



# Central Drug Standard Control Organization (CDSCO)

## Guideline Document

For

## Uploading Manufacturing Sites And Formulation Data

Version 1.0

Release Date: 9/7/2018

### 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

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.cdsonline.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 .

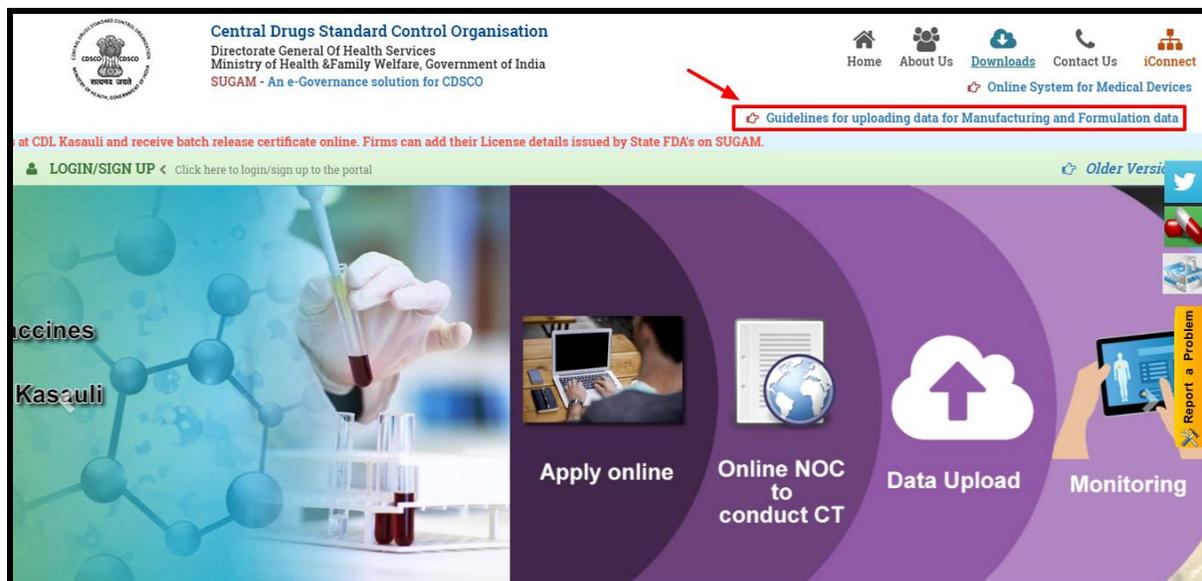
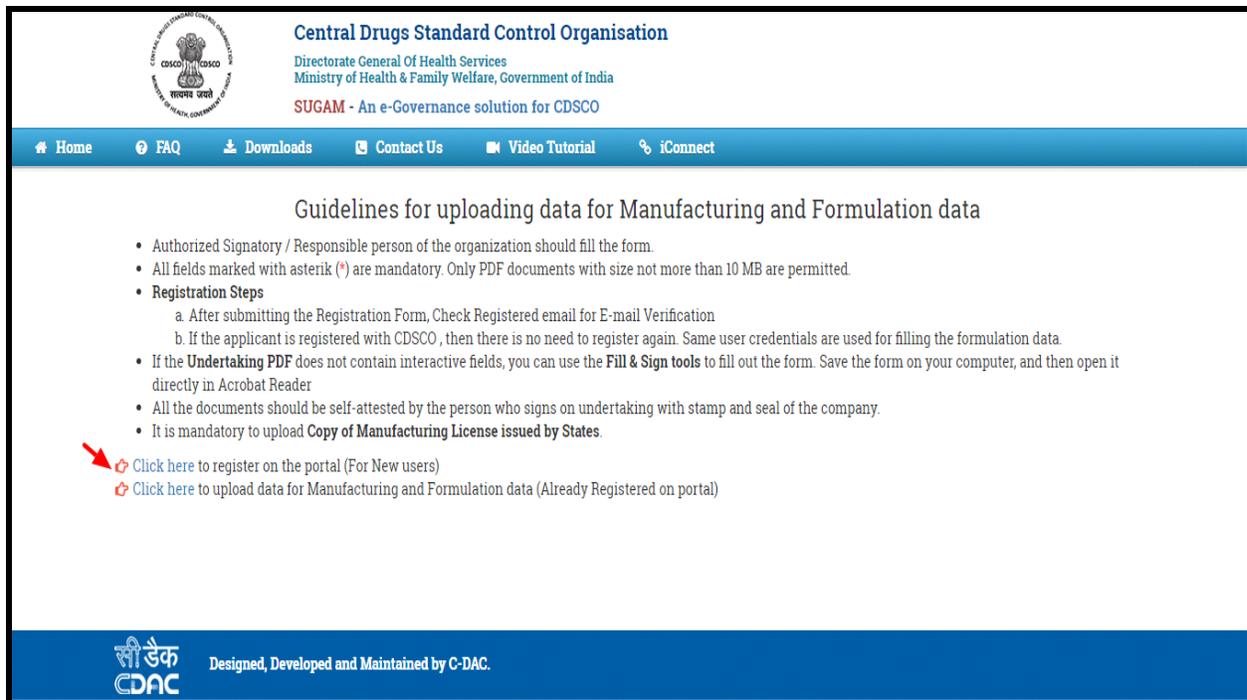


Figure 1 : Homepage

- 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.



The screenshot shows the SUGAM portal interface. At the top, there is a header with the Central Drugs Standard Control Organisation (CDSCO) logo and name, along with the Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India. Below this is a navigation bar with links for Home, FAQ, Downloads, Contact Us, Video Tutorial, and iConnect. The main content area is titled "Guidelines for uploading data for Manufacturing and Formulation data" and contains a list of instructions. A red arrow points to the link "Click here to register on the portal (For New users)".

**Central Drugs Standard Control Organisation**  
Directorate General Of Health Services  
Ministry of Health & Family Welfare, Government of India  
SUGAM - An e-Governance solution for CDSCO

Home | FAQ | Downloads | Contact Us | Video Tutorial | iConnect

### Guidelines for uploading data for Manufacturing and Formulation data

- Authorized Signatory / Responsible person of the organization should fill the form.
- All fields marked with asterik (\*) are mandatory. Only PDF documents with size not more than 10 MB are permitted.
- **Registration Steps**
  - a. After submitting the Registration Form, Check Registered email for E-mail Verification
  - b. If the applicant is registered with CDSCO, then there is no need to register again. Same user credentials are used for filling the formulation data.
- If the **Undertaking PDF** does not contain interactive fields, you can use the **Fill & Sign tools** to fill out the form. Save the form on your computer, and then open it directly in Acrobat Reader
- All the documents should be self-attested by the person who signs on undertaking with stamp and seal of the company.
- It is mandatory to upload **Copy of Manufacturing License issued by States**.

[Click here to register on the portal \(For New users\)](#)  
[Click here to upload data for Manufacturing and Formulation data \(Already Registered on portal\)](#)

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**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.

## Applicant Registration

Regi  
Guid

**Note:**

1. Authorized Signatory / Responsible person of the organization should fill the form.
2. All fields marked with asterisk (\*) are mandatory. Only PDF documents with size not more than 10 MB are permitted.
3. **Registration Steps**
  - a. After submitting the Registration Form, Check Registered email for E-mail Verification
  - b. If the applicant is registered with CDSCO, then there is no need to register again. Same user credentials are used for filling the formulation data.
4. If the **Undertaking PDF** does not contain interactive fields, you can use the **Fill & Sign tools** to fill out the form. Save the form on your computer, and then open directly in Acrobat Reader
5. All the documents should be self-attested by the person who signs on undertaking with stamp and seal of the company.
6. It is mandatory to upload **Copy of Manufacturing License issued by States**.

### Applicant Details

**Applicant Type:\*** Manufacturing Sites and Product Information / Applicant for COPP and GMP

**User-Name:\***

**Password:\***   
Only Best Passwords are accepted

**Confirm Password:\***   
Only Best Passwords are accepted

**Name:\*** Mr.

**Mobile Number:\*** I am Authorized person on behalf of firm to register and for uploading data

**Gender:\***  Male  Female

**Nationality:\***

**ID Proof Details:\*** (Single PDF < 10 MB)  
  No file selected.

If identity proof is other than Aadhar card, then Applicants are required to upload their Aadhar details in SUGAM Portal within 2 months of obtaining Login Credentials.

**Undertaking:\*** (Single PDF < 10 MB)  
 No file selected. [Download, Fill and Sign this Undertaking PDF Template and Upload the same here \(Undertaking\) - Available in Enterable PDF Format](#)

**Designation:\***

**Alternate Email ID:**

**Manufacturing Sites**

**Are you Member with Any Association**

### Corporate / Registered Office Address (If Corporate / Registered Address is same as Manufacturing Site Address then mention Manufacturing Site Address)

**Organization Name:\***

**Organization Type:\***

**CIN (Corporate Identification Number):**

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

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

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

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

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

**Upload Your Corporate Address Proof Details (Certificate of Incorporation):\*** (Single PDF < 10 MB)  
 No file selected.

