

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, then 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 want 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.cdsconline.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 .

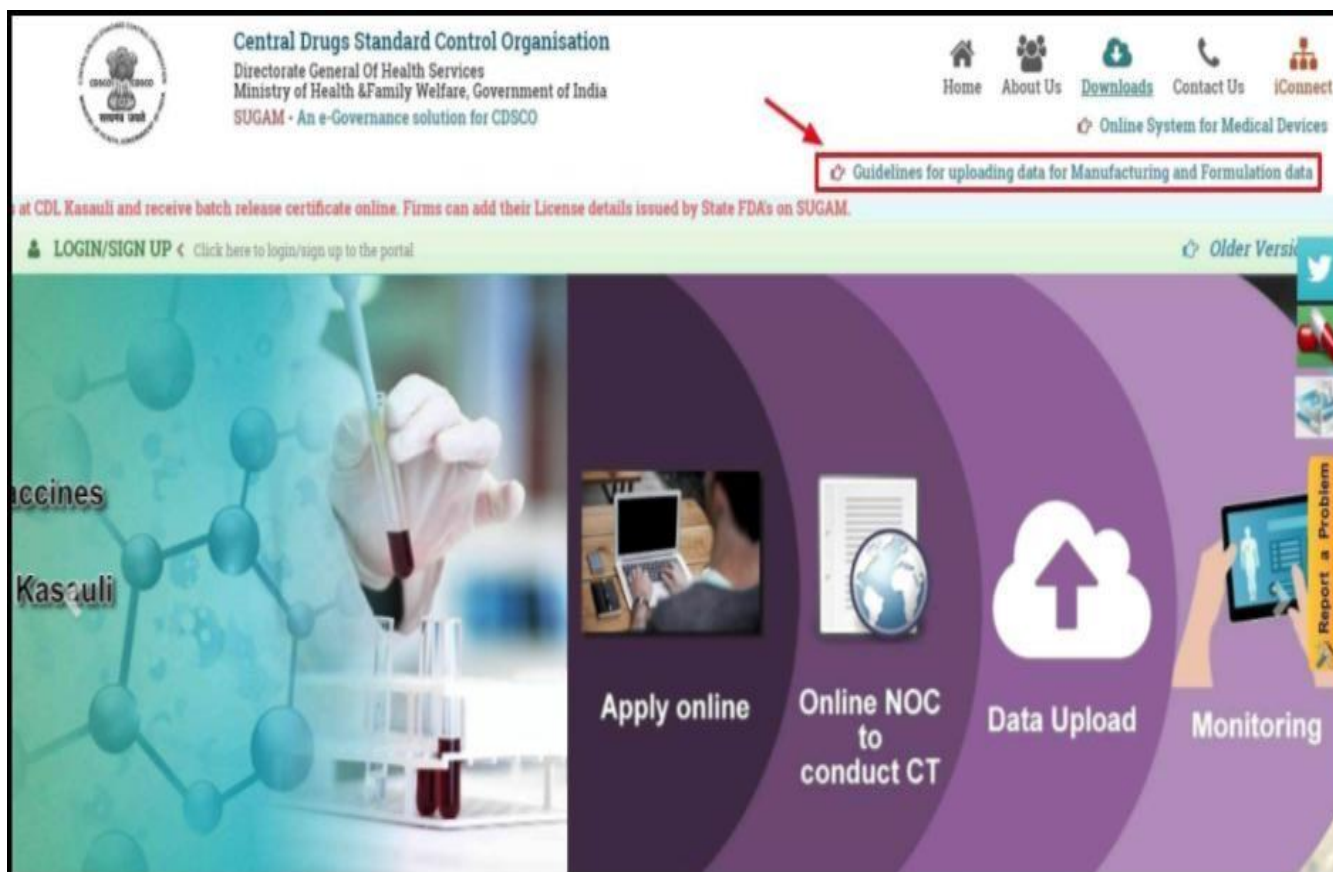
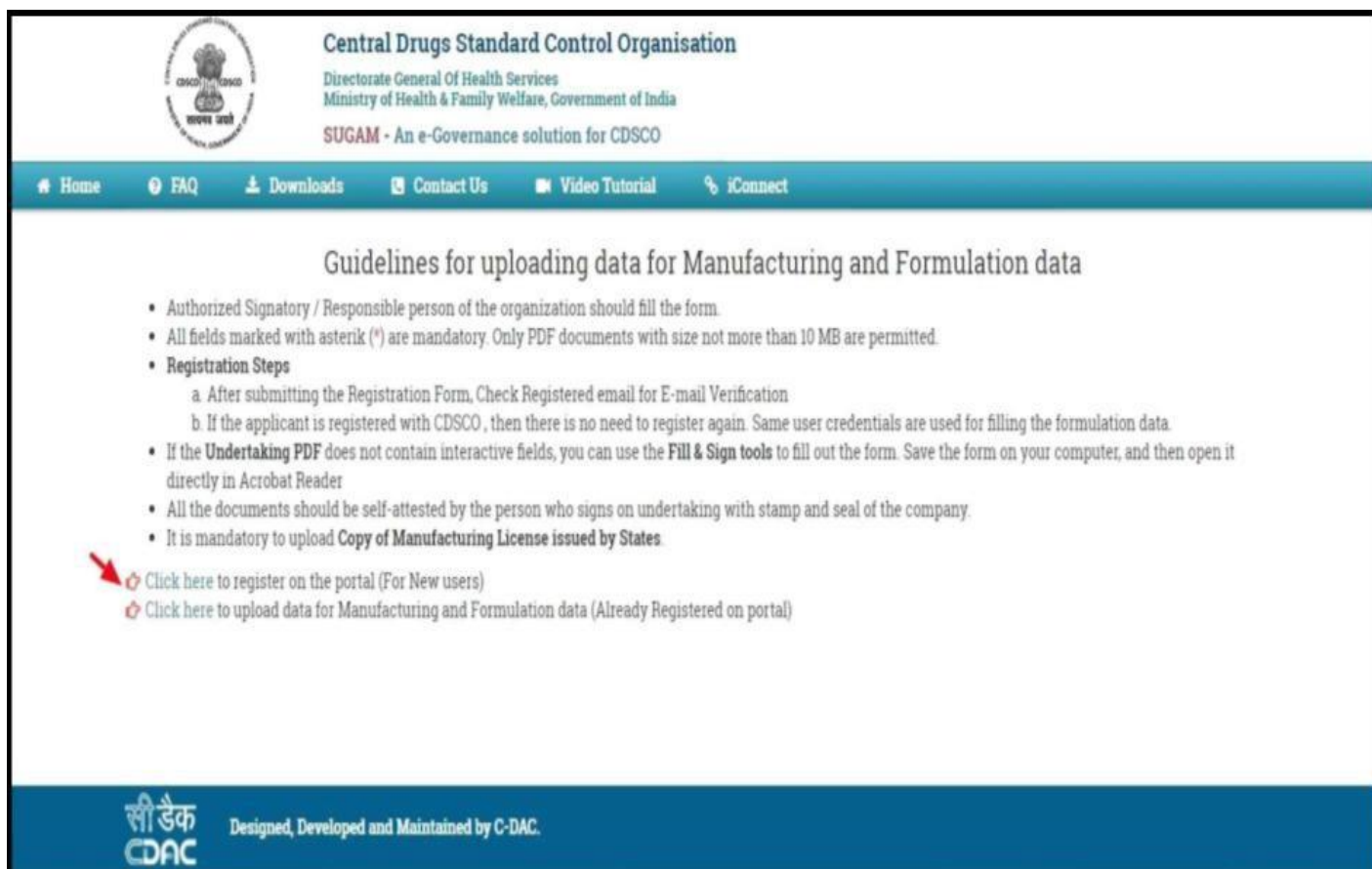


