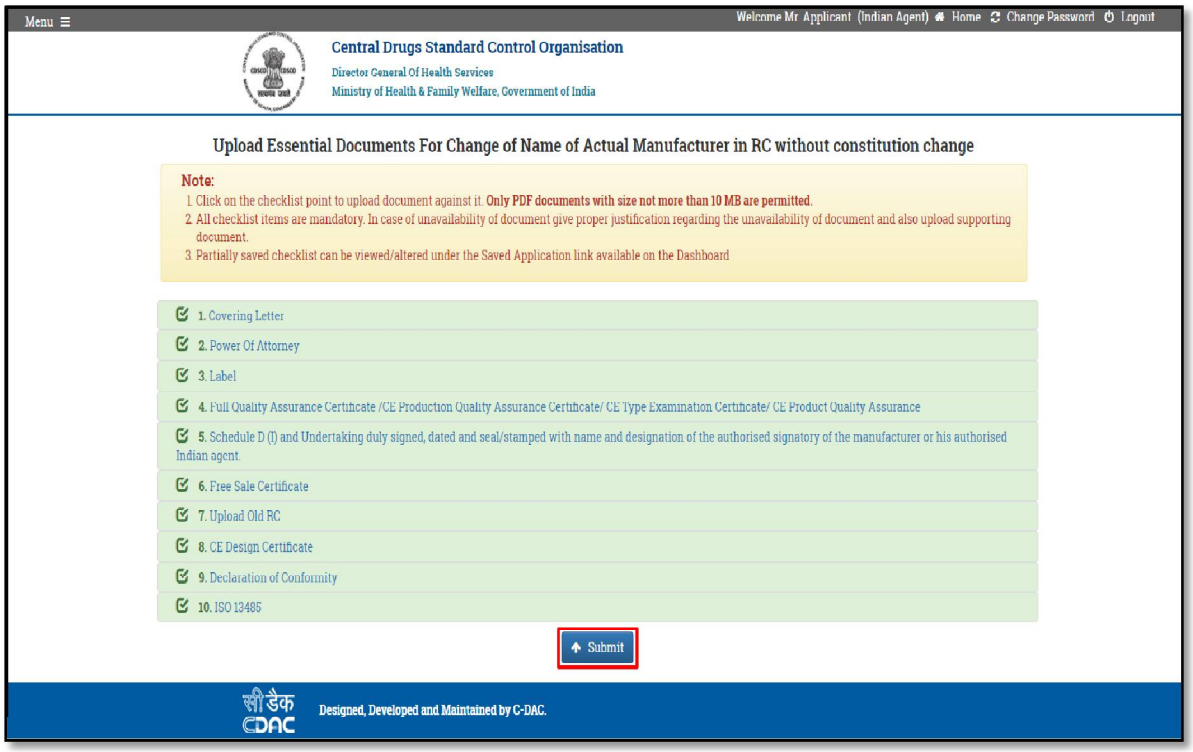


Figure 131 : Checklist of documents to be uploaded for this case

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

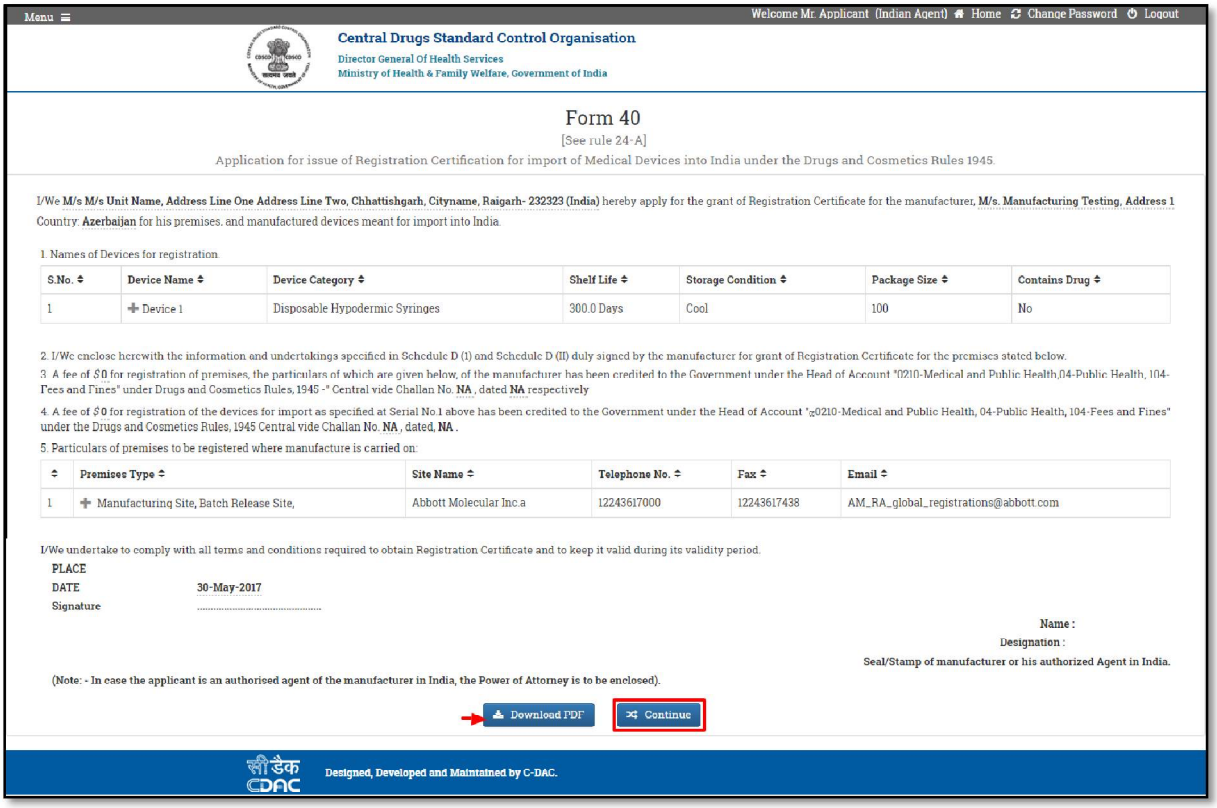


Figure 132 : Preview Form 40 -- Download the Form

- Upload the system generated Form 40.

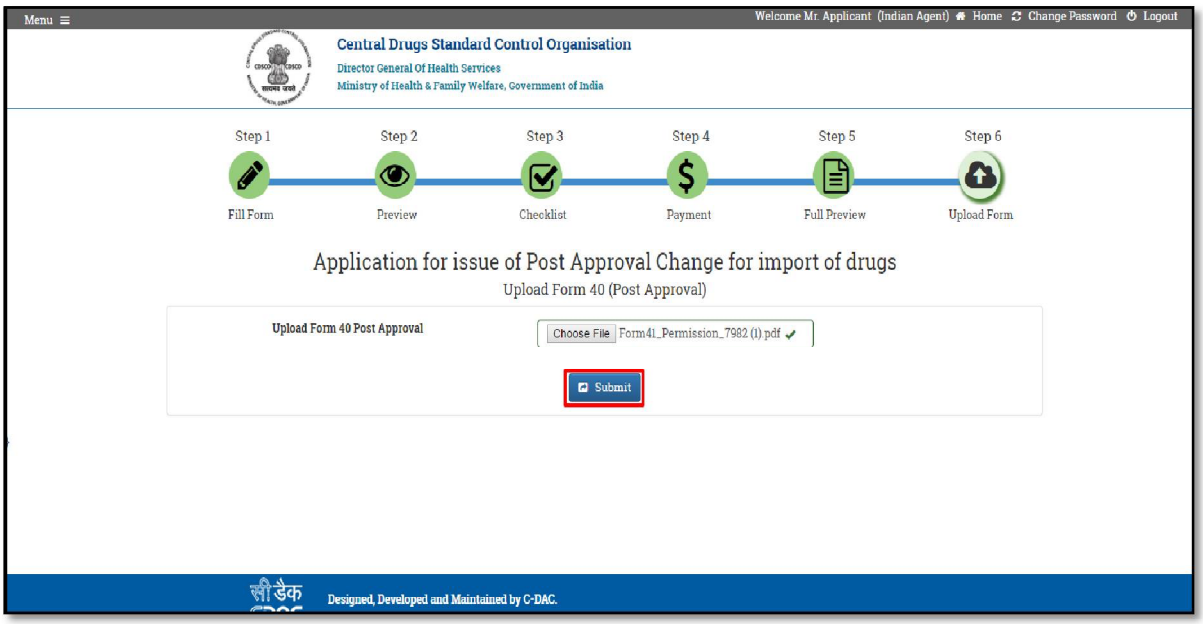


Figure 133 : Upload the system generated Form 40

- 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.

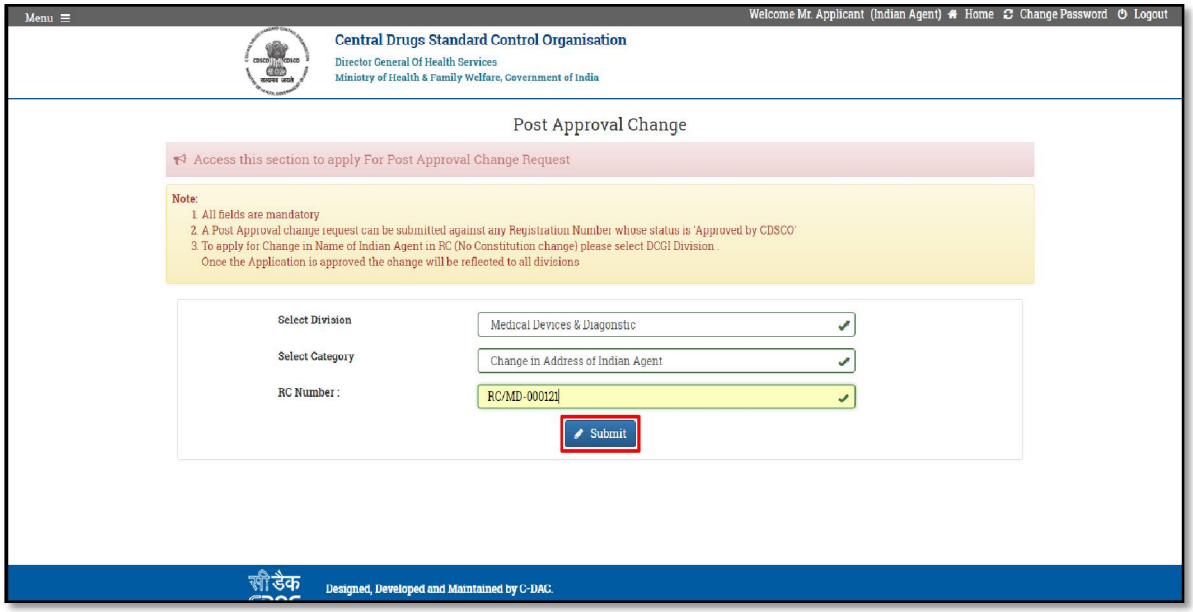


Figure 134 : Change in address of Indian agent

- 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.

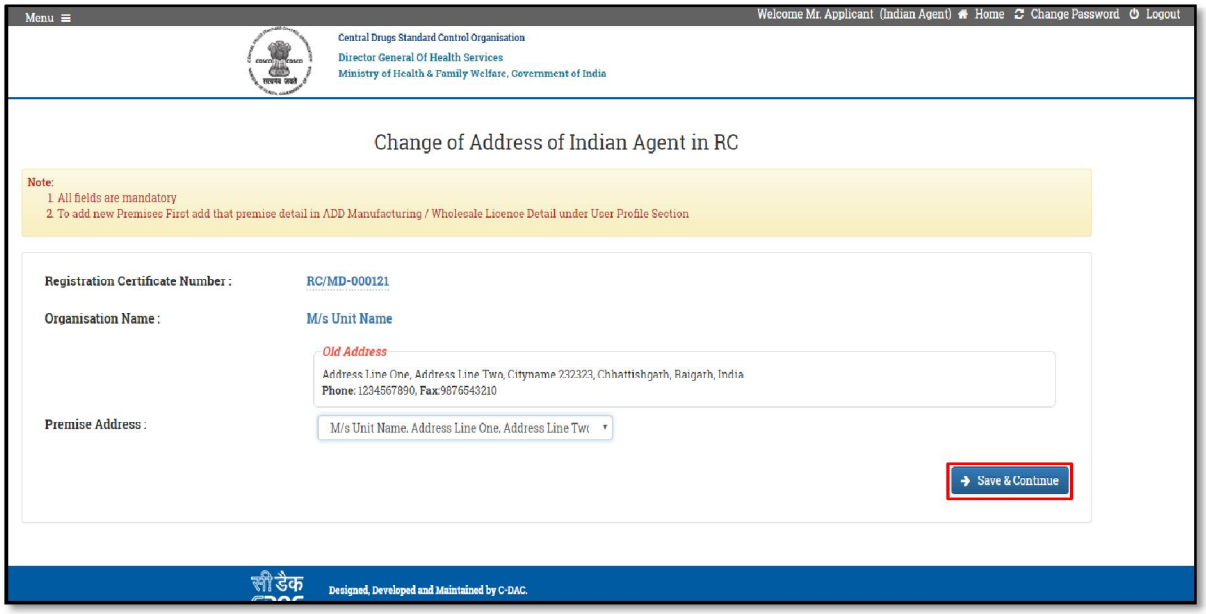


Figure 135 : 'Add wholesale/manufacturing license'

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

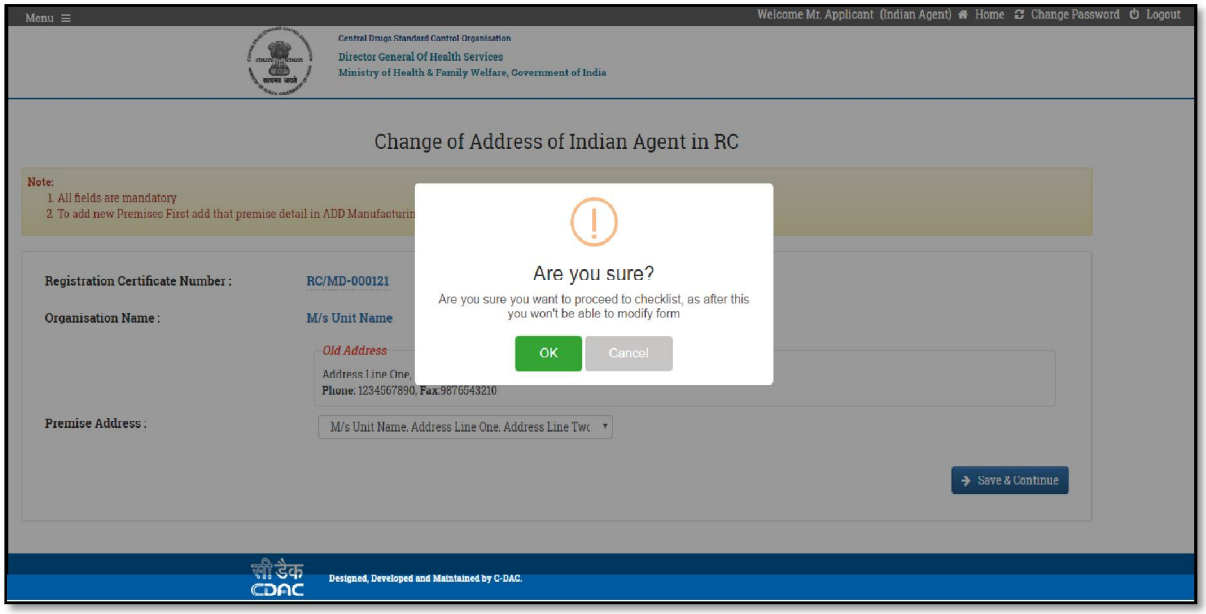


Figure 136 : Popup Message for proceed further

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

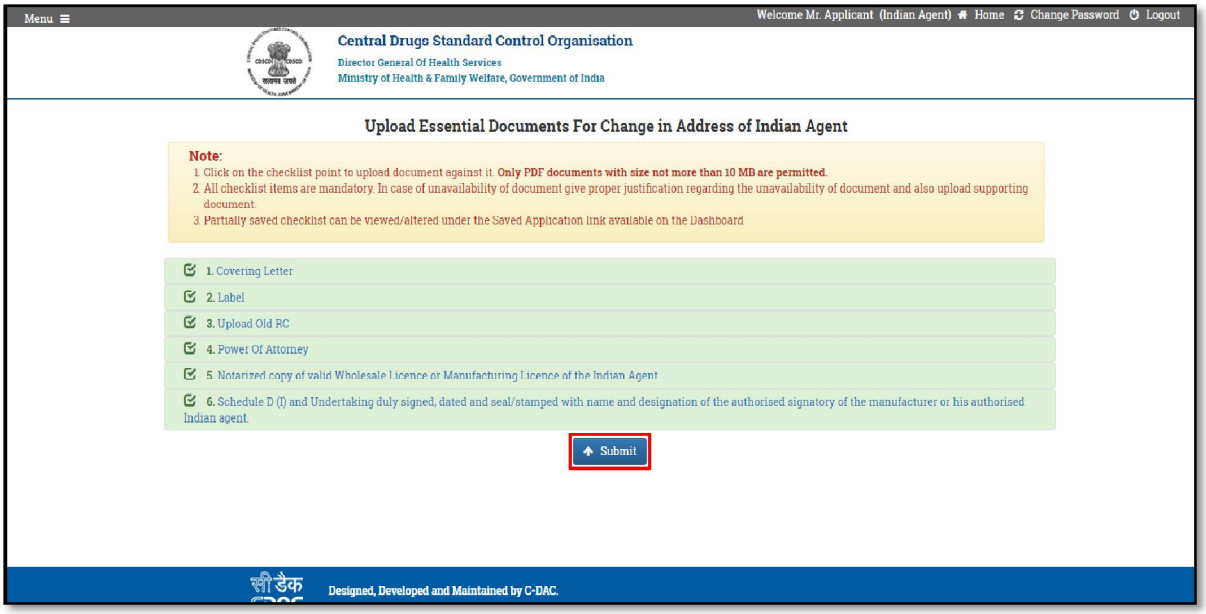


Figure 137 : Checklist of the documents to be uploaded

- Payment Details

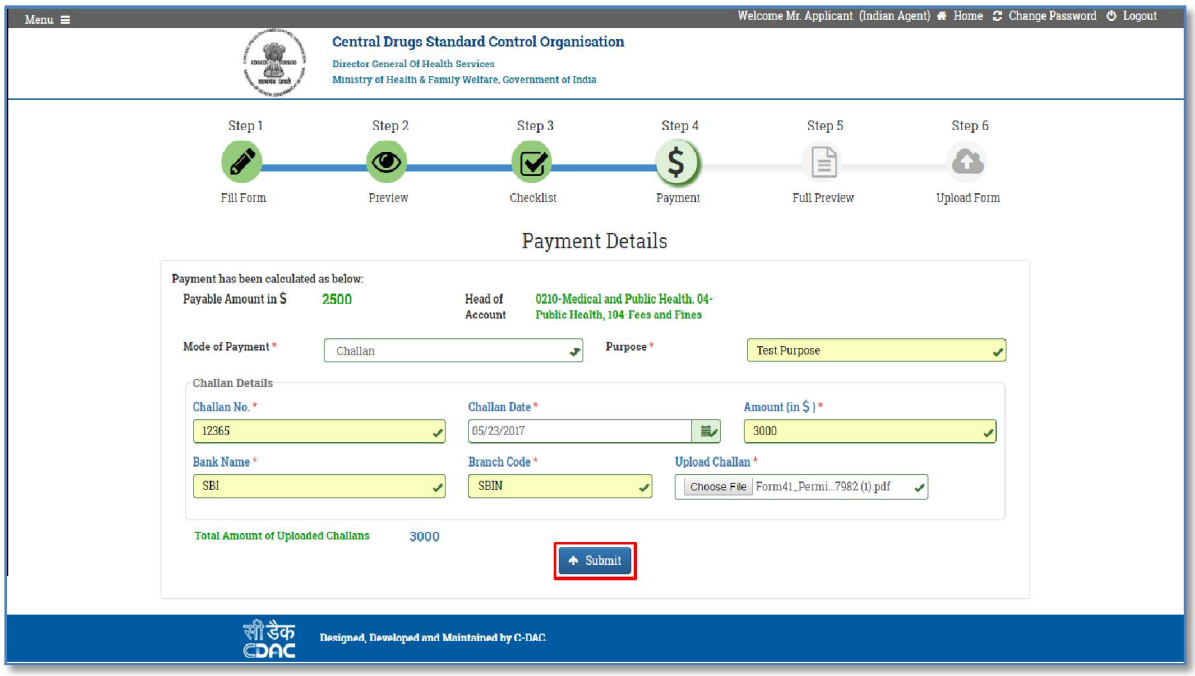


Figure 138 : Payment Details

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

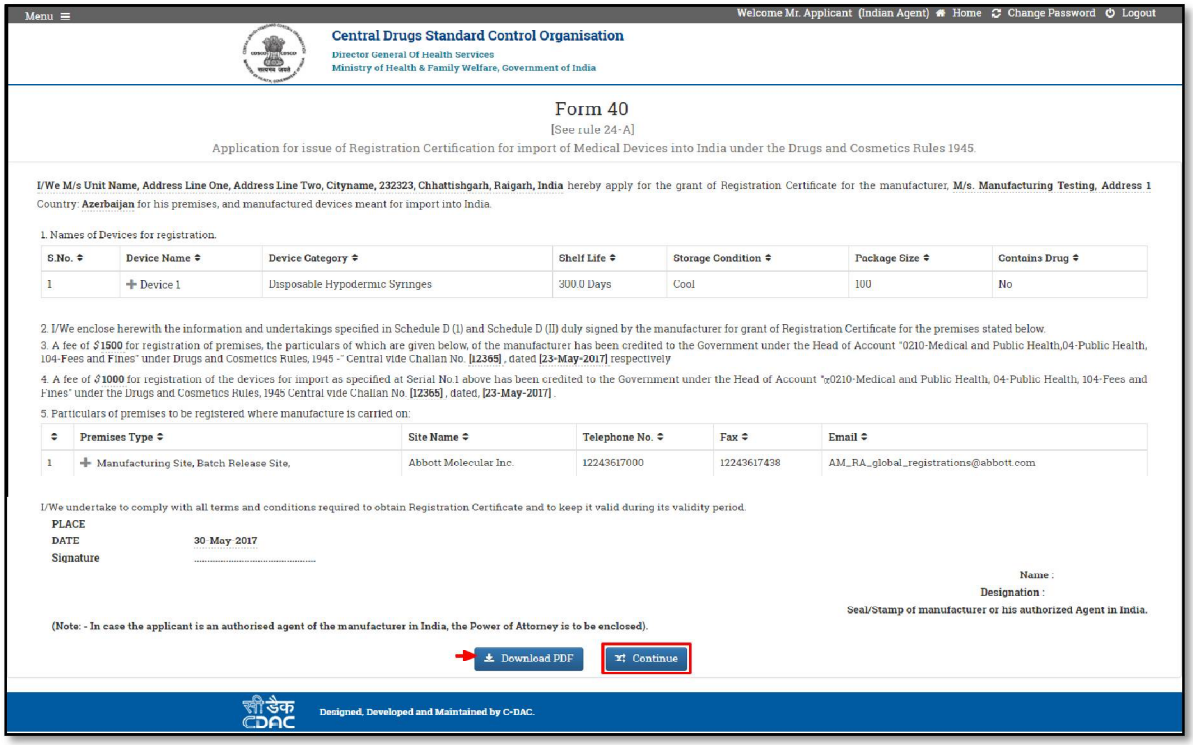


Figure 139 : Preview of Form 40 with changed Indian Agent Address

- Upload the online generated Form 40.

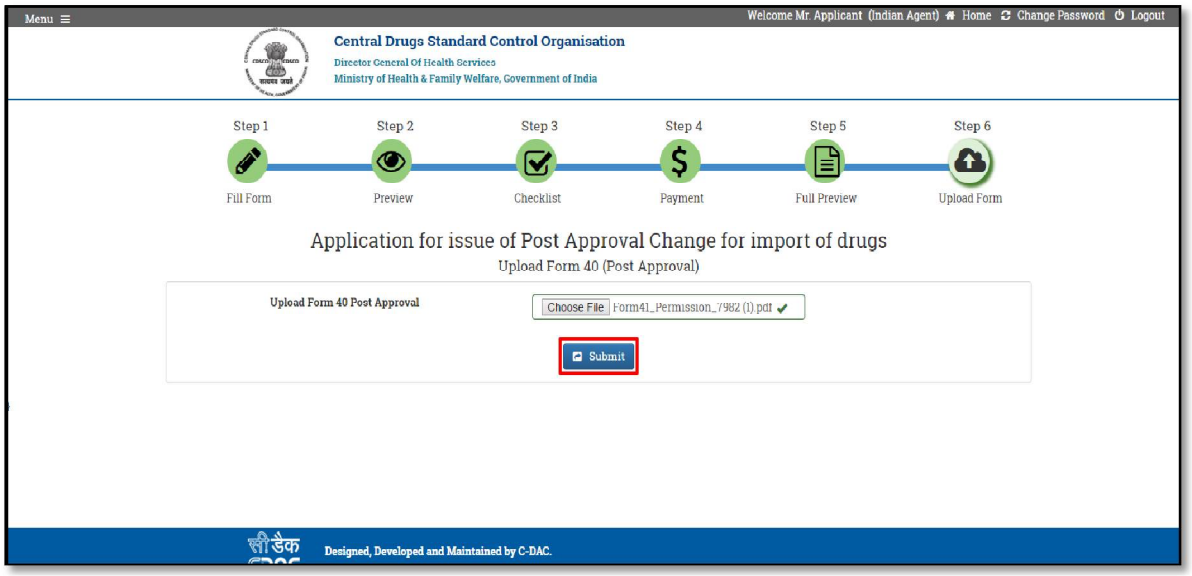


Figure 140 : Upload the online generated Form 40

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

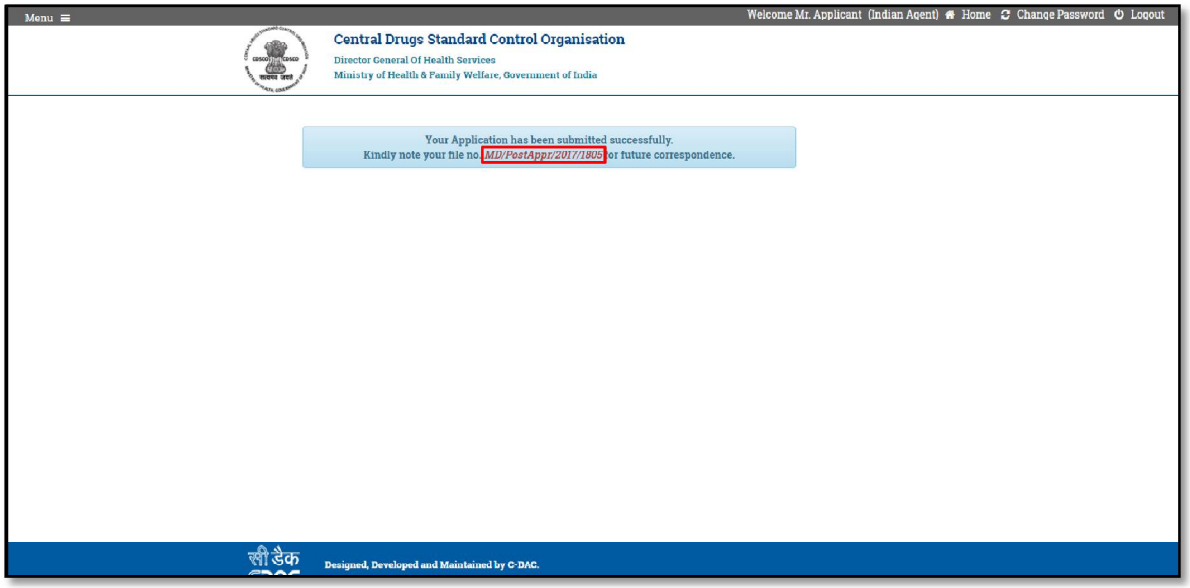


Figure 141 : File number is generated

- **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.