It is mandatory to upload Copy of Manufacturing License

**Copy of Manufacturing License :\*** (Single PDP < 10 MB)  
 No file selected.

Please tick (✓) this option if you want to receive SMS alerts.  
6KZX0

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

**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

The screenshot displays a registration form with two main sections:

- Applicant Details:** Includes fields for Applicant Type (Manufacturing Sites and Product Information / Applicant for COPP and CMP), User-Name (monika@cdac.in), Password, Confirm Password, Name (Mr. Monika Choudhary), Mobile Number (9434343433), Gender (Female), Nationality (Indian), ID Proof Details (Aadhar Card), Undertaking (downloaded PDF), Designation (test), and Alternate Email ID (monika.chy9@gmail.com).
- Manufacturing Sites:** A dropdown menu with options: Own Site, Loan Site, and Loan Site. A red arrow points to this section.
- Corporate / Registered Office Address:** Includes fields for Organization Name (Tescan), Organization Type (Trust), CIN (302000202), Address Line 1 (Salind), Address Line 2 (Salind), Country (India), State (Haryana), District (Rohtak), City/Taluka/Mandal/Talati (Dinda), Pin Code (202002), Contact No., and Fax No.

**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.

## Applicant Registration

Registration Guidelines

**Note:**

1. Authorized Signatory / Responsible person of the organization should fill the form.
2. All fields marked with asterik (\*) are mandatory. Only PDF documents with size not more than 10 MB are permitted.
3. Registration Steps
  - a. After submitting the Registration Form, Check Registered email for E-mail Verification
  - b. If the applicant is registered with CDSCO, then there is no need to register again. Same user credentials are used for filling the formulation data
4. If the **Undertaking PDF** does not contain interactive fields, you can use the **Fill & Sign tools** to fill out the form. Save the form on your computer, and then open it directly in Acrobat Reader
5. All the documents should be self-attested by the person who signs on undertaking with stamp and seal of the company.
6. It is mandatory to upload **Copy of Manufacturing License issued by States**.

### Applicant Details

**Applicant Type:\*** Manufacturing Sites and Product Information / Applicant for COPP and GMP

**User-Name:\***  ✓

**Password:\***  ✓  
Only Best Passwords are accepted

**Confirm Password:\***  ✓  
Only Best Passwords are accepted

**Name:\***   ✓

I am Authorized person on behalf of firm to register and for uploading data

**Mobile Number:\***  ✓

**Gender:\***  Male  Female

**Nationality:\***

**ID Proof Details:\***  ✓   ✓  
(Single PDF < 10 MB) Remove

If identity proof is other than Aadhar card, then Applicants are required to upload their Aadhar details in SUGAM Portal within 2 months of obtaining Login Credentials.

**Undertaking:\***     ✓  
(Single PDF < 10 MB)

**Designation:\***  ✓

**Alternate Email ID:**  ✓

**Manufacturing Sites**  ✓

**Are you Member with Any Association**  ✓

**Association Name**  ✓

### Corporate / Registered Office Address

(If Corporate / Registered Address is same as Manufacturing Site Address then mention Manufacturing Site Address)

**Organization Name:\***  ✓

**Organization Type:\***  ✓

**CIN (Corporate Identification Number):**  ✓

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

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

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

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

**Upload Your Corporate Address Proof Details (Certificate of Incorporation):\***

It is mandatory to upload Copy of Manufacturing License

**Copy of Manufacturing License:\***   (Single PDF < 10 MB)

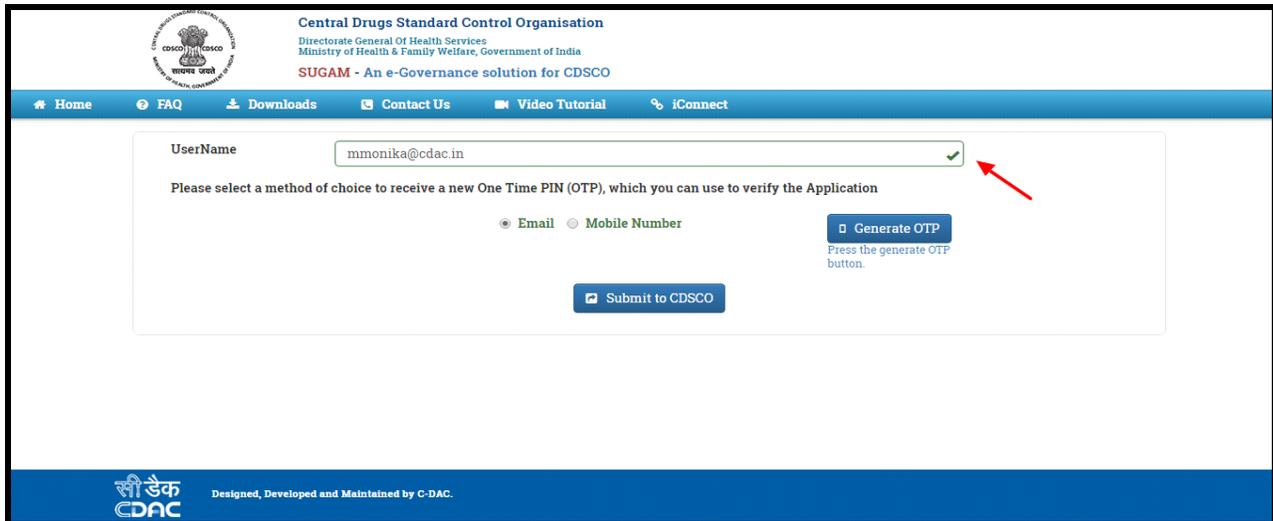
Please tick (✓) this option if you want to receive SMS alerts.

**6KZX0**

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

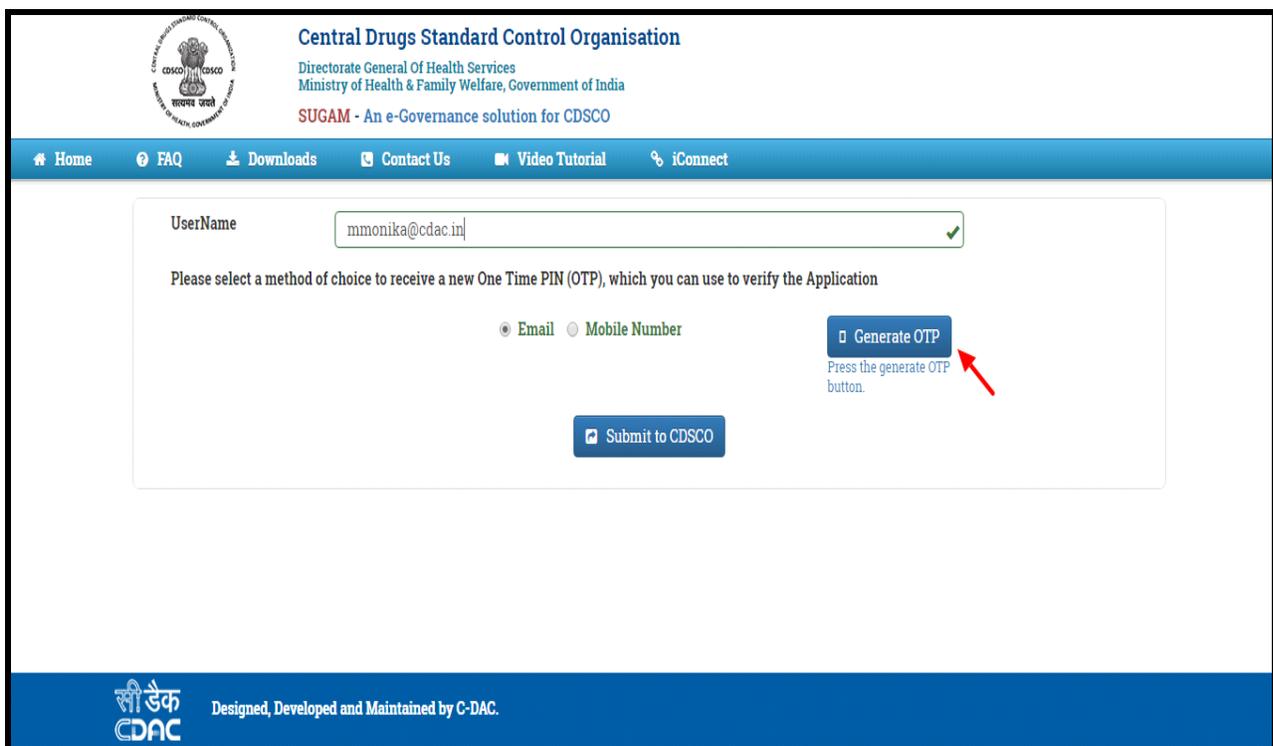
**Figure 5 : Filled Application**

- 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.