Figure 1 : Homepage

- 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.



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 Directorate General Of Health Services
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 SUGAM - An e-Governance solution for CDSCO

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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

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 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

User-Name:

Password:
Only Best Passwords are accepted

Confirm Password:
Only Best Passwords are accepted

Name: Mr. First Name Middle Name Last Name

Mobile Number: I am Authorized person on behalf of firm to register and for uploading data. +91

Gender: ☒ Male ☐ Female

Nationality: Indian

ID Proof Details: (Single PDF - 10 MB) Select One No file selected. ID Proof No.
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 Editable PDF Format](#)

Designation:

Alternate Email ID:

Manufacturing Sites: select

Are you Member with Any Association: select

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

Organization Name:

Organization Type: Select

CIN (Corporate Identification Number):

Address Line 1:

Address Line 2:

Country: India **State:** Select **District:** Select

City/Tahuka/Mandal/Tehsil: City/Tahuka/Mandal/Tehsil

Pin Code: Pin Code

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

Fax No.: (Please include STD Code - Fax Number) +91 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 PDF - 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

Applicant Registration

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 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: User Name: Password: Confirm Password: Name: Mobile Number: Gender: Nationality: ID Proof Details: Undertaking: Designation: Alternate Email ID: Manufacturing Sites: Are you Member with Any Association: Association Name:	Manufacturing Sites and Product Information <input type="text" value="TEST@GMAIL.COM"/> <input type="password" value="*****"/> <input type="password" value="*****"/> <div> <input type="text" value="Mr"/> <input type="text" value="TEST"/> <input type="text" value=""/> <input type="text" value=""/> </div> <input type="text" value="+91 2345678965"/> <input checked="" type="radio"/> Male <input type="radio"/> Female <input type="text" value="Indian"/> <input type="text" value="Aadhar Card"/> Download/consultation.pdf <input type="text" value="22345345"/> Download/change.pdf Remove Download/Fill and Sign this Undertaking PDF Template and Upload the same here <input type="text" value="ABC"/> <input type="text" value="ROMP2@GMAIL.COM"/> <input type="text" value="Loan Site"/> <input type="text" value="Yes"/> <input type="text" value="BDMA"/>
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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: Country: City/Tehsila/Mandal/Tehsil: Contact No.: Upload Your Corporate Address Proof Details (Certificate of Incorporation):	<input type="text" value="Cidac"/> <input type="text" value="Government"/> <input type="text" value="1234454657"/> <input type="text" value="SR/1 Sector 62"/> <div> <input type="text" value="India"/> <input type="text" value="uttar pradesh"/> <input type="text" value="Lucknow"/> </div> <input type="text" value="Fbhbrbrt"/> <input type="text" value="+91 54576876879"/> Download/consultation.pdf Remove	Address Line 2: State: District: Pin Code: Fax No.: Upload Your Corporate Address Proof Details (Certificate of Incorporation):	<input type="text" value="Cidac Noide"/> <input type="text" value="uttar pradesh"/> <input type="text" value="Lucknow"/> <input type="text" value="201301"/> <input type="text" value="+91 685867969879"/> Download/consultation.pdf Remove
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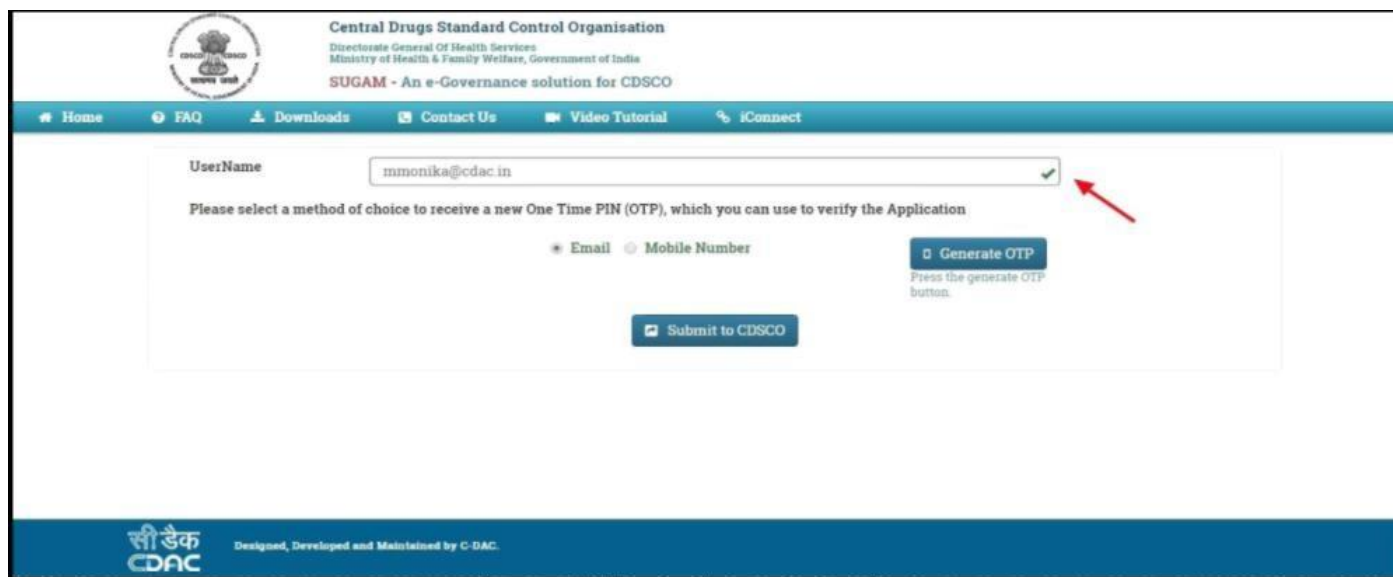
It is mandatory to upload Copy of Manufacturing License