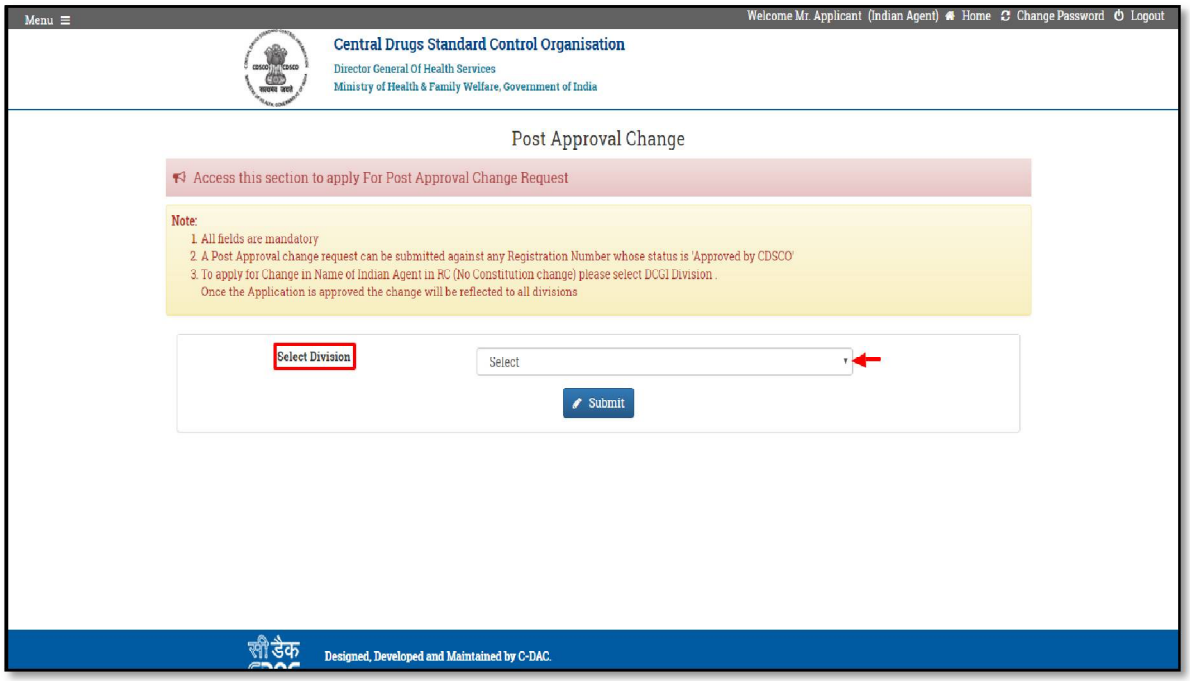


Figure 142 : Change in name of the firm

- Post Approval Change (Category & RC Number)

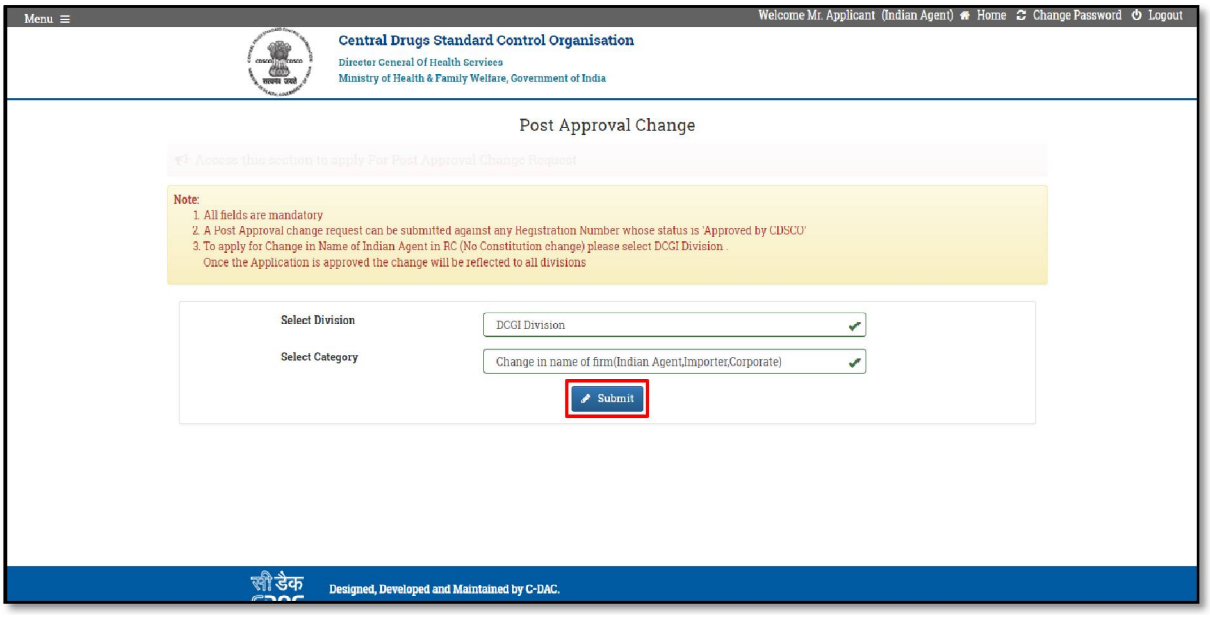
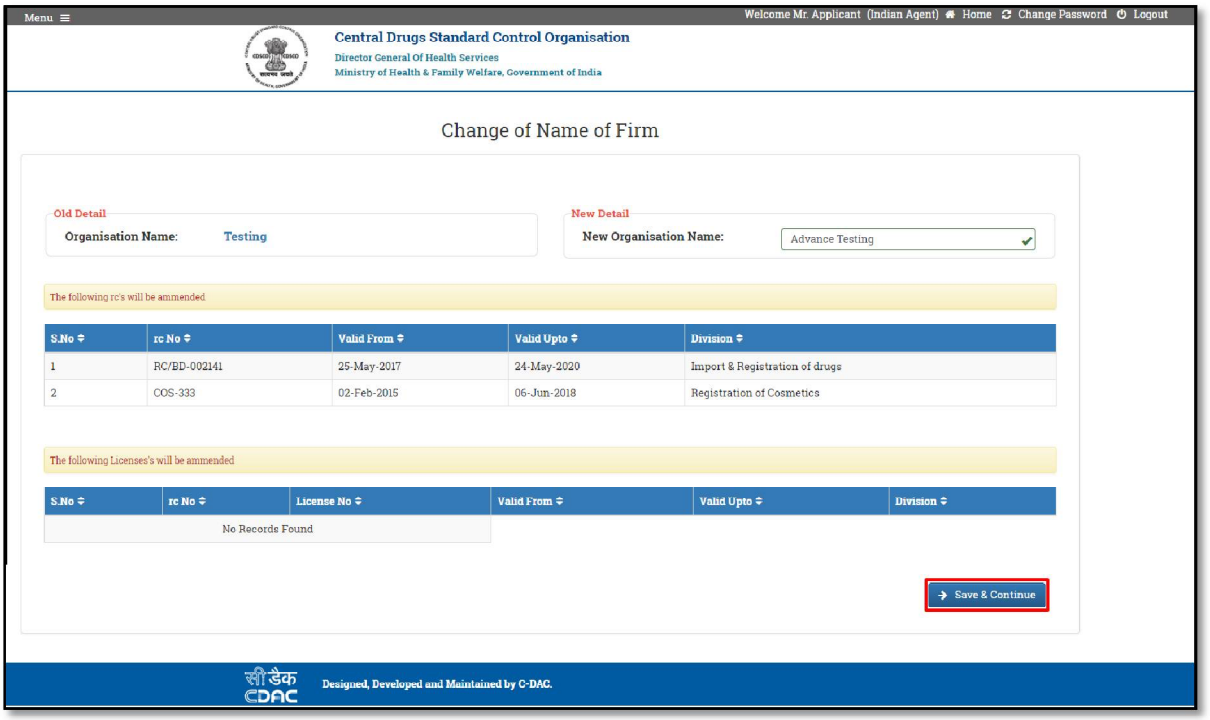


Figure 143 : Post Approval Change (Category & RC Number)

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



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

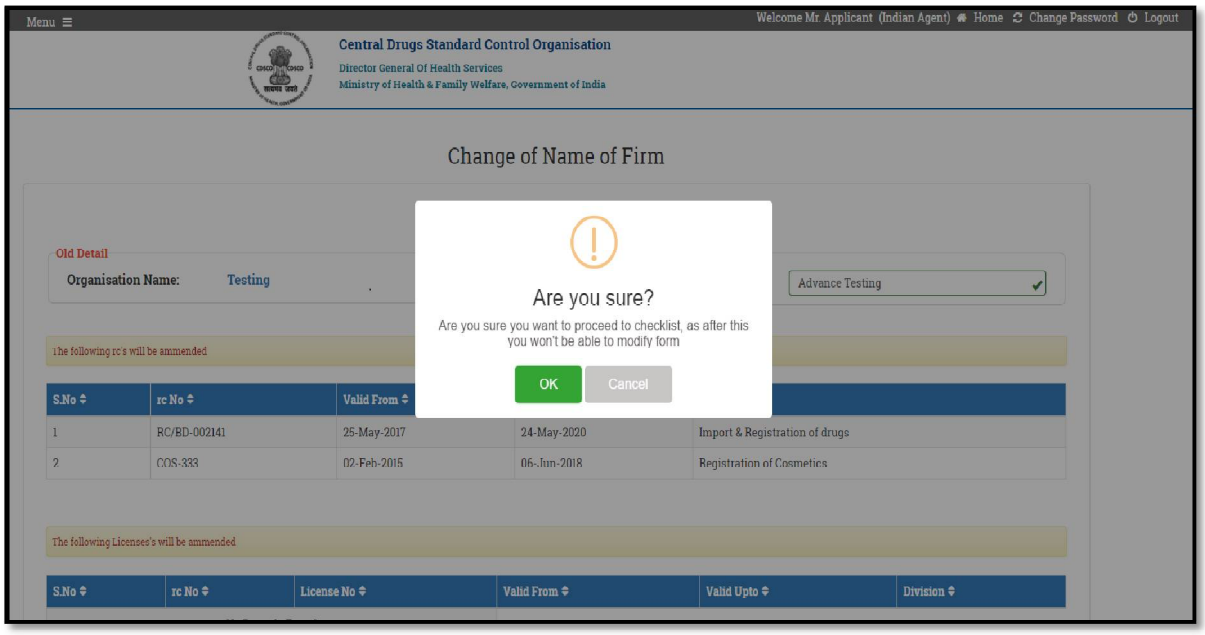


Figure 144 : Confirmation alert -- Proceed to checklist

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

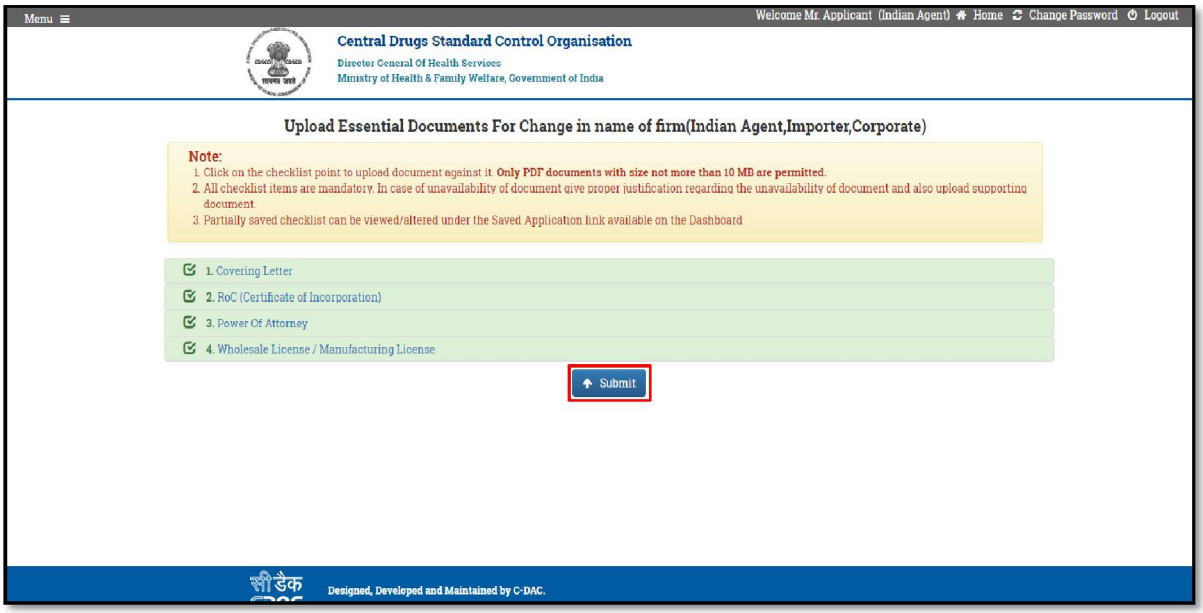


Figure 145 : Checklist of the documents

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

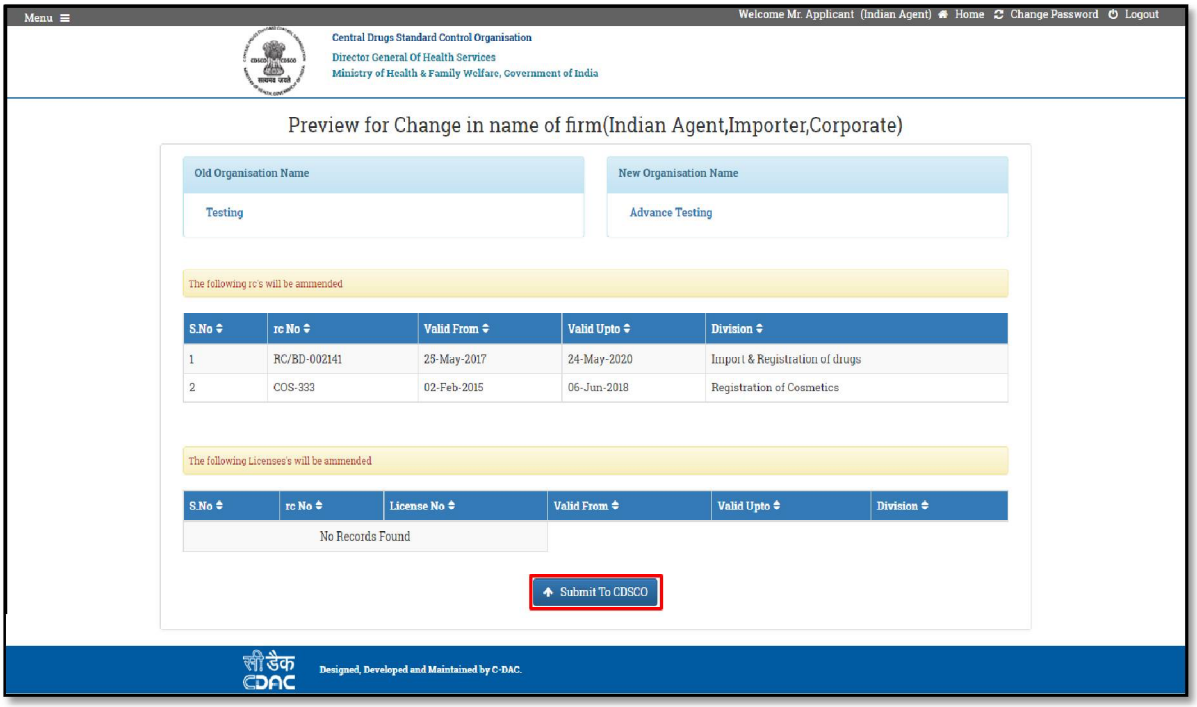


Figure 146 : Preview of change in name

- File number generated after submission of the application

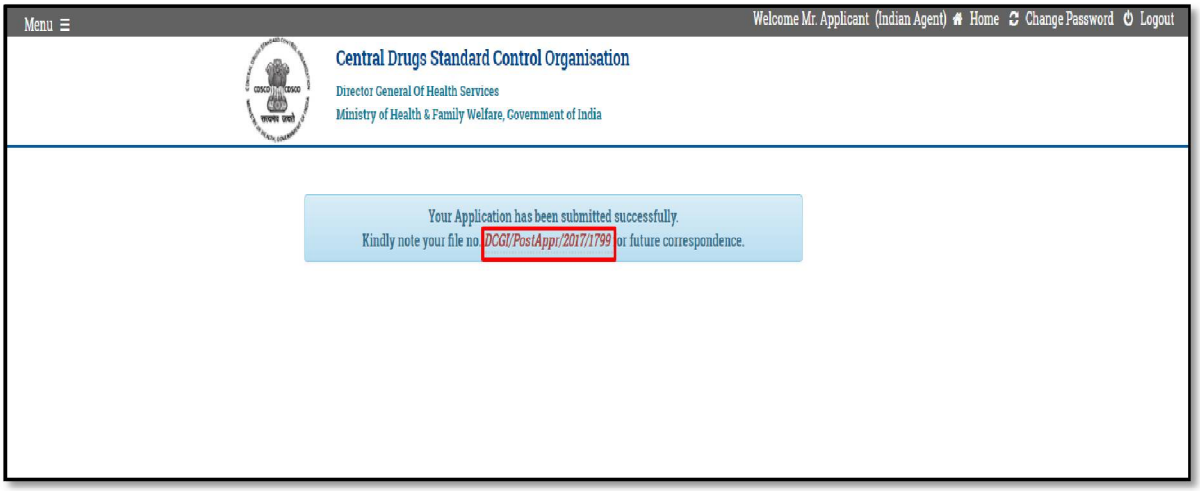


Figure 147 : File number generated

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.cdscoonline.gov.in) by using any internet browser and enter your login Credentials in the sign in box and as shown in below **Figure**

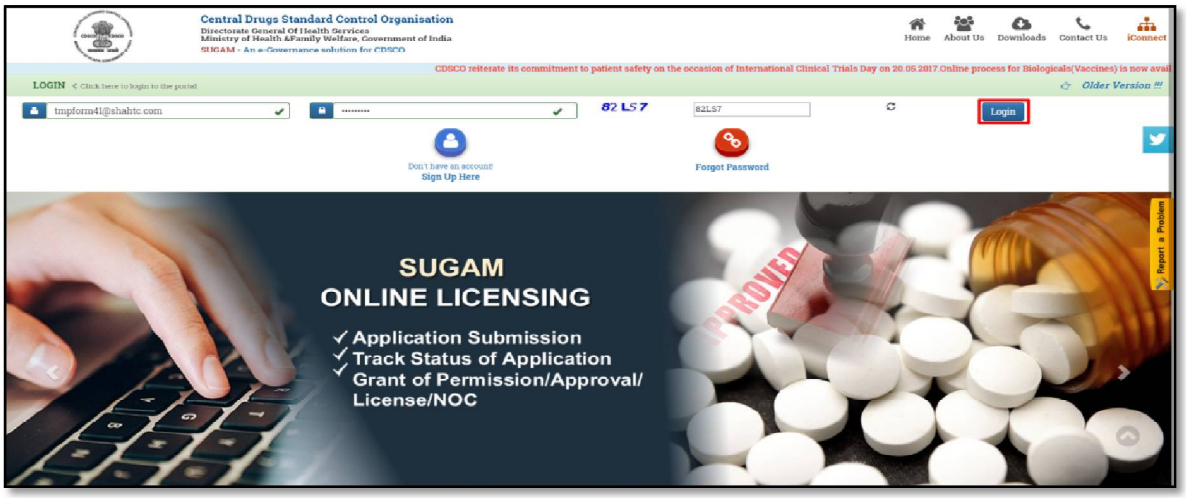


Figure 148 : Login to SUGAM Portal

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

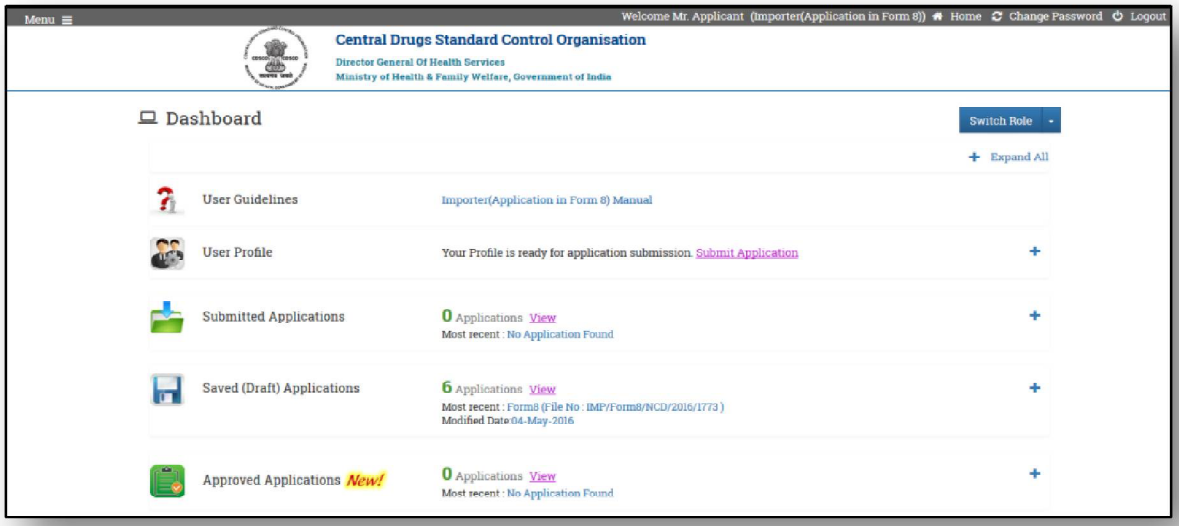


Figure 149 : Select the online payment

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

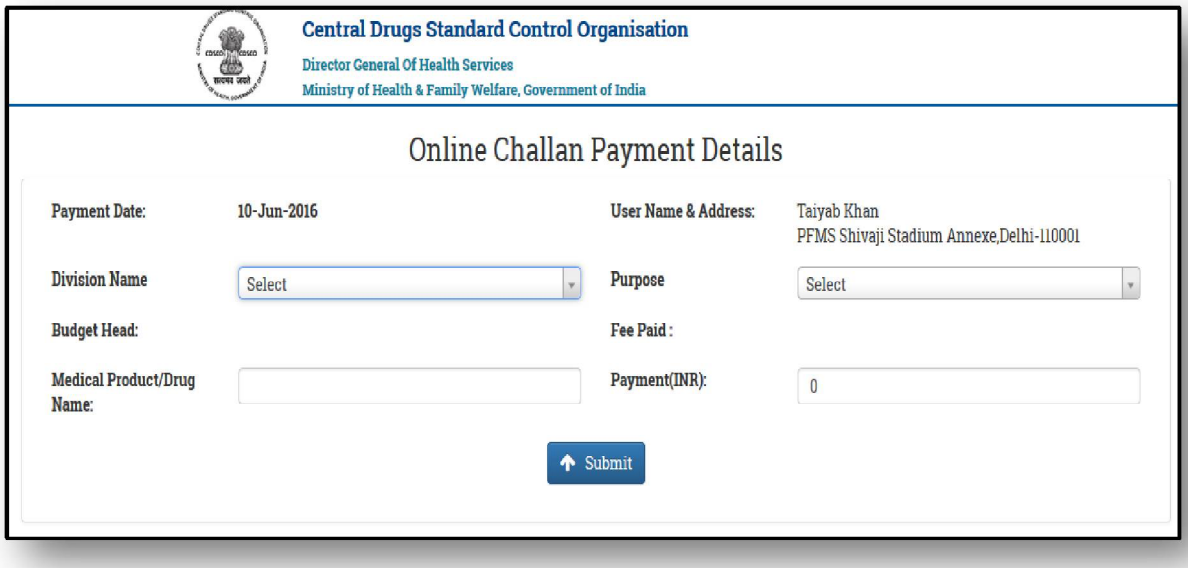


Figure 150 : Online Payment Details

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).