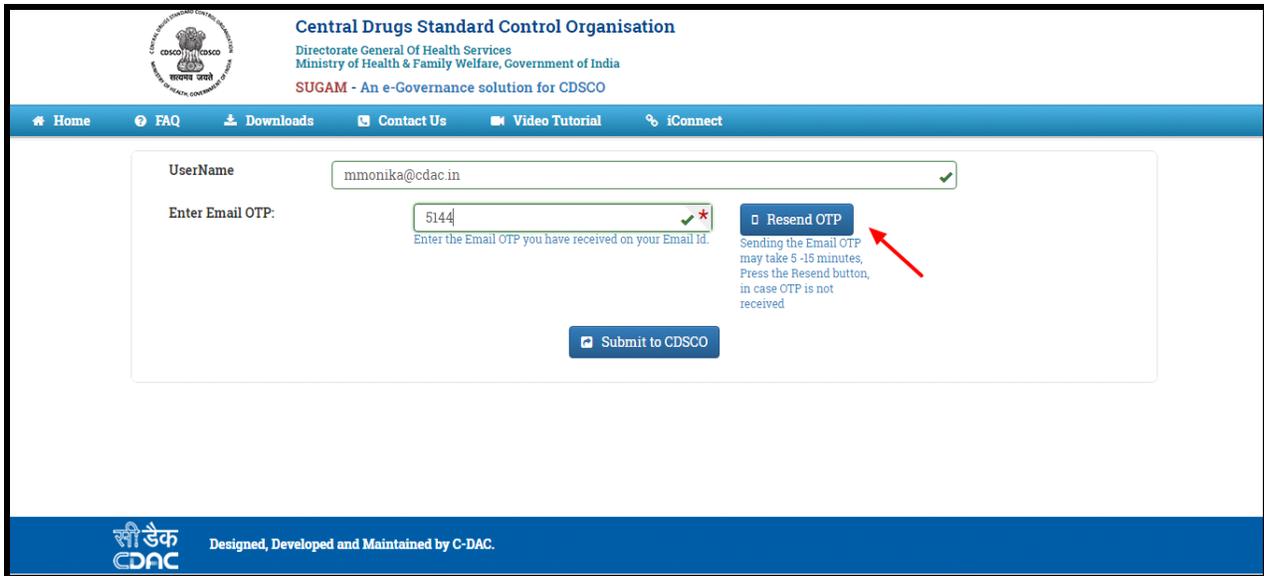


Figure 8 : Resend OTP

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

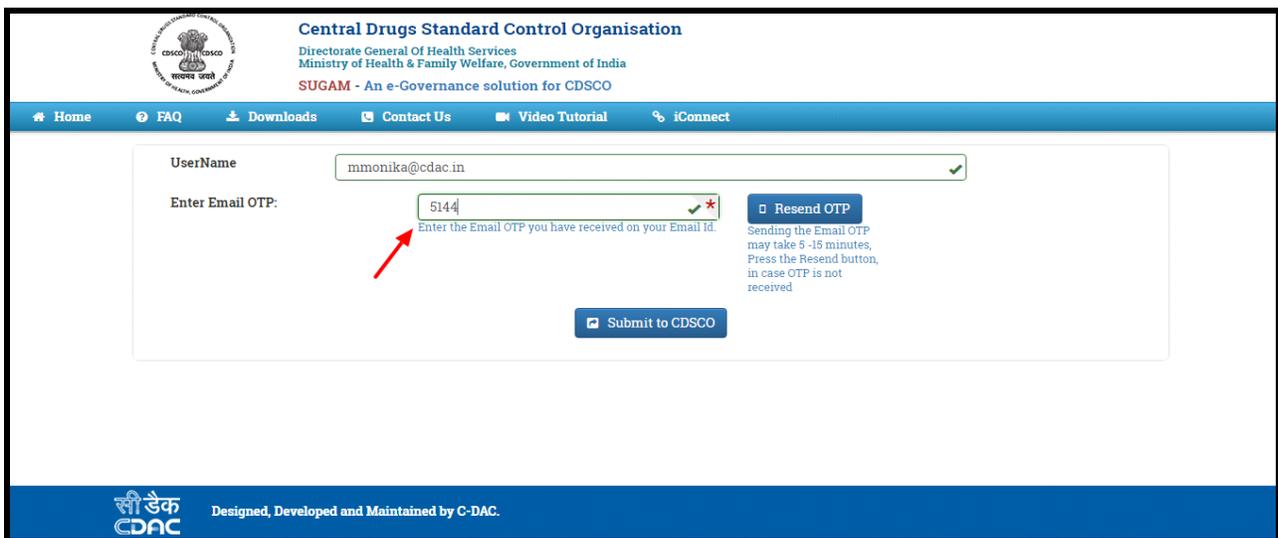
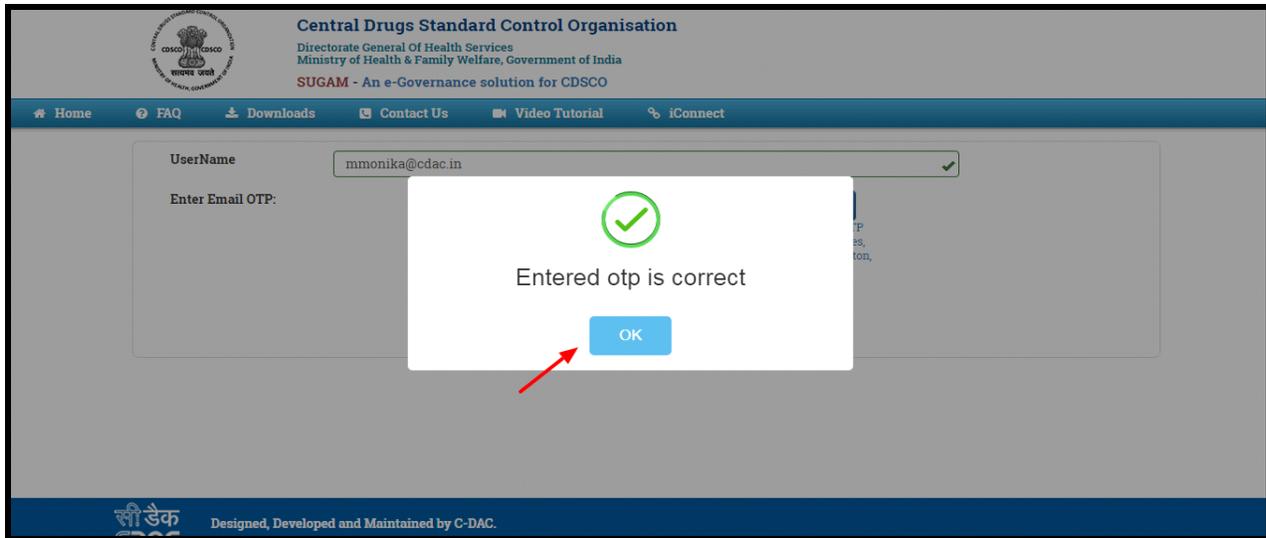


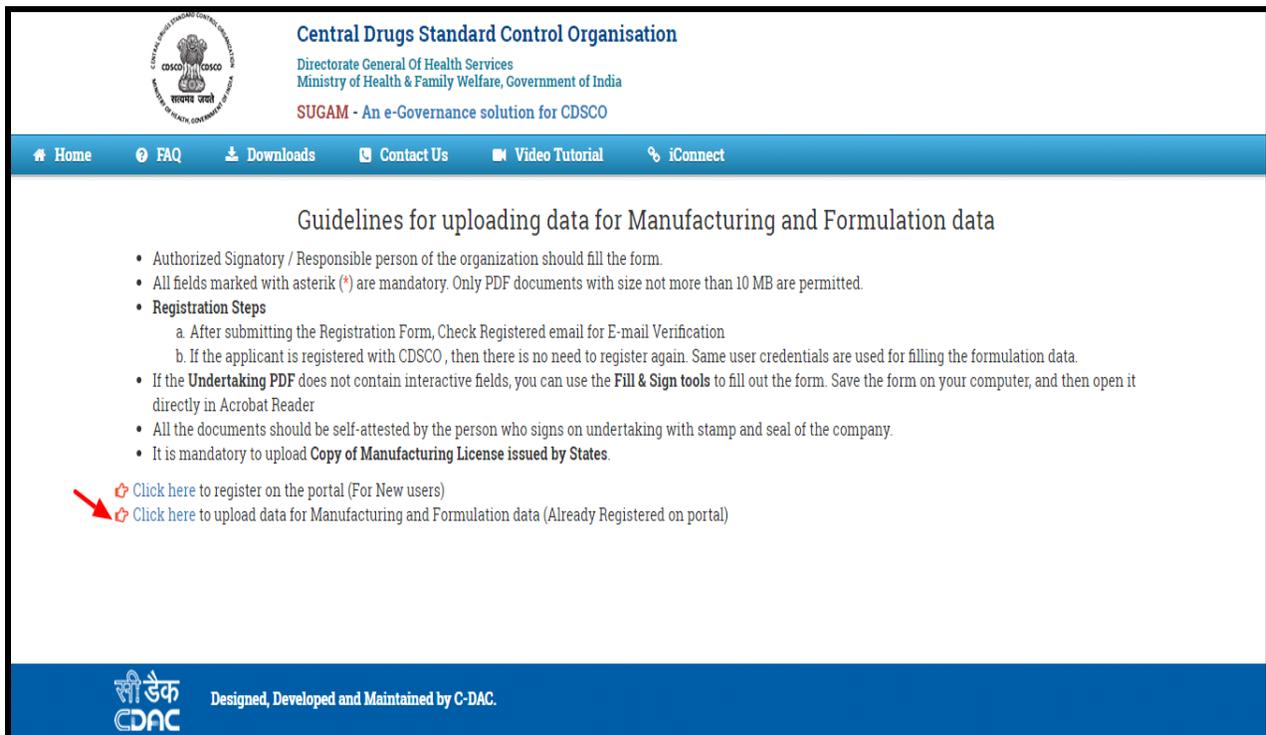
Figure 9 : OTP Submission

- 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://cdsconline.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 re-directed to homepage.



