Guidelines for the Pharmaceutical manufacturers

Central Drug Standard Control Organization
(CDSCO)
Guideline Document
For Uploading Manufacturing Sites and Formulation Data
Version 1.0 Release Date: 9/7/2018

Summary

This guideline is intended for the Pharmaceutical manufacturers for uploading data of permissions and licenses issued to them by State FDAs. All manufacturers have to upload their manufacturing Sites and Formulation data on the SUGAM Portal and also time to time update the information as per the approved amendments. The submitted & approved information will be available on the manufacturer dashboard of SUGAM portal.

1. Three Simple Steps to upload Manufacturing Sites and Formulation Data

1.1 Registration

Applicant has to first register on the portal for all his manufacturing Sites separately. If already registered on the portal, than directly Login to the portal otherwise first register and verify the account.

1.2 Upload Data

Once the Registration Process is completed applicant can Login to the portal to upload the Manufacturing Sites and Formulation Data

1.2.1 Manufacturing Site Detail: (Click here to view details)

Manufacturing Sites needs to be entered once after that it will be fetched automatically and applicant will be required to only enter all the licenses detail on this manufacturing site.

1.2.2 Formulation Detail: (Click here to view details)

Applicant needs to enter the formulation Detail for the licenses that he selects. Applicant can enter multiple Formulations for same License. Once applicant submits the application it will go to State FLA for Approval. All the approved applications will be visible in Approved Formulation Detail Section.

1.2.3 Formulation Production Detail: (Click here to view details)

Applicant needs to enter the production Details for each Formulations Quarterly/ Yearly basis.

1.2.4 Product Production Capacity: (Click here to view details)

Submit the volume of products that are generated by the Manufacturing Site.

1.3 Approved Formulations / Amendments

It will show all the Approved Formulations. In case applicants wants any amendment in the Formulation detail, he can communicate to State FLA through the option 'reply to official' and asked for the amendment . Official can also reply back to applicant.

2. Detailed Steps

2.1 Registration

- **Homepage:** - Open link "www.cdscoonline.gov.in" The homepage of the SUGAM portal is shown in the figure 1. To upload data for Manufacturing Sites and Formulation data click on the link "Guidelines for uploading data for Manufacturing and Formulation data, as shown in Figure .

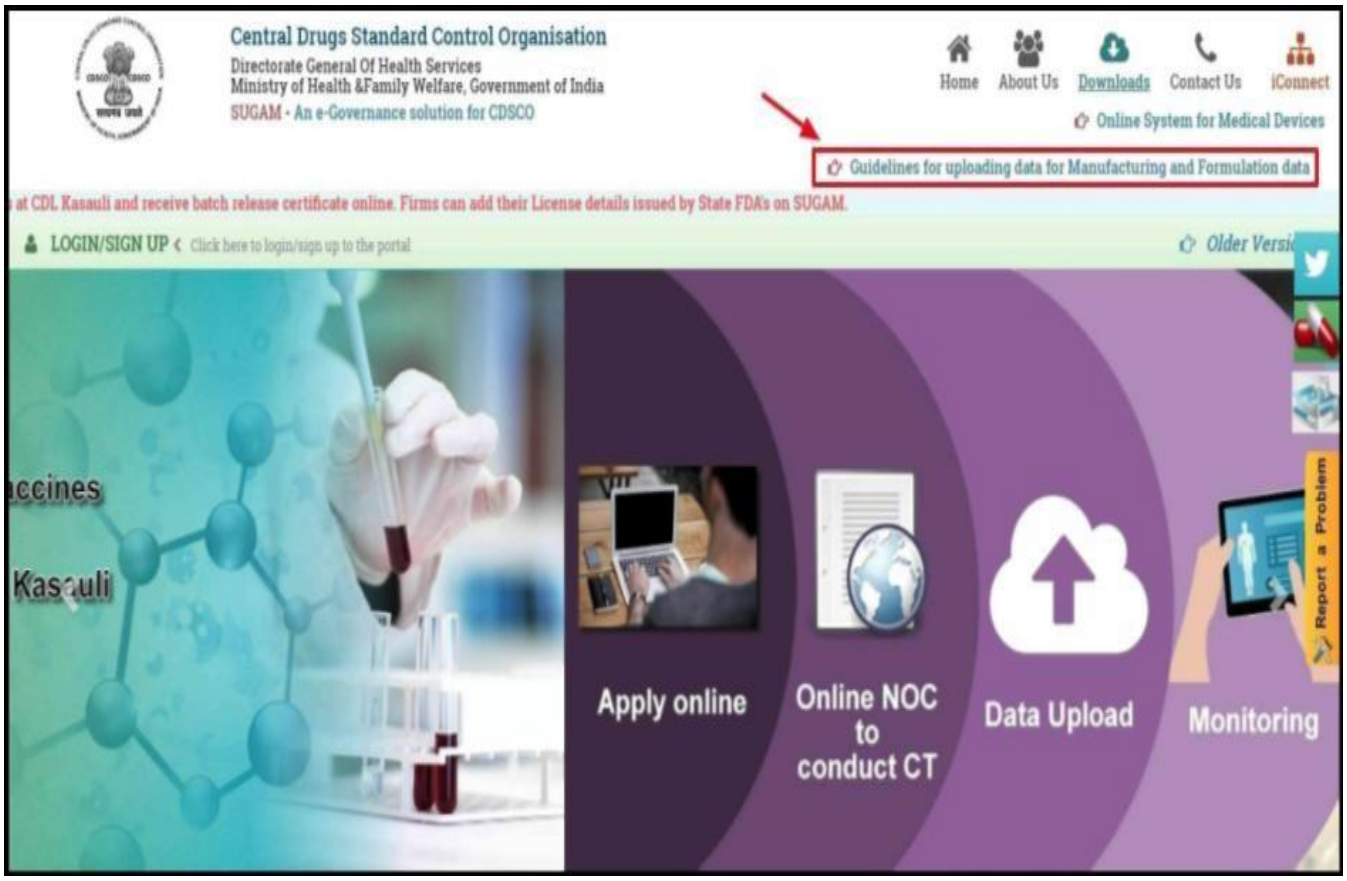

Figure 1 : Homepage

- Once the user clicks on the link he will be redirected to Guidelines Page. They need to read the Guidelines carefully.
  - New Registration :
- If the applicant is not registered on portal click on the link as shown in figure to register on the portal and you will be redirected to Registration page.

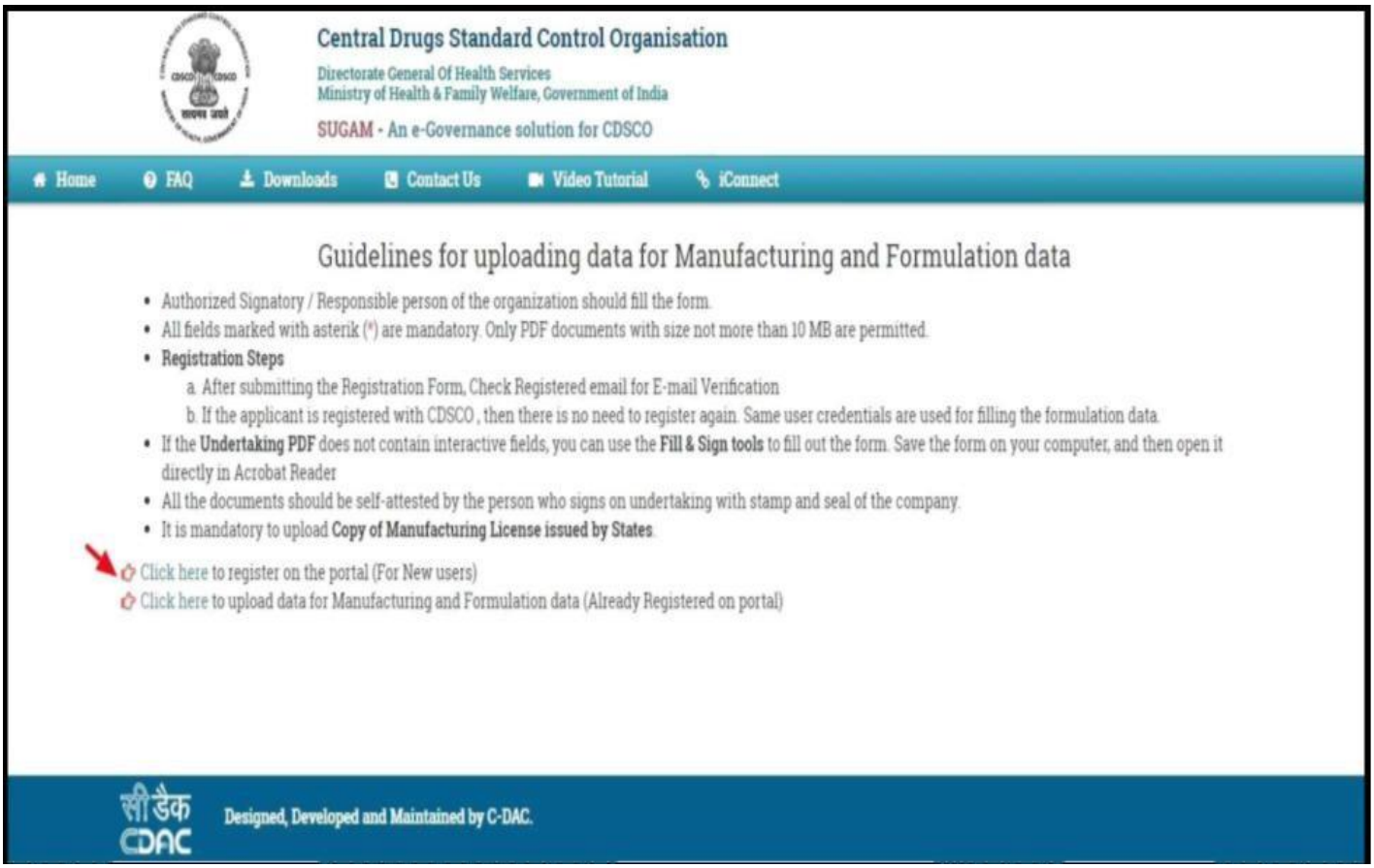

Figure 2 : Guidelines for uploading data for Manufacturing and Formulation Data

➢ When the applicant registers on the portal, he will be given 2 roles as shown in figure.

- **Manufacturing Sites and Product Formulation:** To upload Manufacturing and Formulations Data.
- **Applicant for COPP and GMP**: To submit COPP and GMP applications.

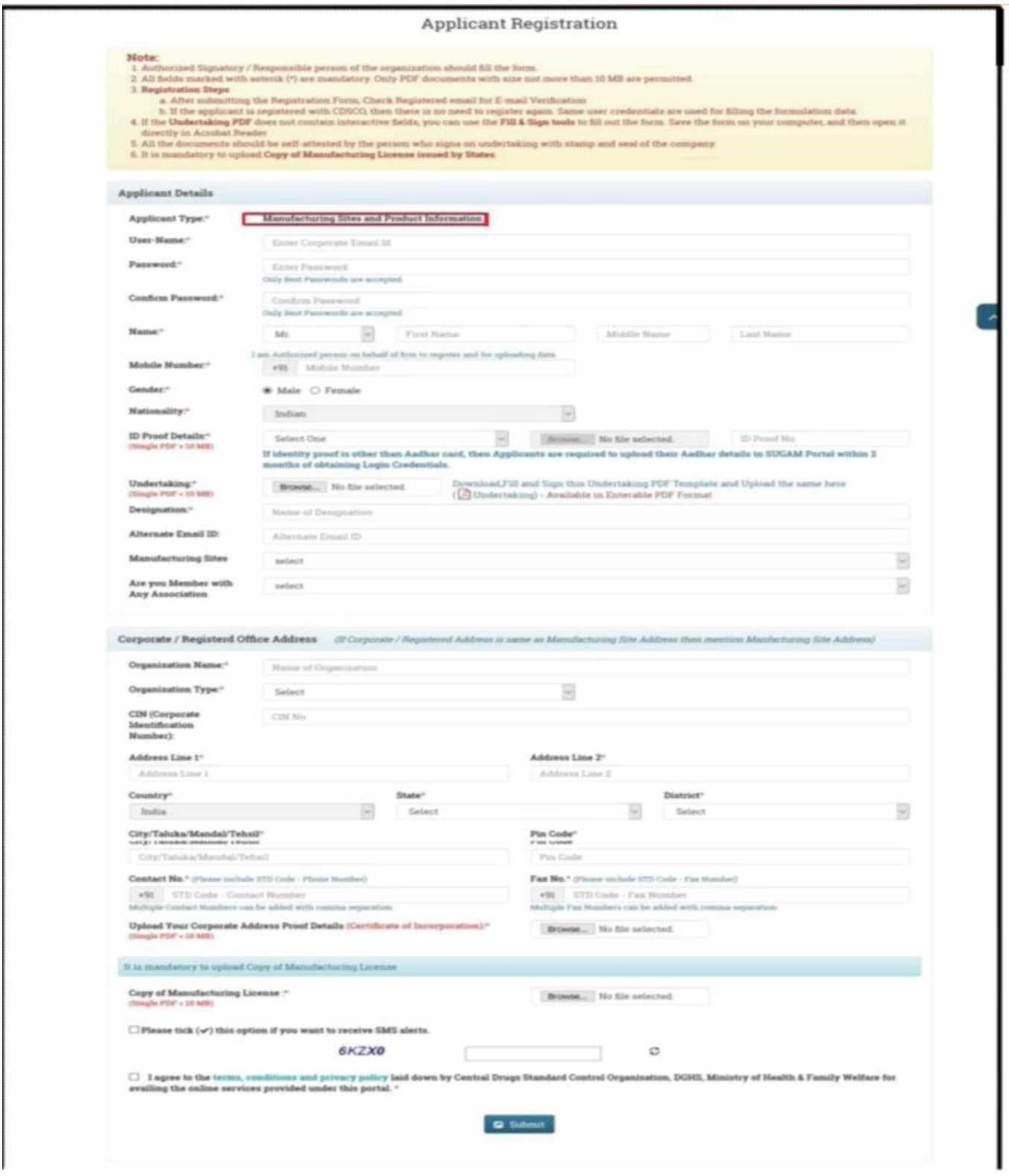

Figure 3 : Applicant Registration

➢ Each Manufacturer has to create separate logins for all his sites (Loan or Own) .The applicant has to select the sites for which he is registering as shown in figure

Figure 4 : Manufacturing Sites

➢ User needs to fill all the information on the registration form and then clicks on Submit button as shown in figure.