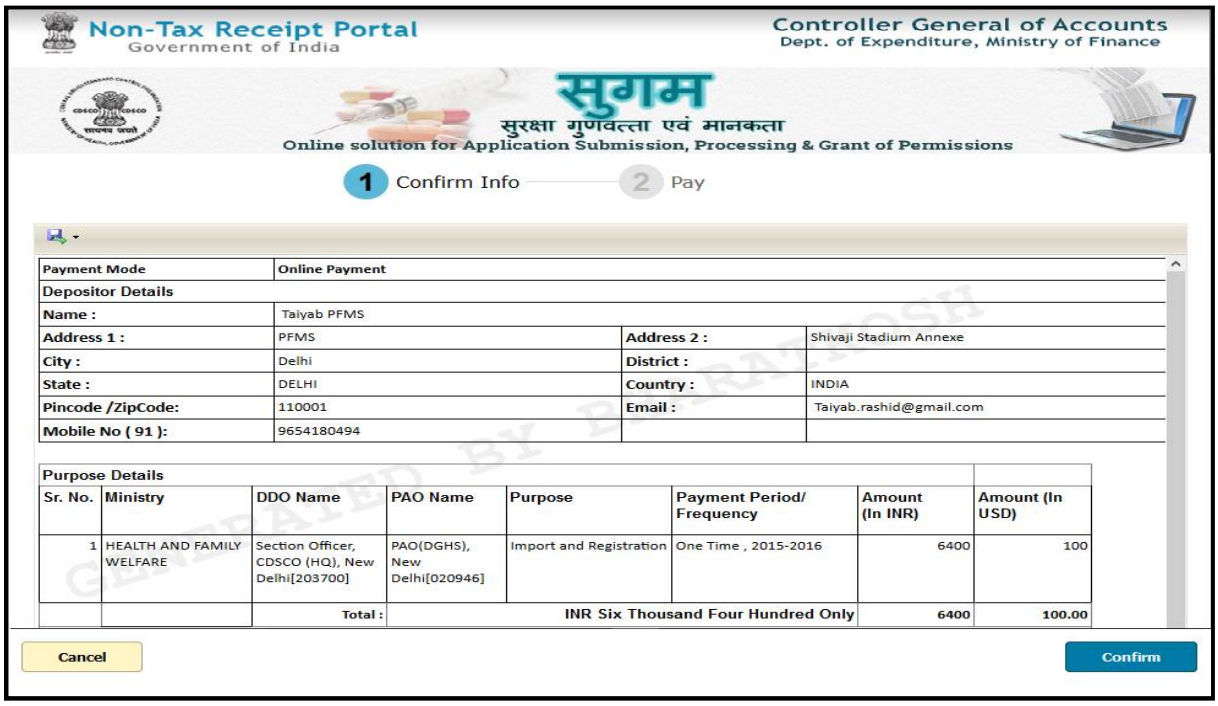


Figure 152 : BHARATKOSH Payment View Details

- 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

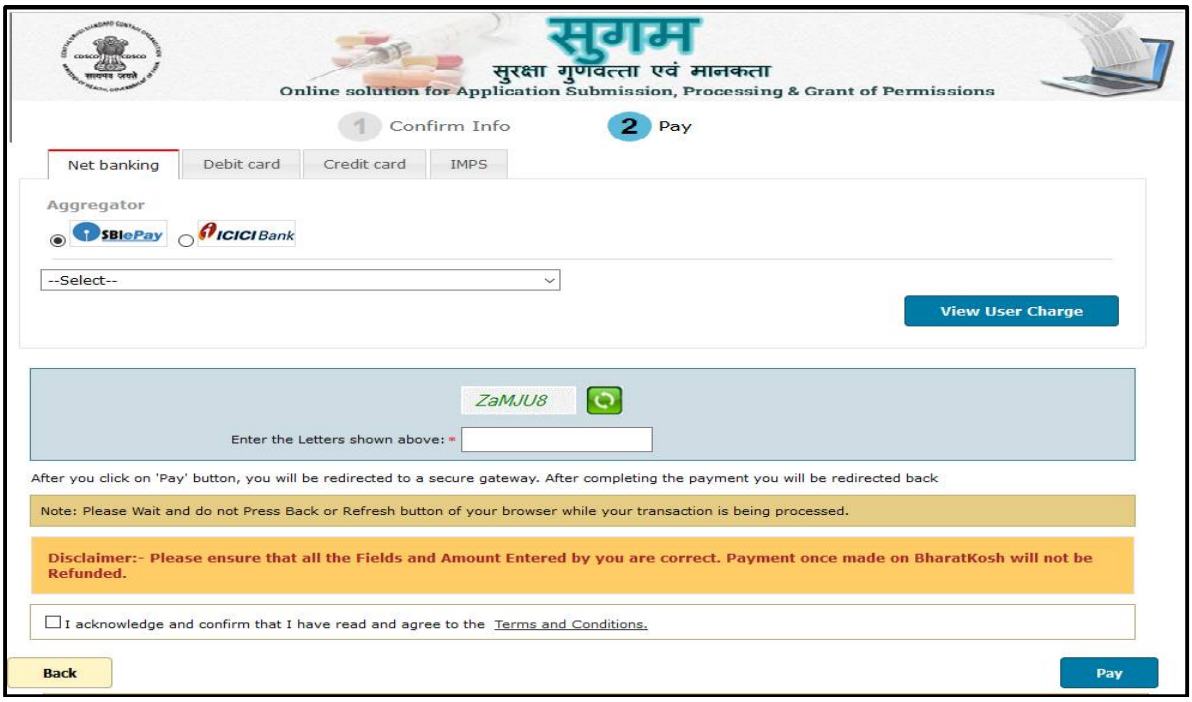


Figure 153 : Payment Gateway

- 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 drop down 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.

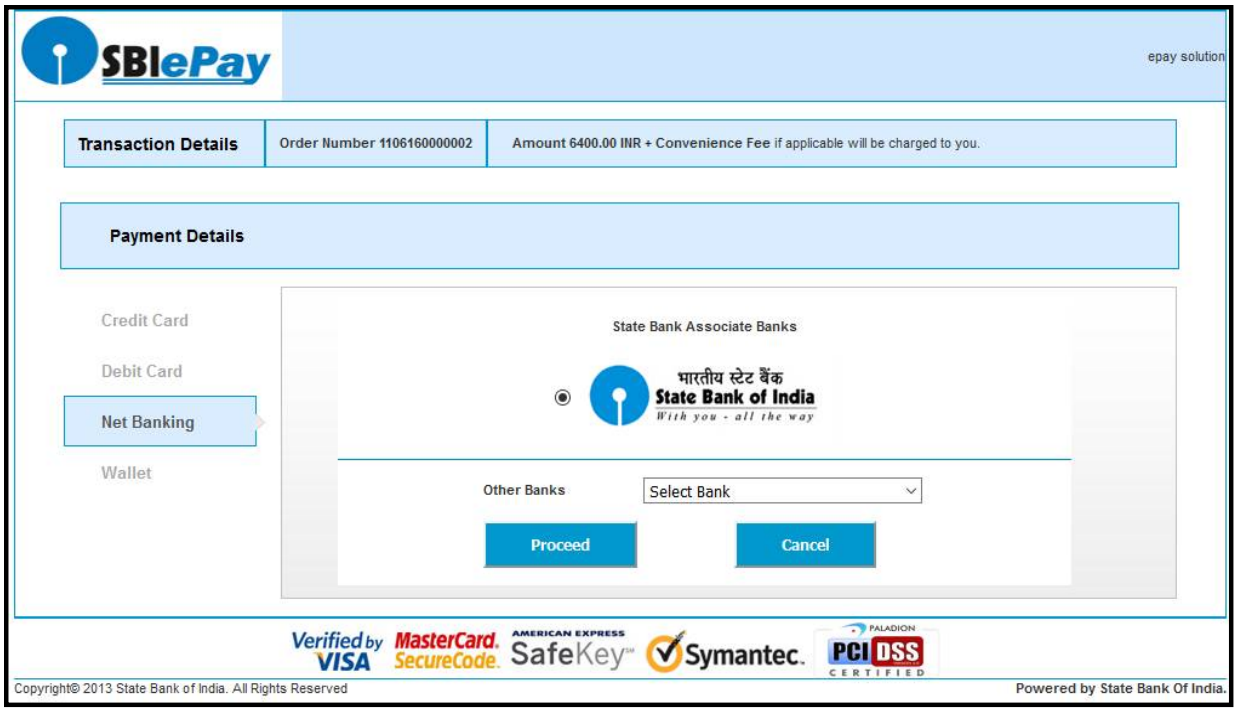


Figure 154 : Screen of SBI ePay

- **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.

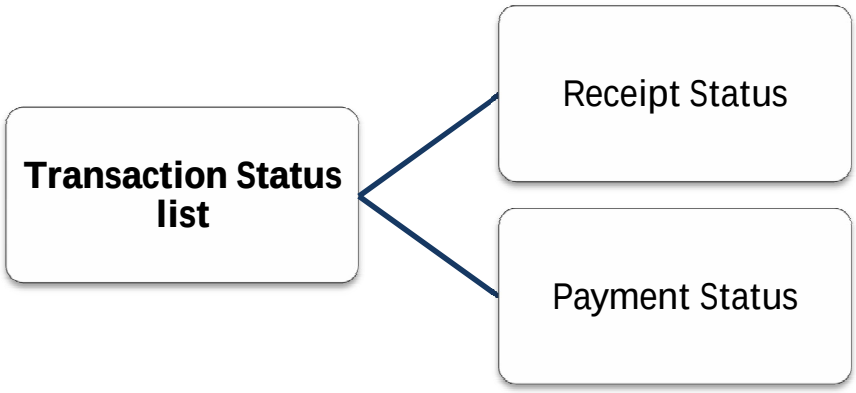
SBIePAY Test Bank	
OrderNumber :	1106160000002
Amount :	6400.0
Successful	Decline

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 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 (Bharat-kosh). User can navigate to 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**

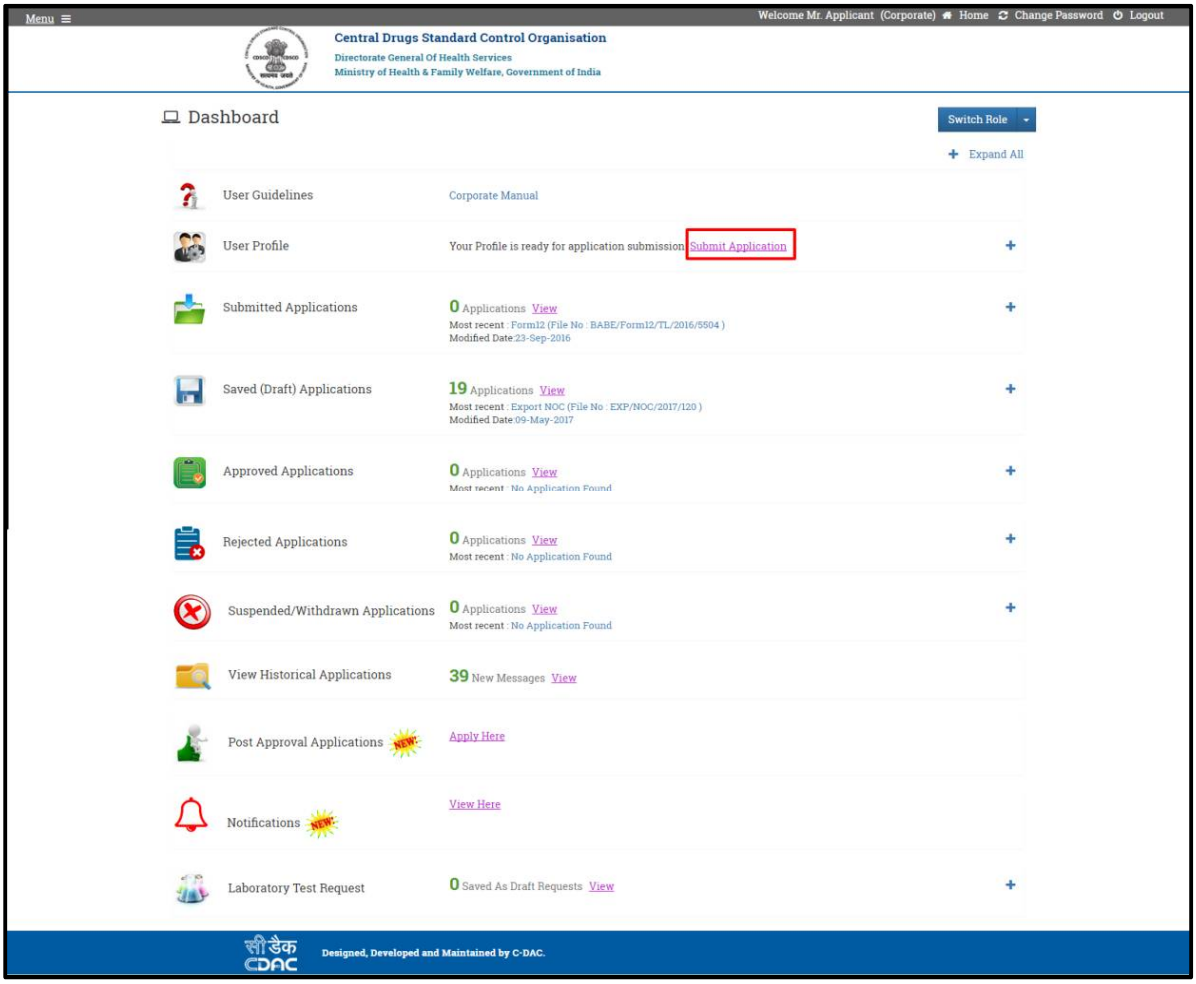


Figure 158 : Application for export NOC

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.

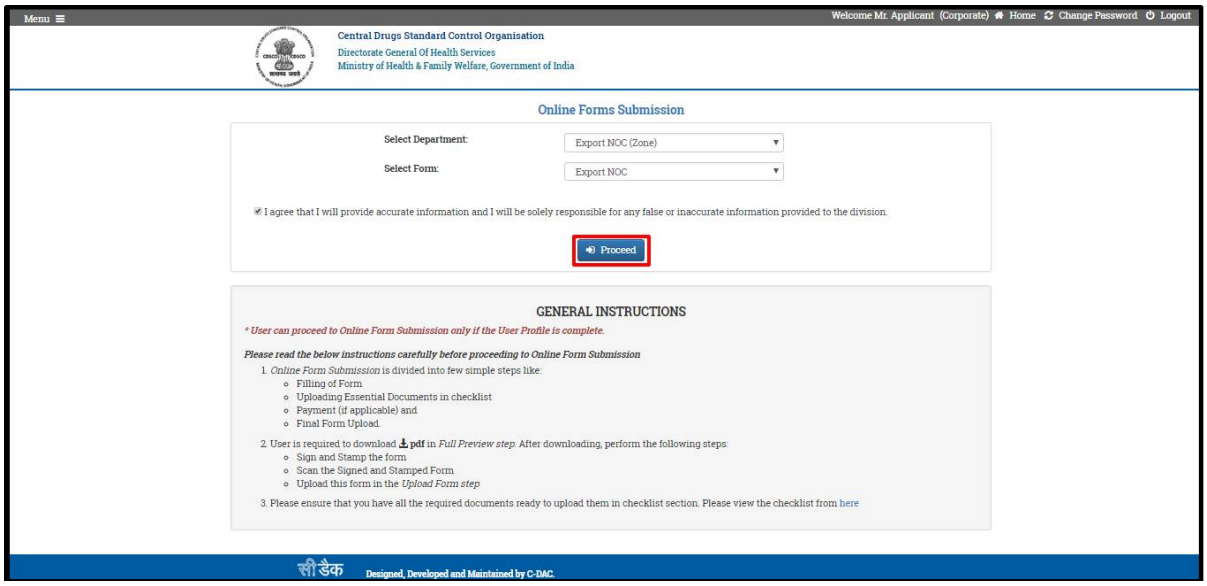


Figure 159 : Online Form Submission

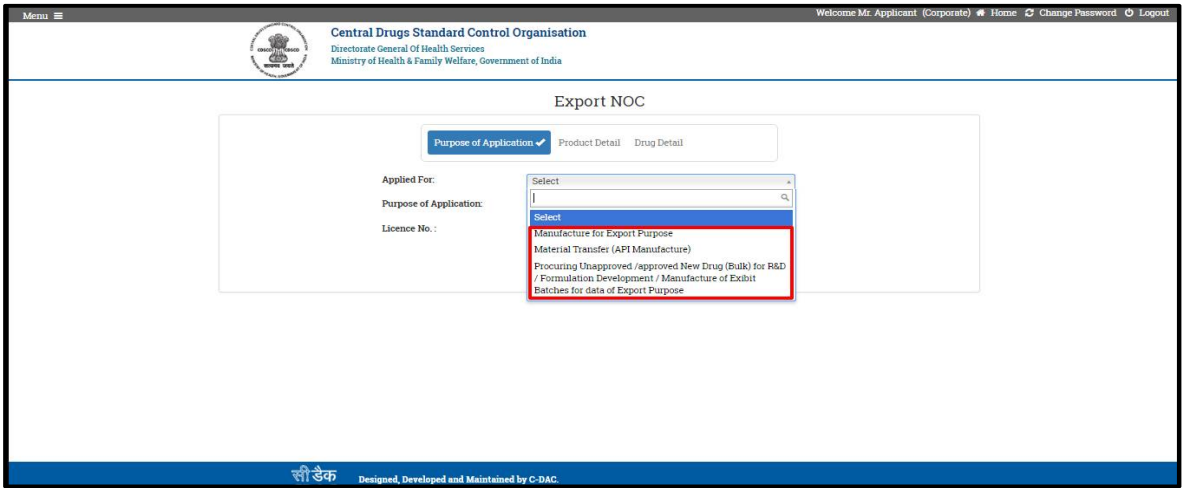
NOTES:

- 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.**

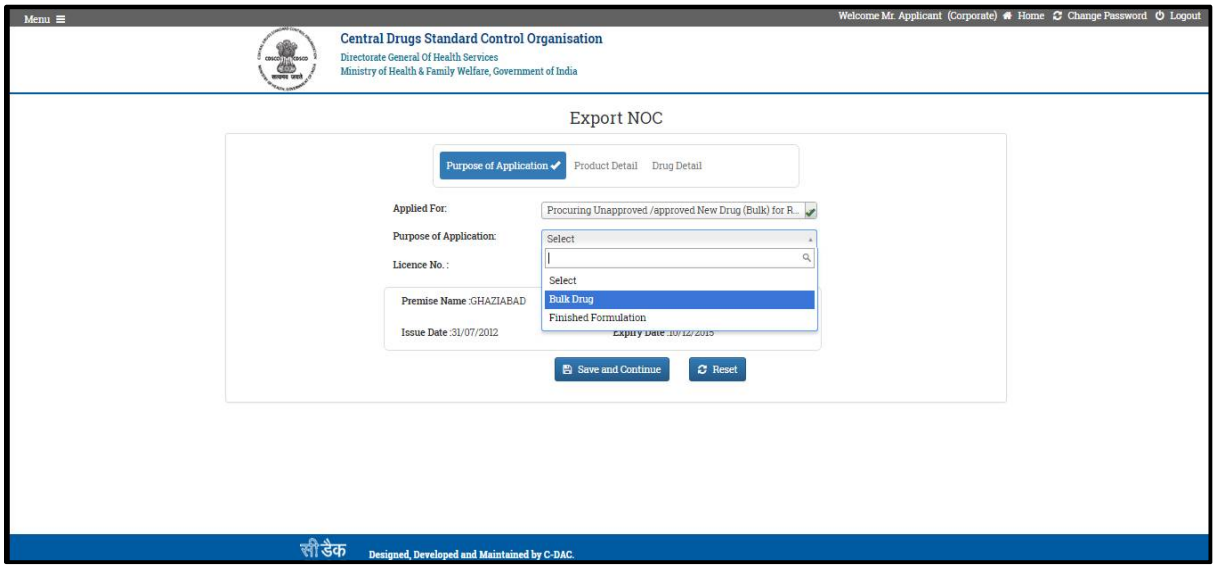
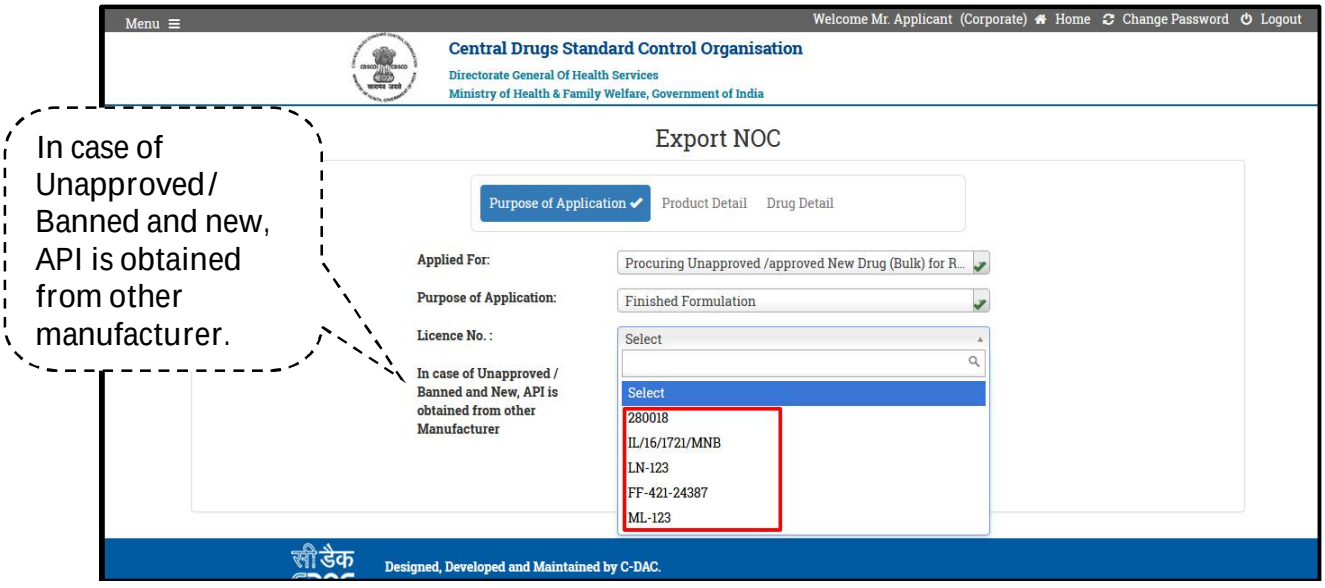


Figure 160 : Purpose of Application

- 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.**

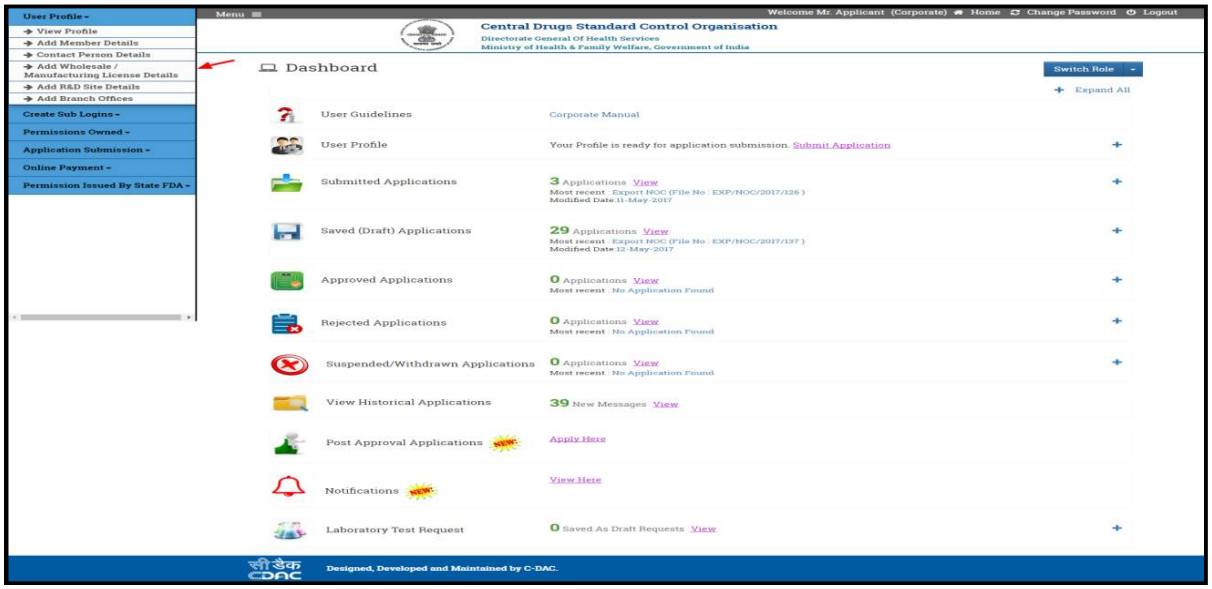


Figure 161 : Add Wholesale/Manufacturing Licensing Details

- 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.**

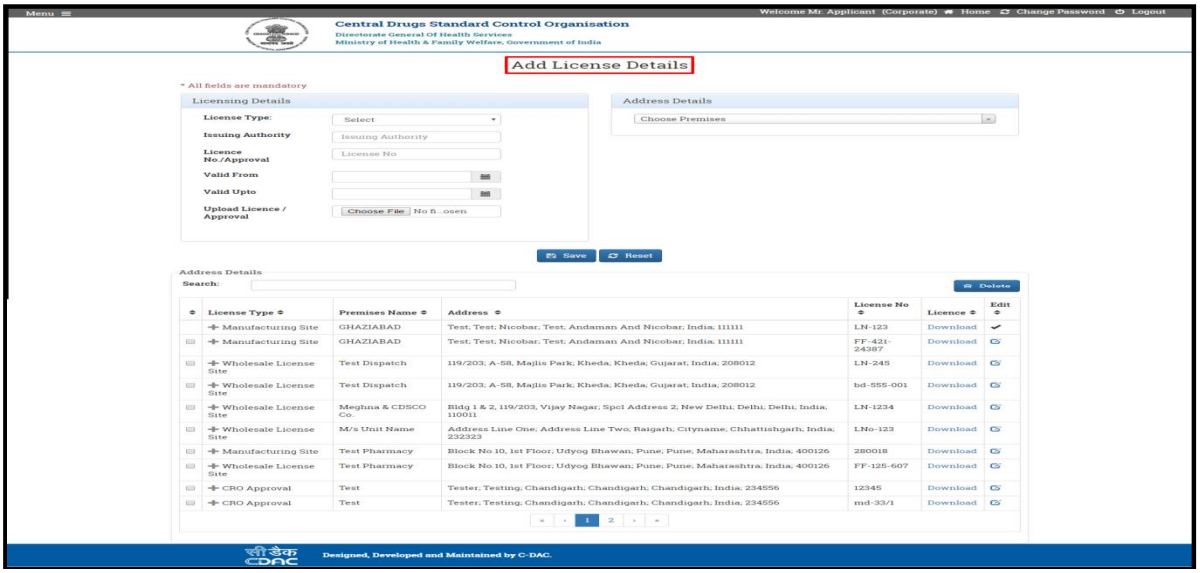


Figure 162 : Add License details

- **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.