**Figure 11 : Already Registered**

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

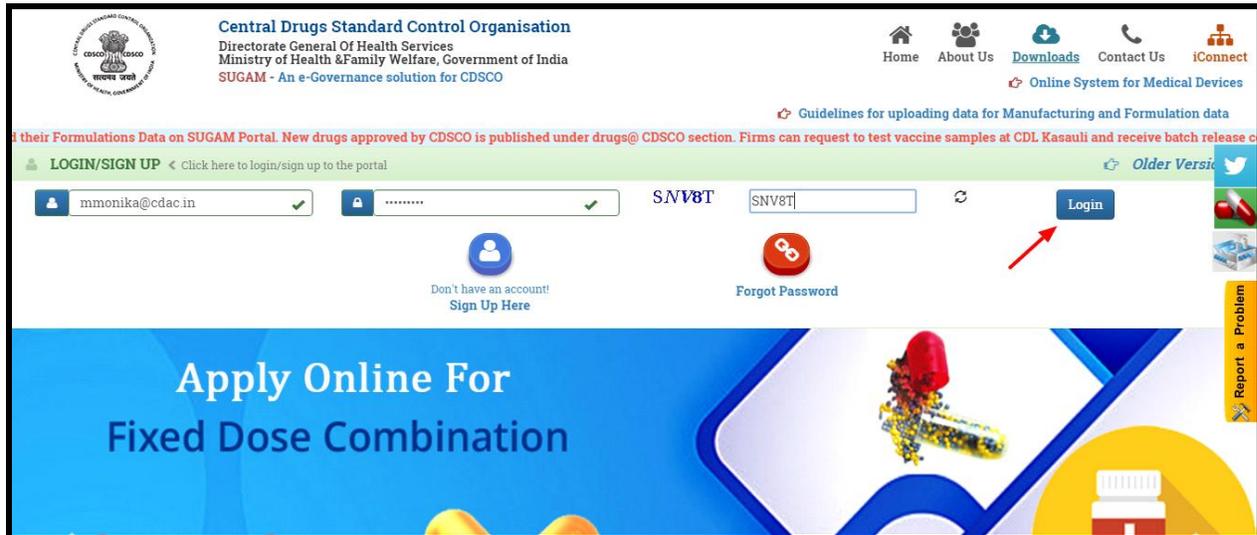


Figure 12 : Login

- 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.
- **Loan Site**
  - 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.

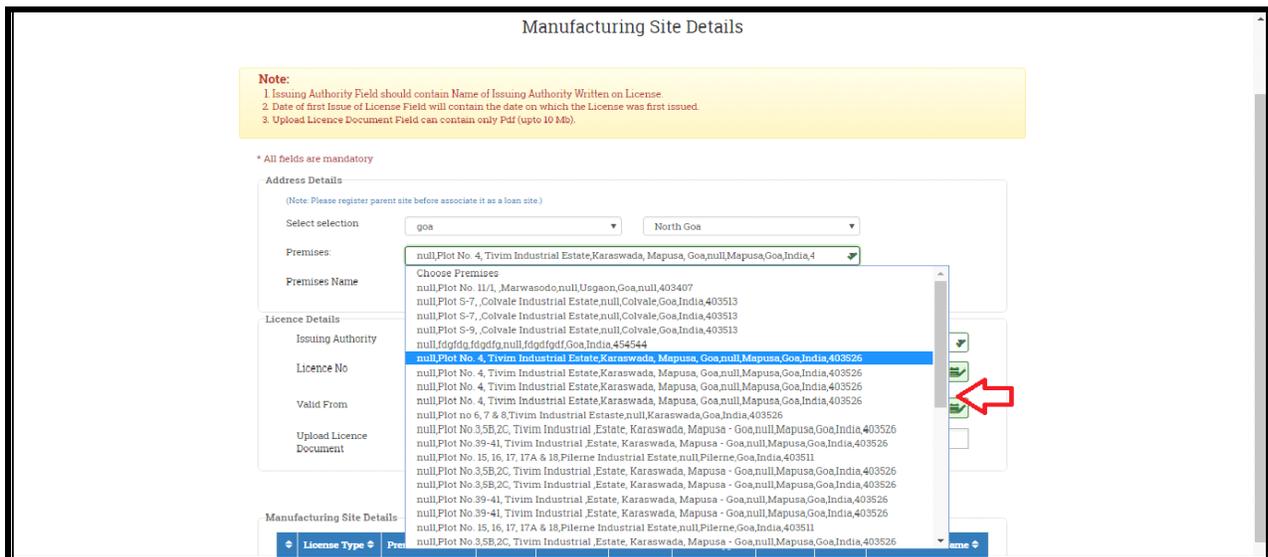


Figure 15 : Manufacturing Premises

- 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.

The screenshot displays a web form for license application. A dropdown menu for 'Issuing Authority' is open, listing states like Andhra Pradesh, Goa, Uttarakhand, Jammu And Kashmir, Bihar, Jharkhand, West Bengal, Orissa, Madhya Pradesh, Chhattishgarh (highlighted), Gujarat, Maharashtra, Tamil Nadu, Assam, and Manipur. A red arrow points to 'Chhattishgarh Licensing Authority'. The form includes sections for 'Address Details' (with a note to register parents), 'Licence Details' (with fields for Issuing Authority, Licence No, Valid From, Valid Upto, and Upload Licence Document), and other fields like 'Form No', 'Date of First Issue of Licence', 'Valid Upto', and 'Certificate Held'. A 'Save Details' button is at the bottom.

**Figure 16 : Issuing Authority**

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

Menu Welcome Mr. Monika Bhupathiraju (Manufacturing Sites and Product Information) [Home](#) [Change Password](#) [Logout](#)

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

### Manufacturing Site Details

**Note:**

1. Issuing Authority Field should contain Name of Issuing Authority Written on License.
2. Date of first Issue of License Field will contain the date on which the License was first issued.
3. Upload Licence Document Field can contain only Pdf (upto 10 Mb).

**\* All fields are mandatory**

**Address Details**

(Note: Please register parent site before associate it as a loan site.)

Select selection: goa (dropdown) North Goa (dropdown)

Premises: null,Plot No. 11/1, ,Marwasodo,null,Usgaon,Goa,null,403407

Premises Name: Test

**Licence Details**

Issuing Authority: Chhattishgarh Licensing Autorit' ✓ Form No: Form 25A ✓

Licence No: tester-01 ✓ Date of First Issue of Licence: 07/08/2018 ✓

Valid From: 07/17/2018 ✓ Valid Upto: 07/17/2018 ✓

Upload Licence Document: Browse... Licence Details.pdf ✓ Certificate Held: \* Andorra

**Save Details**

**Manufacturing Site Details**

License Type	Premises Name	Address	License No	Remarks	License Type	Licence	Status	Loan Premises Name
No Records Found								

**Figure 17 : Filled details**

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

**Note:**

1. Issuing Authority Field should contain Name of Issuing Authority Written on License.
2. Date of first Issue of License Field will contain the date on which the License was first issued.
3. Upload Licence Document Field can contain only Pdf (upto 10 Mb).

**\* All fields are mandatory**

**Address Details**

(Note: Please register parent site before associate it as a loan site.)