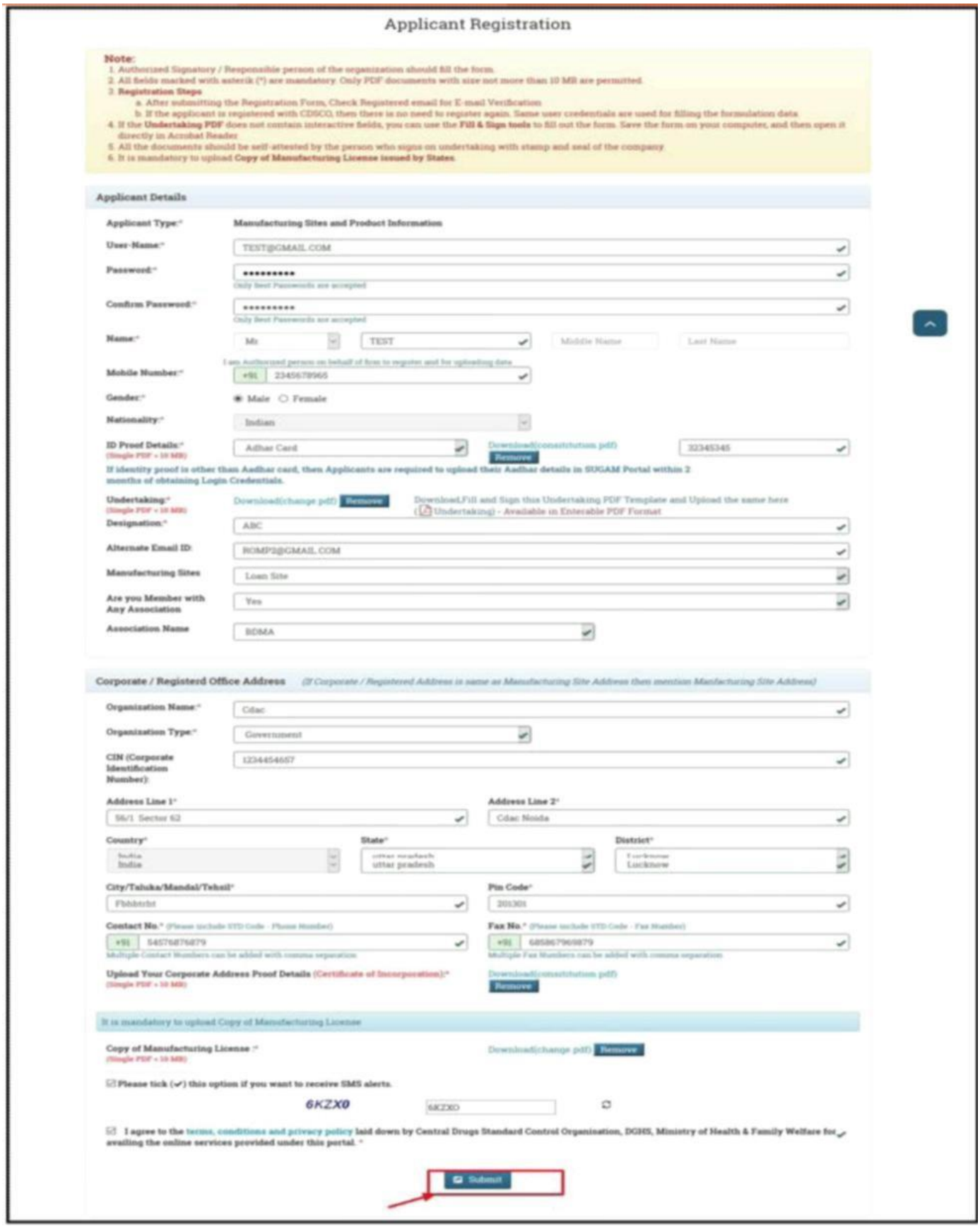

Figure 5 : Filled Application

➢ Once user fills all the details and clicks on Submit button he will be redirected to another page to verify the account .The applicant has to enter the user name that he used while filling the registration as shown in figure.

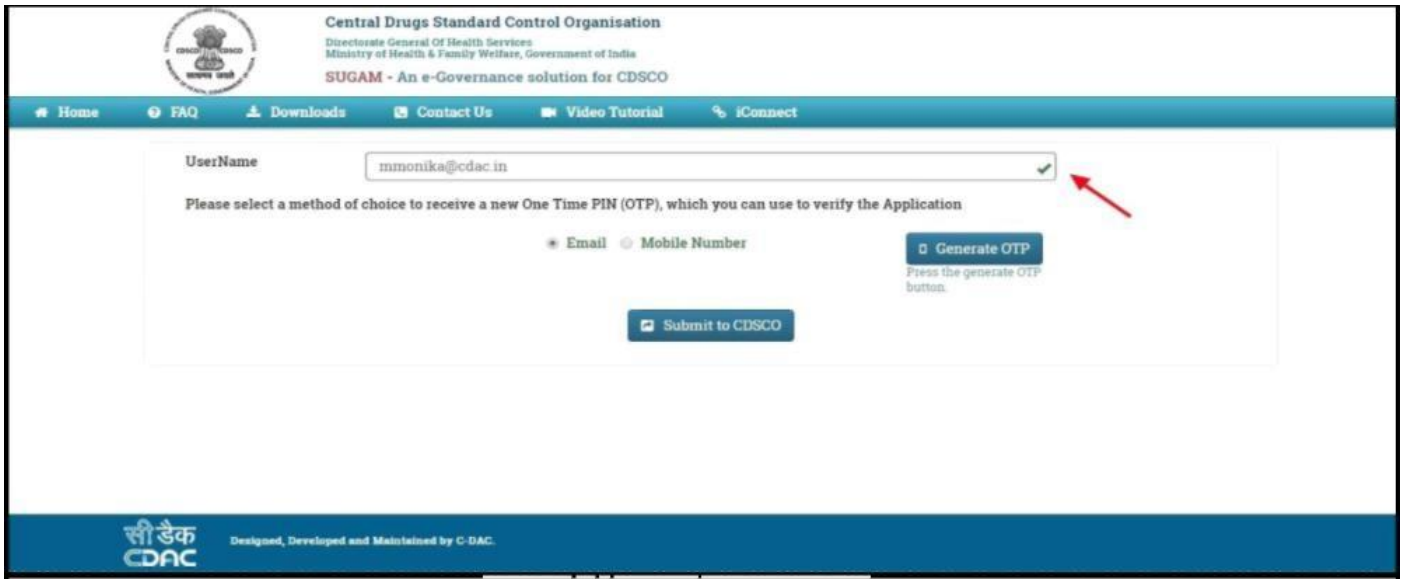

Figure 6 : Verify Registration

➢ To verify the account select either Email or Mobile Number to send the OTP and click on Generate OTP button as shown in figure. The OTP will be send to selected option.

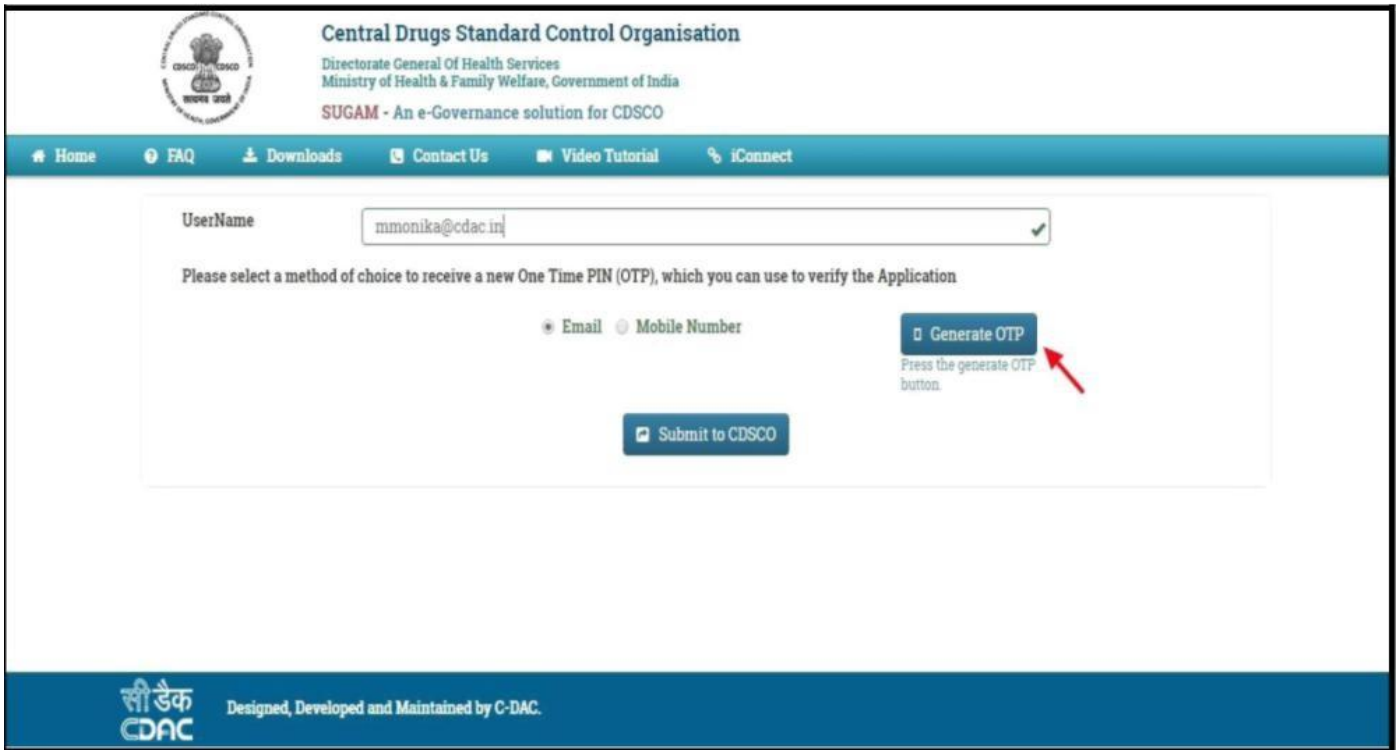

Figure 7 : OTP Generation

➢ In case if applicant did not receive the OTP click on the 'Resend OTP' Button as shown in figure, a new OTP will be sent to applicant.

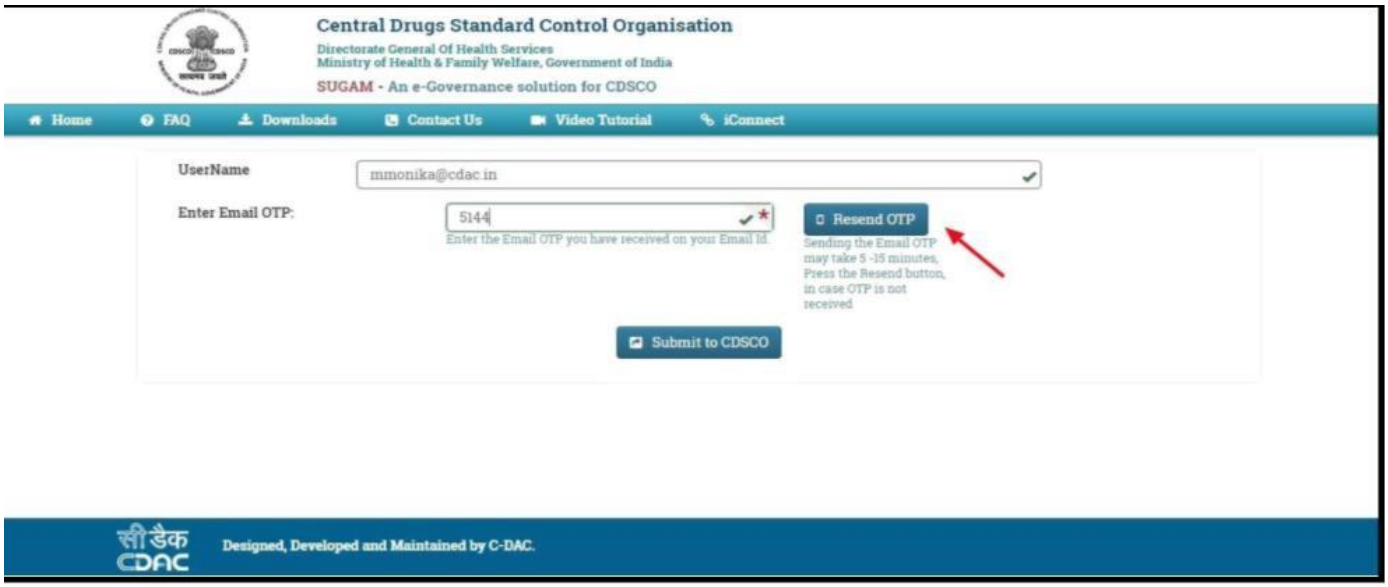

Figure 8 : Resend OTP

➢ Applicant needs to enter the OTP in the text box as shown in figure.

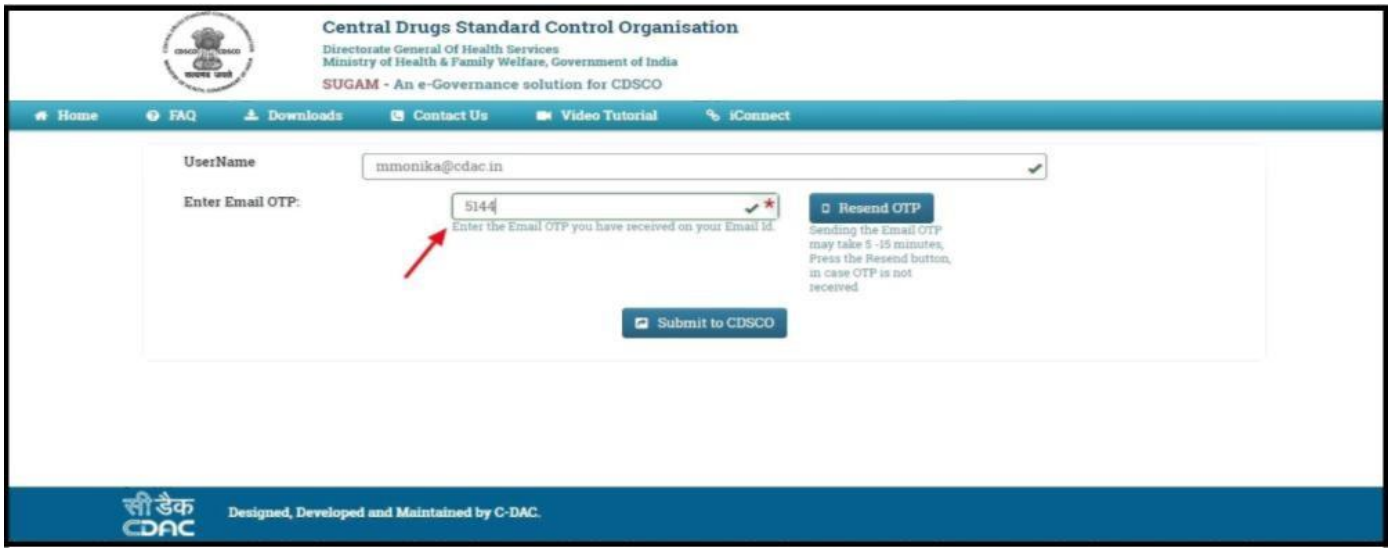

Figure 9 : OTP Submission

➢ If the entered OTP is correct applicant will see the message box as shown below. Further the applicant needs to click on 'Submit to CDSCO' button. Applicant will be redirected to **https://cdscoonline.gov.in/CDSCO/homepage.**

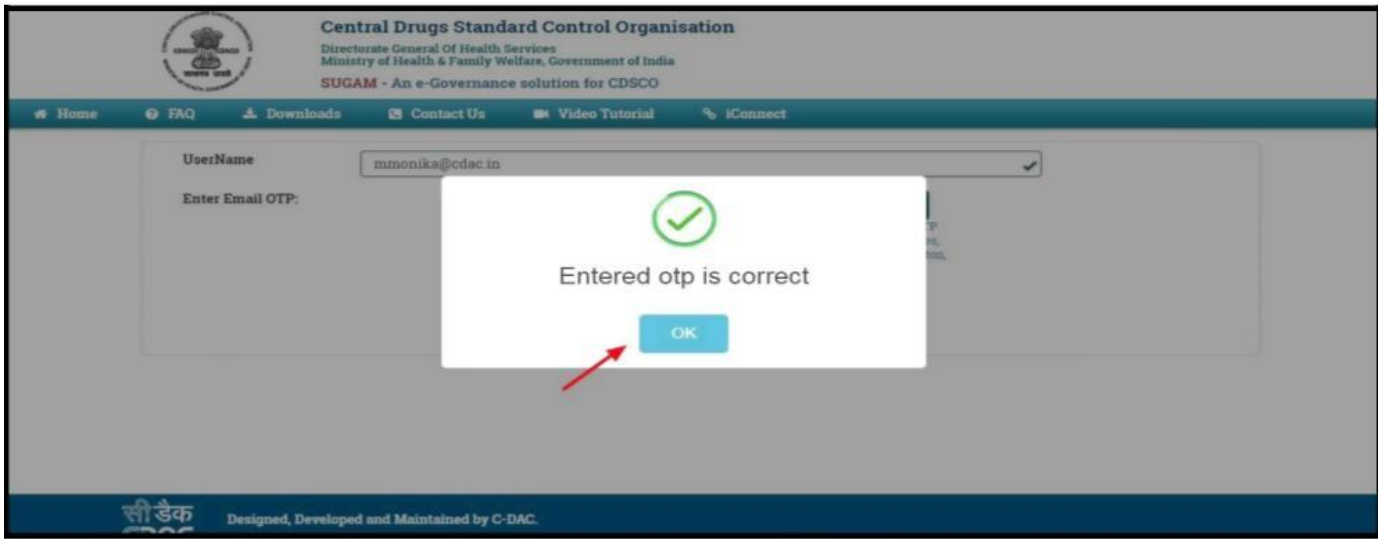

Figure 10 : OTP Correction Modal

➢ **Your registration is completed and now you can login on the SUGAM Portal**

• **Already Registered:**

➢ If the applicant has already registered himself on the portal, click on '**upload data for manufacturing and formulation data'** link as shown in figure and you will be redirected to homepage.