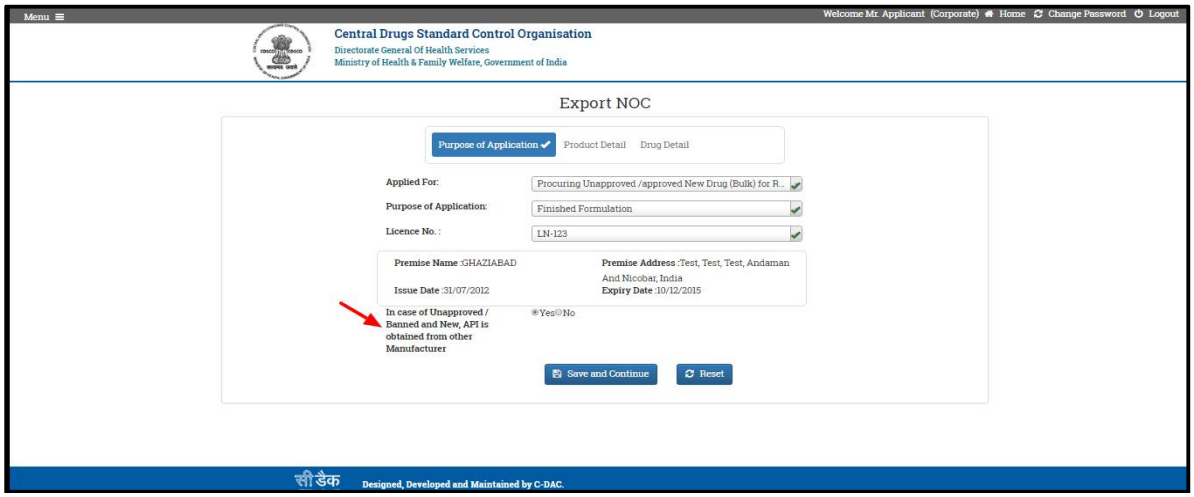


Figure 163 : Click on Save and Continue

- 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.

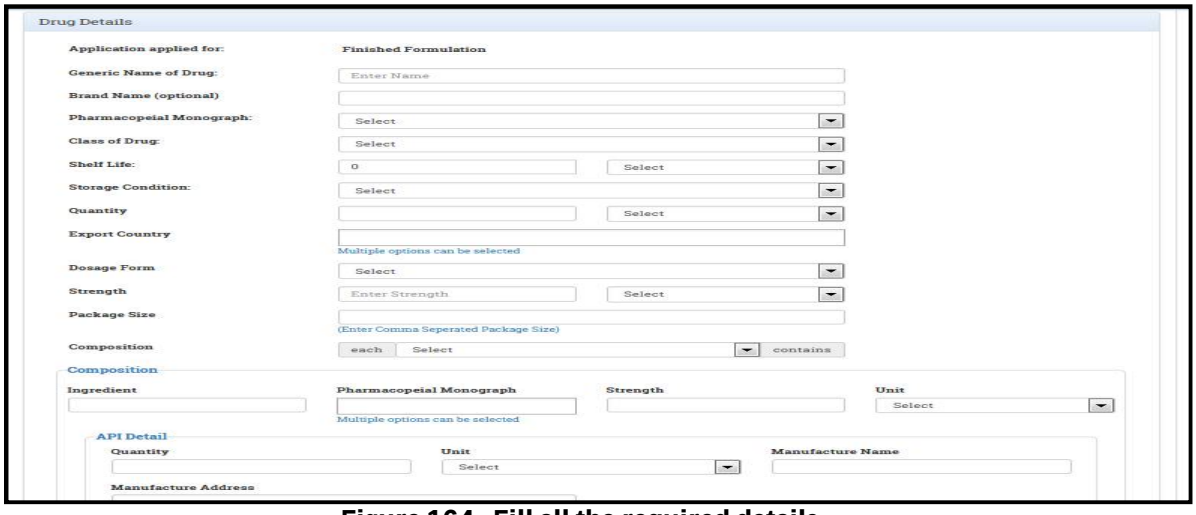


Figure 164 : Fill all the required details

- 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.

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.

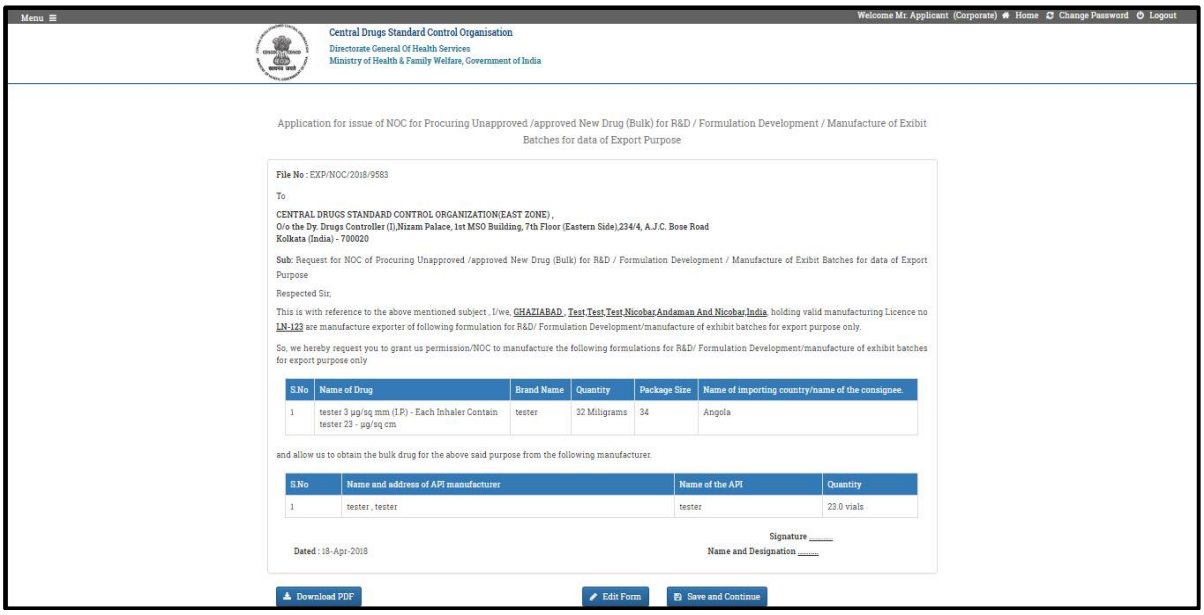


Figure 166 : User can download the PDF

- 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.

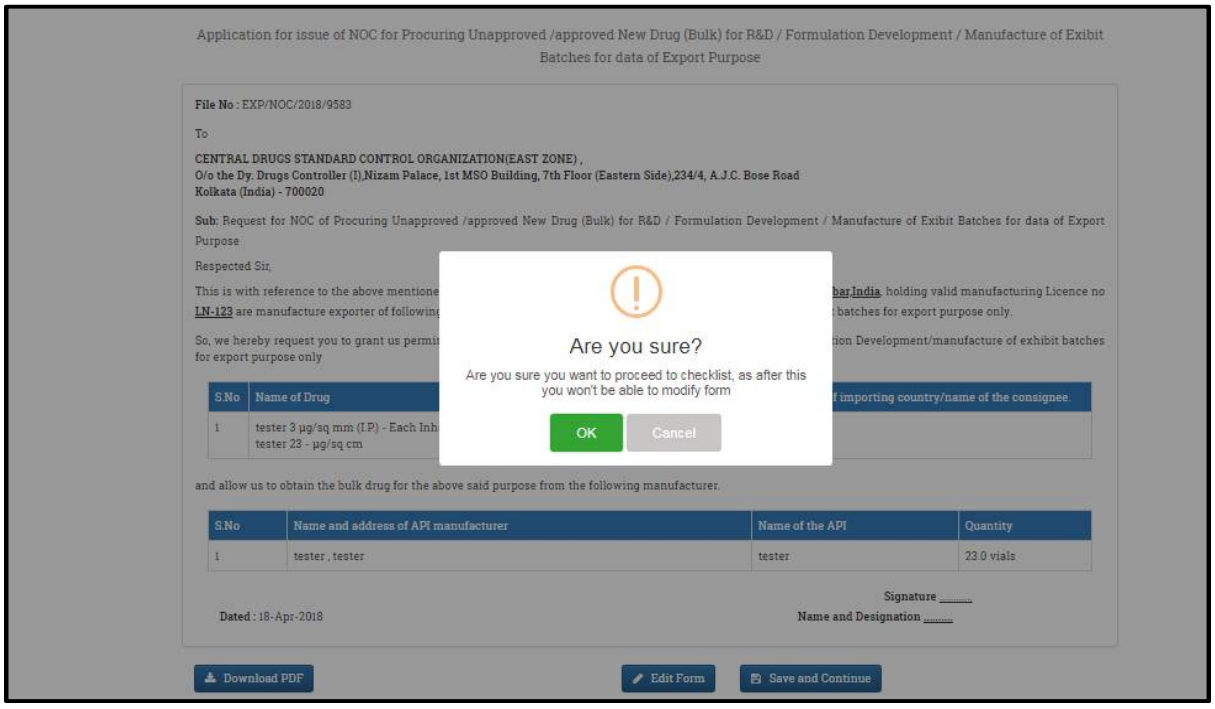


Figure 167 : Confirmation Message – Proceed to checklist

- 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.***

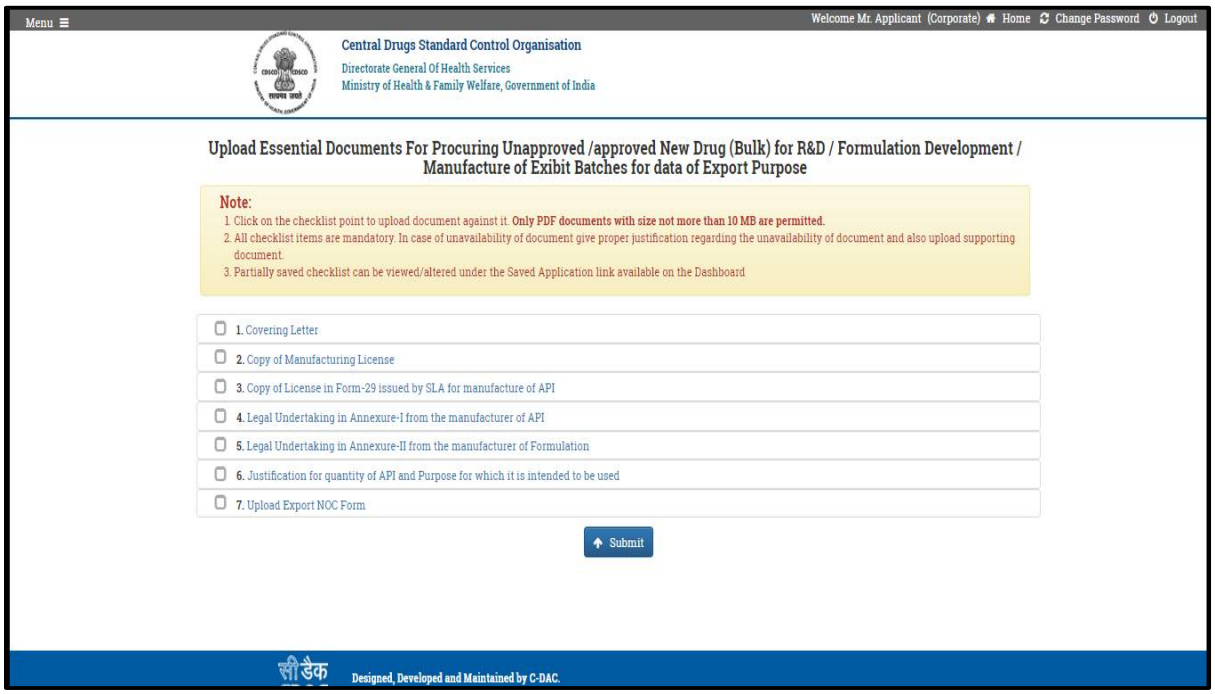


Figure 168 : Before proceeding read the "Note",

- 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.**

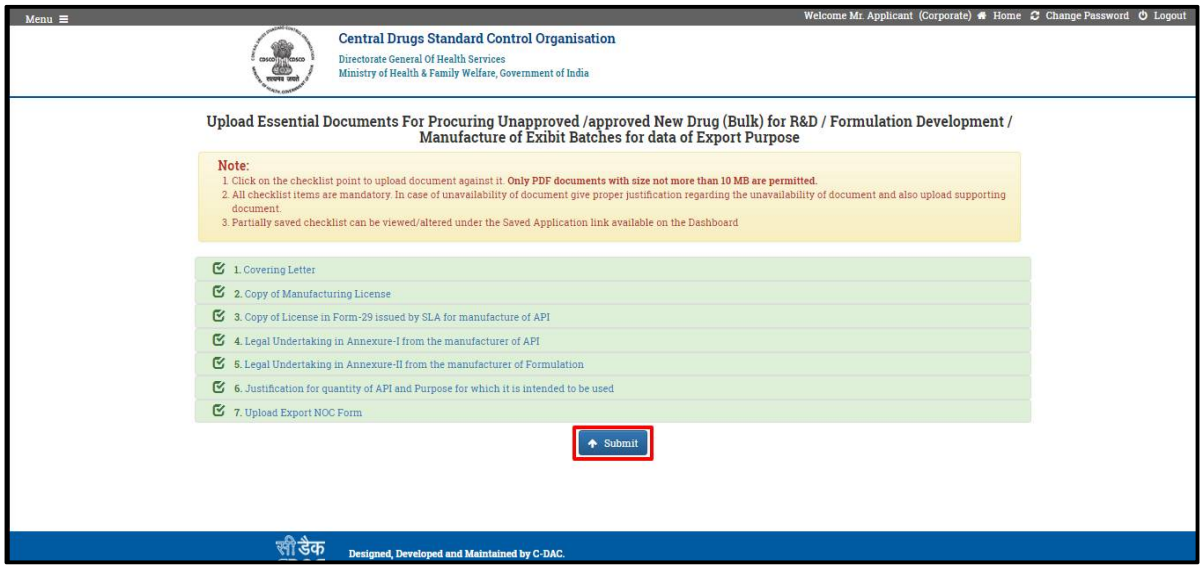


Figure 169 : "Save" button to further proceed

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

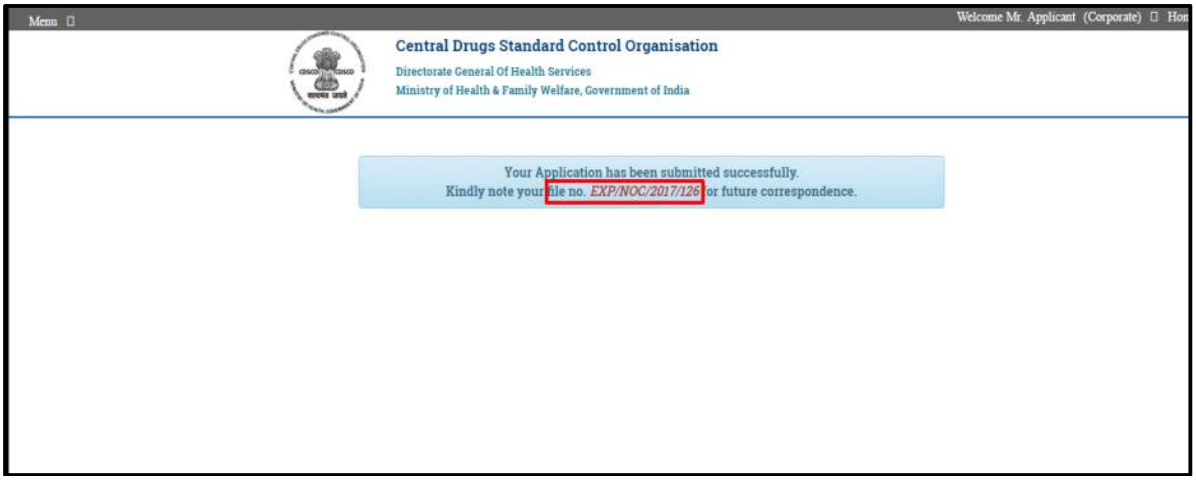


Figure 170 : Message Shown -- Application has been submitted successfully

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.**

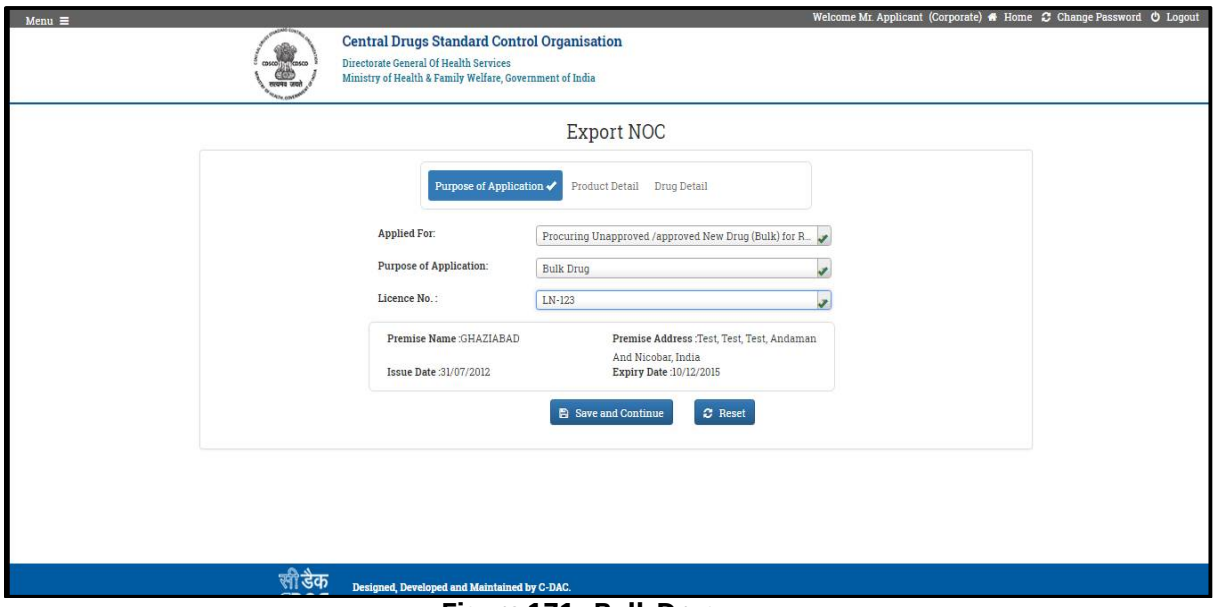


Figure 171 : Bulk Drug

- 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.

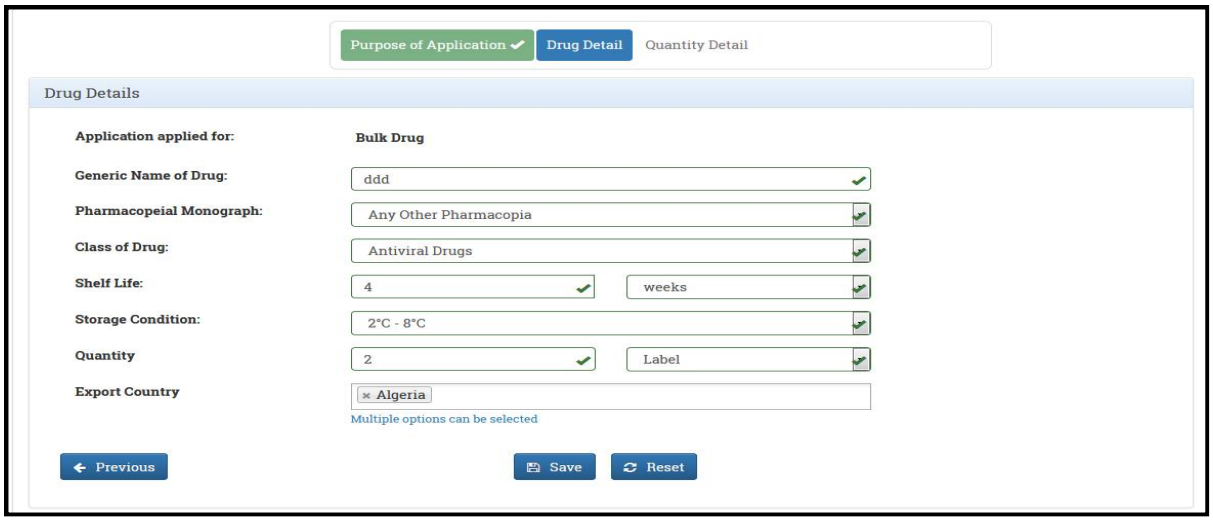
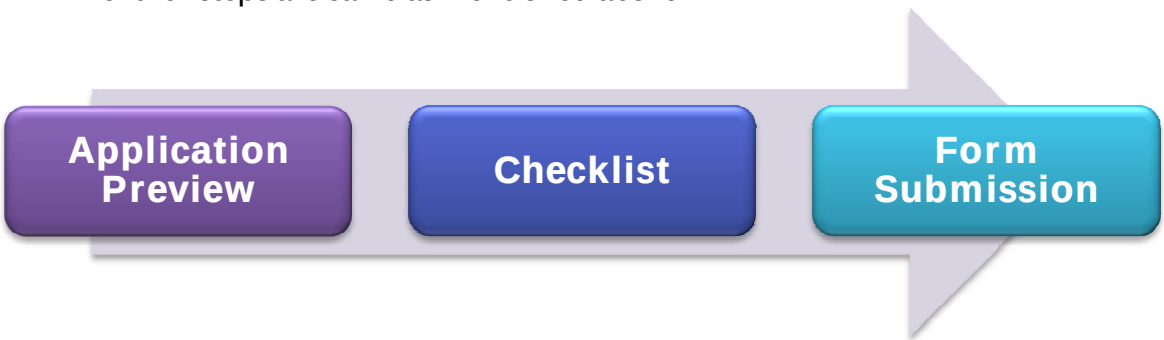


Figure 172 : after the completion of Form Click on Save button

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.

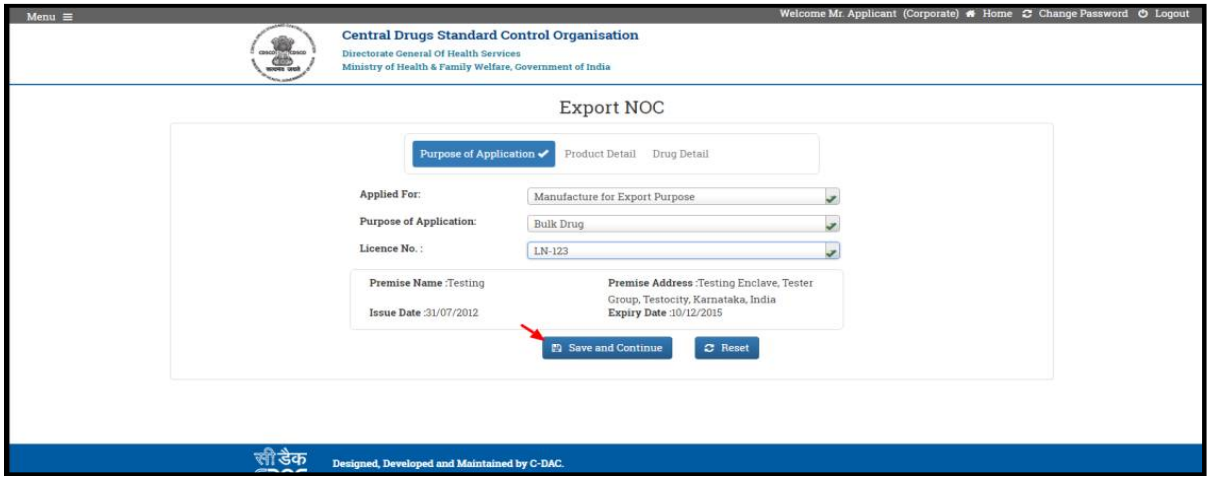


Figure 173 : Manufacture for Export Purposes

- 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.