Copy of Manufacturing License: <input checked="" type="checkbox"/> Please tick (✓) this option if you want to receive SMS alerts. <input checked="" type="checkbox"/> 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.	Download/change.pdf Remove <input type="text" value="6KZX0"/>
---	--

[Submit](#)

Figure 5 : Filled Application

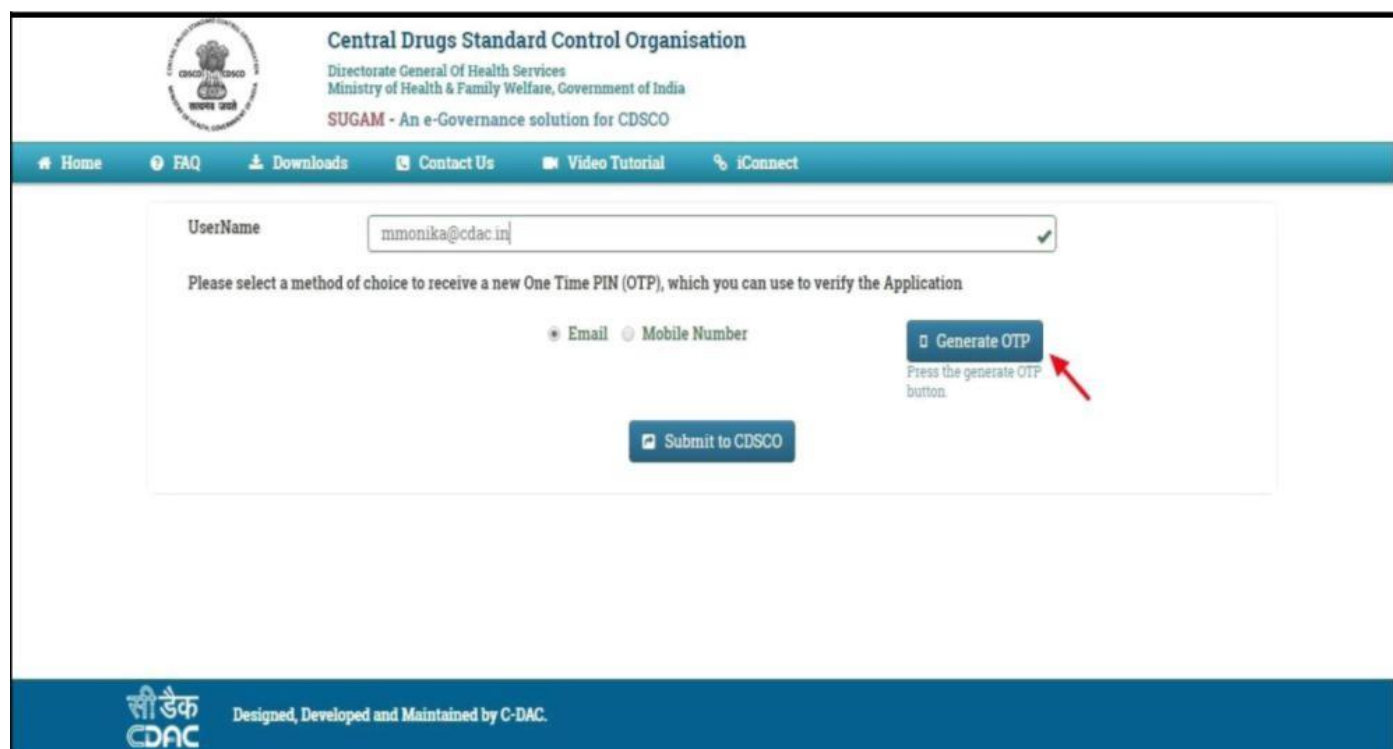
- Once user fills all the details and clicks on Submit button he will be redirected to another page to verify the account. The applicant has to enter the user name that he used while filling the registration as shown in figure.



The screenshot shows the SUGAM portal interface for account verification. At the top, the header includes the Central Drugs Standard Control Organisation logo and name, along with the Directorate General of Health Services and Ministry of Health & Family Welfare, Government of India. Below the header, a navigation bar contains links for Home, FAQ, Downloads, Contact Us, Video Tutorial, and iConnect. The main content area features a form with a 'UserName' field containing 'mmonika@cdac.in'. Below the field, a message states: 'Please select a method of choice to receive a new One Time PIN (OTP), which you can use to verify the Application'. There are two radio buttons for 'Email' (selected) and 'Mobile Number'. To the right of these buttons is a 'Generate OTP' button with a red arrow pointing to it. Below the radio buttons is a 'Submit to CDSCO' button. The footer of the page includes the CDAC logo and the text 'Designed, Developed and Maintained by C-DAC'.