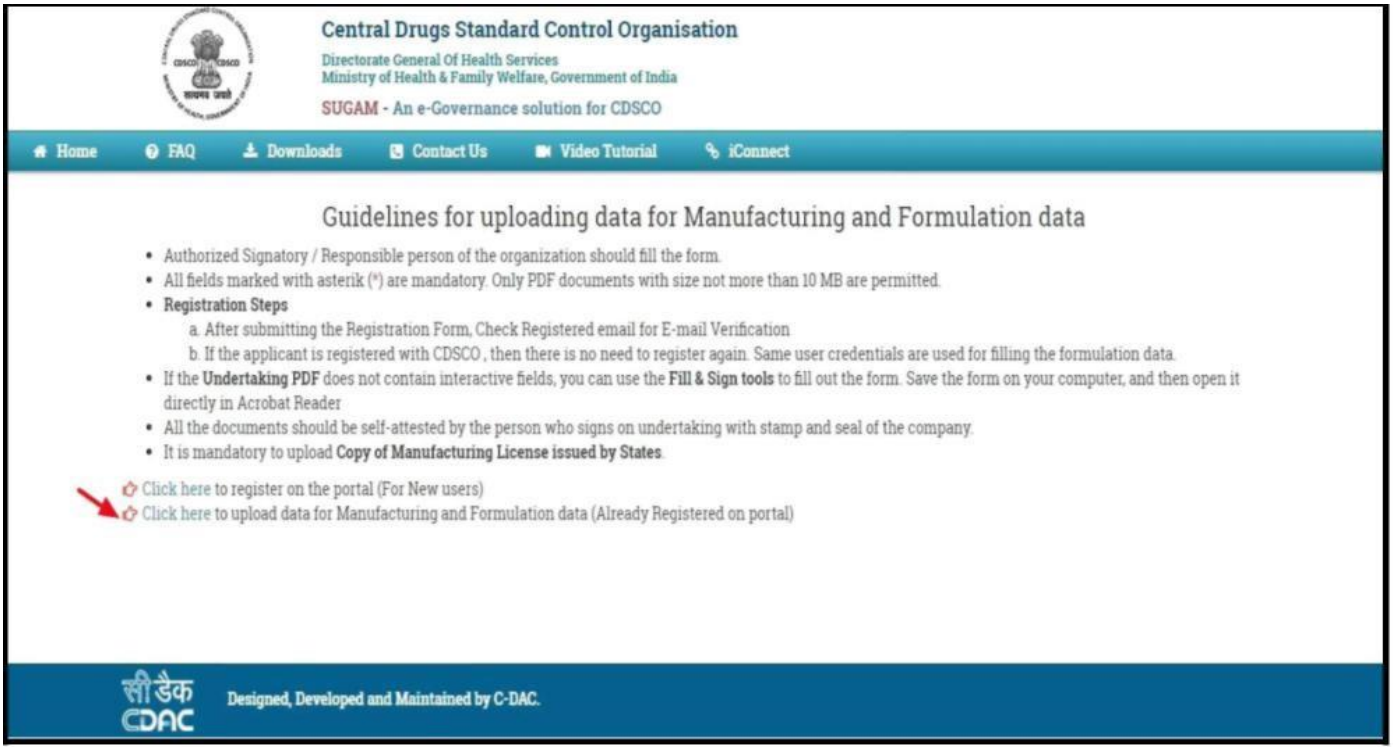

Figure 11 : Already Registered

➢ To login into the portal, Enter Username and Password and click on 'login' button, as shown in figure.

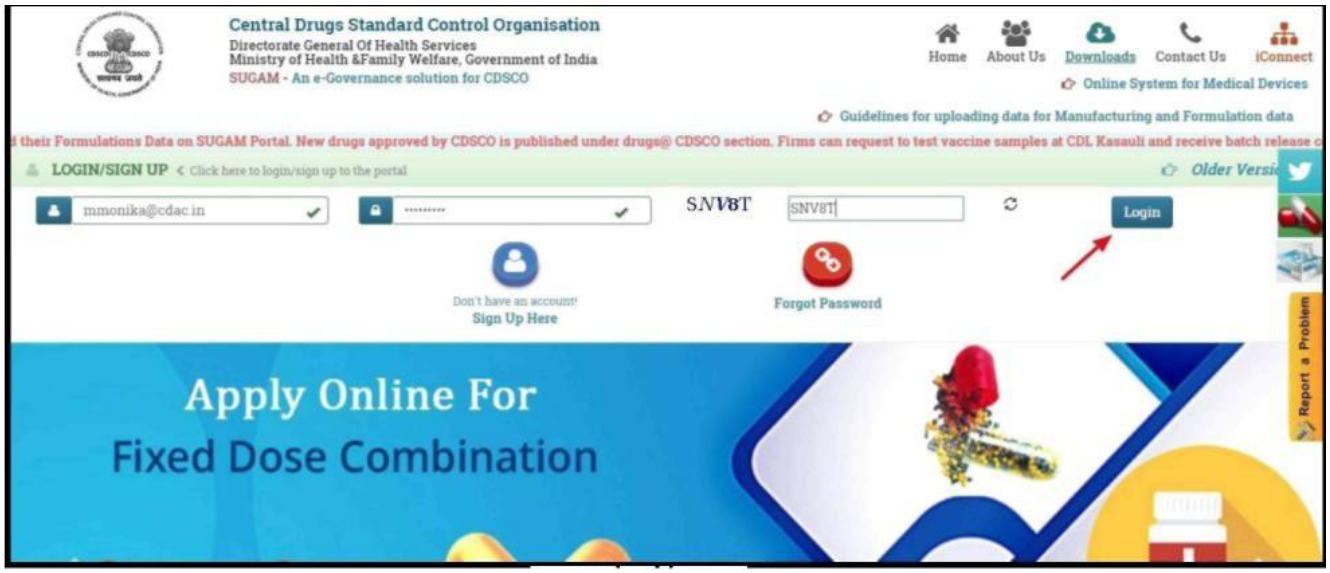

Figure 12 : Login

➢ Once applicant click on 'login' button he will be redirected to the user's Dashboard.

➢ The applicant can change the role by clicking on switch role button as shown in figure. By default Manufacturing sites and Product formulation role is selected where applicant can upload Manufacturing Sites and formulation data.

➢ In case the applicant wants to apply for COPP and GMP, he needs to select Applicant for COPP and GMP role and he will be redirected to another dashboard.

Figure 13 : Applicant Dashboard

2.2 Upload Data

2.2.1 Manufacturing Site Details

➢ To submit the Manufacturing Sites Detail Click on Submit Manufacturing Site, as shown in Figure.

Figure 14 : Submit Manufacturing Site Details

➢ Once the applicant clicks on 'Submit Manufacturing Site Details', applicant is redirected to the page of Manufacturing Site details.

➢ **LoanSite**

- If during registration the applicant has registered for Loan site the user can select a site which is not registered on his/her name, but that is used by him for manufacturing.
- In this case state and district is to be selected, and then all the manufacturing units entered in the portal are populated in premises select box as shown in figure.

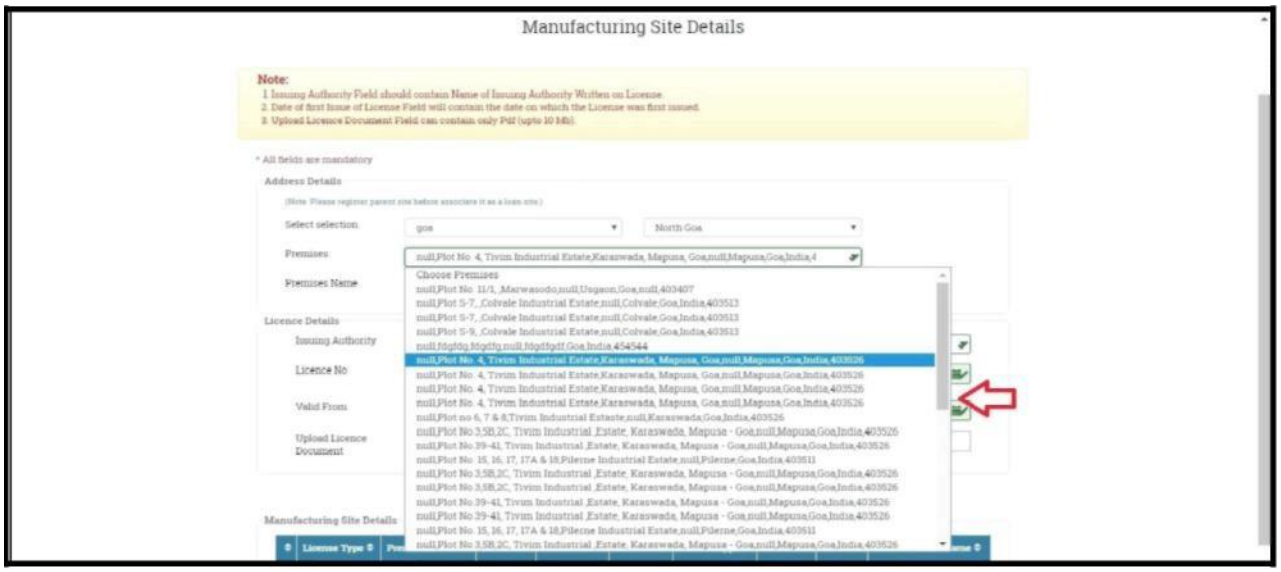

Figure 15 : Manufacturing Premises

- Issuing authority select Box will contain the list of State Issuing Authority. Applicant needs to select the issuing authority which is mentioned on the license.

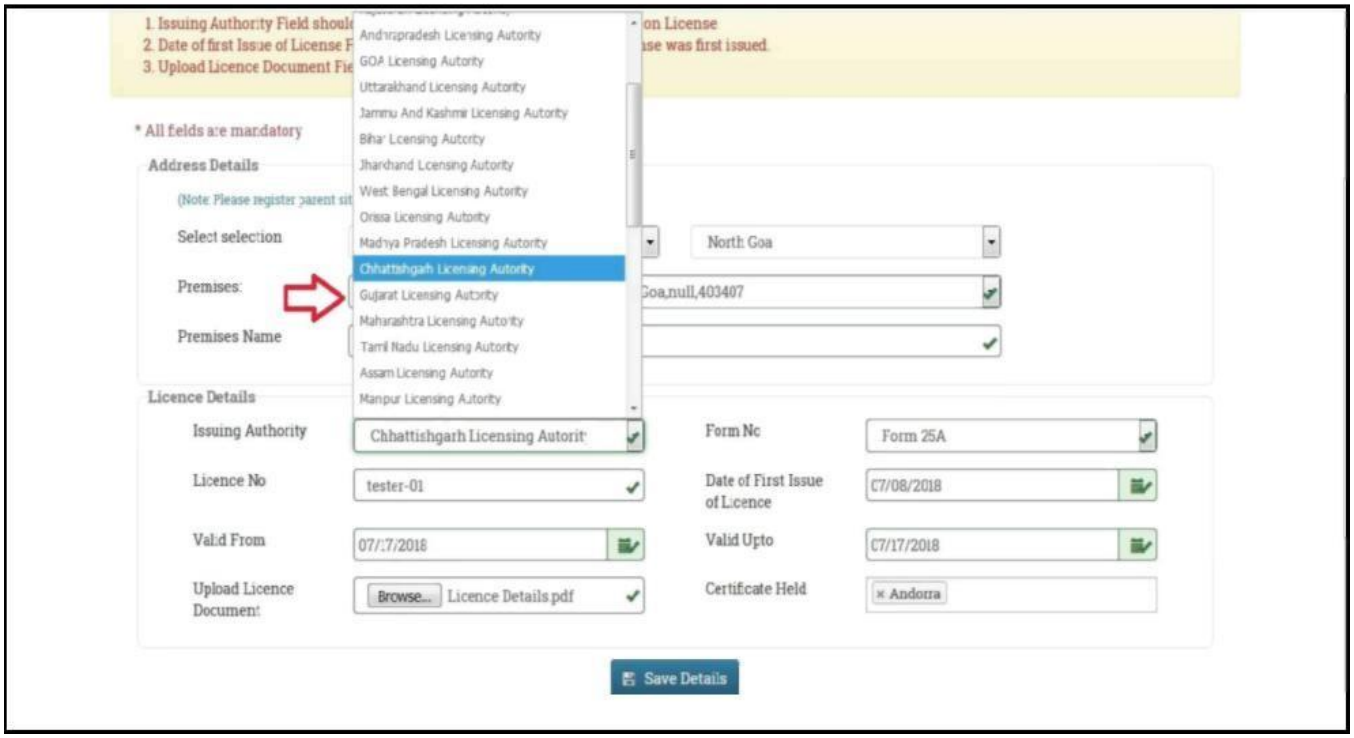

Figure 16 : Issuing Authority

- After filling all the details (Address and license details) user can click on 'Save Details' button to proceed further