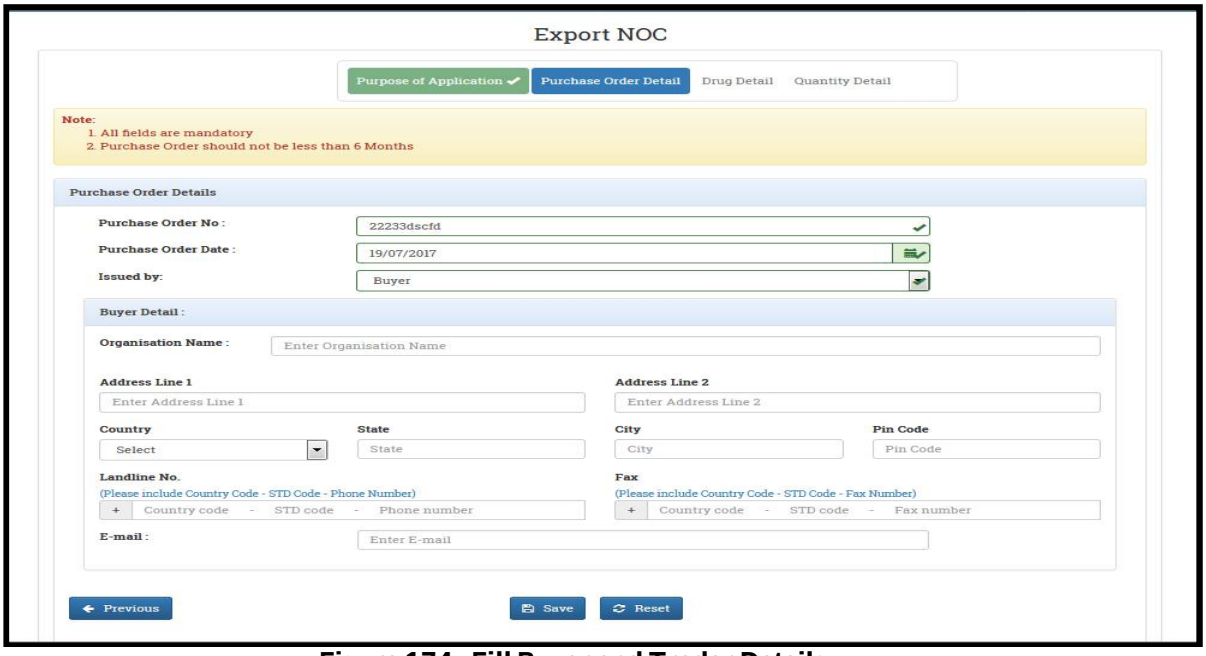


Figure 174 : Fill Buyer and Trader Details

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

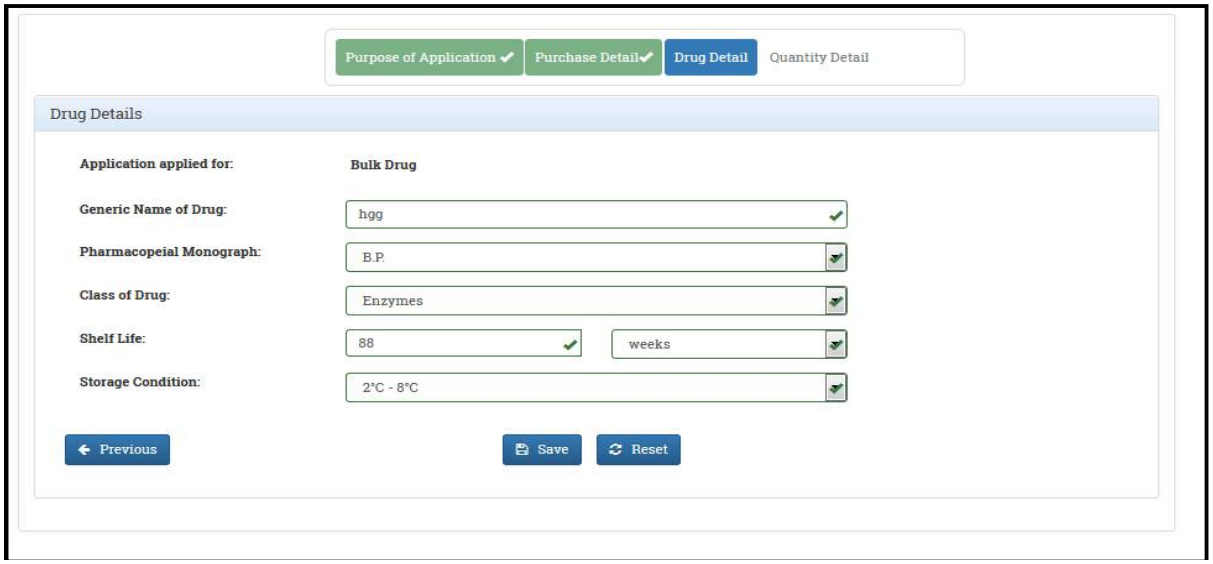


Figure 175 : User will fill the drug details

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

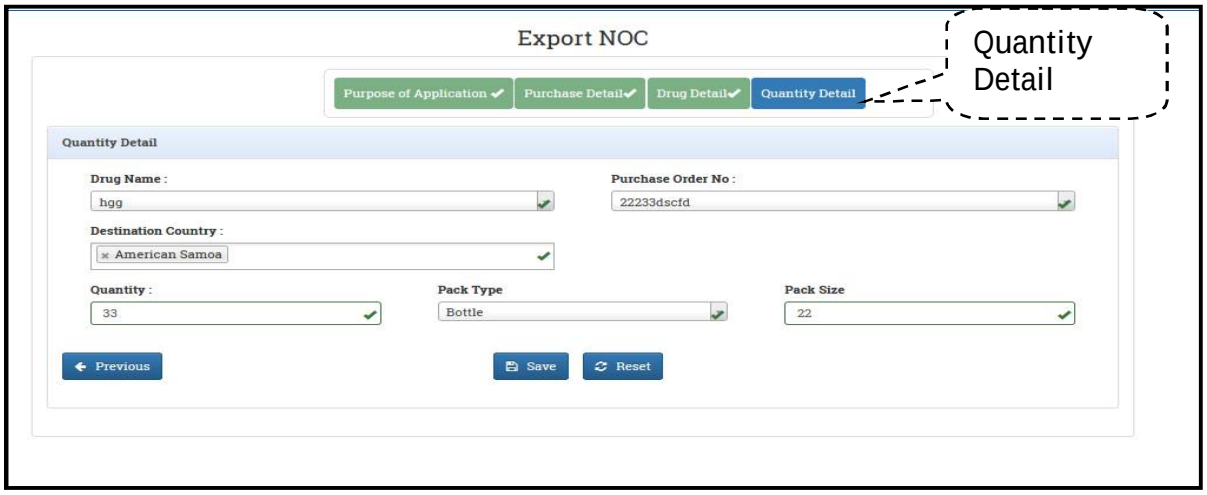
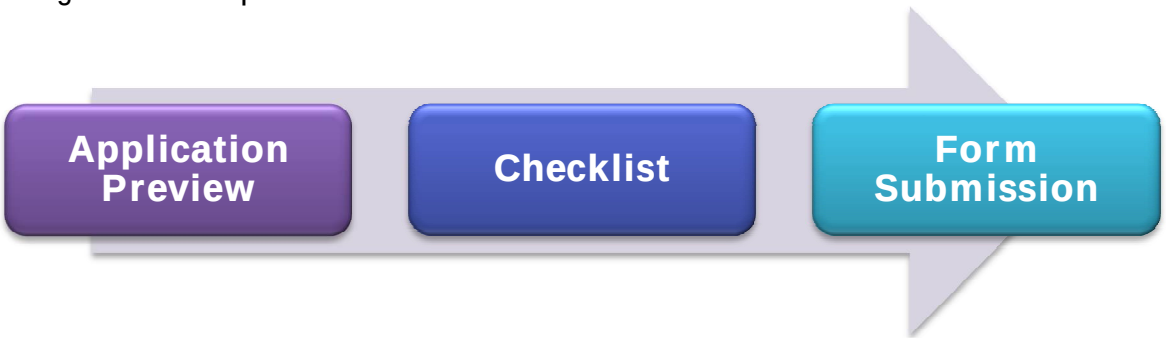


Figure 176 : Quantity Detail

- 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.

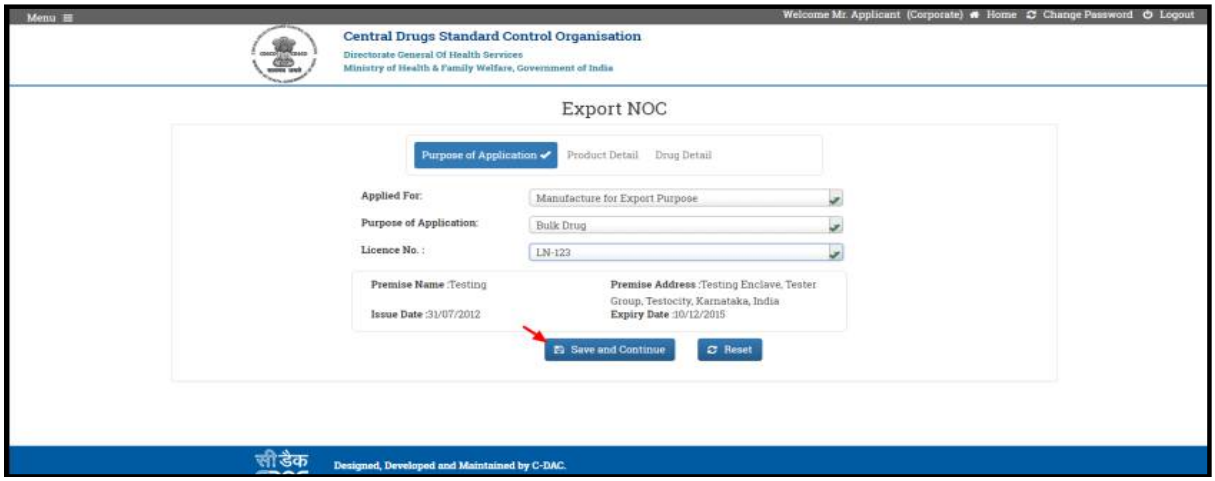


Figure 177 : Material Transfer (API Manufacture)

- 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.

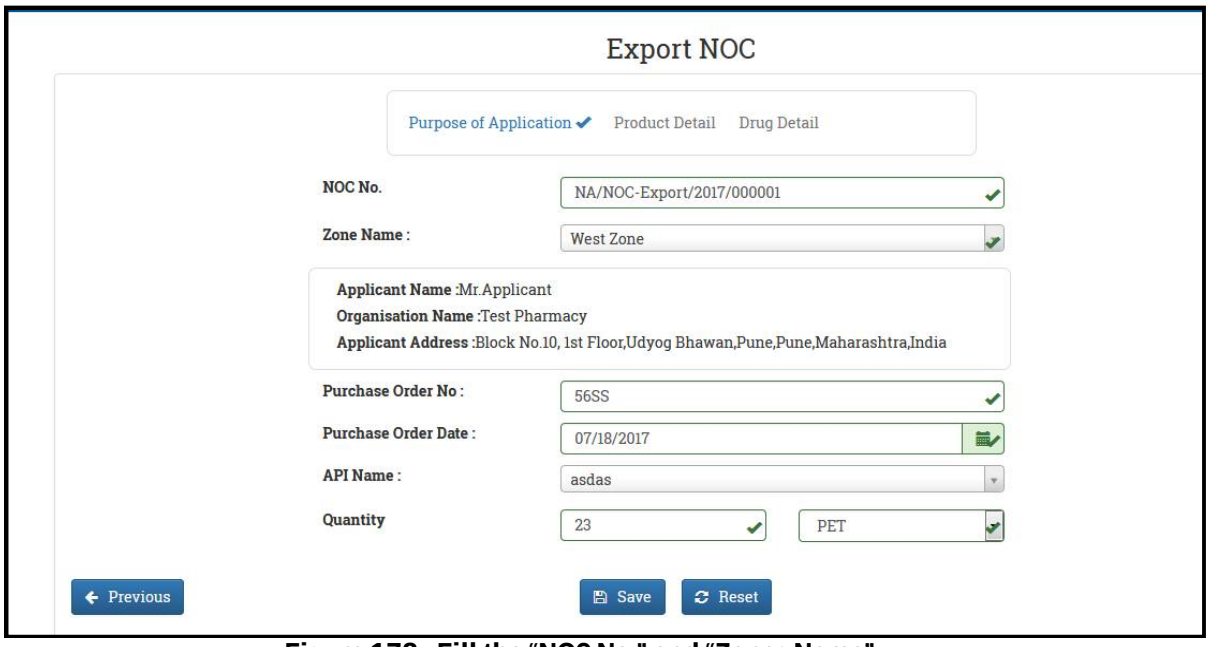
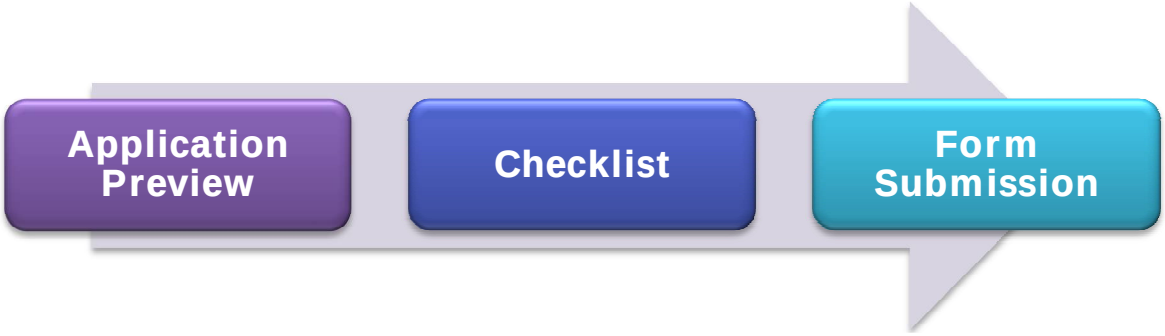


Figure 178 : Fill the “NOC No.” and “Zones Name”

- 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 14th day SAEs reports from investigator, the EC have to send the 30th 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

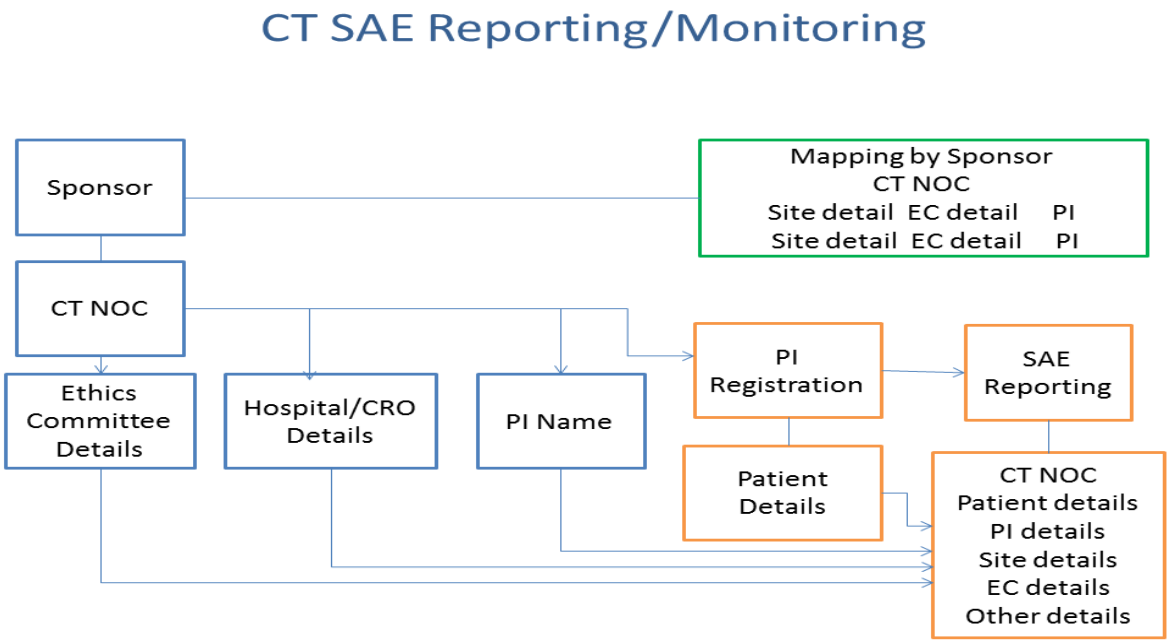


Figure 179 : Workflow for SAE Reporting

➢ 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.

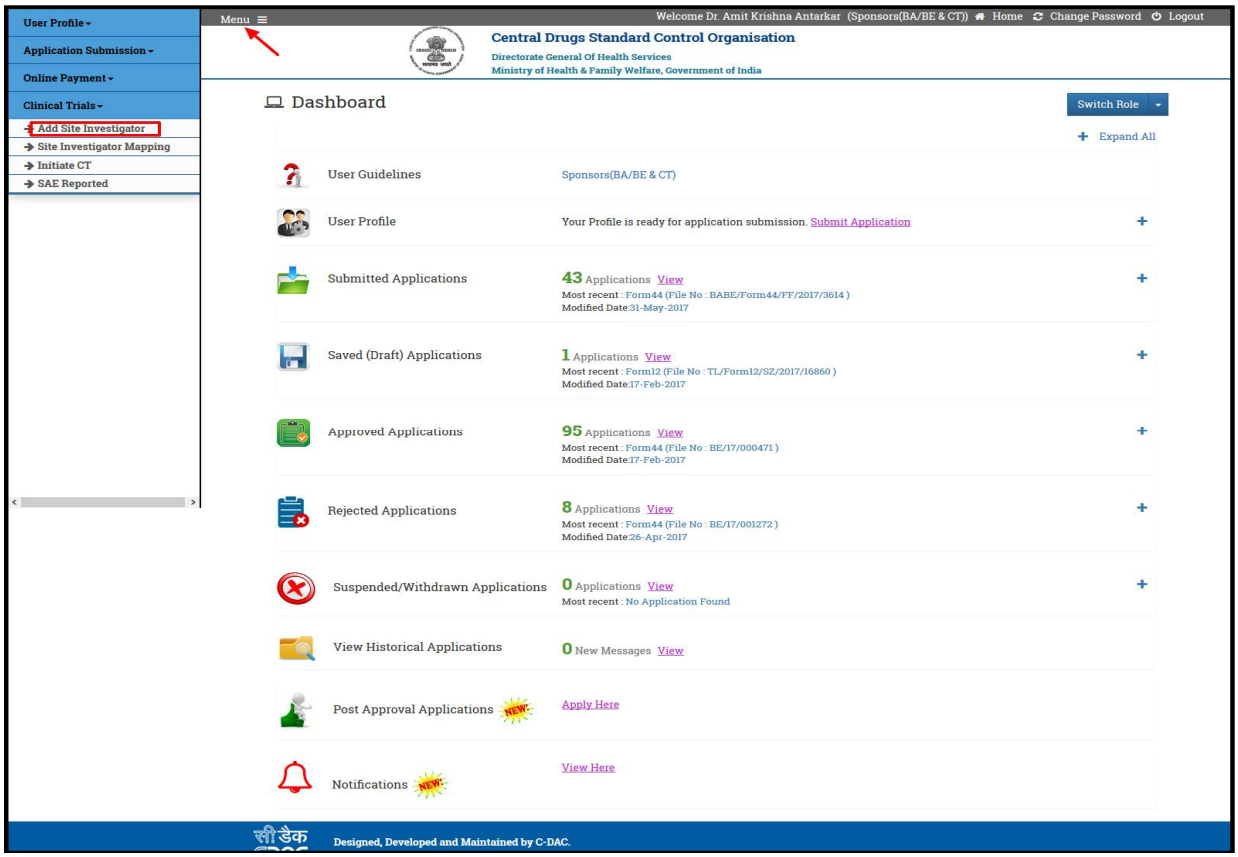


Figure 180 : Add Site Principal Investigator

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.

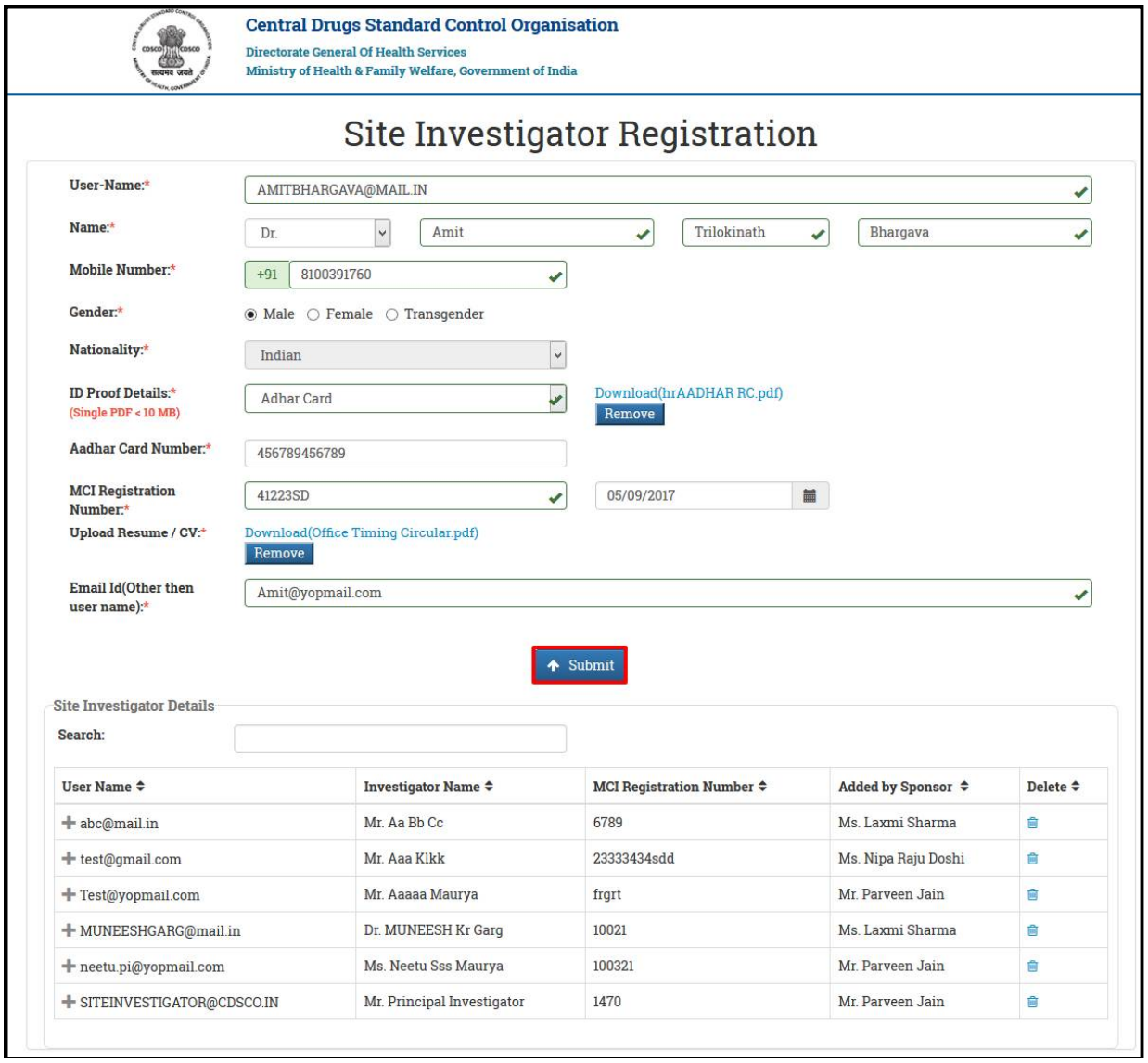


Figure 181 : Screen of Site Investigator Registration

- 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.

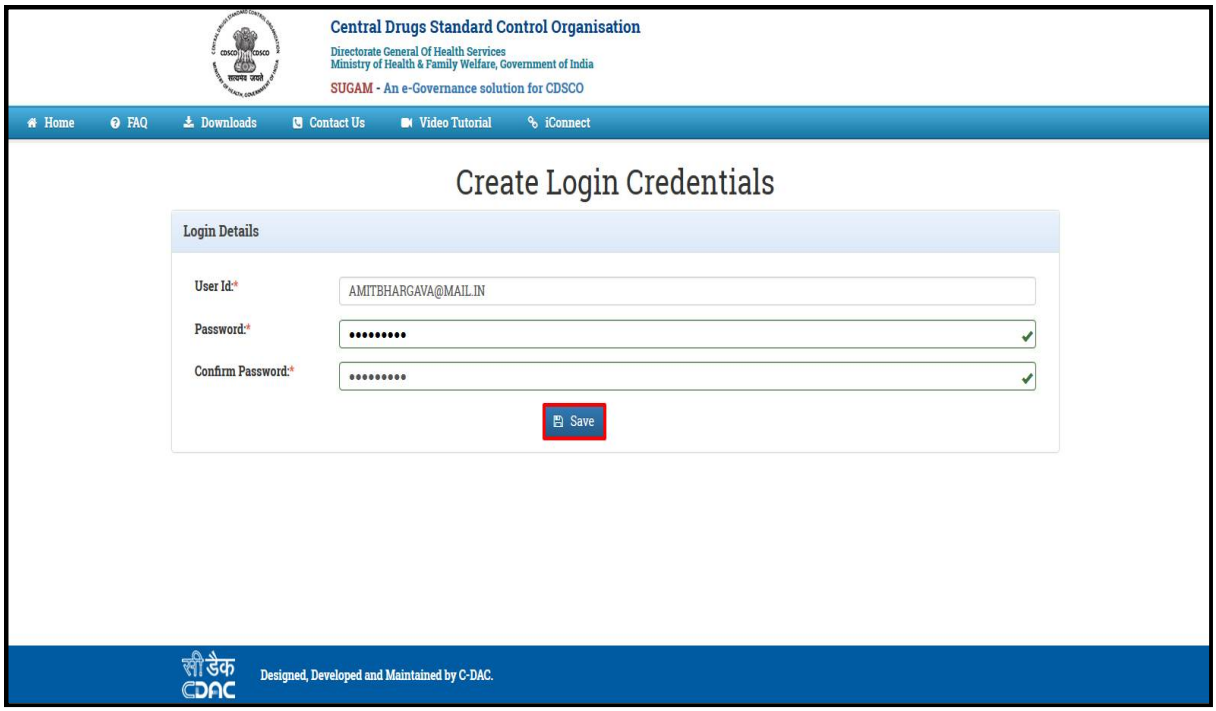


Figure 182 : Screen of Create Login Credential

- 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.

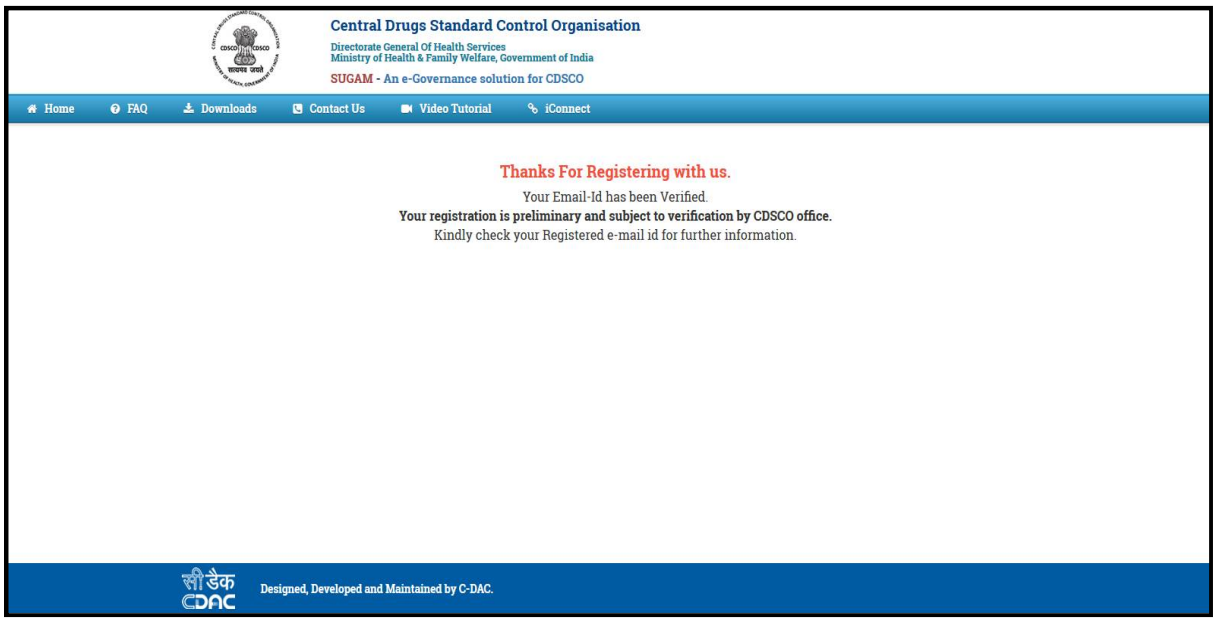


Figure 183 : Popup Message -- Thank you for Registering with us

- 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.