Figure 6 : Verify Registration

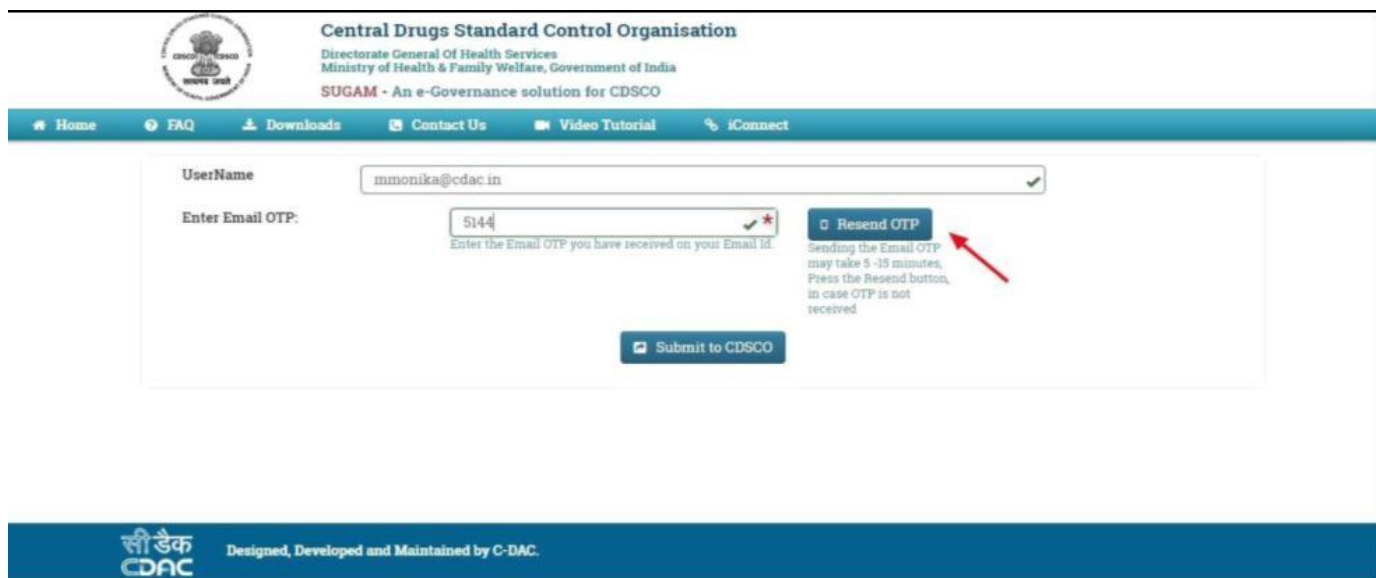
- To verify the account select either Email or Mobile Number to send the OTP and click on Generate OTP button as shown in figure. The OTP will be send to selected option.



This screenshot is identical to Figure 6, showing the SUGAM portal for account verification. The 'UserName' field contains 'mmonika@cdac.in'. The 'Email' radio button is selected. A red arrow points to the 'Generate OTP' button, which is labeled 'Press the generate OTP button.' Below the radio buttons is a 'Submit to CDSCO' button. The footer of the page includes the CDAC logo and the text 'Designed, Developed and Maintained by C-DAC'.

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.



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UserName: mmonika@cdac.in ✓

Enter Email OTP: 5144 ✓*

Enter the Email OTP you have received on your Email Id.

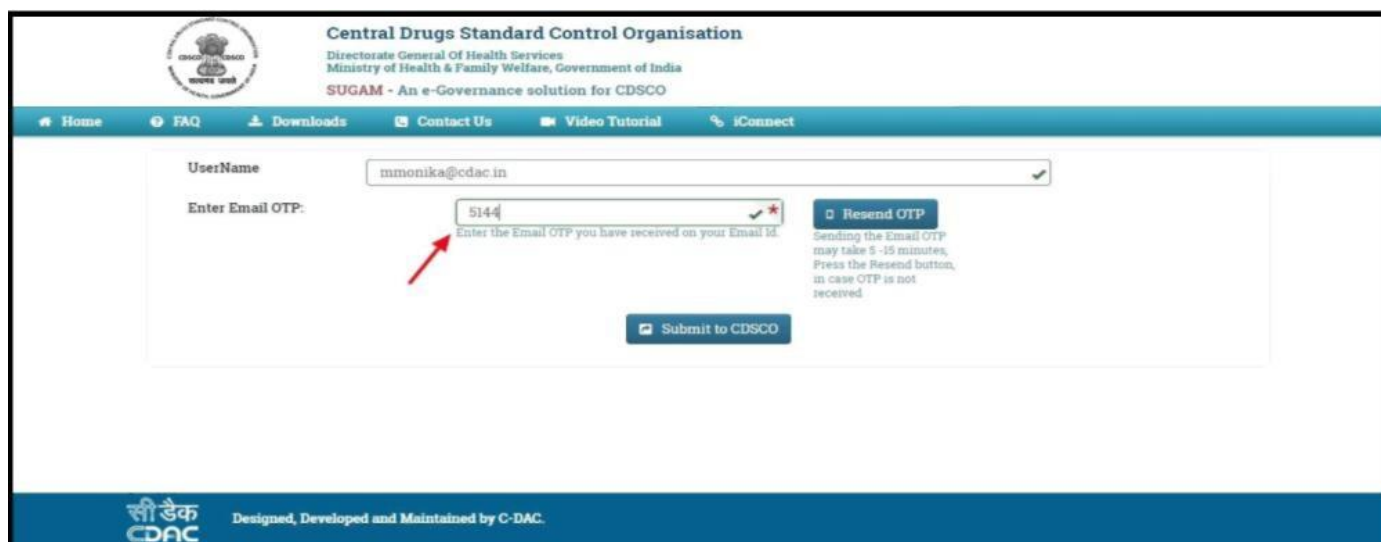
Resend OTP
 Sending the Email OTP may take 5 -15 minutes, Press the Resend button, in case OTP is not received

Submit to CDSCO

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Figure 8 : Resend OTP

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



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UserName: mmonika@cdac.in ✓

Enter Email OTP: 5144 ✓*

Enter the Email OTP you have received on your Email Id.

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

Submit to CDSCO

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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>.

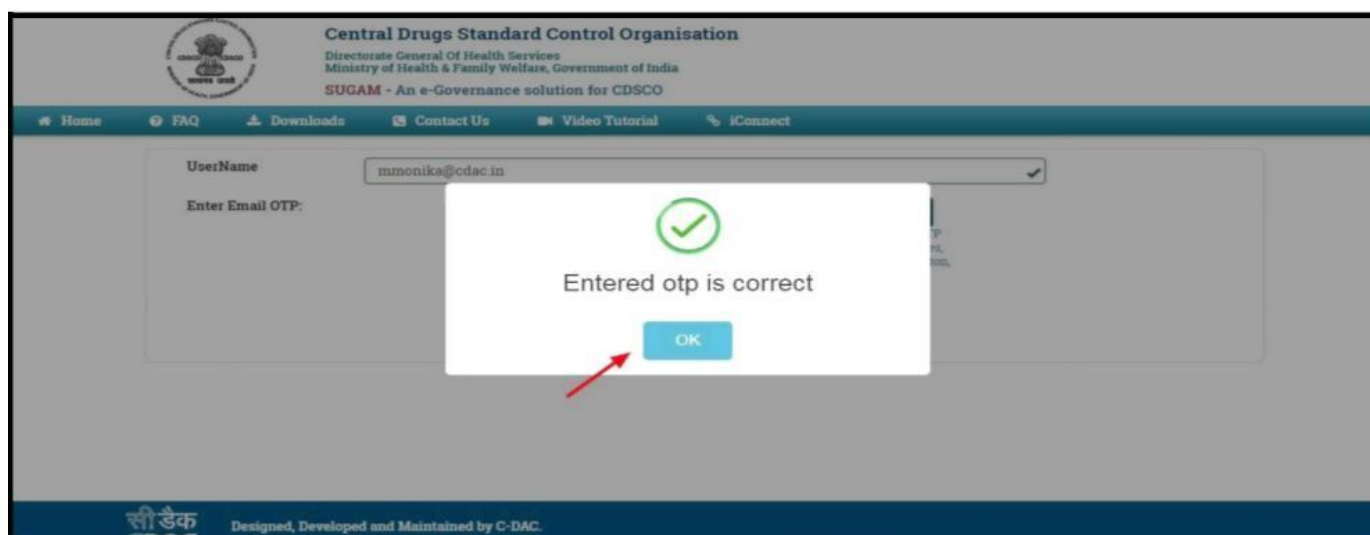


Figure 10 : OTP Correction Modal

➤ 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.