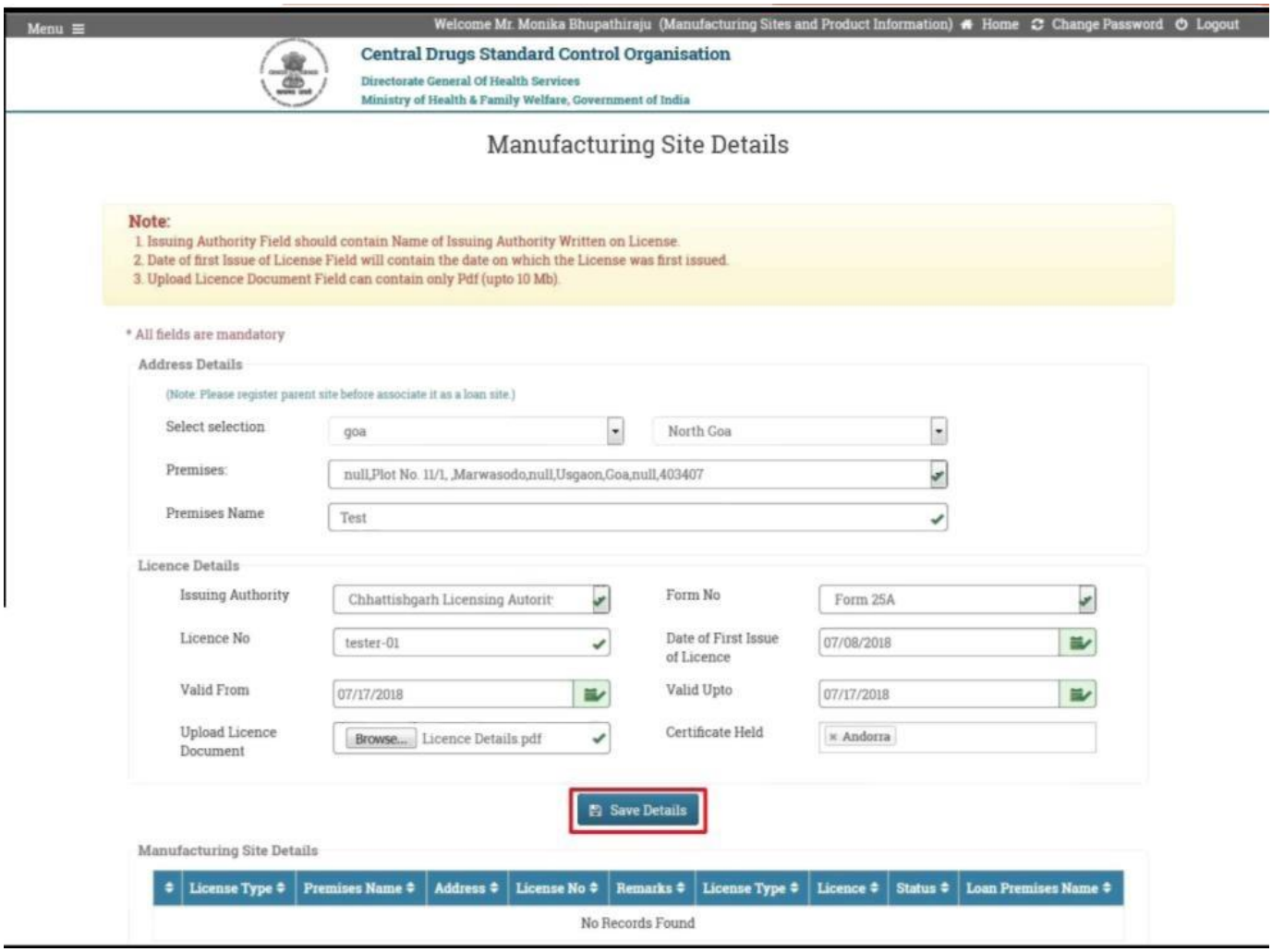

Figure 17 : Filled details

• After clicking on 'Save Details' button a confirmation message will appear on screen as shown in the figure below.

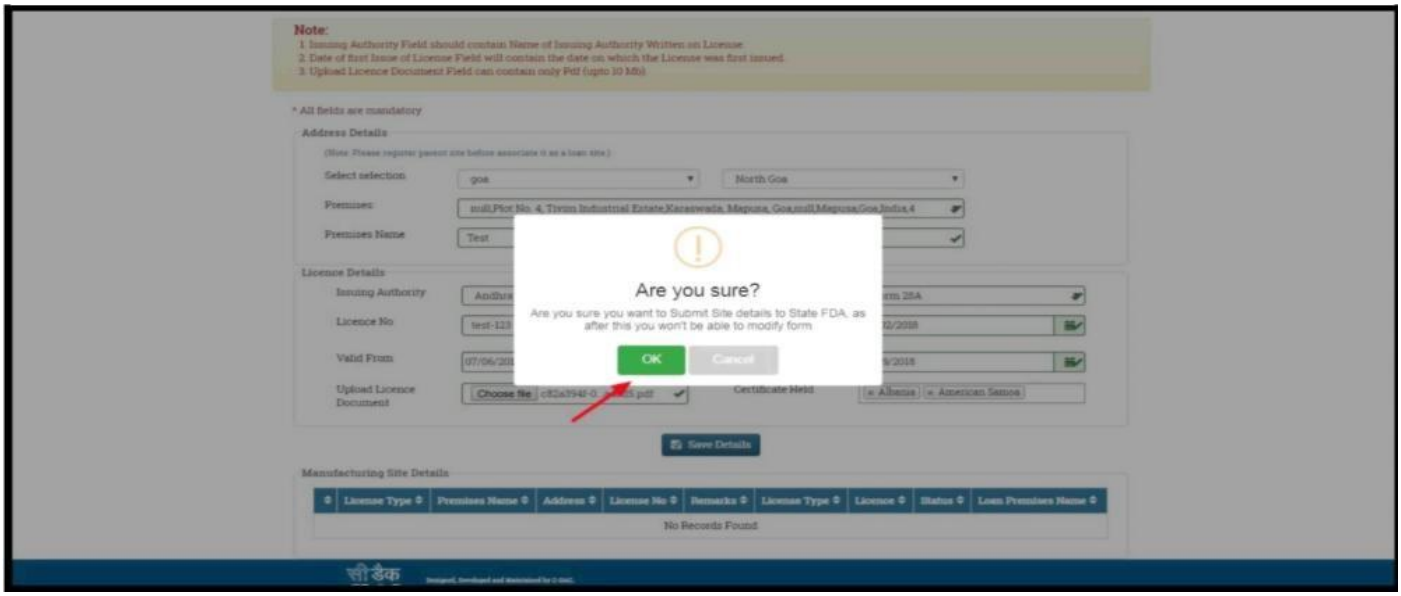

Figure 18 : Confirmation form to submit Application

• If applicant clicks 'OK' then the details entered are saved successfully and the message appears as shown in the figure below.

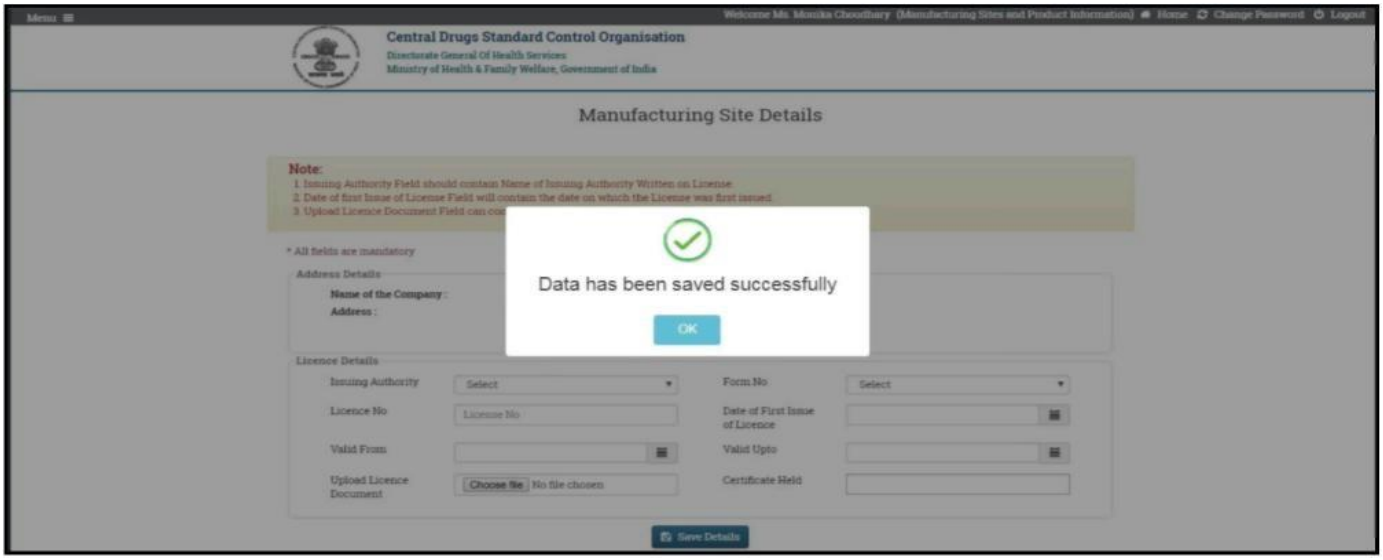

Figure 19 : Submit Details Successfully

• Once the user submits the application the details of manufacturing units added by manufacturer are listed in below section of page as shown in below figure.

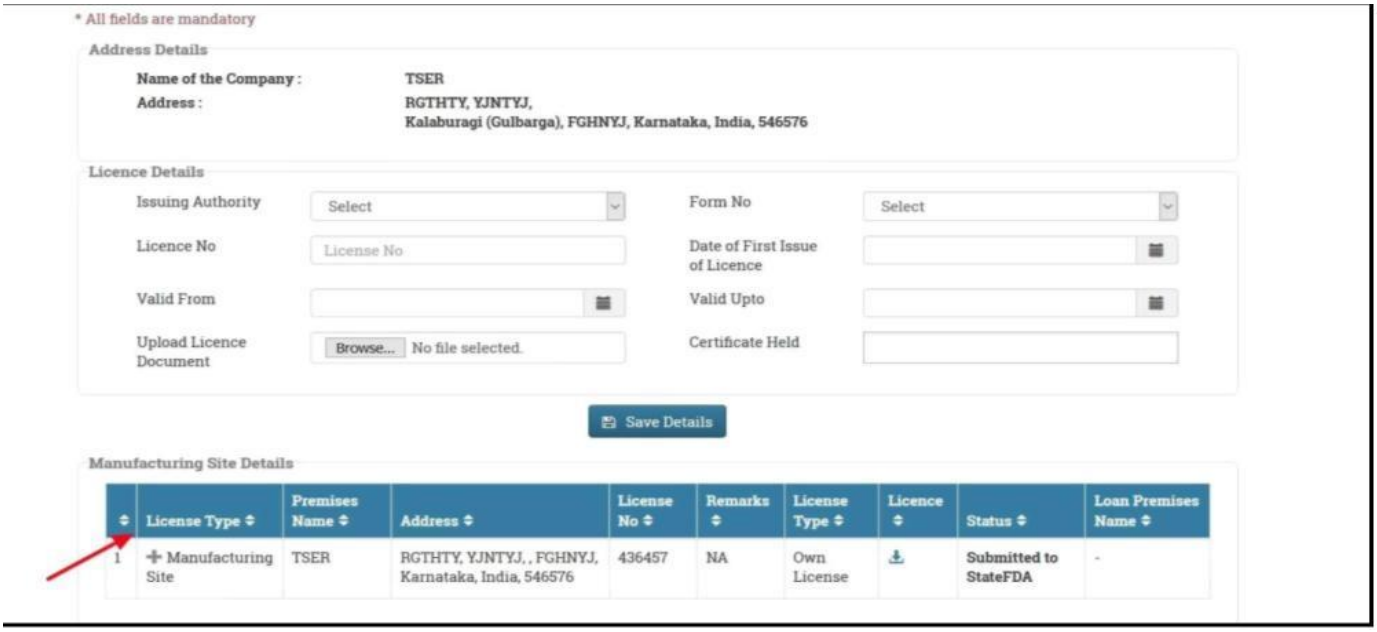

Figure 20 : Saved Manufacturing Site Details

➢ OwnSite

• If during registration the applicant has registered for Own site the user has to enter the Manufacturing Site Detail as shown in figure.

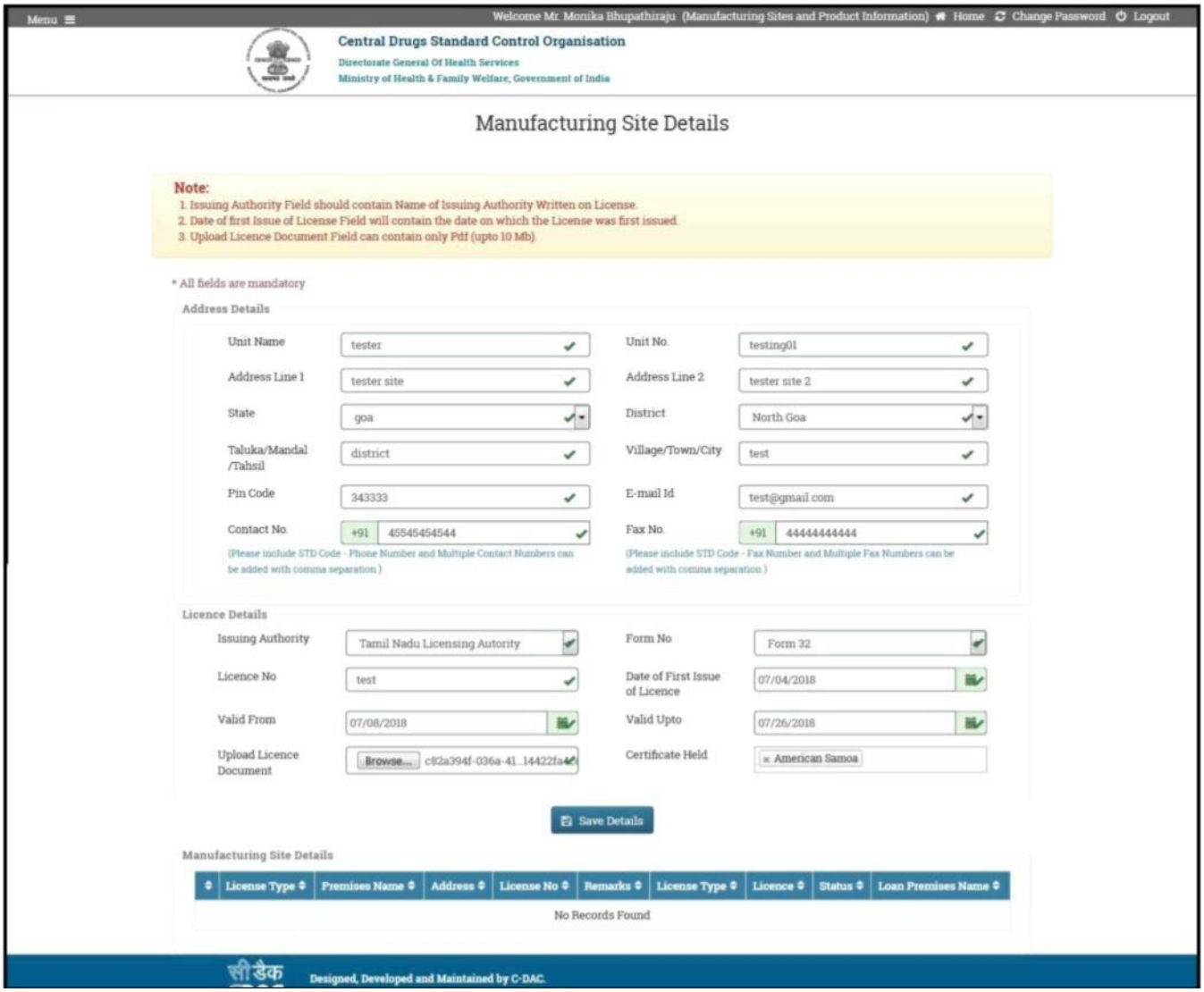

Figure 21 : Own Site Details

- After filling all the details (Address and license details) user can click on 'Save Details' button to proceed further as shown in figure.