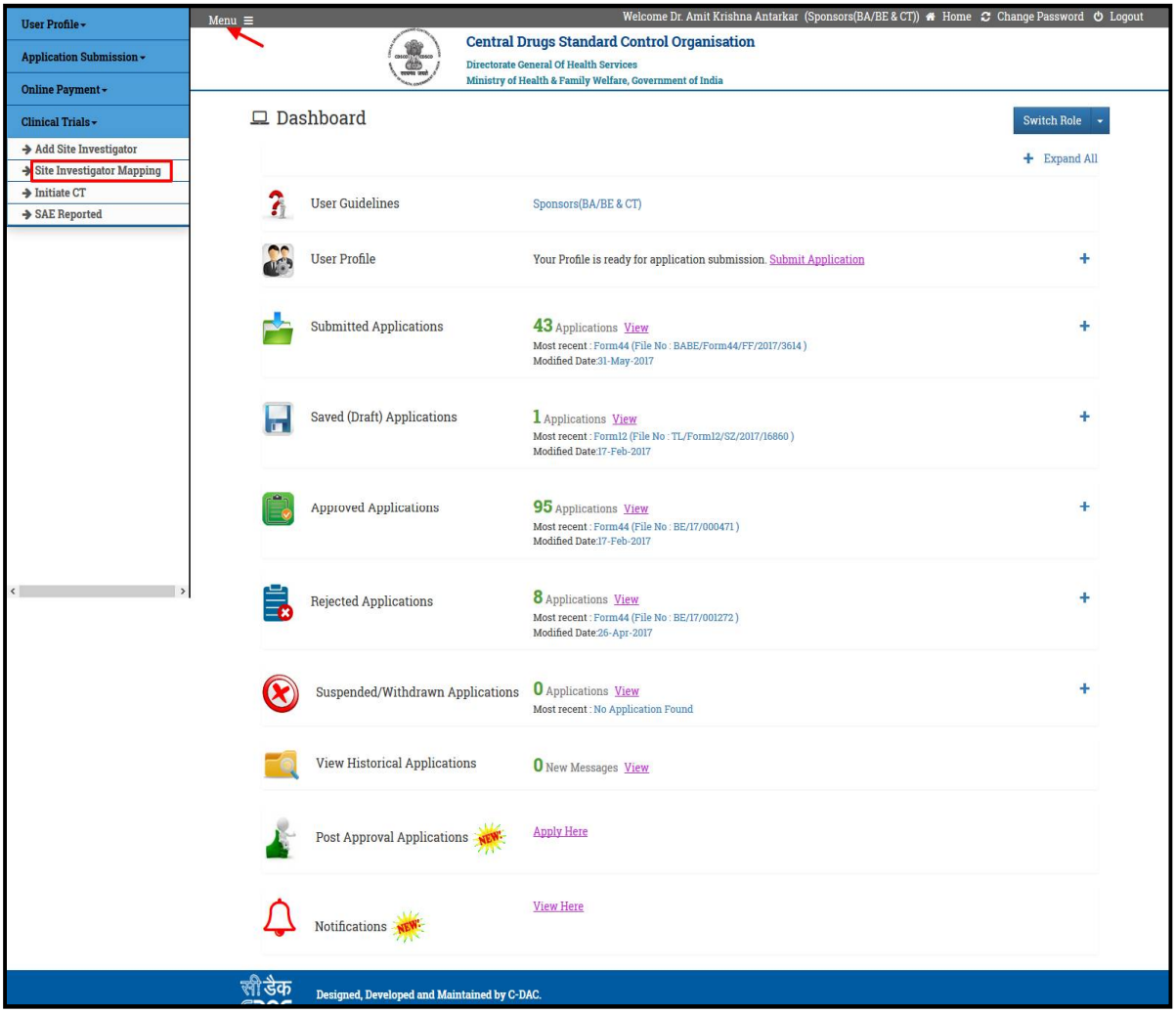


Figure 184 : Site Investigator Mapping

- 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.

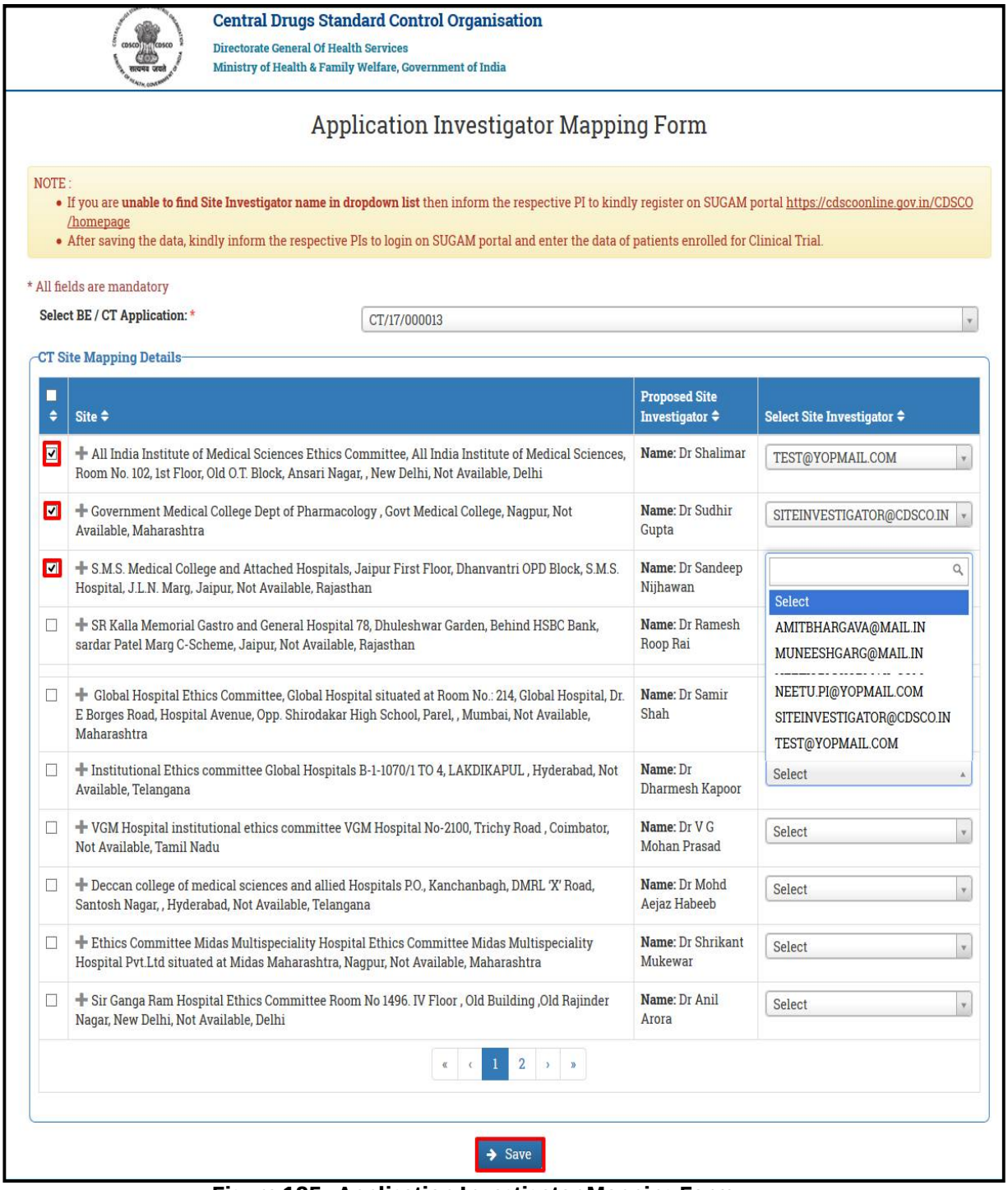


Figure 185 : Application Investigator Mapping Form

- **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.

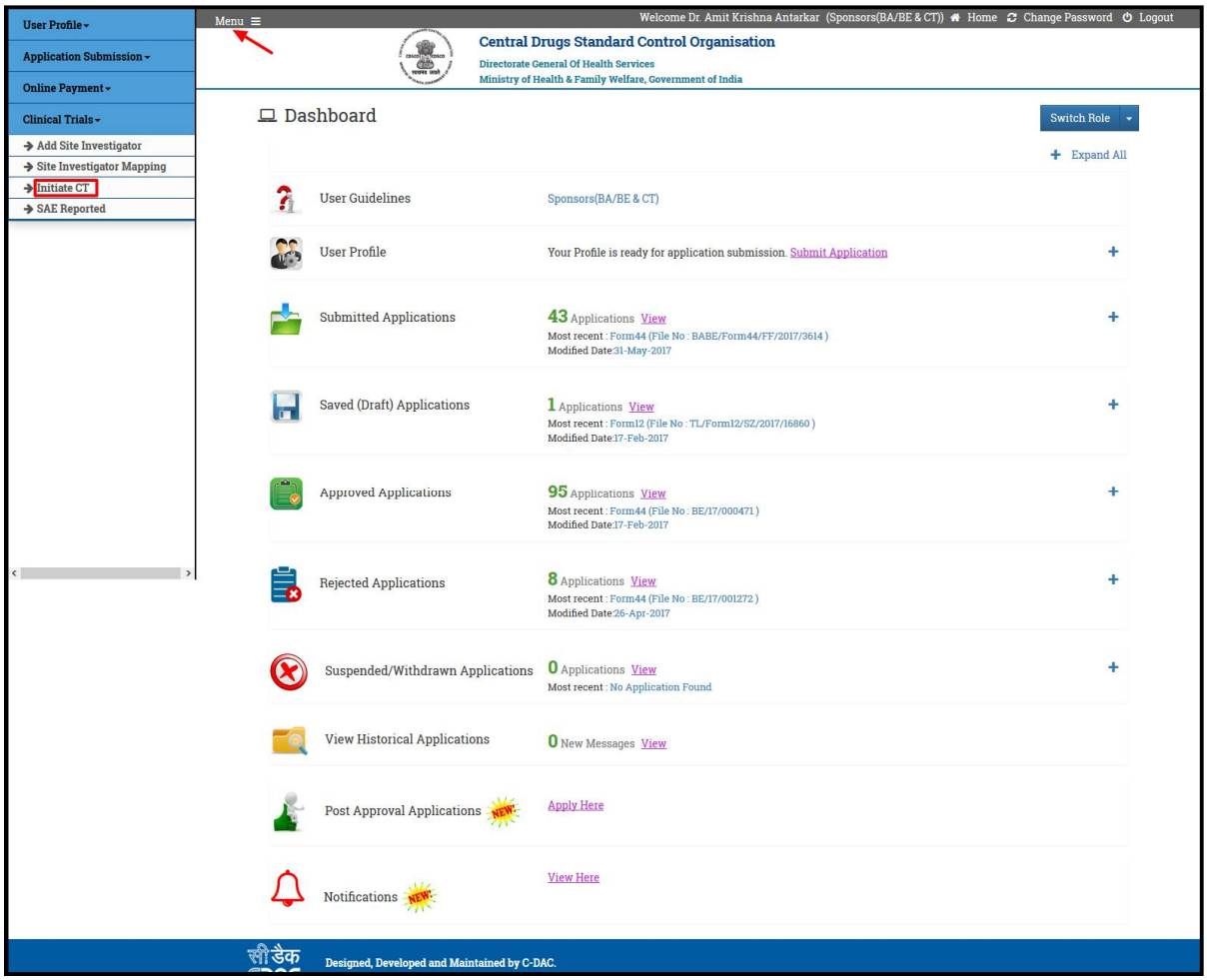


Figure 186 : Initiate Clinical Trial

- 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.

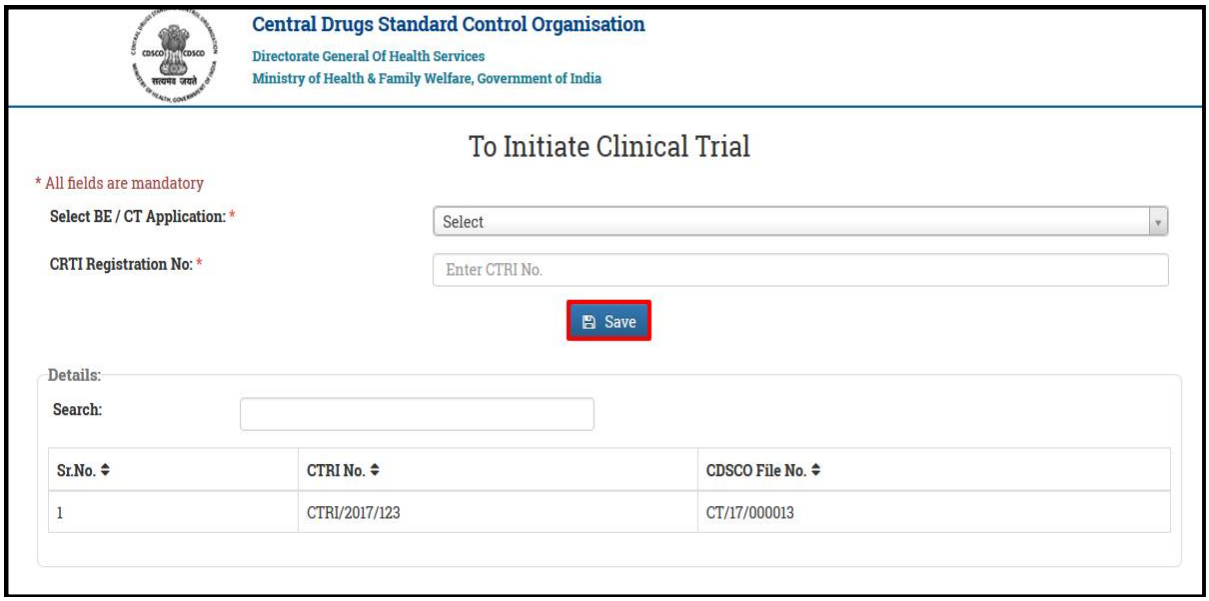


Figure 187 : To Initiate Clinical Trial

➢ 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.

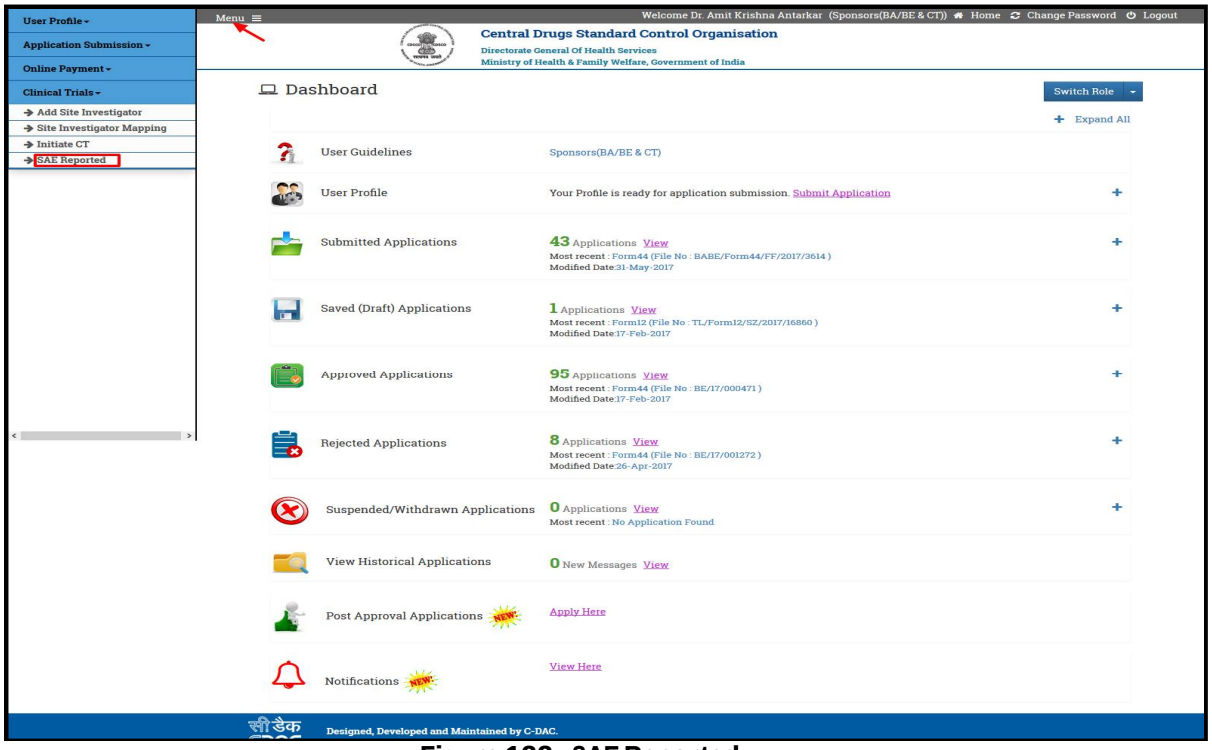


Figure 188 : SAE Reported

- 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).

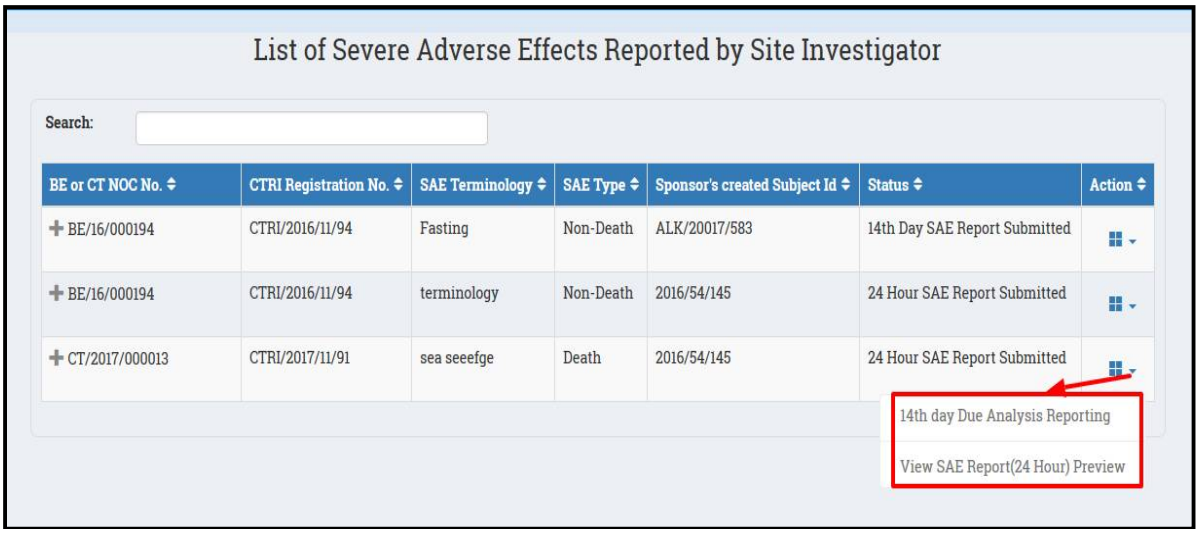


Figure 189 : List of Severe Adverse Effects Reported by site Investigator

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 (14th Day Due Analysis Report)
- SAE Reporting (30th 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)**

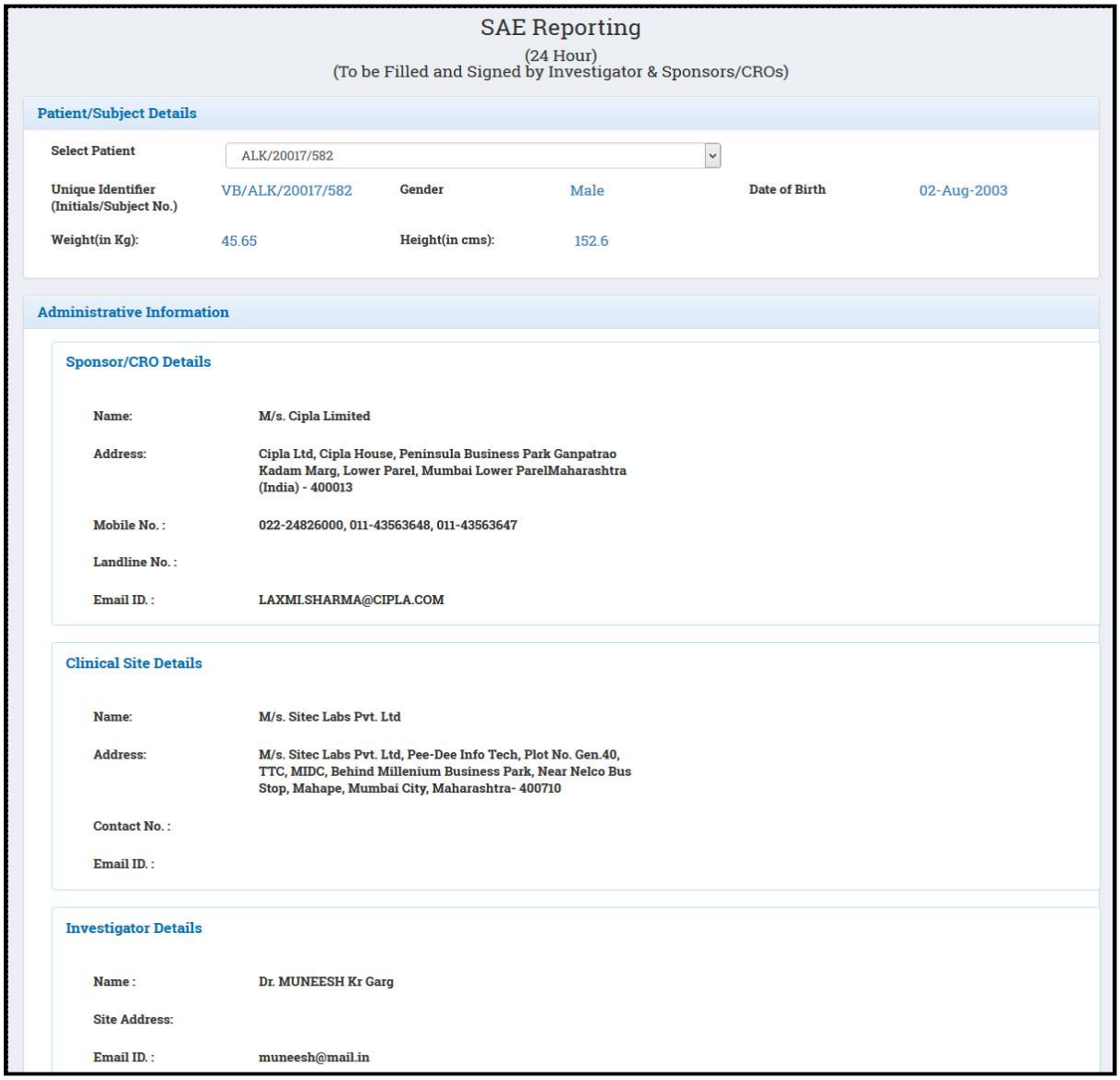


Figure 190 : SAE (s) Reporting

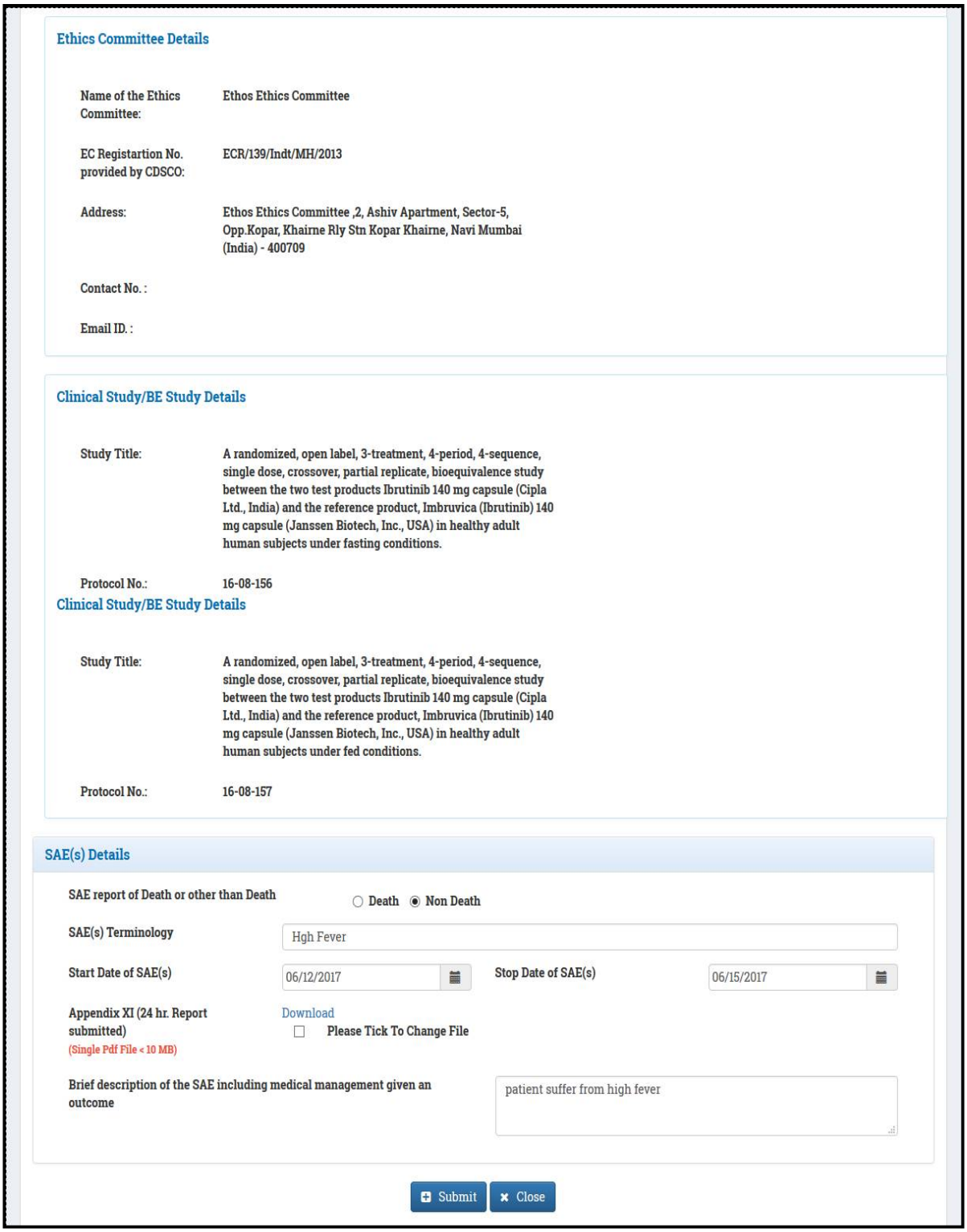


Figure 191 : SAE (s) Reporting (Continue)

- **SAE Reporting (14th 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)