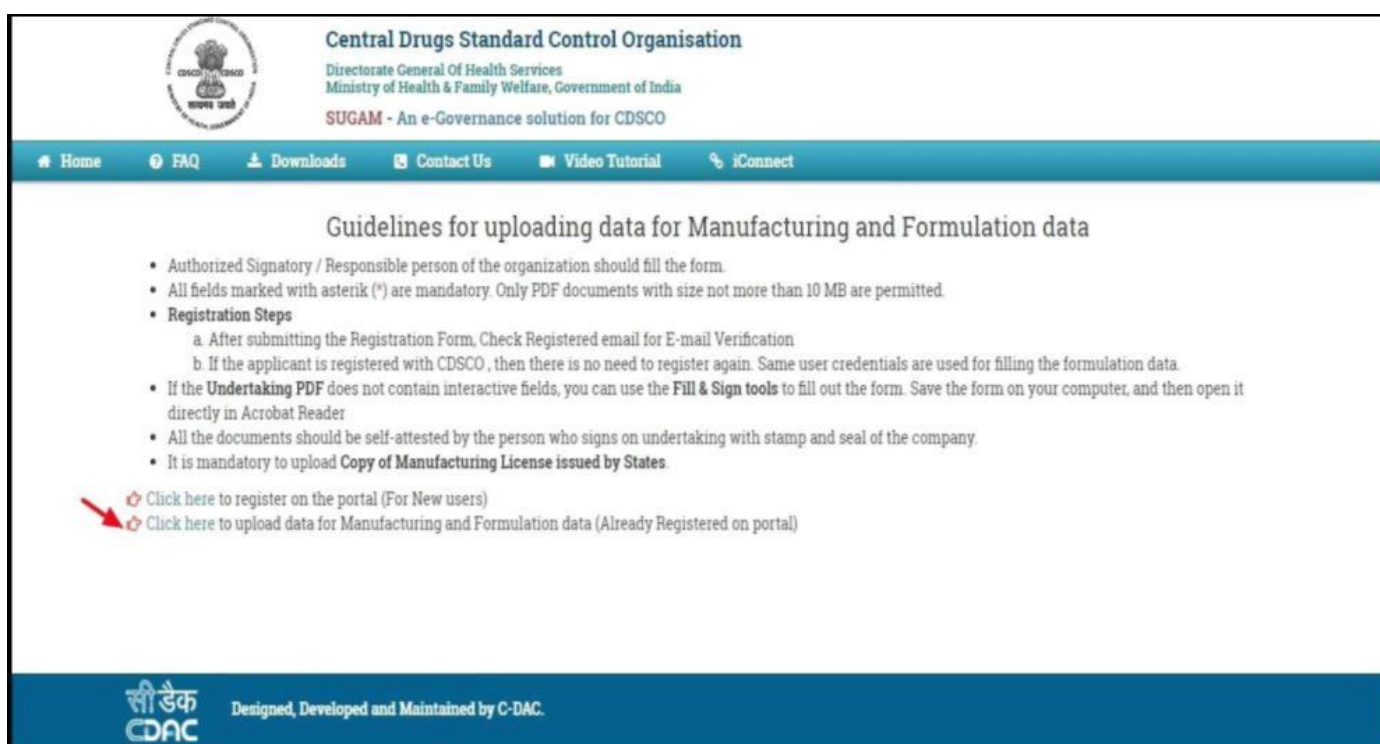


Figure 11 : Already Registered

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

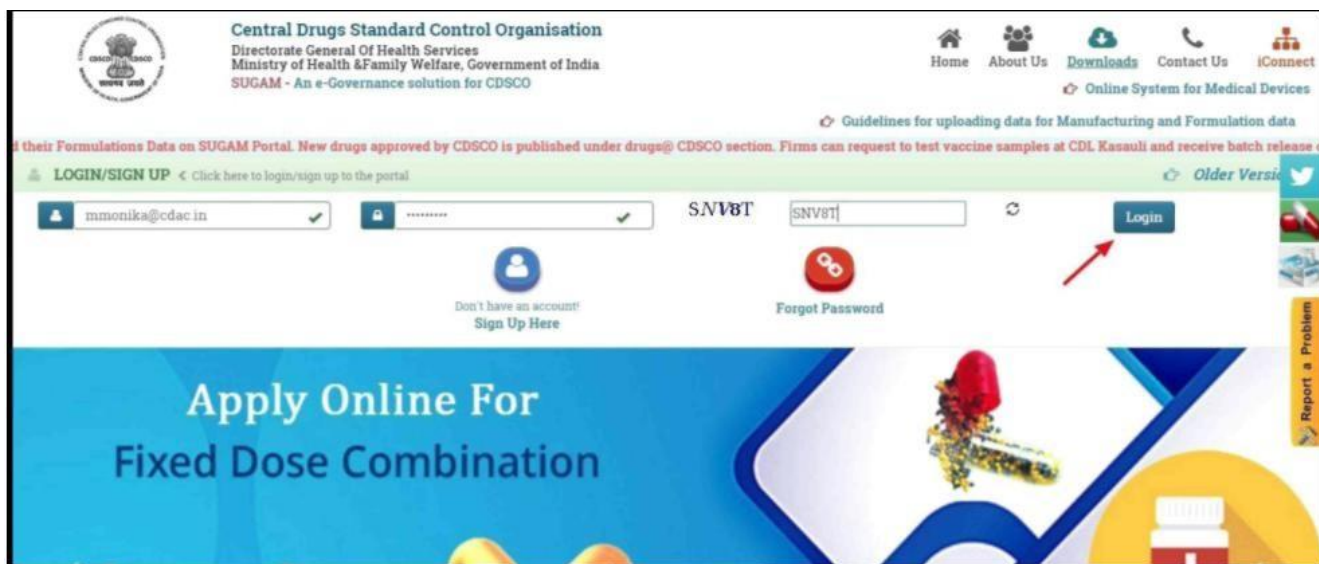


Figure 12 : Login

- 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.