Select selection: goa (dropdown) North Goa (dropdown)

Premises: null,Plot No. 4, Tivim Industrial Estate,Karaszada, Mapusa, Goa,null,Mapusa,Goa,India,4

Premises Name: Test

**Licence Details**

Issuing Authority: Andhra ✓ Form No: Form 28A ✓

Licence No: test-123 ✓ Date of First Issue of Licence: 02/2018 ✓

Valid From: 07/05/2018 ✓ Valid Upto: 09/2018 ✓

Upload Licence Document: Choose file c62a394f-0...45.pdf ✓ Certificate Held: \* Albania \* American Samoa

**Are you sure?**

Are you sure you want to Submit Site details to State FDA, as after this you won't be able to modify form

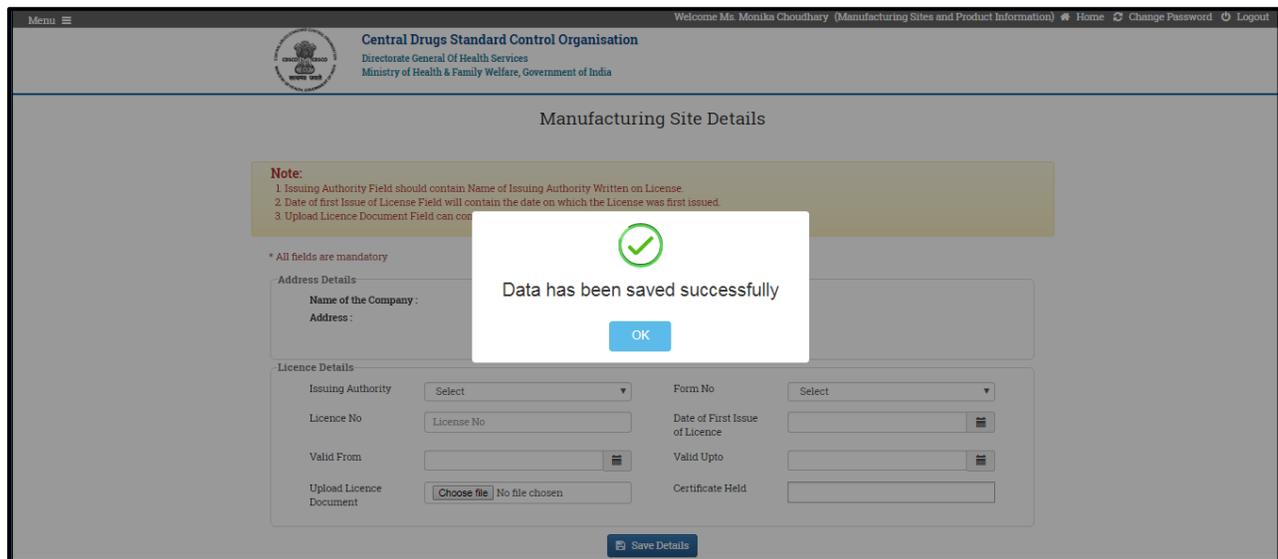
**Save Details**

**Manufacturing Site Details**

License Type	Premises Name	Address	License No	Remarks	License Type	Licence	Status	Loan Premises Name
No Records Found								

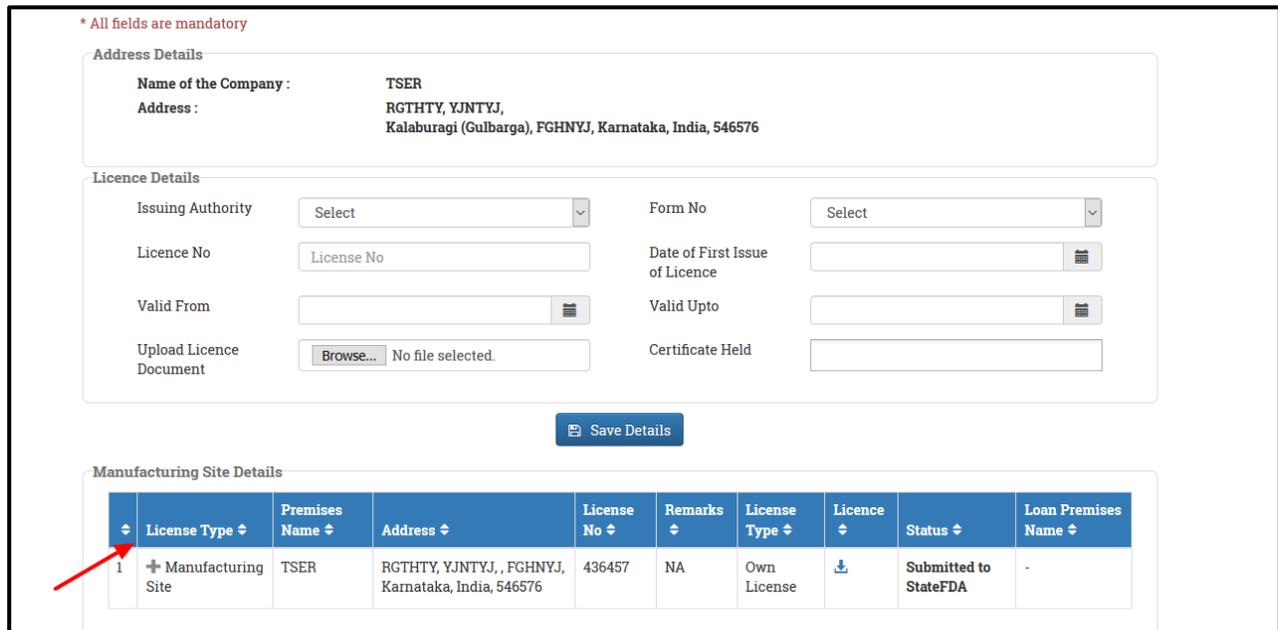
**Figure 18 : Confirmation form to submit Application**

- 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**

➤ **Own Site**

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

Menu Welcome Mr. Monika Bhupathiraju (Manufacturing Sites and Product Information) Home Change Password Logout

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

### Manufacturing Site Details

**Note:**

1. Issuing Authority Field should contain Name of Issuing Authority Written on License.
2. Date of first Issue of License Field will contain the date on which the License was first issued.
3. Upload Licence Document Field can contain only Pdf (upto 10 Mb).

\* All fields are mandatory

**Address Details**

Unit Name	<input type="text" value="tester"/>	Unit No.	<input type="text" value="testing01"/>
Address Line 1	<input type="text" value="tester site"/>	Address Line 2	<input type="text" value="tester site 2"/>
State	<input type="text" value="goa"/>	District	<input type="text" value="North Goa"/>
Taluka/Mandal /Tahsil	<input type="text" value="district"/>	Village/Town/City	<input type="text" value="test"/>
Pin Code	<input type="text" value="343333"/>	E-mail Id	<input type="text" value="test@gmail.com"/>
Contact No.	<input type="text" value="+91 4554545454"/>	Fax No.	<input type="text" value="+91 4444444444"/>

(Please include STD Code - Phone Number and Multiple Contact Numbers can be added with comma separation.)

**Licence Details**

Issuing Authority	<input type="text" value="Tamil Nadu Licensing Authority"/>	Form No	<input type="text" value="Form 32"/>
Licence No	<input type="text" value="test"/>	Date of First Issue of Licence	<input type="text" value="07/04/2018"/>
Valid From	<input type="text" value="07/08/2018"/>	Valid Upto	<input type="text" value="07/26/2018"/>
Upload Licence Document	<input type="button" value="Browse..."/> c82a394f-036a-41_14422fa4	Certificate Held	<input type="text" value="American Samoa"/>

**Manufacturing Site Details**

License Type	Premises Name	Address	License No	Remarks	License Type	Licence	Status	Loan Premises Name
No Records Found								

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**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.

Menu Welcome Mr. Monika Bhupathiraju (Manufacturing Sites and Product Information) Home Change Password Logout



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

### Manufacturing Site Details

**Note:**

1. Issuing Authority Field should contain Name of Issuing Authority Written on License.
2. Date of first Issue of License Field will contain the date on which the License was first issued.
3. Upload Licence Document Field can contain only Pdf (upto 10 Mb).

**\* All fields are mandatory**

**Address Details**

Unit Name: <input style="width: 90%;" type="text" value="tester"/>	Unit No.: <input style="width: 90%;" type="text" value="testing01"/>
Address Line 1: <input style="width: 90%;" type="text" value="tester site"/>	Address Line 2: <input style="width: 90%;" type="text" value="tester site 2"/>
State: <input style="width: 90%;" type="text" value="goa"/>	District: <input style="width: 90%;" type="text" value="North Goa"/>
Taluka/Mandal /Tahsil: <input style="width: 90%;" type="text" value="district"/>	Village/Town/City: <input style="width: 90%;" type="text" value="test"/>
Pin Code: <input style="width: 90%;" type="text" value="343333"/>	E-mail Id: <input style="width: 90%;" type="text" value="test@gmail.com"/>
Contact No.: <input style="width: 90%;" type="text" value="+91 45545454544"/>	Fax No.: <input style="width: 90%;" type="text" value="+91 44444444444"/>

(Please include STD Code - Phone Number and Multiple Contact Numbers can be added with comma separation)

**Licence Details**

Issuing Authority: <input style="width: 90%;" type="text" value="Tamil Nadu Licensing Authority"/>	Form No.: <input style="width: 90%;" type="text" value="Form 32"/>
Licence No.: <input style="width: 90%;" type="text" value="test"/>	Date of First Issue of Licence: <input style="width: 90%;" type="text" value="07/04/2018"/>
Valid From: <input style="width: 90%;" type="text" value="07/08/2018"/>	Valid Upto: <input style="width: 90%;" type="text" value="07/26/2018"/>
Upload Licence Document: <input type="button" value="Browse..."/> c82a394f-036a-41..14422fa	Certificate Held: <input style="width: 90%;" type="text" value="American Samoa"/>