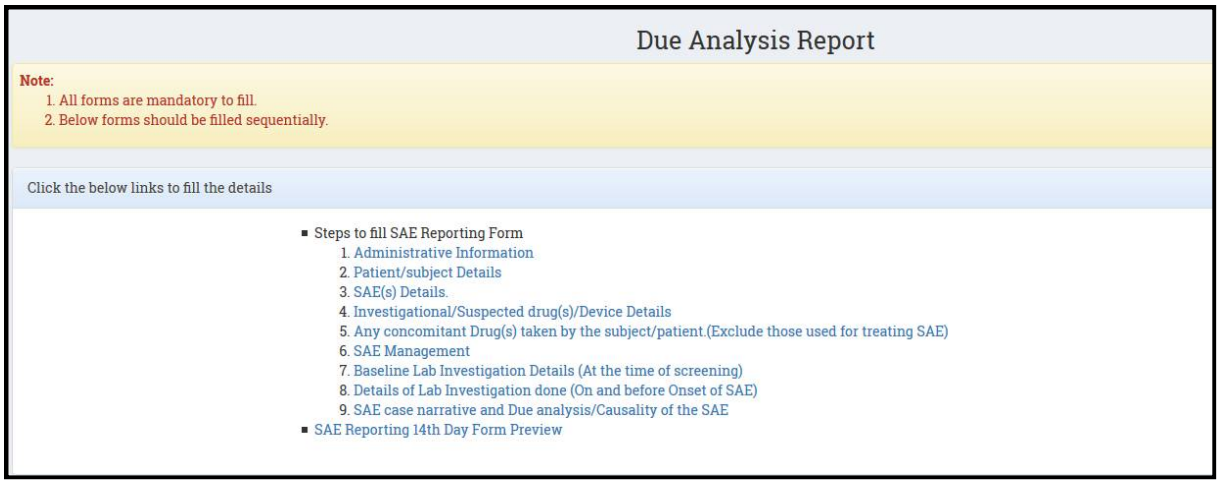


Figure 192 : Due Analysis Report

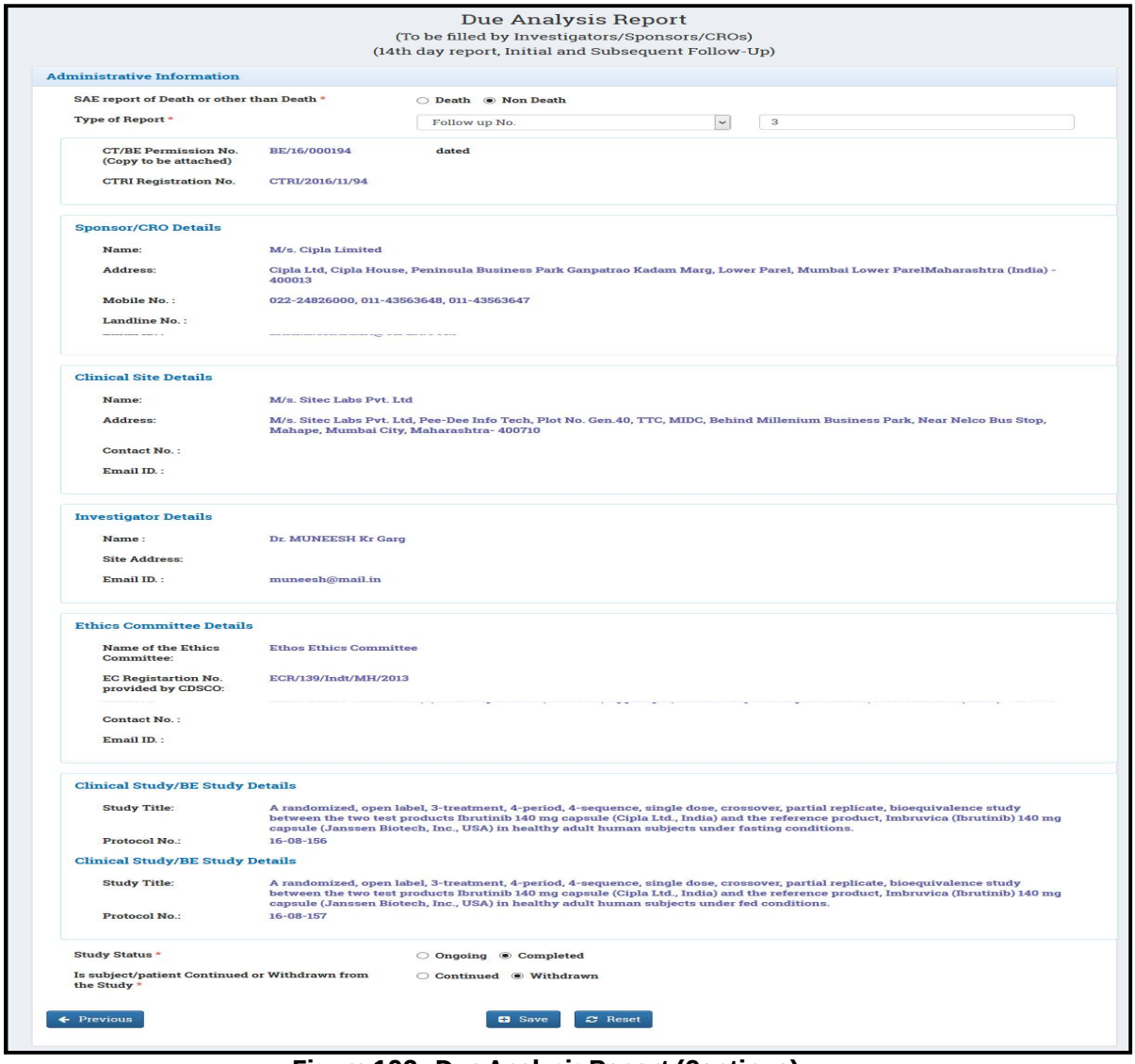


Figure 193 : Due Analysis Report (Continue)

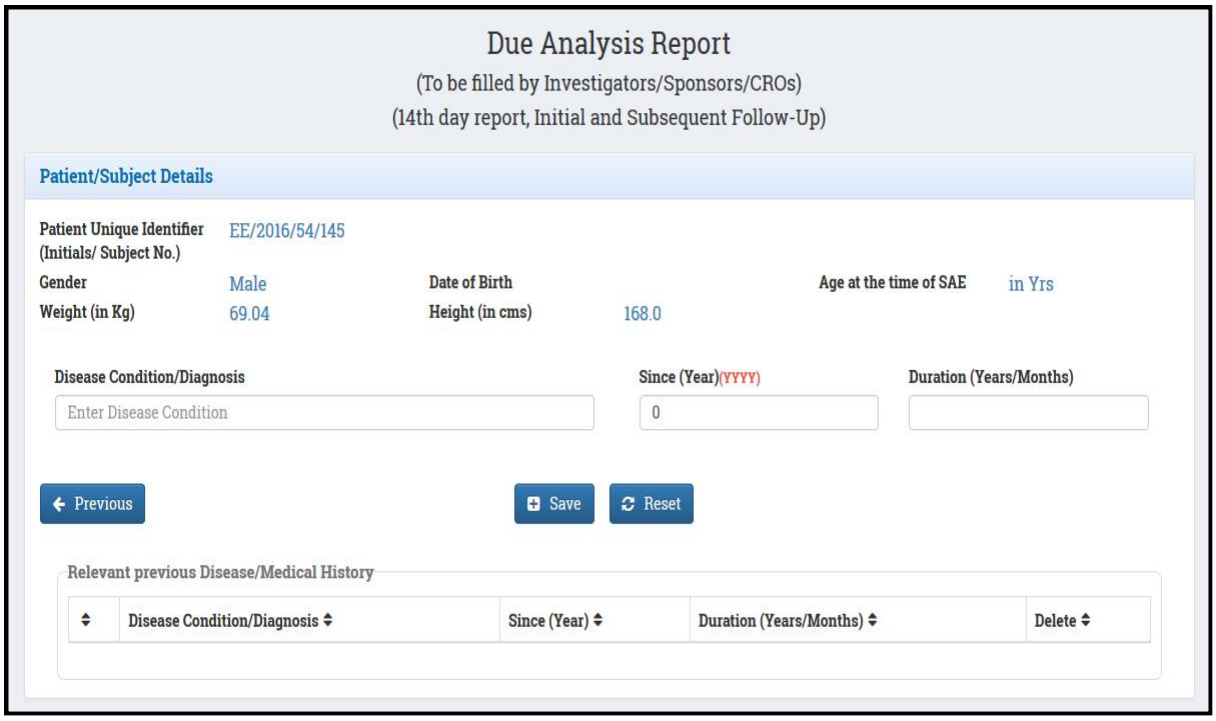


Figure 194 : Due Analysis Report (Continue)

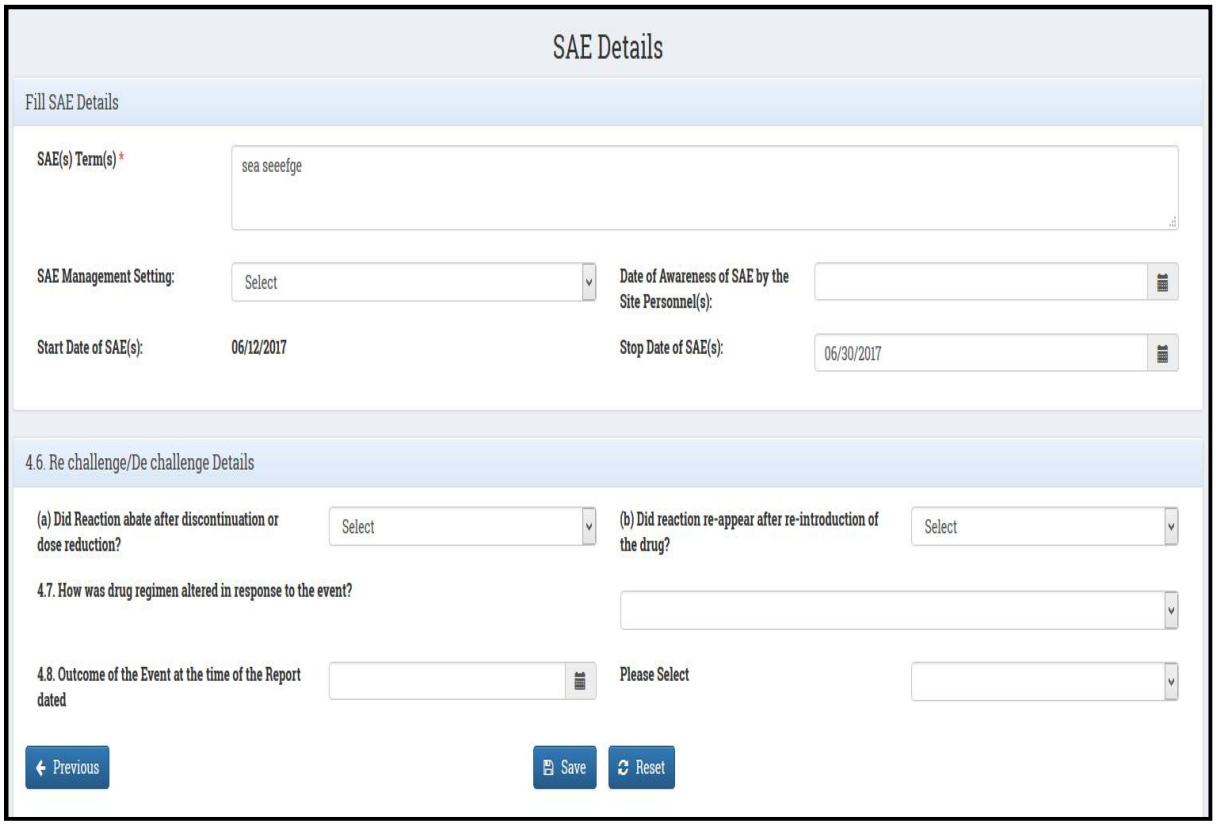


Figure 195 : Screen of SAE Details

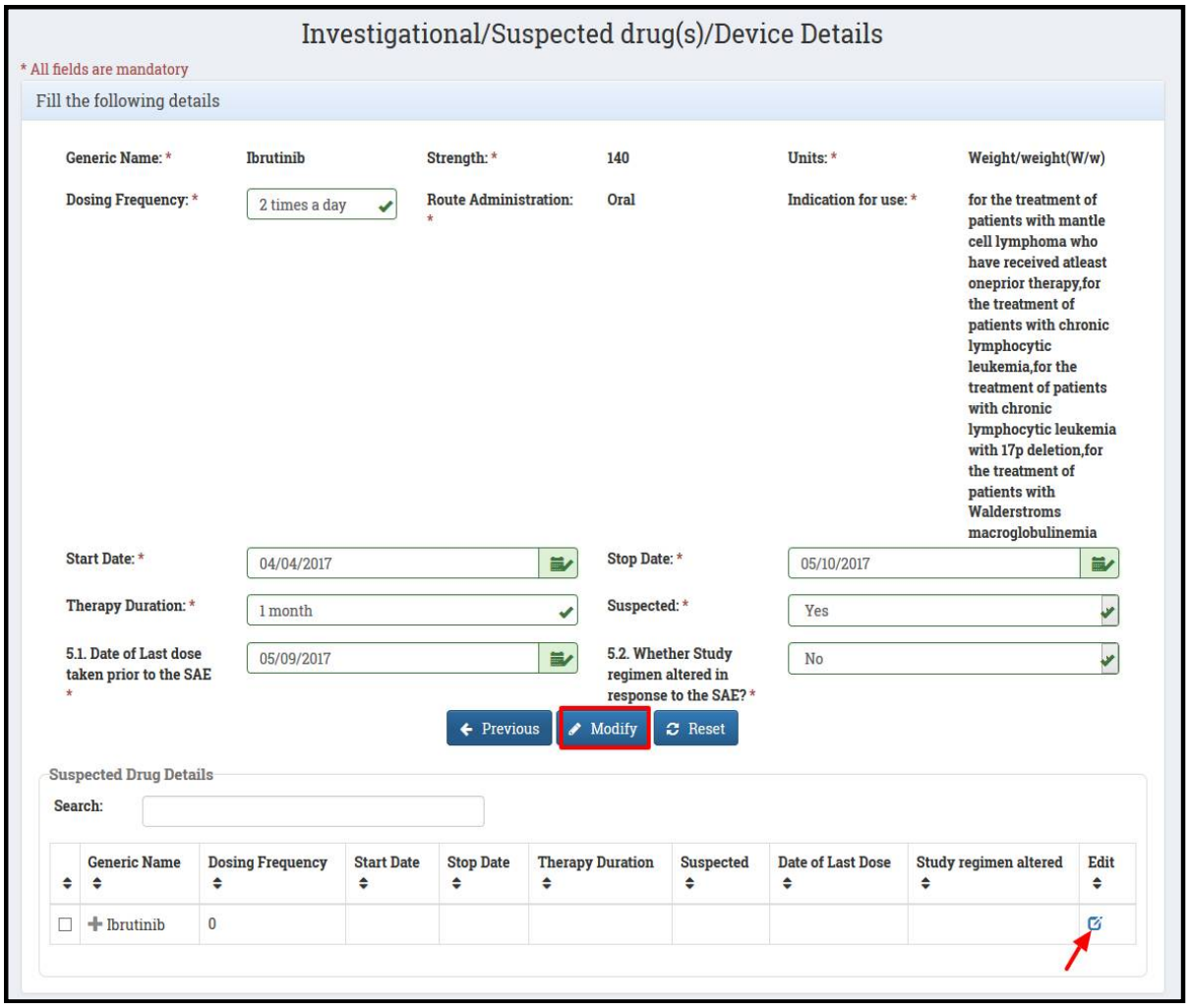


Figure 196 : Investigational / Suspected Drug (s) Device Details

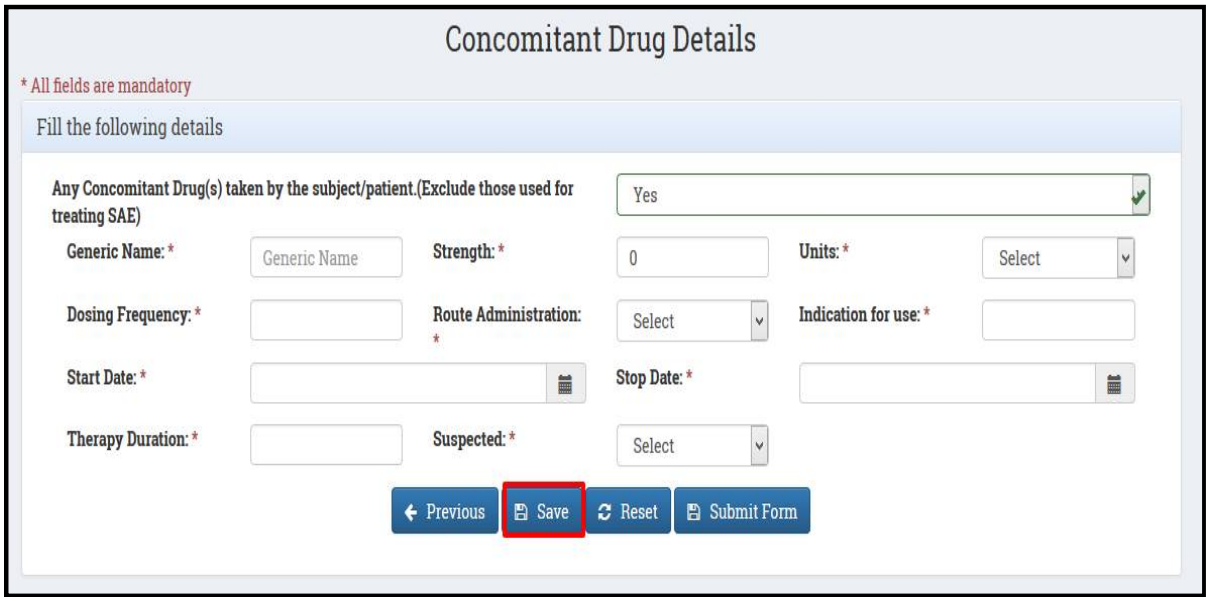


Figure 197 : Concomitant Drug Details

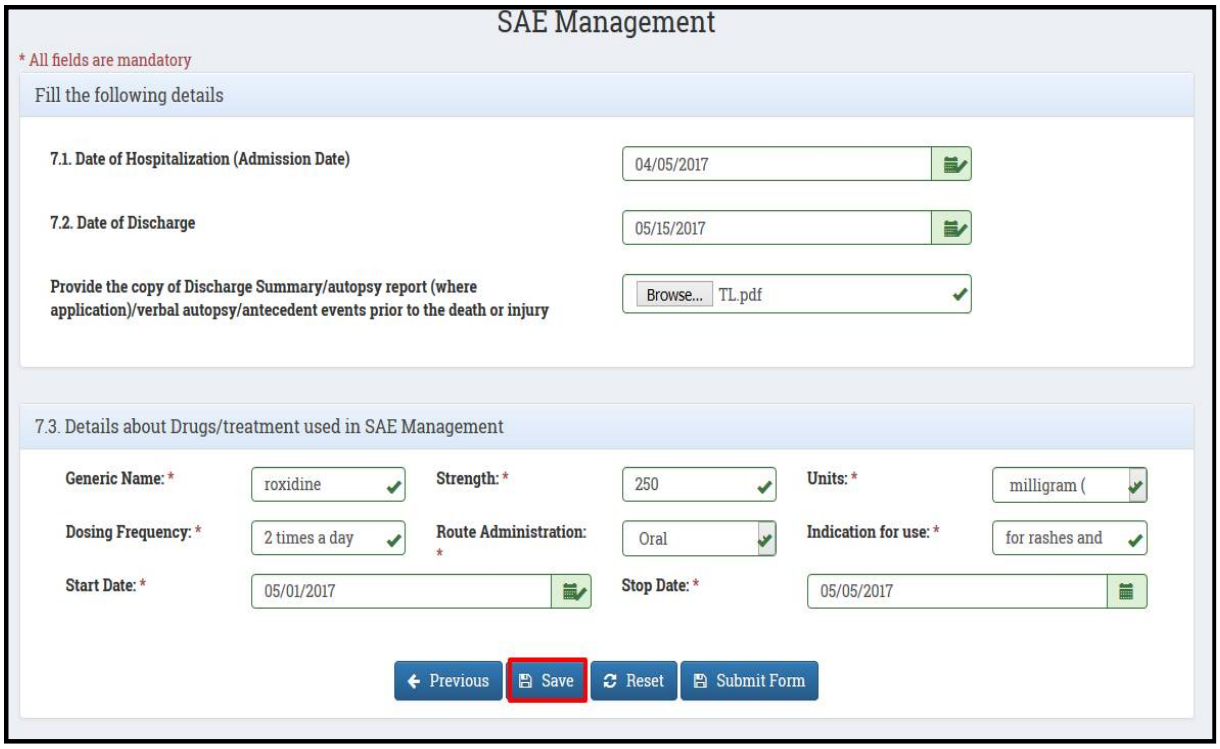


Figure 198 : SAE Management

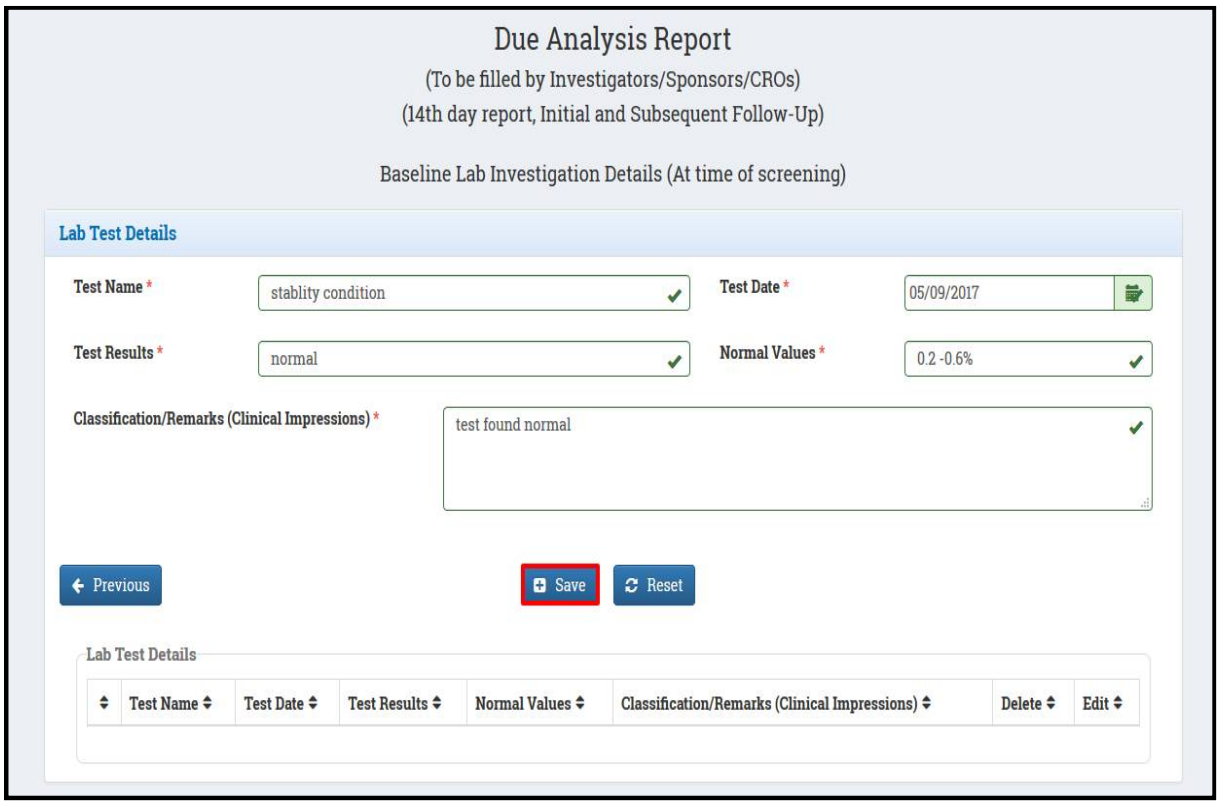


Figure 199 : Due Analysis Report -- Lab Test Details

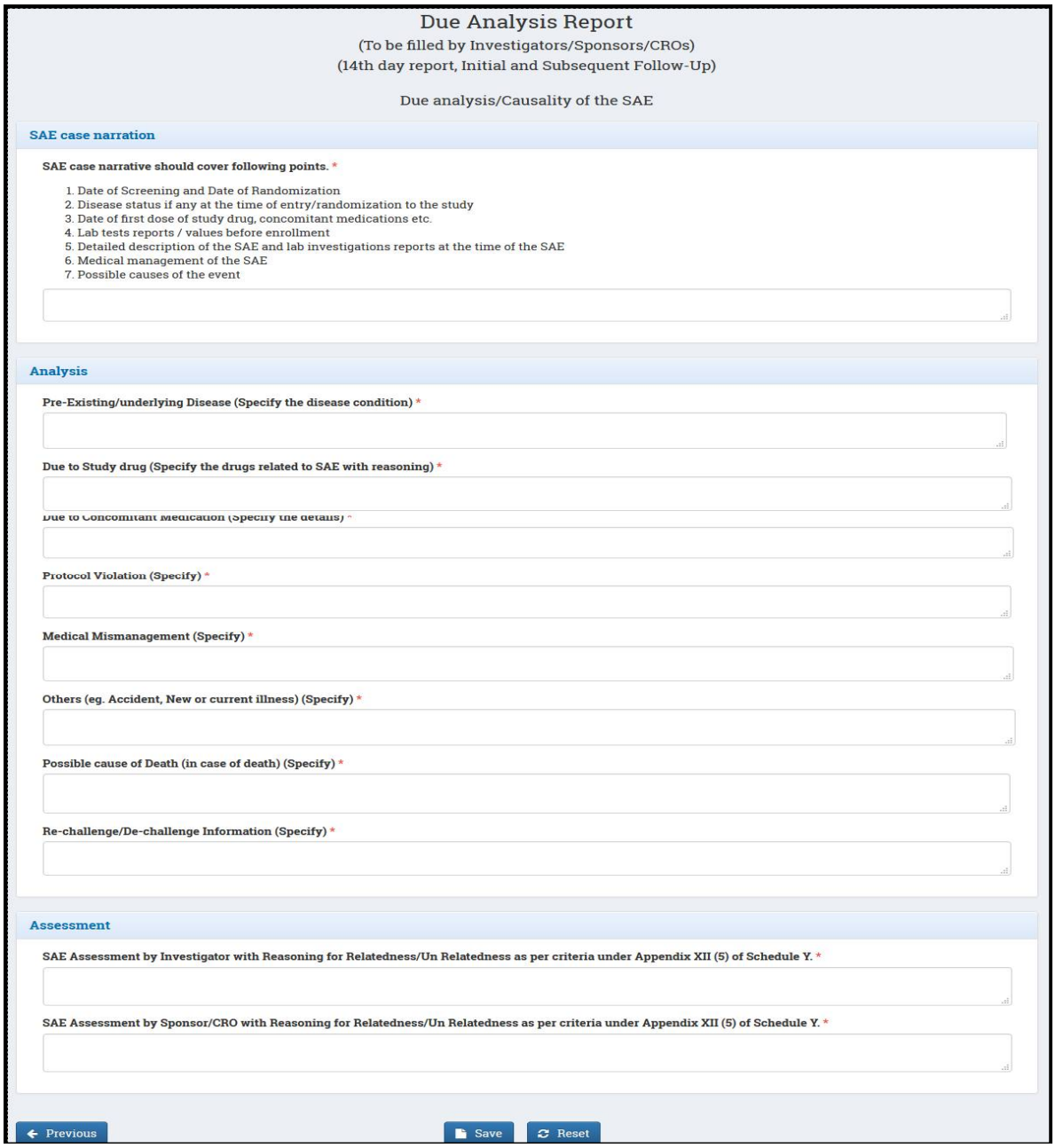


Figure 200 : Due Analysis Report -- SAE Case Narration

- **SAE reporting (30th Day Report):** After 14th day SAE reporting is submitted by investigator, the ethics committee may proceed to fill 30th 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.cdscoonline.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.