1. Issuing Authority Field should be mandatory
2. Date of first Issue of Licence should be mandatory
3. Upload Licence Document Field should be mandatory

* All fields are mandatory

Address Details
(Note: Please register parent site first)

Select selection

Premises: 

Premises Name


Licence Details

Issuing Authority	Chhattishgarh Licensing Authority	Form No	Form 25A
Licence No	tester-01	Date of First Issue of Licence	07/08/2018
Valid From	07/07/2018	Valid Upto	07/17/2018
Upload Licence Document	<input type="button" value="Browse..."/> Licence Details.pdf	Certificate Held	Andorra

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 North Goa

Premises: null,Plot No. 11/1, Marwasoda,null,Usqaon,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	Licence 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 North Goa

Premises: null,Plot No. 4, Tyrom Industrial Estate,Karawanda, Mapusa, Goa,null,Mapusa,Goa,India,4

Premises Name: Test

Licence Details

Issuing Authority: Andhra Form No: Form 25A

Licence No: test-123 Date of First Issue of Licence: 03/2018

Valid From: 07/06/2018 Valid Upto: 09/2018

Upload Licence Document: Choose file c82a3942-0-123.pdf Certificate Held: Andhra American Samoa

Save Details

Manufacturing Site Details

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

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.

OK

Cancel

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.

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 Licence.
 2. Date of First Issue of Licence Field will contain the date on which the Licence was first issued.
 3. Upload Licence Document Field can only upload one file.

* All fields are mandatory

Address Details
 Name of the Company :
 Address :

Licence Details
 Issuing Authority: Select
 Licence No: License No
 Valid From:
 Valid Upto:
 Upload Licence Document: Choose file No file chosen
 Form No: Select
 Date of First Issue of Licence:
 Certificate Held:
 Save Details

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.

* All fields are mandatory

Address Details
 Name of the Company : TSER
 Address : RGTHTY, YJNTYJ, Kalaburagi (Gulbarga), FGHNYJ, Karnataka, India, 546576

Licence Details
 Issuing Authority: Select
 Licence No: License No
 Valid From:
 Valid Upto:
 Upload Licence Document: Browse... No file selected.
 Form No: Select
 Date of First Issue of Licence:
 Certificate Held:
 Save Details

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	Download	Submitted to StateFDA	-

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.

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	tester	Unit No.	testing01
Address Line 1	tester site	Address Line 2	tester site 2
State	goa	District	North Goa
Taluka/Mandal /Tahsil	district	Village/Town/City	test
Pin Code	343333	E-mail Id	test@gmail.com
Contact No.	+91 45545454544	Fax No.	+91 44444444444

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

Licence Details

Issuing Authority	Tamil Nadu Licensing Authority	Form No	Form 32
Licence No	test	Date of First Issue of Licence	07/04/2018
Valid From	07/08/2018	Valid Upto	07/26/2018
Upload Licence Document	Browse... c82a394f-036a-41_14422fa44		
Certificate Held	American Samoa		

Save Details

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: ✓

Address Line 1: ✓

State: ✓

Taluka/Mandal /Tahsil: ✓

Pin Code: ✓

Contact No.: ✓

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

Unit No.: ✓

Address Line 2: ✓

District: ✓

Village/Town/City: ✓

E-mail Id: ✓

Fax No.: ✓

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

Licence Details

Issuing Authority: ✓

Licence No.: ✓

Valid From: ✓

Upload Licence Document: c82a394f-036a-41_14422fa46

Form No.: ✓

Date of First Issue of Licence: ✓

Valid Upto: ✓

Certificate Held:

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.

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: ✓

Address Line 1: ✓

State: ✓

Taluka/Mandal /Tahsil: ✓

Pin Code: ✓

Contact No.: ✓

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

Unit No.: ✓

Address Line 2: ✓

District: ✓

Village/Town/City: ✓

E-mail Id: ✓

Fax No.: ✓

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

Licence Details

Issuing Authority: ✓

Licence No.: ✓

Valid From: ✓


Upload Licence Document: c82a394f-036a-41_14422fa46

Form No.: ✓

Date of First Issue of Licence: ✓

Valid Upto: ✓

Certificate Held:



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

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.

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: tester
Address: tester site, tester site 2, North Goa, test, Goa, India, 343333

Licence Details

Issuing Authority: Select Form No: Select
Licence No: License No Date of First Issue of Licence:
Valid From: Valid Upto:
Upload Licence Document: Browse... No file selected. Certificate Held:

Save Details

Manufacturing Site Details

#	License Type	Premises Name	Address	License No	Remarks	License Type	Licence	Status	Loan Premises Name
1	Manufacturing Site	tester	tester site, tester site 2, test, Goa, India, 343333	test	NA	Own License	Submitted to StateFDA	-	

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

Licence No

Valid From

Upload Licence Document No file selected.

Form No

Date of First Issue of Licence

Valid Upto

Certificate Held

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.

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.

Manufacturing Formulation Details

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

Manufacturing Unit : Plot No. 4, Tirum Industrial Estate, Karatwada, Margosa, Goa, North Goa, Margosa, Goa

Select Licenses : type-123
The Products approved under this License Number are to be entered here.

Drug Details

Drug Type: Single Ingredient

Generic name: Amelofetac

Dosage form: Cream

Brand Name (Optional): Amelofetac

Pharmacological classification of Drug (Optional): Amelofetac

Indication for which proposed to be used (Optional):

Indication 1: Amelofetac

Indication 2: Amelofetac

Indication 3: Amelofetac

Pack Presentation

Pack Size: 12

Unit of Measure: Inhalation Powder

Ingredients Details

Category: Active

Pharmacological Monograph: Any Other Pharmacopoeia

Ingredient: Nicotine Polacrilline 15 Percent

Strength: 15

Added Ingredients: [Add More Ingredients](#)

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 : RGTHTY, 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 ✓	Brand Name (Optional)
Generic name Acarbose ✓	Pharmacological classification of Drug (Optional) Anthelmintics
Dosage form Blood & Blood Products (Lyophilizer) ✓	
Indication for which proposed to be used (Optional) +	

Pack Presentation

Pack Size 23 ✓	Blood & Blood Products (Liquid) ✓
------------------------------------	--

Ingredients Details

Category Select Category ✓	Ingredient
Pharmacopial Monograph Select pharmacopia ✓	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 Browse... Amendment_Letter_6755.pdf ✓	Copy of Analytical procedure Browse... 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.