**Manufacturing Site Details**

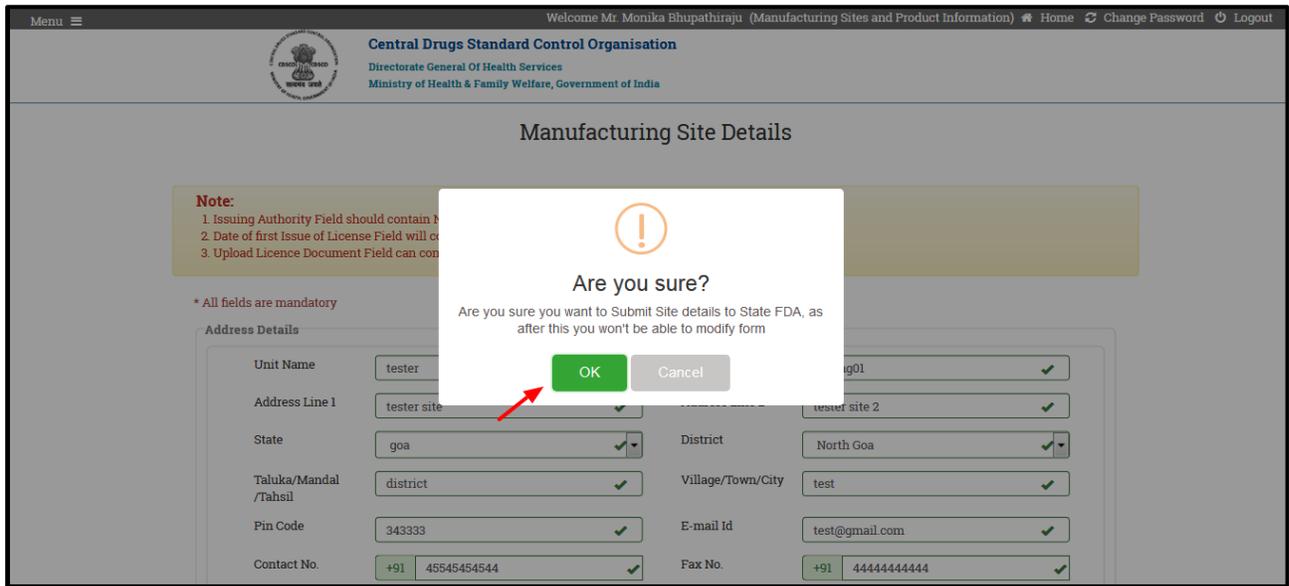
License Type	Premises Name	Address	License No	Remarks	License Type	Licence	Status	Loan Premises Name
No Records Found								



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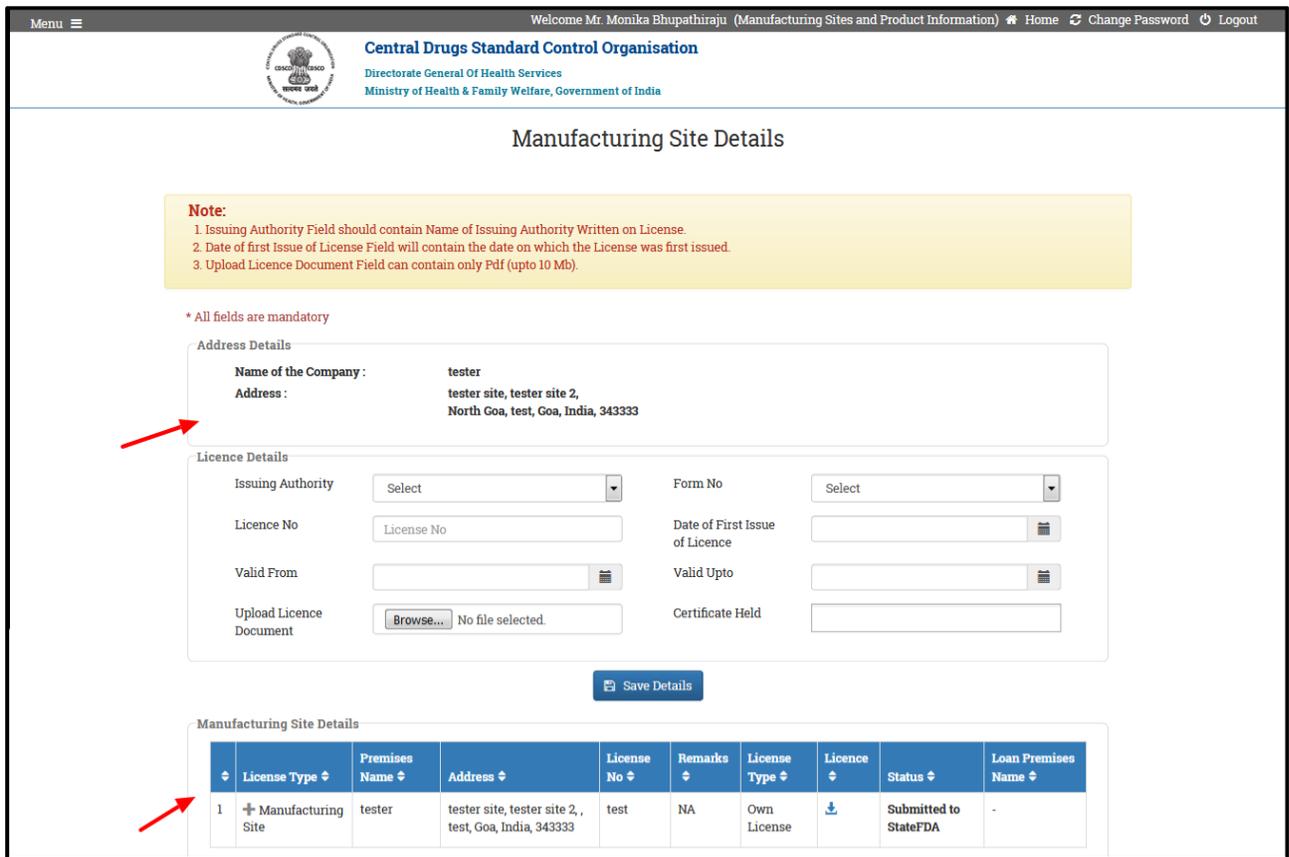
**Figure 22 : Fill Details**

- 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.

### Manufacturing Site Details

**Note:**

1. Issuing Authority Field should contain Name of Issuing Authority Written on License.
2. Date of first Issue of License Field will contain the date on which the License was first issued.
3. Upload Licence Document Field can contain only Pdf (upto 10 Mb).

*\* All fields are mandatory*

**Address Details**

**Name of the Company :** TSER

**Address :** RGTHTY, YJNTYJ,  
Kalaburagi (Gulbarga), FGHNYJ, Karnataka, India, 546576

**Licence Details**

Issuing Authority	<input type="text" value="Select"/>	Form No	<input type="text" value="Select"/>
Licence No	<input type="text" value="License No"/>	Date of First Issue of Licence	<input type="text"/>
Valid From	<input type="text"/>	Valid Upto	<input type="text"/>
Upload Licence Document	<input type="button" value="Browse..."/> No file selected.	Certificate Held	<input type="text"/>

**Manufacturing Site Details**

License Type	Premises Name	Address	License No	Remarks	License Type	Licence	Status	Loan Premises Name
1 + Manufacturing Site	TSER	RGTHTY, YJNTYJ, FGHNYJ, Karnataka, India, 546576	436457	NA	Own License		Submitted to StateFDA	-

**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.

The screenshot shows the 'Manufacturing Formulation Details' form. At the top, there is a 'Note' box stating: '1. In case of FDC, Generic Name is automatically generated as concatenation of Ingredient Name plus Dosage Form.' Below this, the 'Manufacturing Unit' is set to 'Plot No. 4, Tivim Industrial Estate, Karaswada, Mapusa, Goa, North Goa, Mapusa, Go'. The 'Select Licenses:' dropdown menu is open, showing a list of licenses with 'test-123' selected. A red arrow points to this dropdown. Other fields include 'Drug Type' (Single Ingredient), 'Brand Name' (tester), 'Dosage form' (Creams), 'Pharmacological classification of Drug' (Antidiabetic), 'Pack Presentation' (Pack Size: 12, Inhalation Powder), and 'Ingredients Details' (Category: Active, Ingredient: Nicotine Polacriflex 15 Percent, Strength: 21 ug/sq cm). There is an 'Add More Ingredients' button at the bottom of the ingredients section.

**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.

This screenshot shows the same 'Manufacturing Formulation Details' form, but with more data entered. The 'Select Licenses:' dropdown now shows 'test-123' with the subtext 'The Products approved under this License Number are to be entered here.' The 'Drug Details' section is filled: 'Drug Type' is 'Single Ingredient', 'Generic name' is 'Aceclofenac', 'Brand Name' is 'tester', and 'Pharmacological classification of Drug' is 'Antidiabetic'. The 'Indication' section has one entry: 'ttttt'. The 'Pack Presentation' section has 'Pack Size' as '12' and 'Inhalation Powder'. The 'Ingredients Details' section has 'Category' as 'Active', 'Ingredient' as 'Nicotine Polacriflex 15 Percent', and 'Strength' as '21 ug/sq cm'. A red arrow points to the 'Add More Ingredients' button at the bottom of the ingredients section.