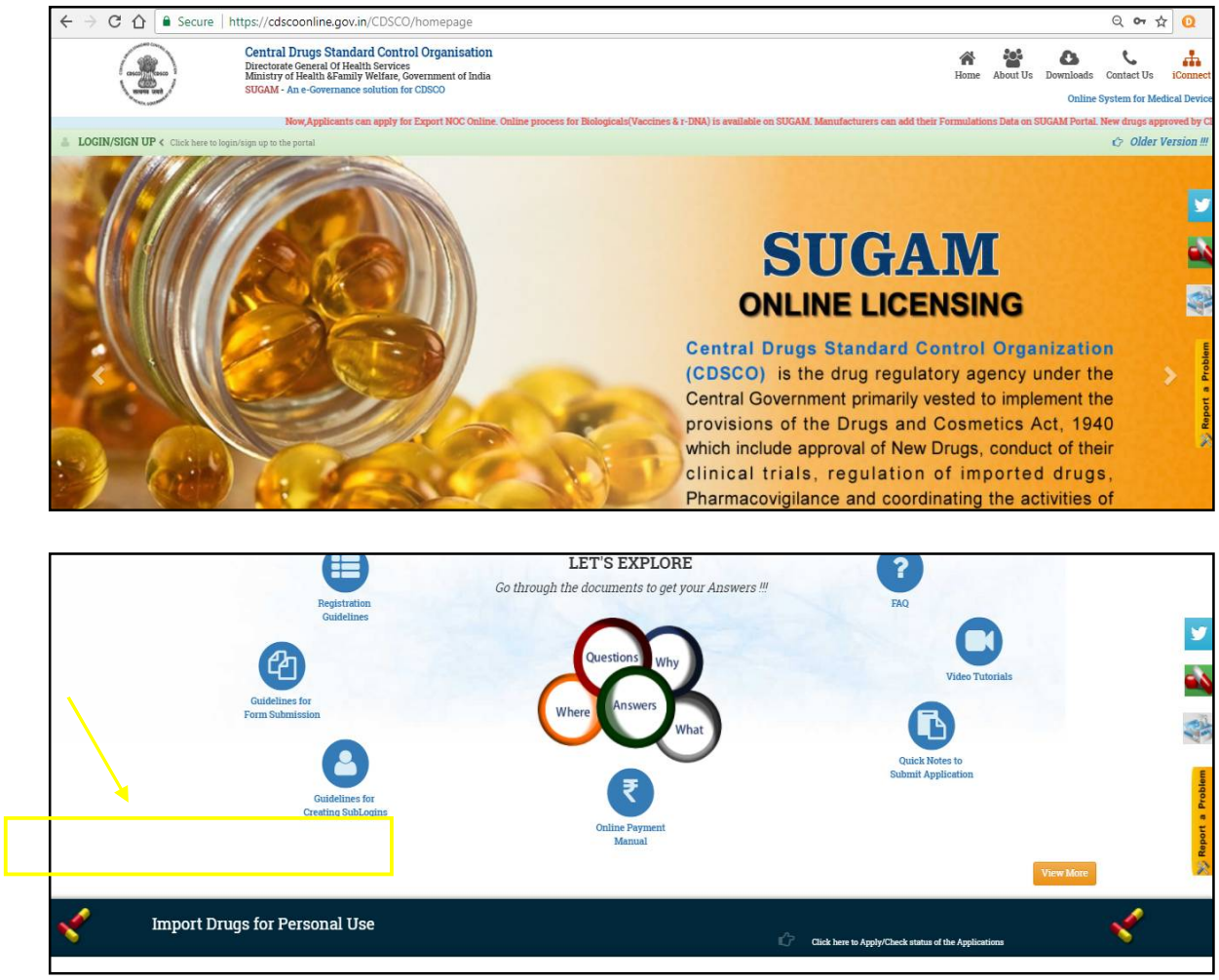


Figure 201 : Apply for Personal License

- 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.**

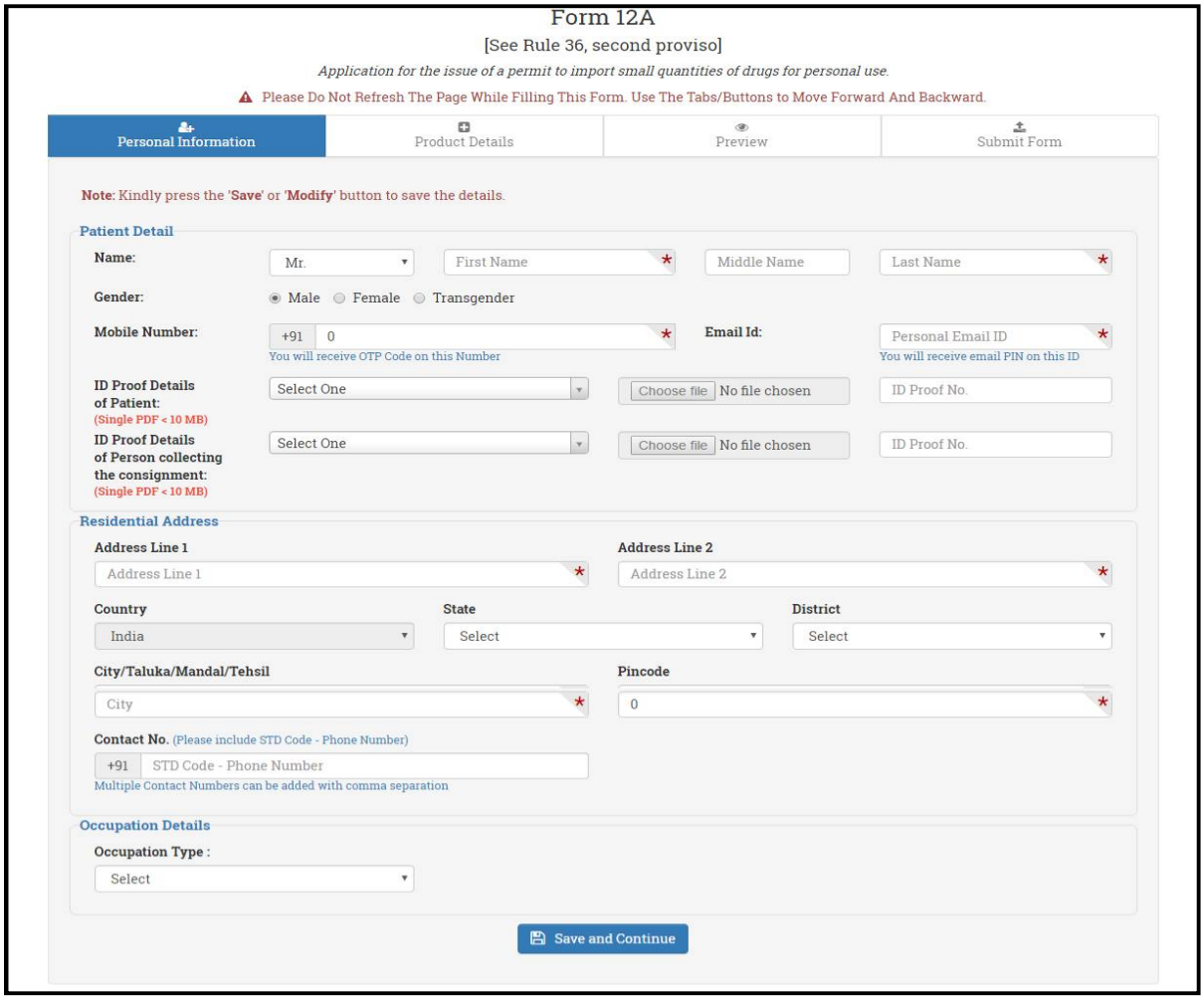


Figure 203 : Form 12A Application

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

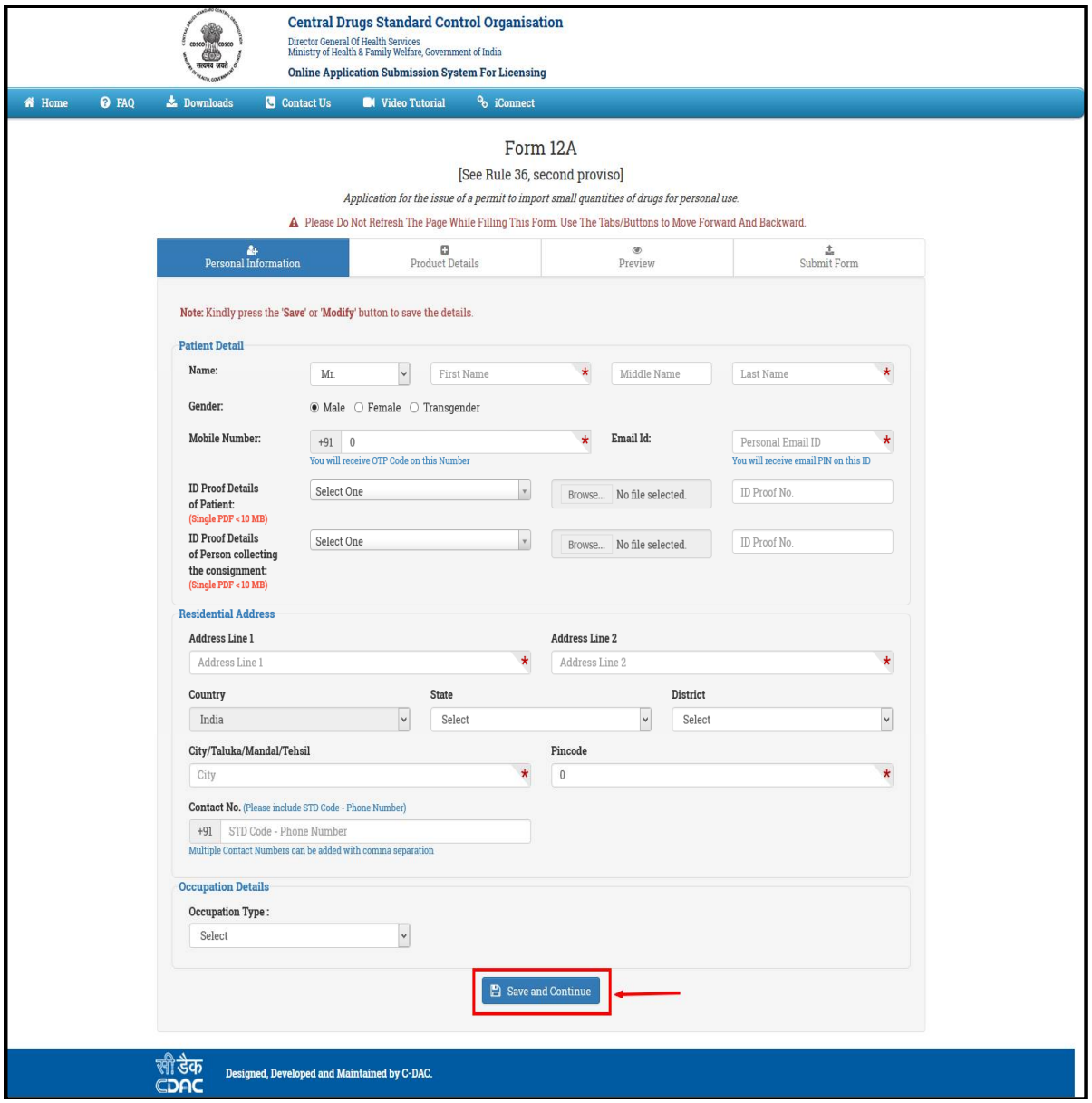


Figure 204 : Personal Information

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**

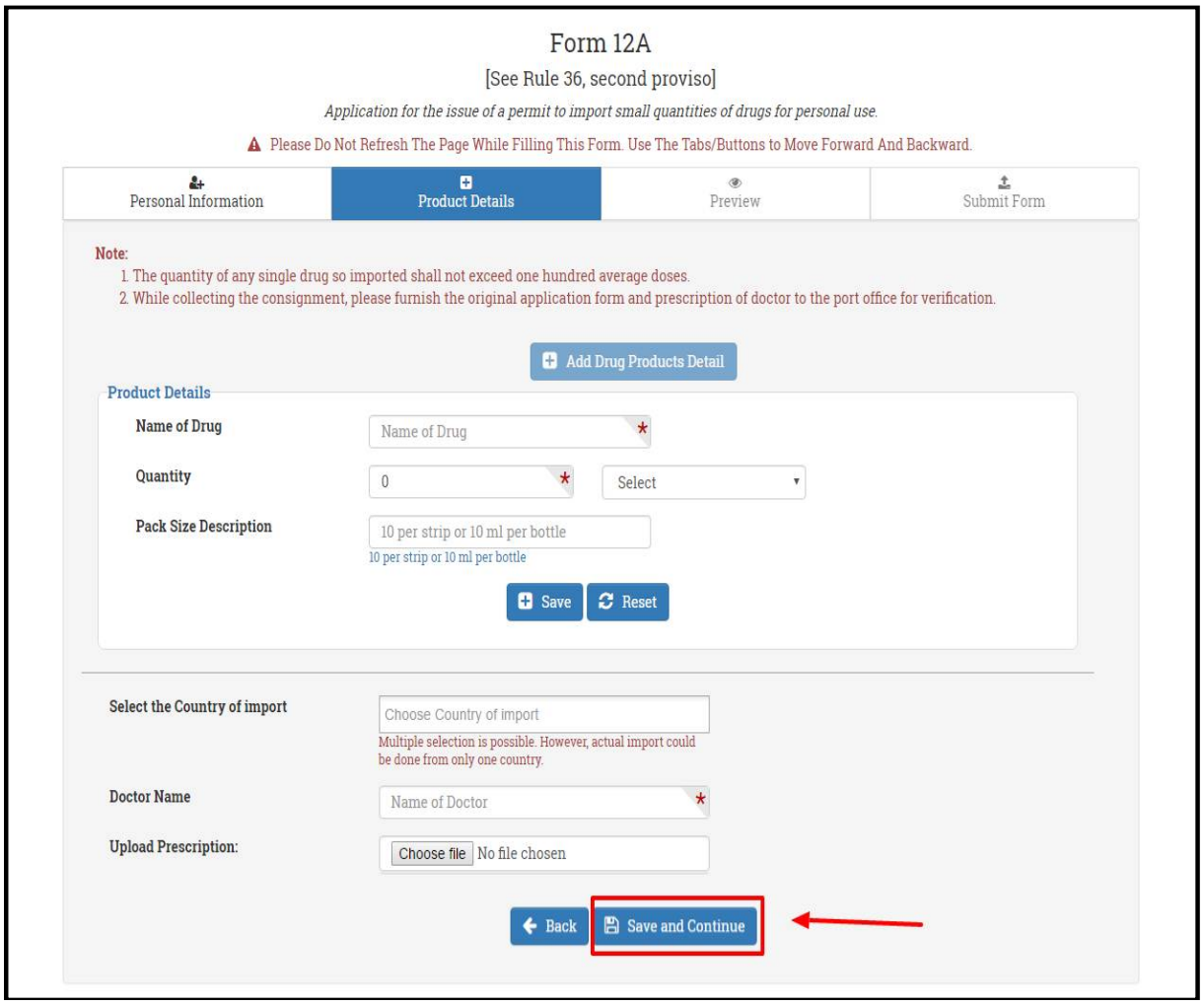


Figure 205 : Product Details

➢ **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

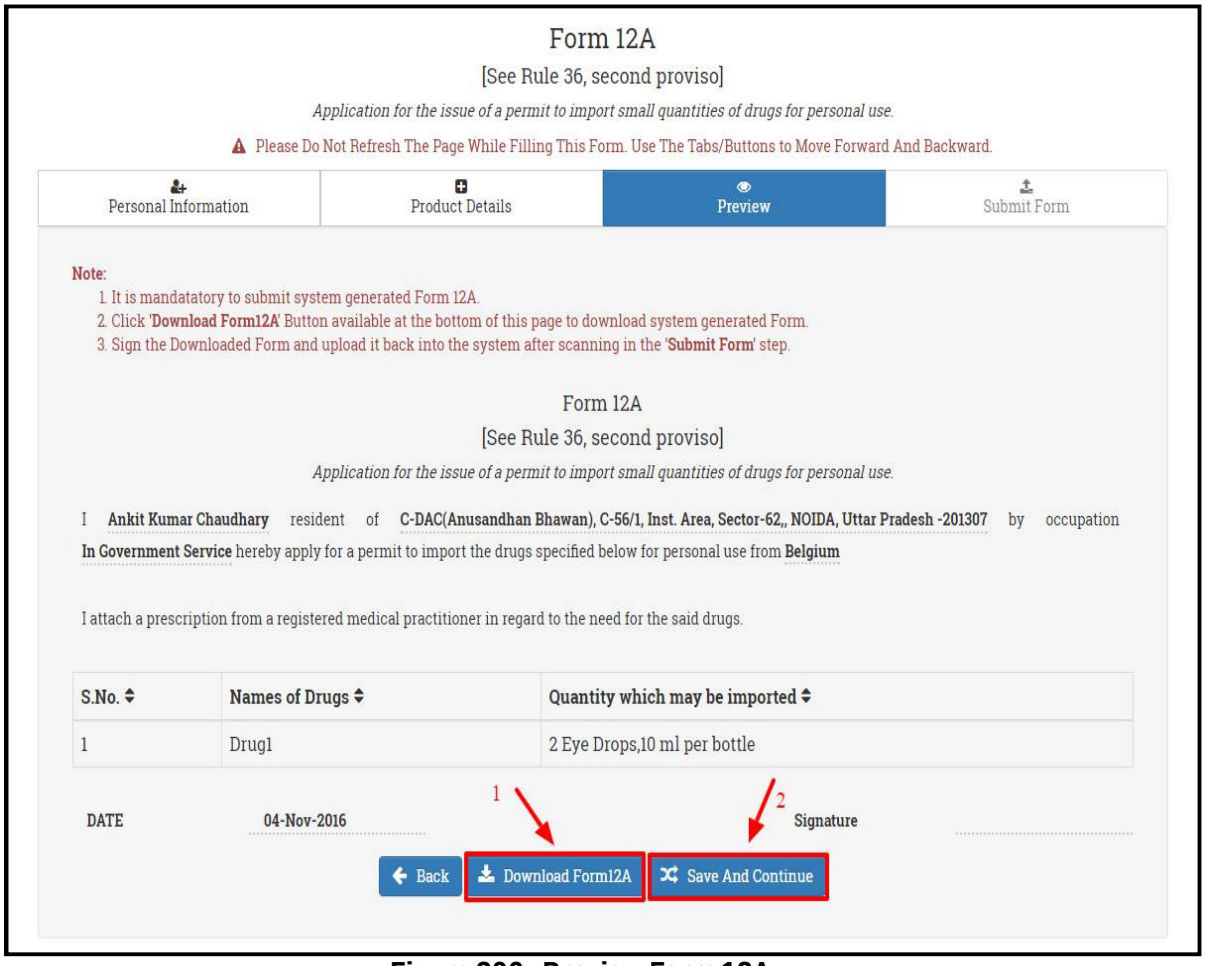


Figure 206 : Preview Form 12A

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**

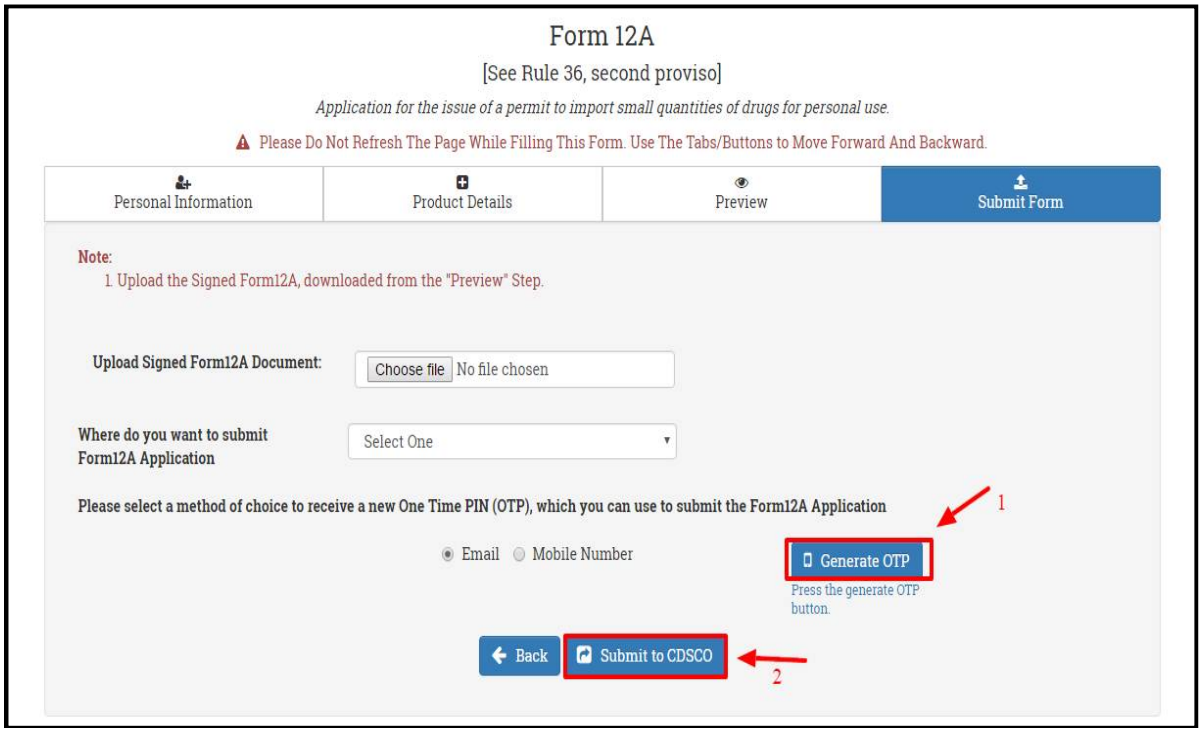


Figure 207 : Submit Form

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.

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.**

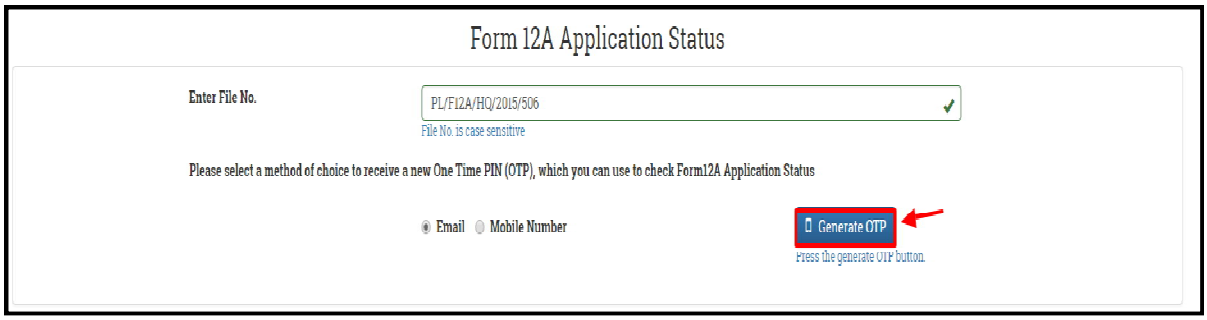


Figure 210 : Form 12A Application Status

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.**

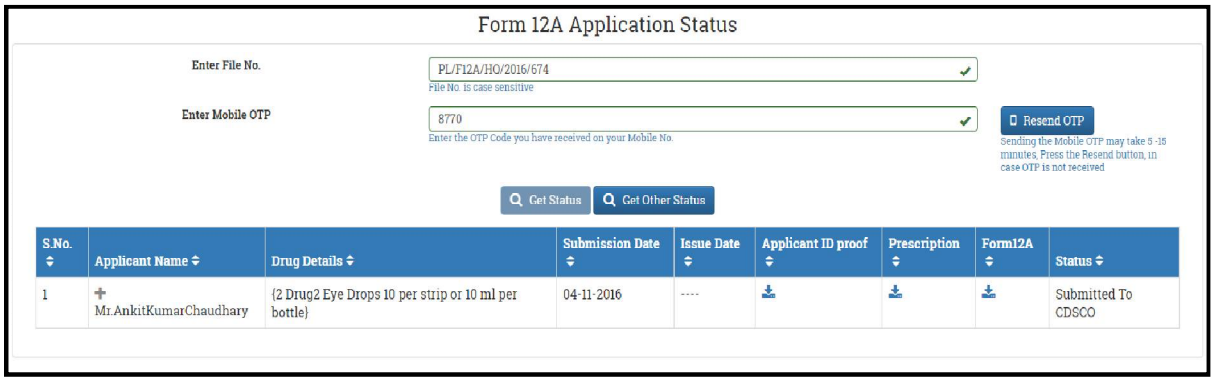


Figure 211 : View Status of Application

- 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**".

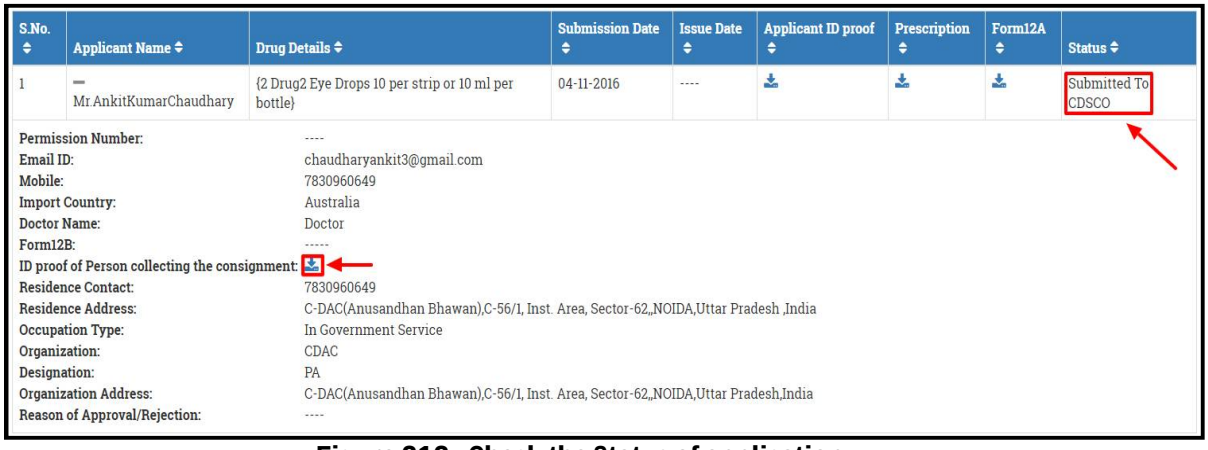


Figure 212 : Check the Status of application

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"

Annexure

List of Figure

List of Table