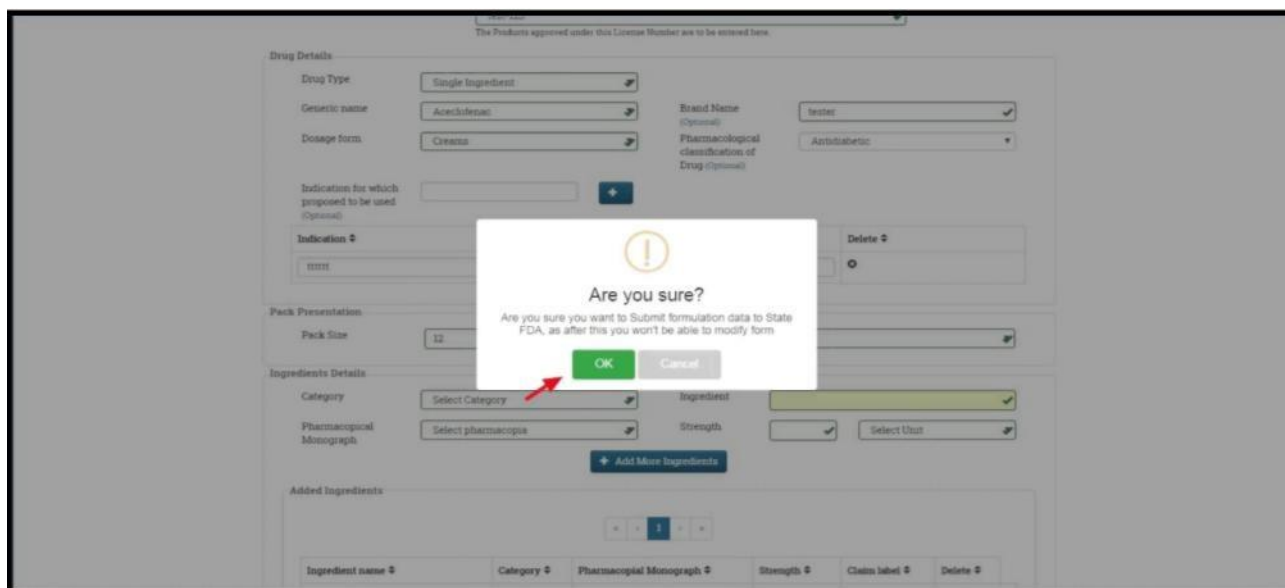


Figure 31 : Confirmation box to submit Application

- 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.

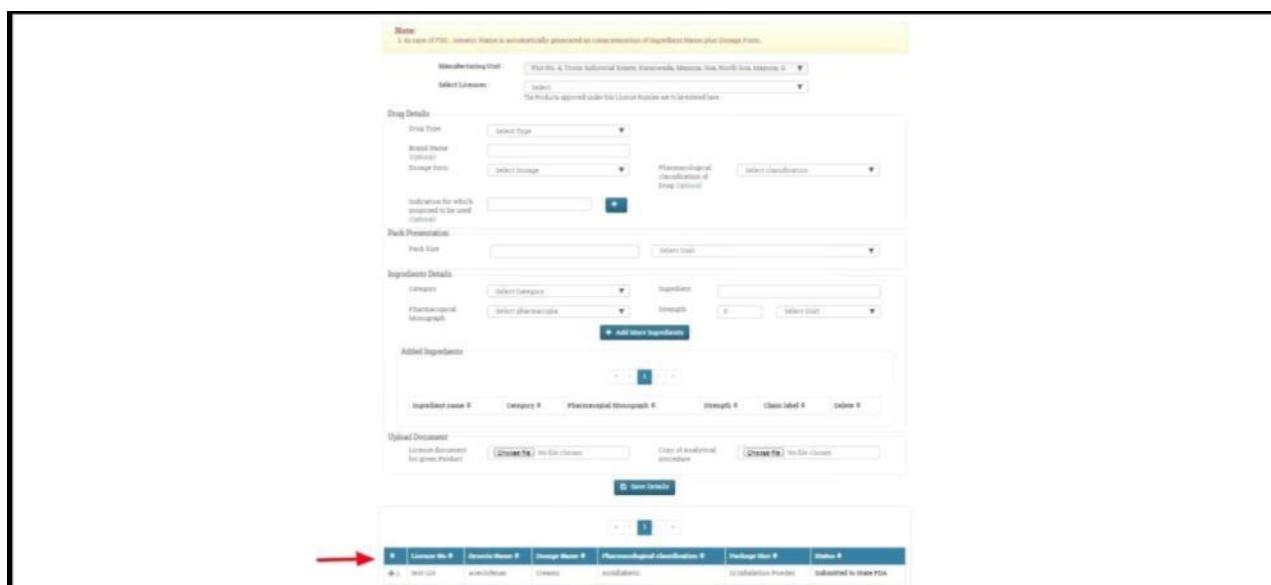


Figure 32 : Filled Formulations Detail

- 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.

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.

Menu Welcome Ms. Monika Choudhary (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

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.

Menu Welcome Ms. Monika Choudhary (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

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

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: Plot No. 4, Tivim Industrial Estate, Karaswada, Mapusa, Goa, North Goa, Mapusa, Goa, India, 40352

Select Licenses: test-123

Select API / Formulation: Acetofenac

Production Details

Select Quarter: Jan-Mar (dropdown menu open with options: Select, Jan-Mar, Apr-Jun, Jul-Sep, Oct-Dec, Financial Year)

Year: (dropdown)

Quantity: (input field)

Choose unit: (dropdown)

Choose Pack size: (dropdown)

MRP (Optional): (input field)

Batch No: (input field)

Save Details

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

CDAC
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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

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: Plot No. 4, Tivim Industrial Estate, Karaswada, Mapusa, Goa, North Goa, Mapusa, Goa, India, 40352

Select Licenses: test-123

Select API / Formulation: Acetofenac

Production Details

Select Quarter: Jan-Mar

Year: 2016

Quantity: 10

Choose unit: Concentrate or

Choose Pack size: 12

MRP (Optional): 2240

Batch No: test

Save Details

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

CDAC
Designed, Developed and Maintained by C. DAC

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.