**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.

### Formulation Details

**Note:**  
1. In case of FDC , Generic Name is automatically generated as concatenation of Ingredient Name plus Dosage Form.

**Manufacturing Unit :** RCTHTY, YJNTYJ, Kalaburagi (Gulbarga), FGHNYJ, Karnataka, India, 546576

**Select Licenses :** 436457  
The Products approved under this License Number are to be entered here.

**Drug Details**

Drug Type: Single Ingredient ✓

Generic name: Acarbose ✓

Dosage form: Blood & Blood Products (Lyophilize) ✓

Brand Name (Optional):

Pharmacological classification of Drug (Optional): Anthelmintics

Indication for which proposed to be used (Optional):  +

**Pack Presentation**

Pack Size: 23 ✓

Blood & Blood Products (Liquid) ✓

**Ingredients Details**

Category: Select Category ✓

Pharmacological Monograph: Select pharmacopia ✓

Ingredient:

Strength:  ✓

Select Unit:  ✓

+ Add More Ingredients

**Added Ingredients**

Ingredient name ↕	Category ↕	Pharmacopial Monograph ↕	Strength ↕	Claim label ↕	Delete ↕
	Color	Any Other Pharmacopia	3 Volume/Volume(V/v)	yes	✖

**Upload Document**

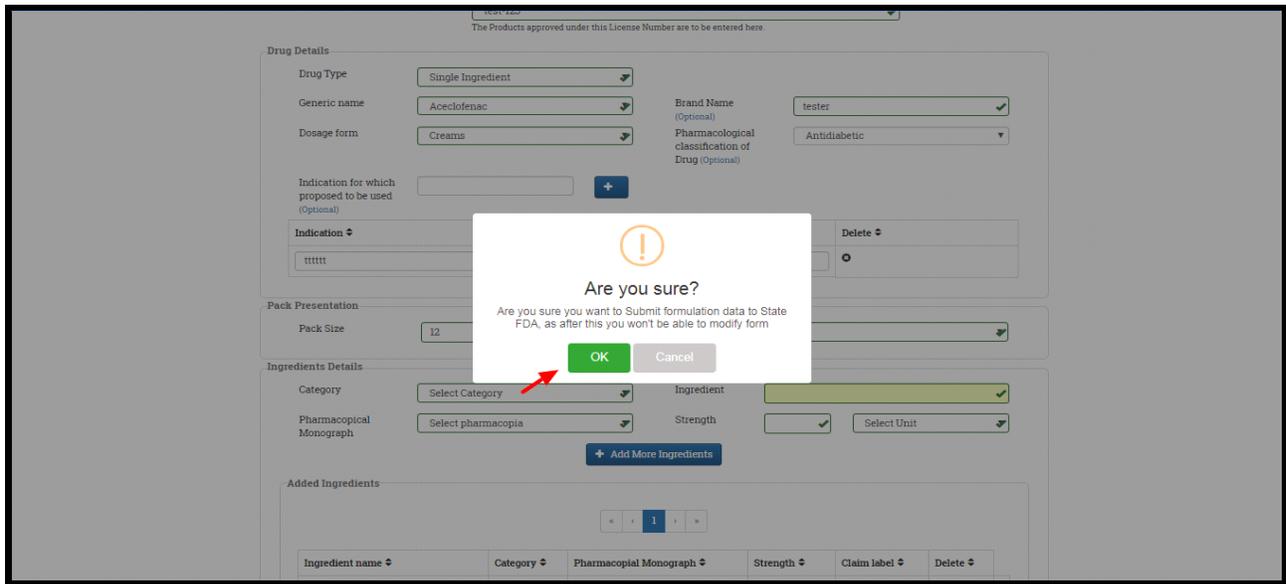
License document for given Product:  Amendment\_Letter\_6755.pdf ✓

Copy of Analytical procedure:  Amendment\_Letter\_6755.pdf ✓

Save Details

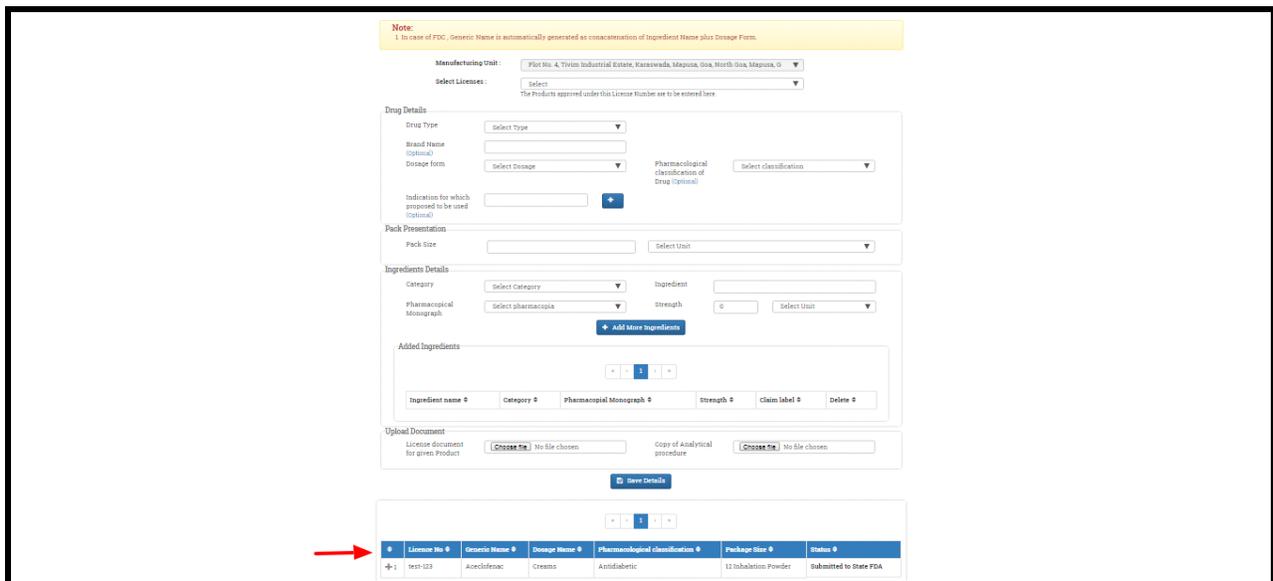
**Figure 30 : Submit Application**

- 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.

The screenshot shows the 'Add Production Details (For Formulations)' form. It includes a note: '\* All fields are mandatory'. The form has three main sections:
 

- Manufacturing Unit:** A dropdown menu showing ',RGTHTY, YJNTYJ, Kalaburagi (Gulbarga), FGHNYJ, Karnataka, India, 546576'. A red arrow points to this dropdown.
- Select Licenses:** A dropdown menu with 'Select' as the current value.
- Select API / Formulation:** A dropdown menu with 'Choose Drug' as the current value.

 Below these is a 'Production Details' section with several input fields:
 

- Select Quarter:** A dropdown menu with 'Select' as the current value.
- Year:** A dropdown menu.
- Quantity:** A text input field.
- Choose unit:** A dropdown menu.
- Pack Size:** A text input field.
- Choose Pack ur:** A dropdown menu.
- MRP (Optional):** A text input field.
- Batch No:** A text input field.

 At the bottom of the form is a 'Save Details' button.

**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.

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

### Add Production Details (For Formulations)

\* All fields are mandatory

Manufacturing Unit:

Select Licenses:

Select API / Formulation:

Production Details

Select Quarter:  Year:  Quantity:  Choose unit:

Pack Size:  Choose Pack u:  MRP (Optional):

Batch No:

License No	Drug Name	Quarter	Quantity	Pack Size	Batch No	MRP
------------	-----------	---------	----------	-----------	----------	-----

**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.

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

### Add Production Details (For Formulations)

\* All fields are mandatory

Manufacturing Unit:

Select Licenses:

Select API / Formulation:

Production Details

Select Quarter:  Year:  Quantity:  Choose unit:

Pack Size:  Choose Pack u:  MRP (Optional):

Batch No:

License No	Drug Name	Quarter	Quantity	Pack Size	Batch No	MRP
------------	-----------	---------	----------	-----------	----------	-----

**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.

Licence No	Drug Name	Quarter	Quantity	Pack Size	Batch No	MRP
test-123	Aceclofenac	Jan-Mar 2016	12 Concentrate solution for infusion	12 mm	3248	test1