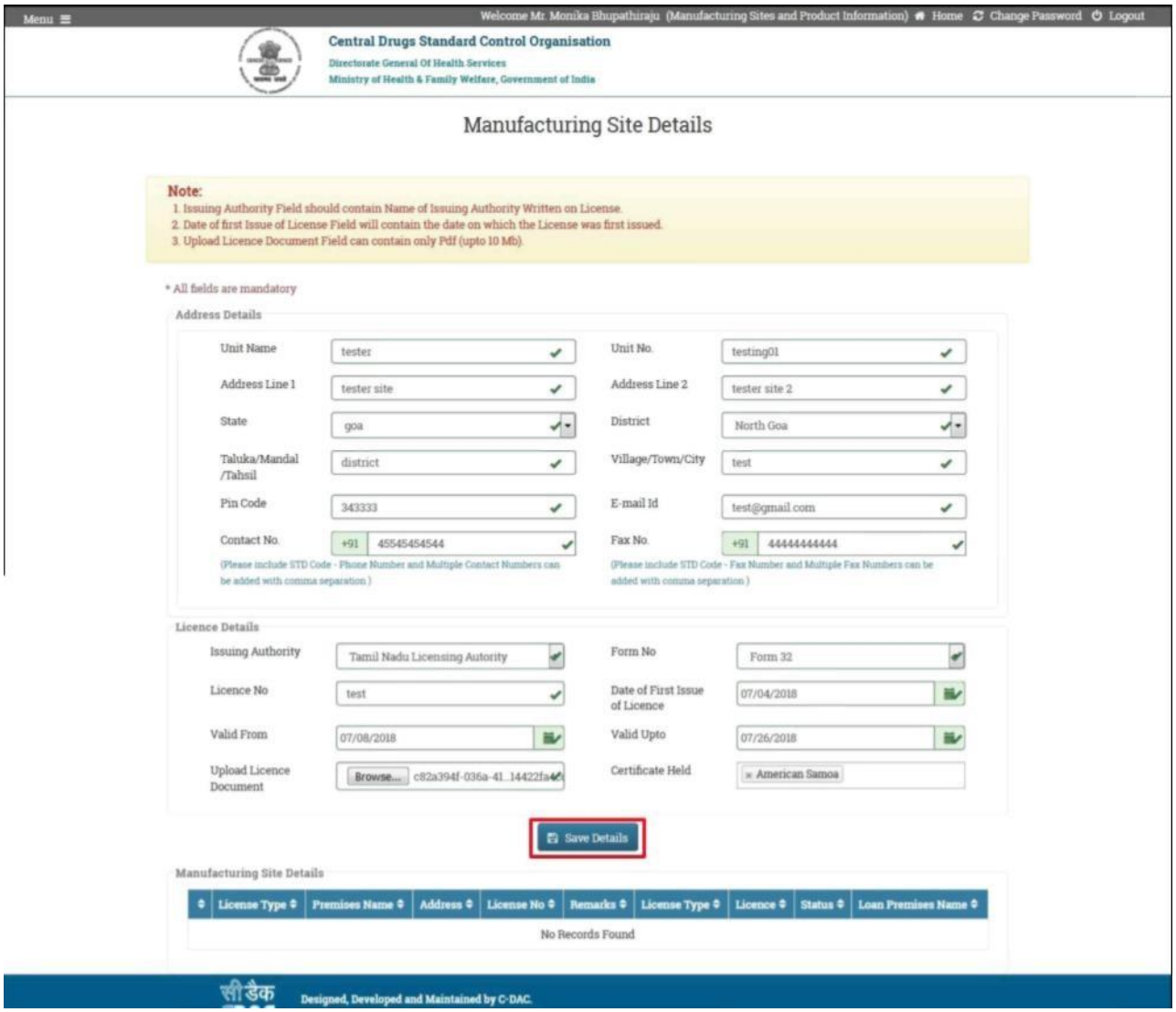

Figure 22 : Fill Details

• After clicking on 'Save Details' button a confirmation message will appear on screen as shown in the figure below.

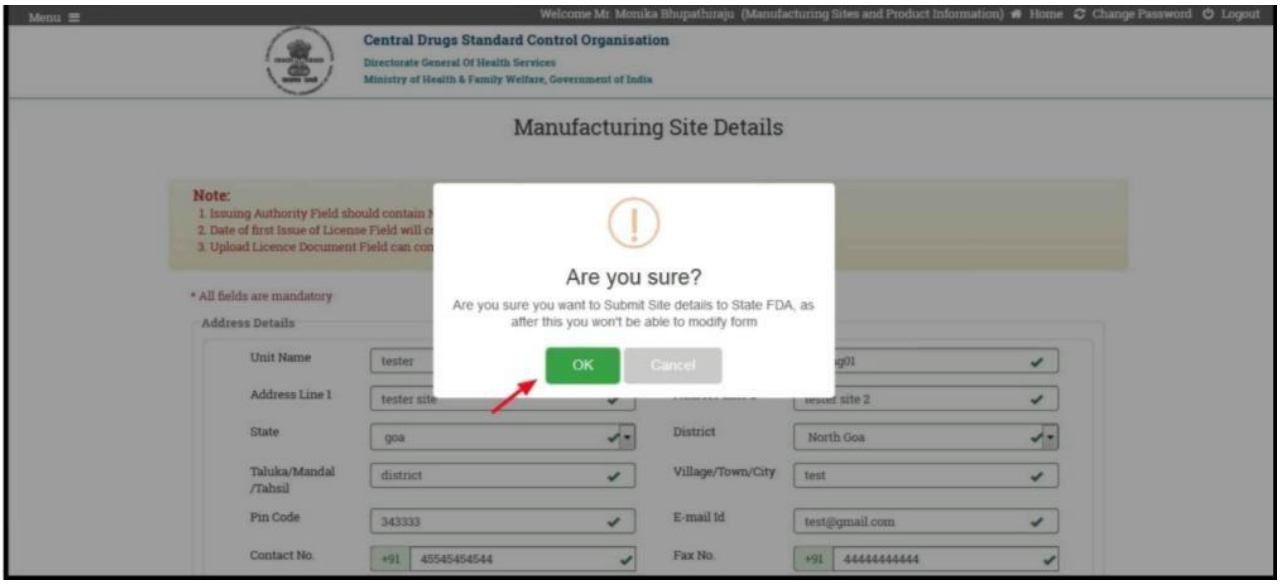

Figure 23 : Confirmation Window

• Once the user submits the application the details of manufacturing units added by manufacturer are listed in below section of page as shown in below figure.

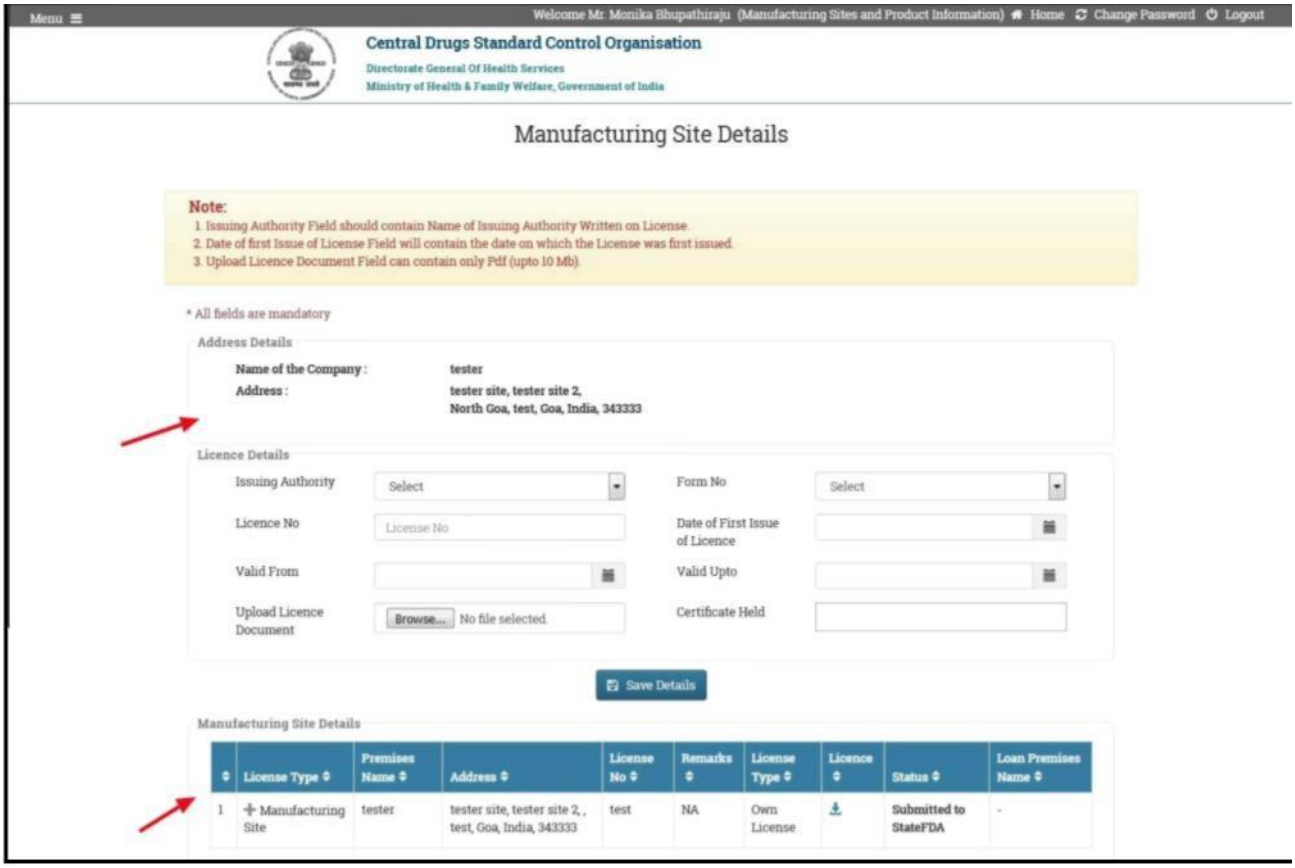

Figure 24 : Save Details

• The applicant has to add the premises details only once, after that it will be fetched automatically as shown in figure.

• If the applicant is holding more than one license he only has to enter the license detail, the premises details will be automatically fetched.

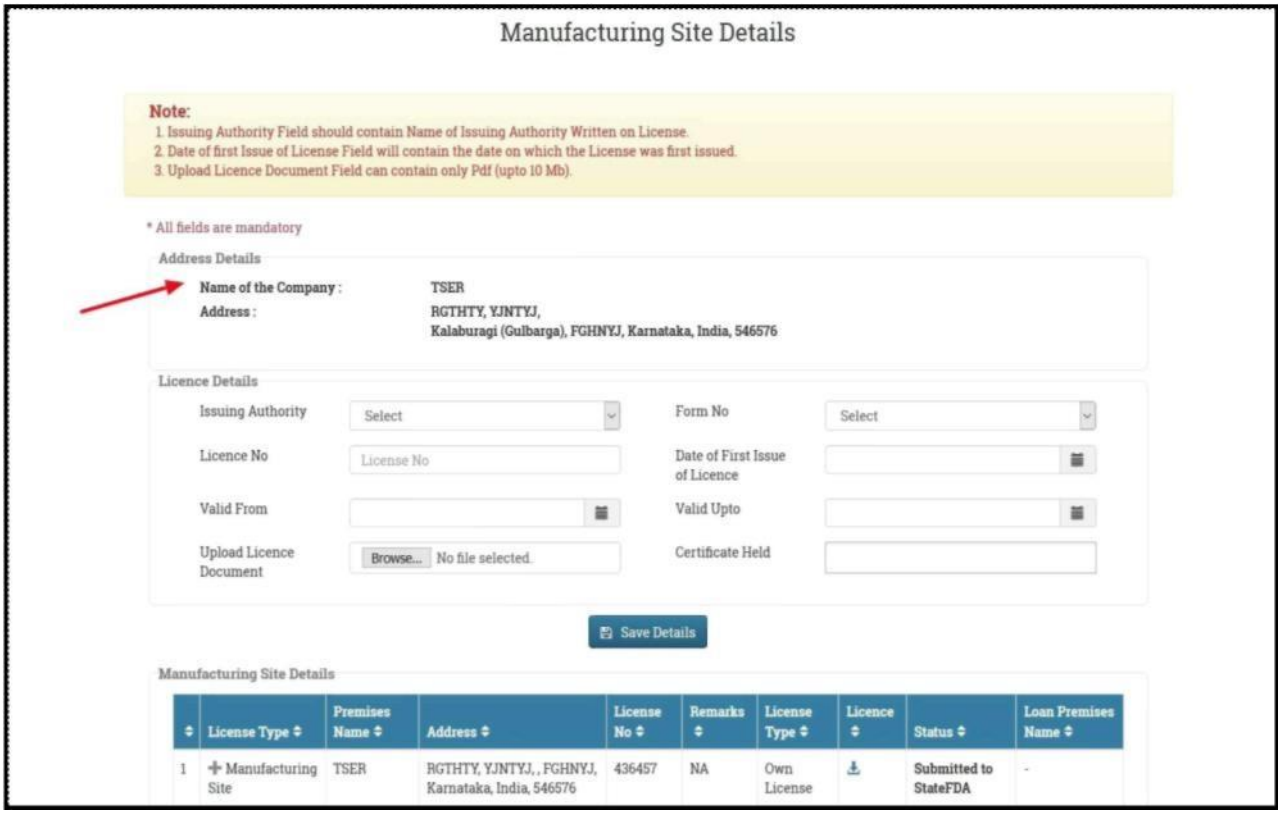

Figure 25 : Name of Company and Address

2.2.2 Formulation Details

➢ To submit the Formulation Details go to Submit Formulation Details, as shown in Figure.

Figure 26 : Submit Formulation details

➢ On clicking 'Submit Formulation Details', applicant is redirected to the Manufacturer Formulation details page as shown in figure.

➢ The Manufacturing Unit select box will fetch the Site Address which the applicant has entered and it is not editable as shown in below figure.

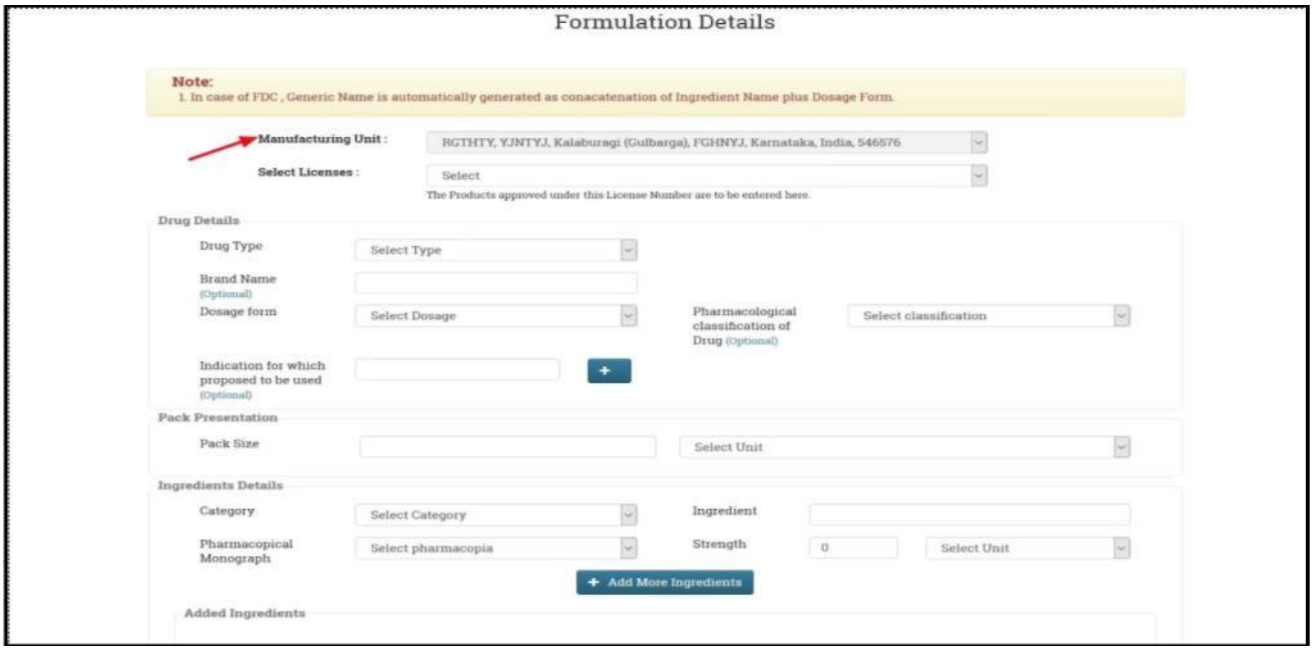

Figure 27 : Manufacturing Formulation Form

➢ All the licenses entered by the applicant for the particular manufacturing Site are populated in Select License dropdown; applicant needs to select the license for which he/she wants to add formulations as shown in below figure.