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

Add Production Details (For Formulations)

* All fields are mandatory

Manufacturing Unit:

Select Licenses:

Select API / Formulations:

Production Details

Select Quarter: Year: Quantity: Choose unit:

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

Batch No:

Licence No	Drug Name	Quarter	Quantity	Pack Size	Batch No	MRP
test 123	Acetofenac	Jan-Mar 2016	12 Concentrate solution for injection	12 mm	3046	test

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:

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

Dashboard

Submit Manufacturing Site Details

More Info

Submit Formulation Details

More Info

Submit Formulation Production Detail

More Info

Production Capacity

More info

Approved Formulations Details

More info

सी डेक Designed, Developed and Maintained by C-DAC.

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.

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

Production Capacity Details

Note:
 1. All fields are mandatory.
 2. Small volume parenterals range from 1 ml to 30 ml or upto 100 ml and large volume parenterals range from 100 ml to 1000 ml.

Dosage :

Strength :

Show entries

Search:

S.No	Dosage	Quantity
No data available in table		

Showing 0 to 0 of 0 entries

Figure 41 : Submit Application

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

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

Production Capacity Details

Note:
 1. All fields are mandatory.
 2. Small volume parenterals range from 1 ml to 30 ml or upto 100 ml and large volume parenterals range from 100 ml to 1000 ml.

Dosage :

Strength :

Show entries

Search:

S.No	Dosage	Quantity
1	Injection	10 Litres

Showing 1 to 1 of 1 entries

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.

The screenshot shows the 'Approved Formulations Details' page with a table containing one entry. The table has the following columns:

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, North Goa, Goa (India) - 403526	Acebutolol Hydrochloride	dsfsdf	dsfsf Inhalation Powder			Click Here	

The page also includes a search bar, a 'Show 10 entries' dropdown, and pagination controls (Previous, 1, Next).

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.

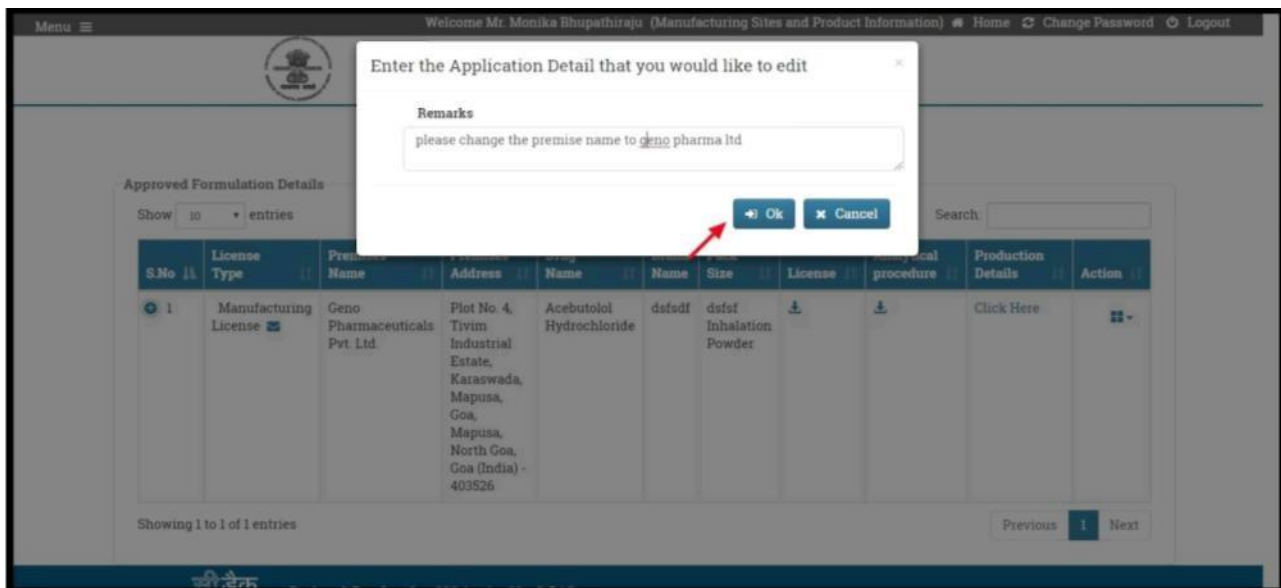


Figure 46 : Remarks Box

- 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.

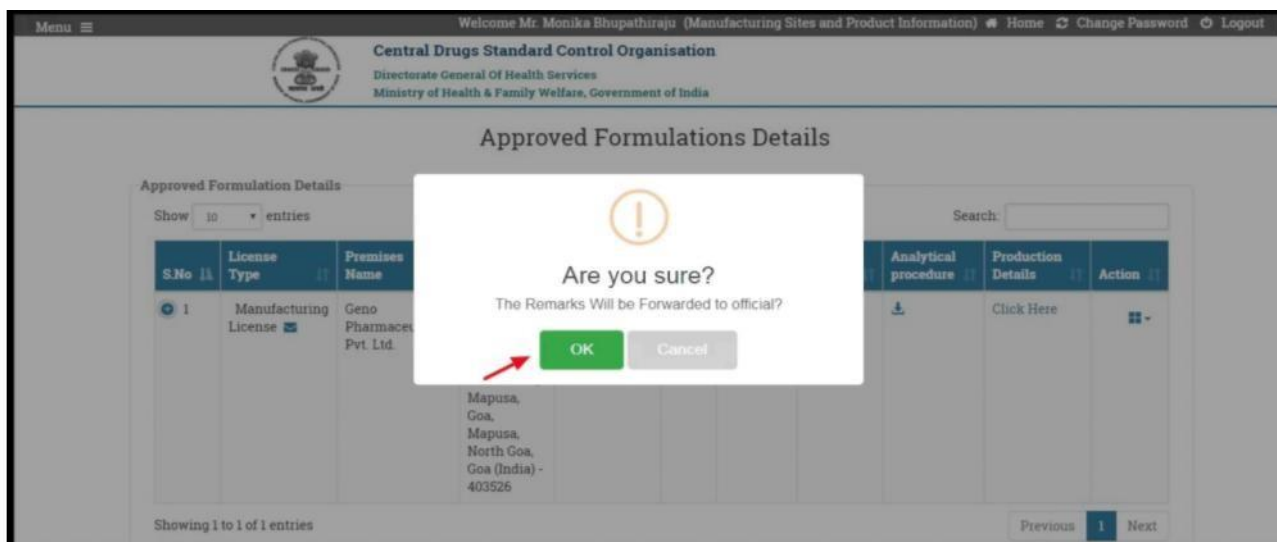


Figure 47 : Confirmation Box

Annexure

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