**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.

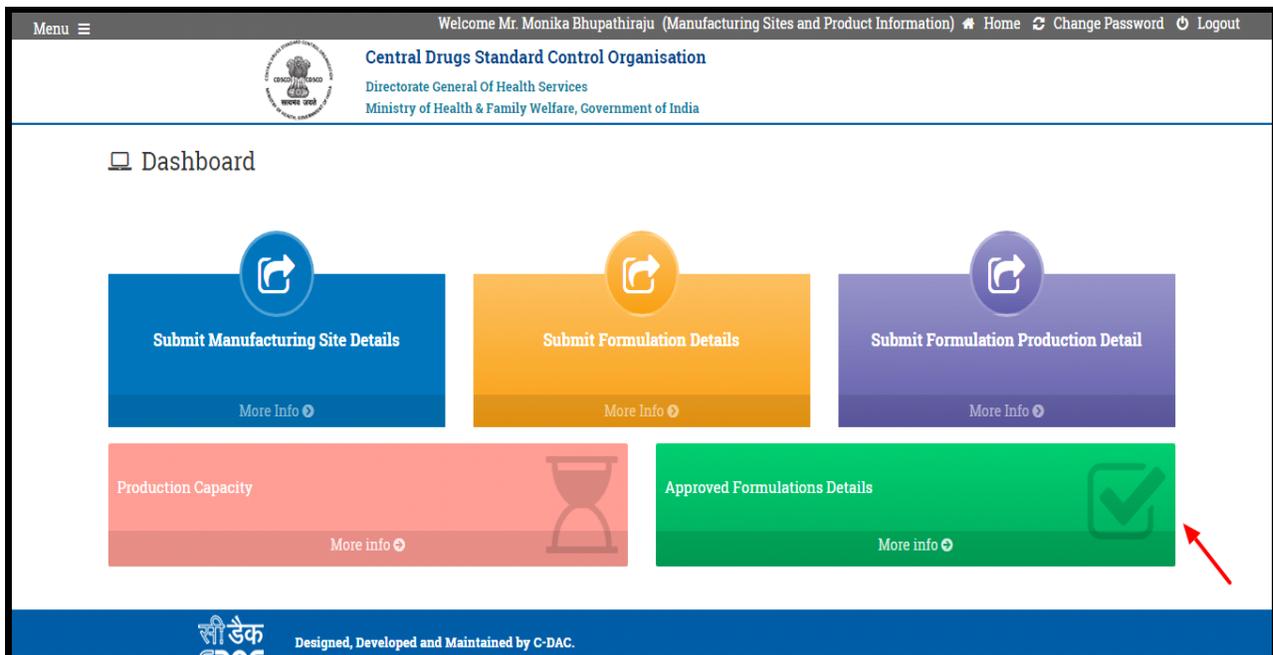
**Figure 41 : Submit Application**

- 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 figure:s



**Figure 43 : Approved Formulation Details**

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

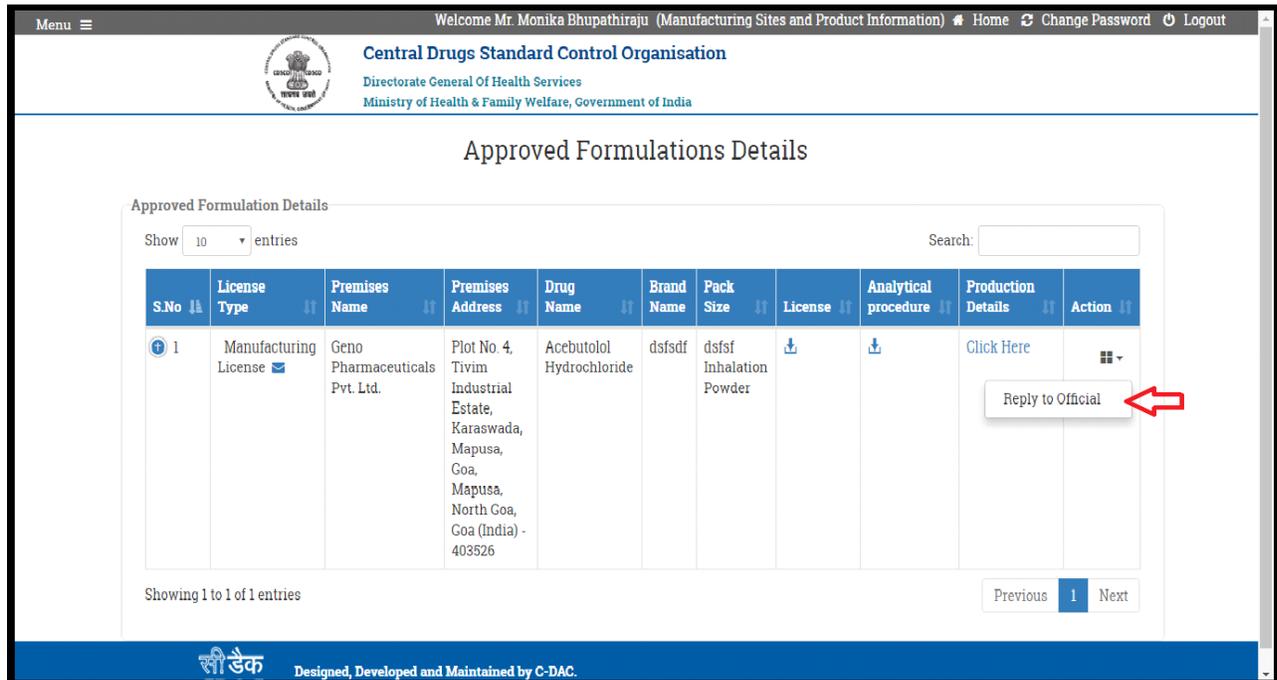
The table displays the following data:

S.No	License Type	Premises Name	Premises Address	Drug Name	Brand Name	Pack Size	License	Analytical procedure	Production Details	Action
1	Manufacturing License	Geno Pharmaceuticals Pvt. Ltd.	Plot No. 4, Tivim Industrial Estate, Karaswada, Mapusa, Goa, Mapusa, North Goa, Goa (India) - 403526	Acebutolol Hydrochloride	dsfsdf	dsfsf Inhalation Powder			Click Here	

Showing 1 to 1 of 1 entries

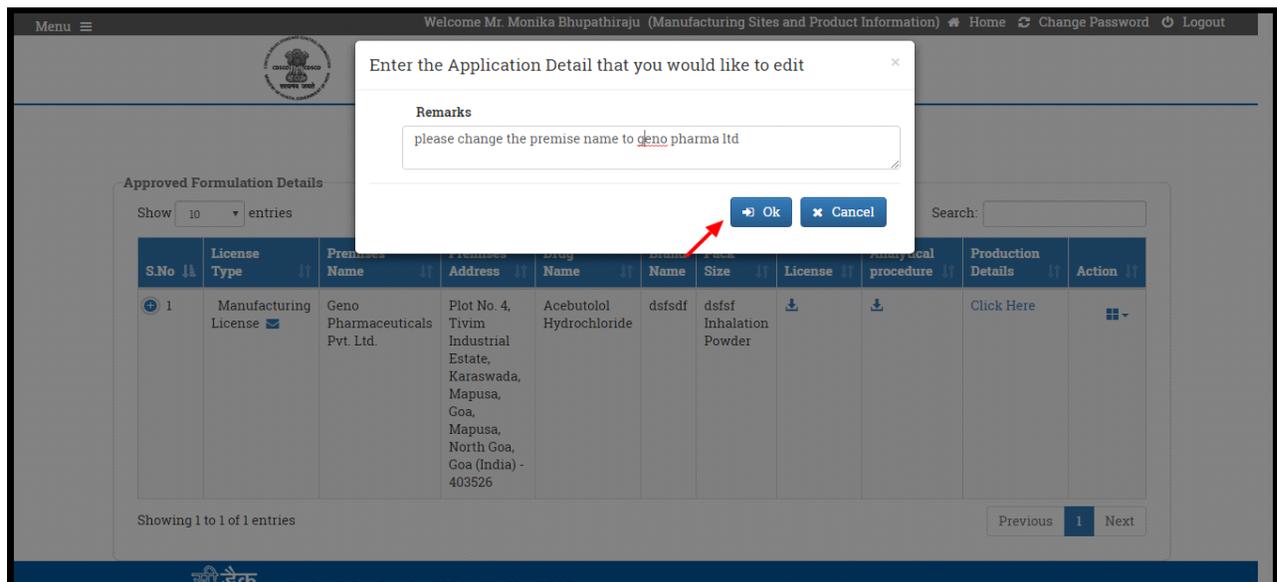
**Figure 44 : Approved formulations List**

- 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.

Menu ☰ Welcome Mr. Monika Bhupathiraju (Manufacturing Sites and Product Information) [Home](#) [Change Password](#) [Logout](#)

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

### Approved Formulations Details

Approved Formulation Details

Show 10 entries

S.No	License Type	Premises Name	Analytical procedure	Production Details	Action
1	Manufacturing License	Geno Pharmaceut Pvt. Ltd. Mapusa, Goa, Mapusa, North Goa, Goa (India) - 403526	<a href="#">Download</a>	<a href="#">Click Here</a>	<a href="#">Details</a>

Showing 1 to 1 of 1 entries

Previous 1 Next

  
**Are you sure?**  
The Remarks Will be Forwarded to official?

**Figure 47 : Confirmation Box**

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