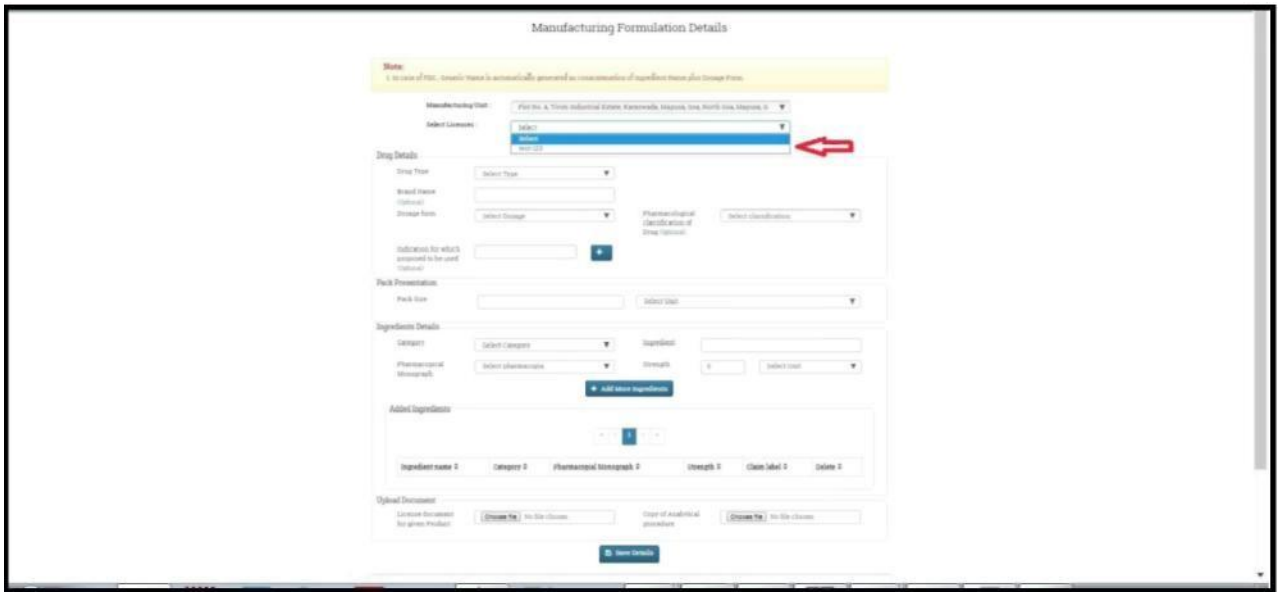

Figure 28 : Licenses List

➢ In the formulation form brand name, pharmacopeia classification and indication are optional and the remaining fields are mandatory.

➢ In case of FDC, Generic Name is automatically generated as concatenation of Ingredient Name plus Dosage Form.

➢ Applicant needs to fill all the details in the form, he can add multiple indications per formulation by clicking '+' button and can add multiple ingredients by clicking Add More Ingredients as shown in figure.

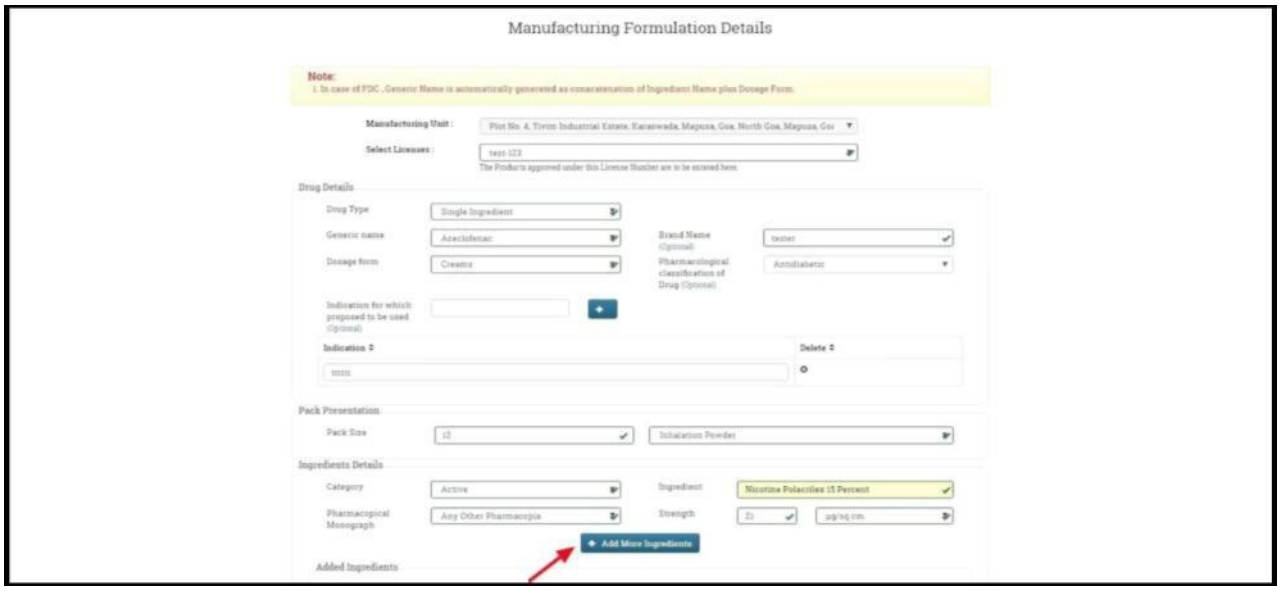

Figure 29 : To Add more ingredients

➢ After filling all the details click on 'Save Details' to save the formulation of a selected license as shown in figure.

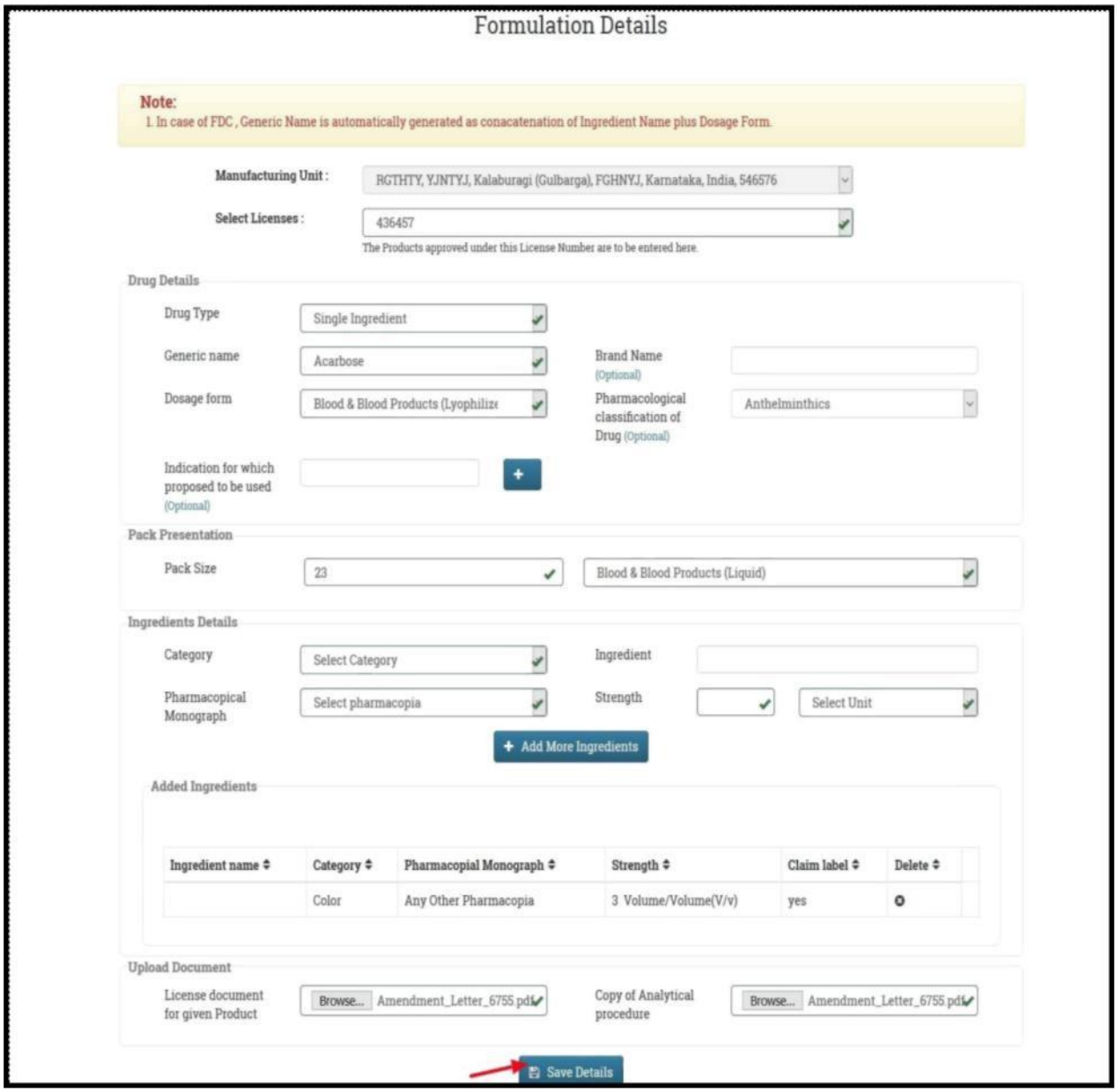

Figure 30 : Submit Application

➢ Once the applicant clicks on 'save details' button, a confirm box will open as shown in figure. If the applicants selects ok than his details will be saved on the portal.

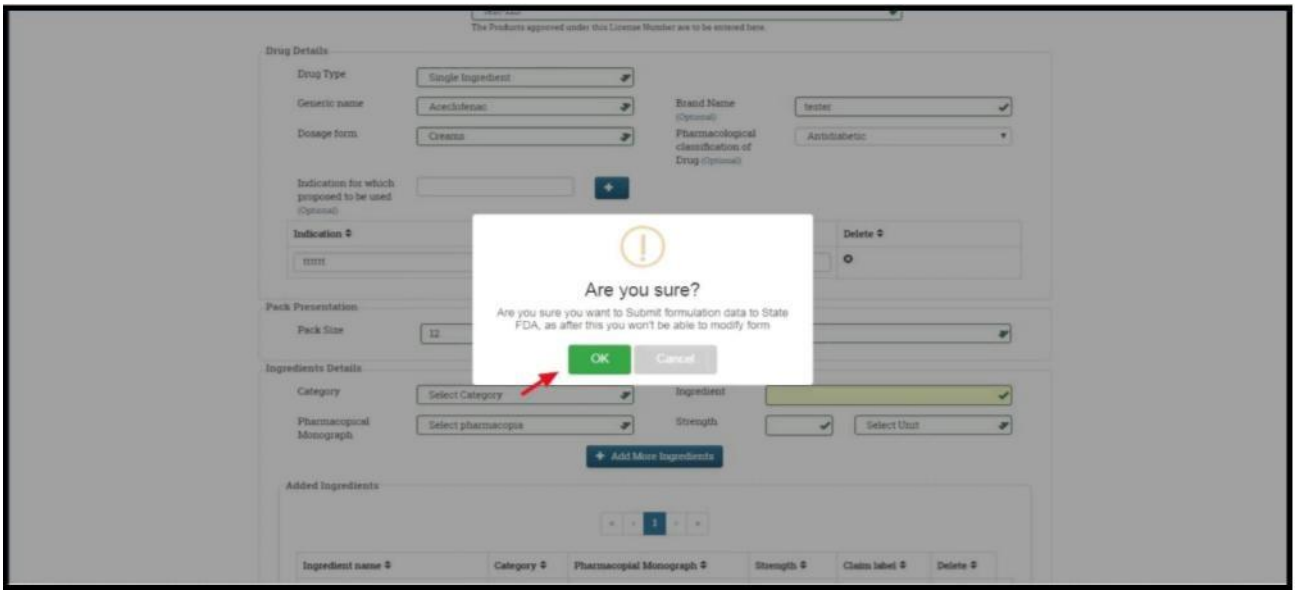

Figure 31 : Confirmation box to submit Application

➢ Once the user submits the application the details of Formulations added by manufacturer are listed in below section of page as shown in below figure.

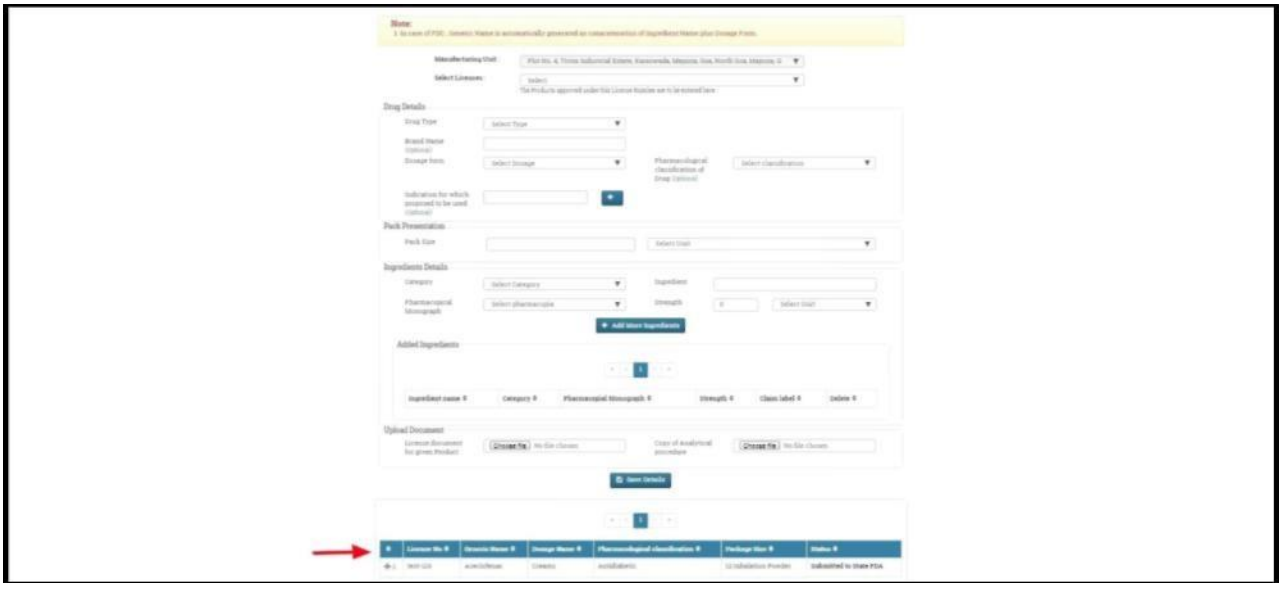

Figure 32 : Filled Formulations Detail

➢ Once the user save the formulation details, then he/she can add the production Details of that particular formulation on quarterly basis.

2.2.3 Production Details

➢ To submit the Formulation Details go to Submit Formulation Production Details, as shown in Figure

Figure 33 : Submit Production Details

➢ Once the formulation details of a particular drug is filled by user, then the user can add the production details of that particular formulation on quarterly / yearly basis under specific licenses. For adding the production details, user needs to click on the Add Production Details for Formulation.

➢ The Manufacturing Unit select box will fetch the Site Address which the applicant has entered and it is not editable as shown in figure.

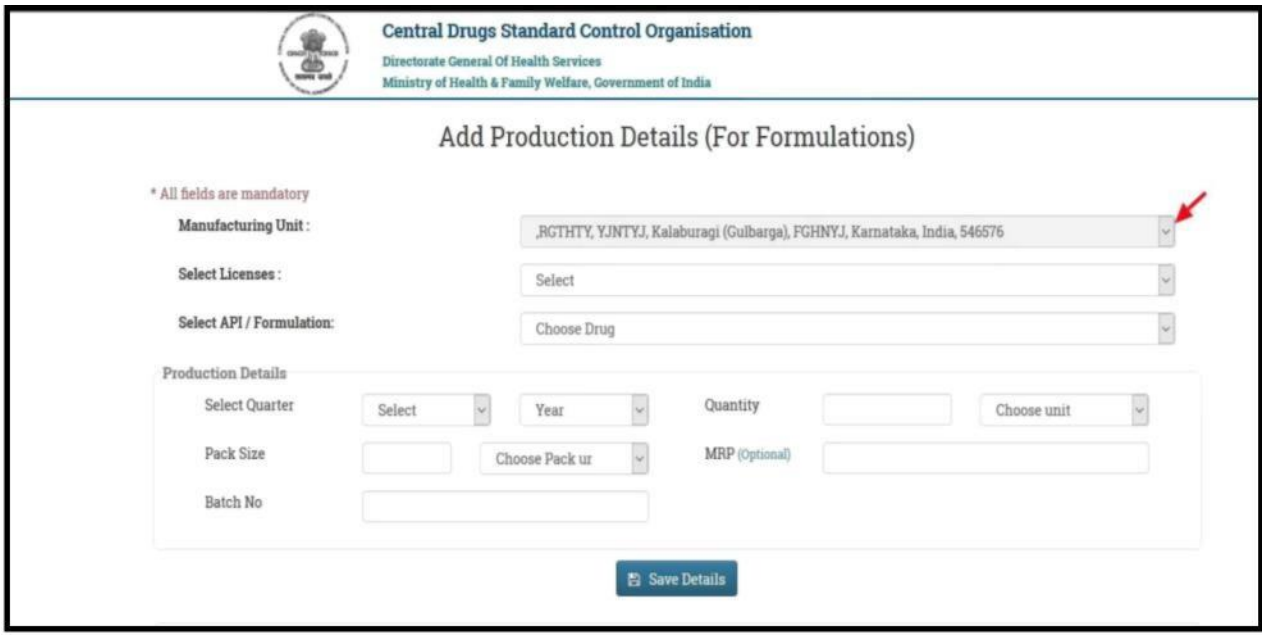

Figure 34 : Manufacturing Site

➢ All the licenses entered by the applicant for the particular manufacturing Site are populated in Select License combo applicant needs to select the license and drug for which he/she is going to add production details.

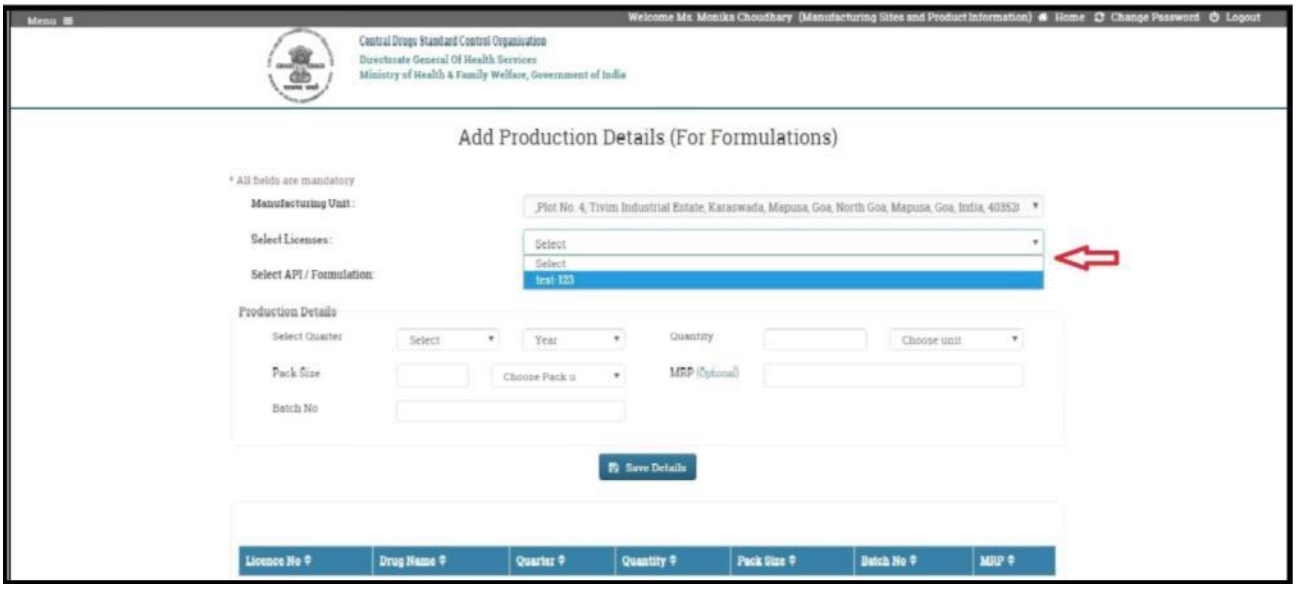

Figure 35 : License List

➢ All the Drugs corresponding to the selected License are populated in Select API/Formulations drop down; applicant needs to select the Formulation for which he/she is going to add production details as shown in figure.

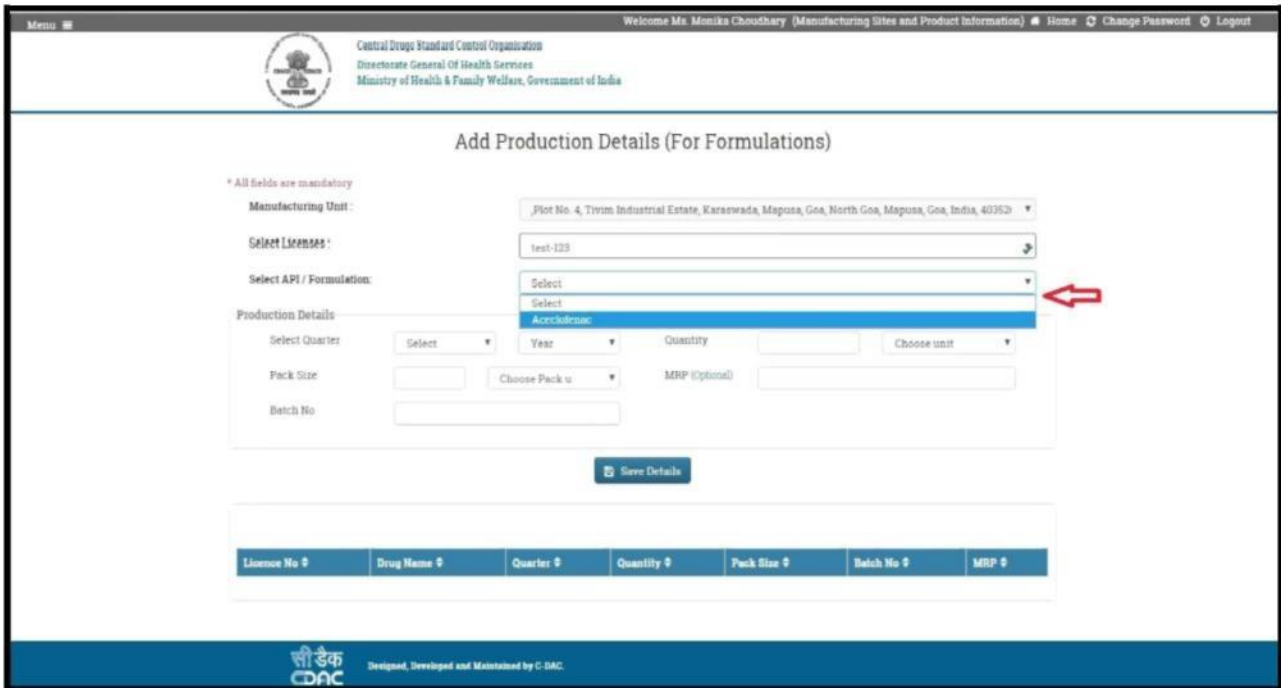

Figure 36 : API/Formulations List

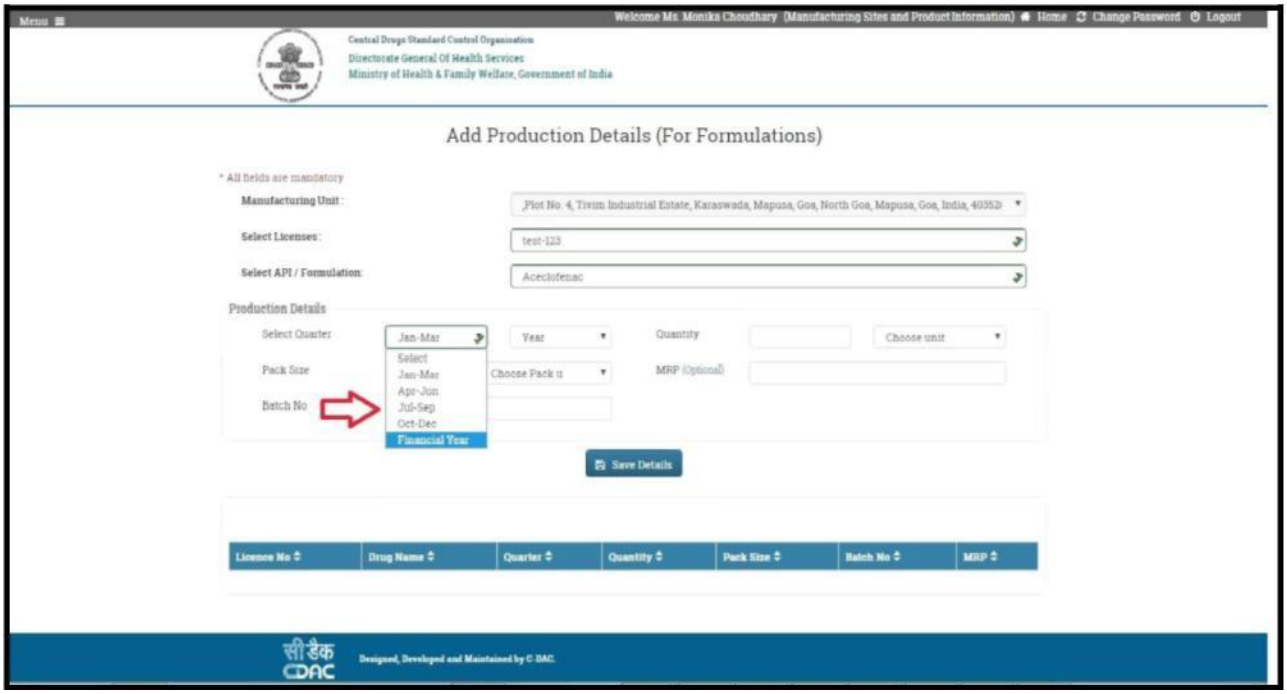

Figure 37 : Quarterly/Yearly List

➢ All fields are mandatory. After filling the form applicant needs to click on 'save details' button to save the details as shown in figure

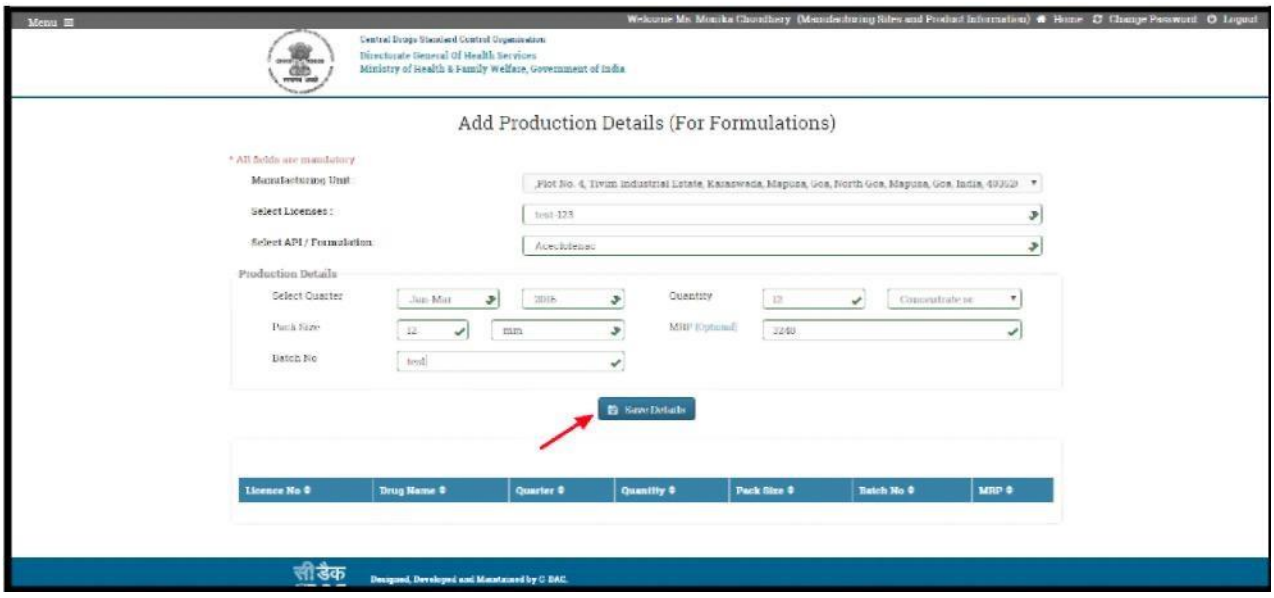

Figure 38 : Submit Application

➢ Once the details are saved, they will be visible in the below table of production details as shown in figure. ➢ User can add multiple productions on quarterly / yearly basis.

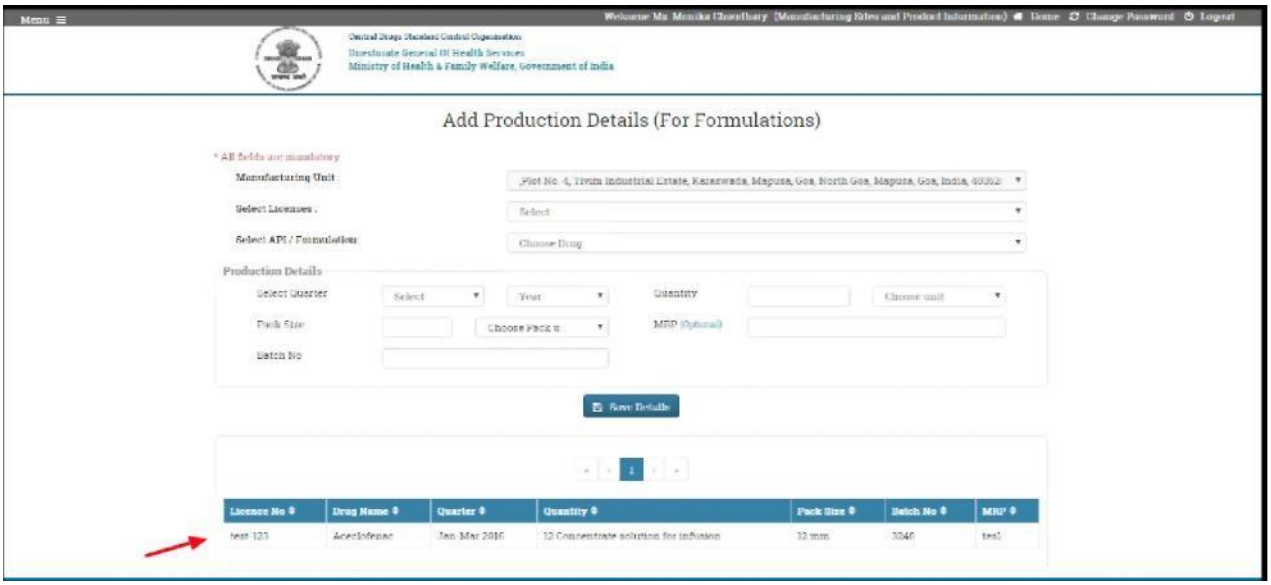

Figure 39 : Submit Detail

2.2.4 Product Production Capacity

➢ Applicant can enter the Volume of products that can be generated by clicking on production capacity as shown in figure:

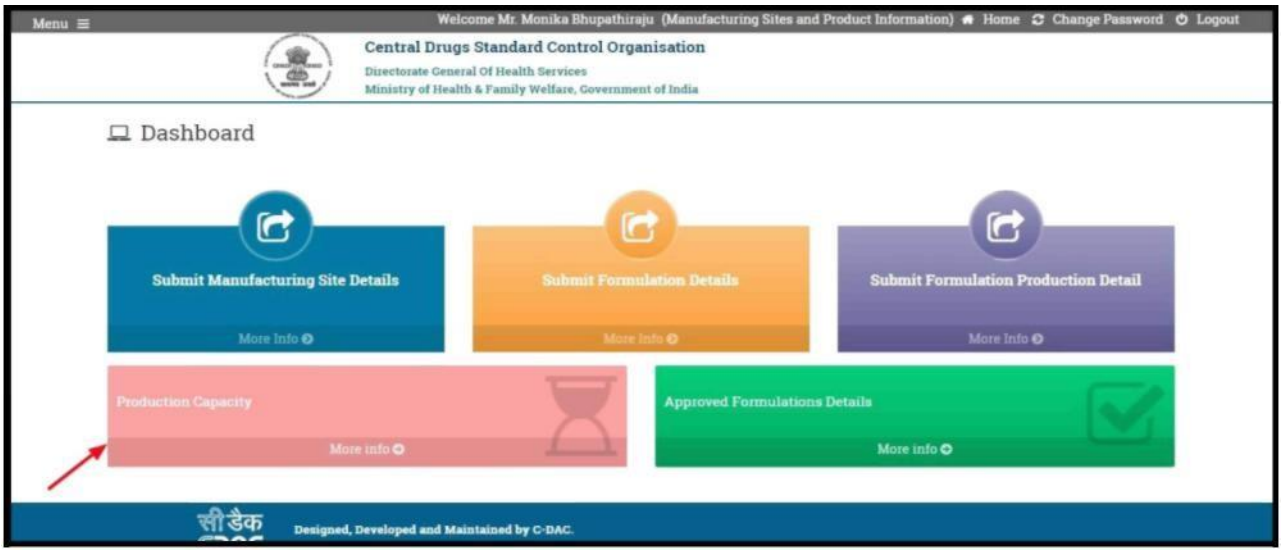

Figure 40 : Production Capacity

➢ The applicant will be redirected to Production Capacity Details Webpage where he has to enter the production capacity.

➢ All fields are mandatory and after filling the fields click on save detail button as shown in figure.

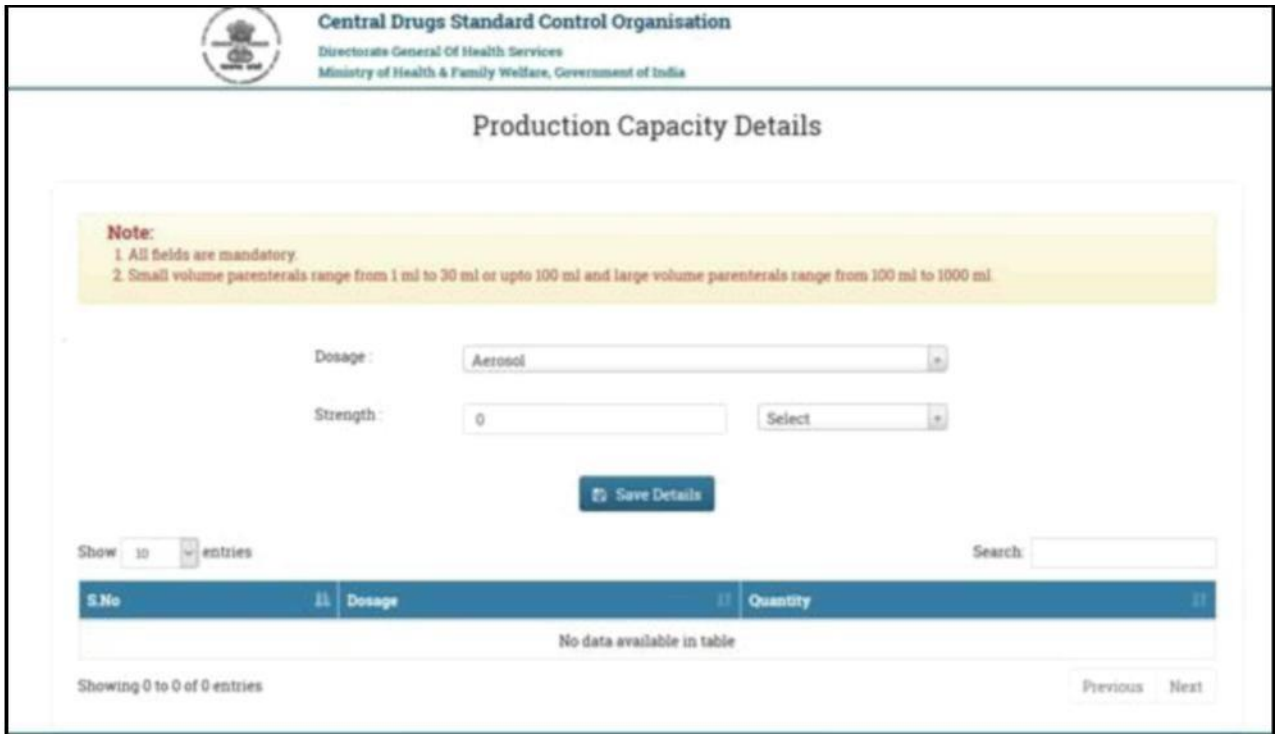

Figure 41 : Submit Application

➢ All the details entered by the applicant will be added in the table as shown in figure below.

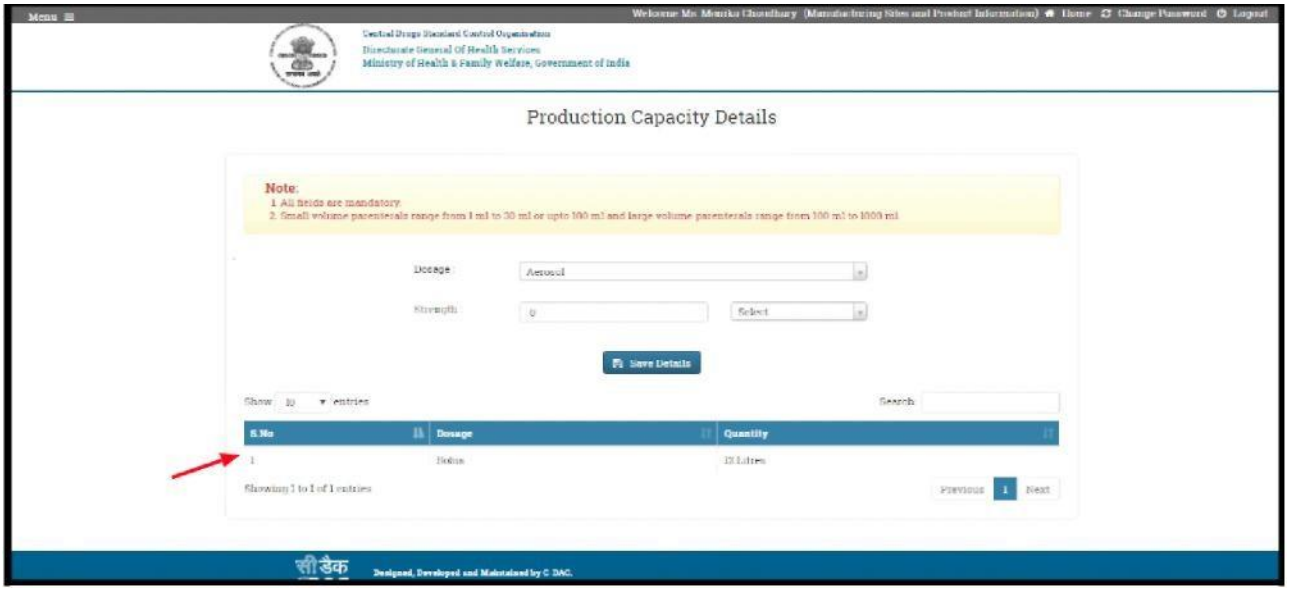

Figure 42 : Submitted Details

2.3 Approved Formulation / Amendment

➢ To view all the approved Formulation click on Approved Formulation Details as shown in figures

Figure 43 : Approved Formulation Details

➢ The formulation approved by State FLA will be shown here as shown in figure.

Figure 44 : Approved formulations List

➢ In case of any amendment, applicant can send message to officials by clicking on reply to official as shown in figure.

Figure 45 Communication from Applicant to Official

➢ Once the applicant clicks on Reply to Official a modal will open as shown in below figure. The applicant can write the message here and sends the message to official by clicking clicks ‘ok’ button.

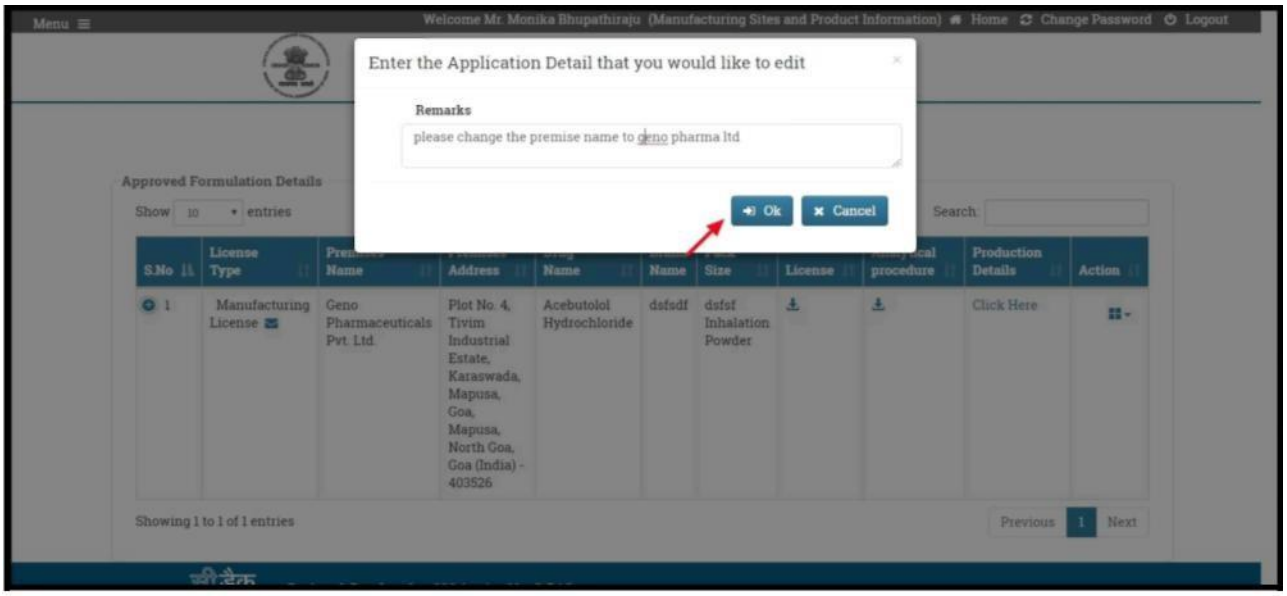

Figure 46 : Remarks Box

➢ Once user clicks ‘ok’ a confirm box will open as shown in figure and when applicant clicks ‘ok’ , the same message will appear to official against the particular application and official can take the action on it.

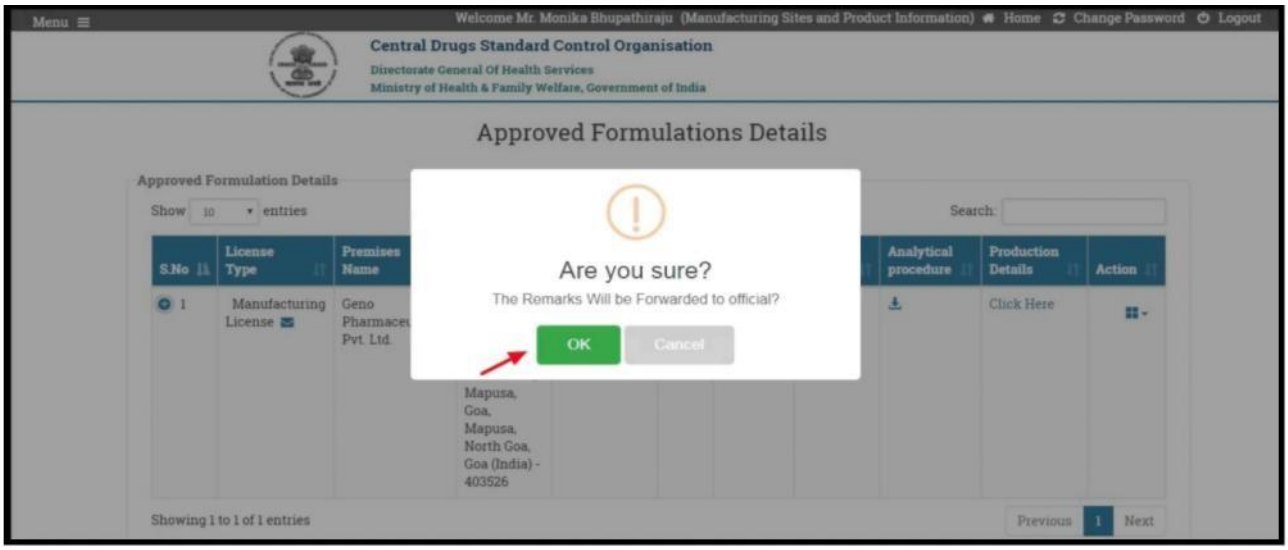

Figure 47 : Confirmation Box

Annexure

❖ List of Figure