Note: It is Adviced to Opt for Email OTP to complete the verification process for registration as new user.

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   About Us   Downloads   Contact Us   iConnect

↻ Guidelines for uploading data for Manufacturing and Formulation data / Written Confirmation

↻ Feedback Form (Annexure-I) for SUGAM online portal

🔒 LOGIN/SIGN UP ‹ Click here to login/sign up to the portal

Apply Online For
Fixed Dose Combination

The Central Drugs Standard Control Organisation(CDSCO) under Directorate General of Health Services,Ministry of Health & Family Welfare,Government of India is the National Regulatory Authority (NRA) of India. Its headquater is located at FDA Bhawan, Kotla Road, New Delhi -110002 and also has six zonal offices,four sub zonal offices,thirteen Port offices and seven laboratories spread across the country.

The Drugs & Cosmetics Act,1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and well being of the patients by regulating the drugs and cosmetics. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.

Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of New Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organisations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.

ABOUT US

Click Here to Register as Fresh Applicant for Written Confirmation/ Formulation

REGISTER DATA WITH STATE FDA

Sugam builds a comprehensive database of the various permissions and licenses issued by State FDAs. This includes details of manufacturers, manufacturing site and drug formulations. Manufacturer can view their consolidated data about permissions issued to them from State FDA.

Click here to Sign Up - For Manufacturer for Adding Manufacturing Unit and Permissions / Written Confirmation

General Guidelines for State FDA Dashboard

General Guidelines for Manufacturer

LET'S EXPLORE
Go through the documents to get your Answers !!!

Registration Guidelines

Guidelines for Form Submission

Guidelines for Creating SubLogins

Questions Why Where Answers What

Online Payment Manual

FAQ

Video Tutorials

Quick Notes to Submit Application

View More

Import Drugs for Personal Use

☞ Click here to Apply/Check status of the Applications

IMPORTANT LINKS

PORTAL STATISTICS
Learn about number of applications submitted on SUGAM portal

PATIENTS
Learn about drug/device approvals

INDUSTRY
Guidelines and Approval related information

DRUGS @ CDSCO
Approved Drugs by CDSCO

CONSUMERS
Learn more about user related information

FEATURES

24 x 7
Uptime

Timely alerts & Notifications

Workflow Enabled System

Anywhere, Any Device

OUR PROCESS

Online Submission → Review → Grant of NOC/ Permission
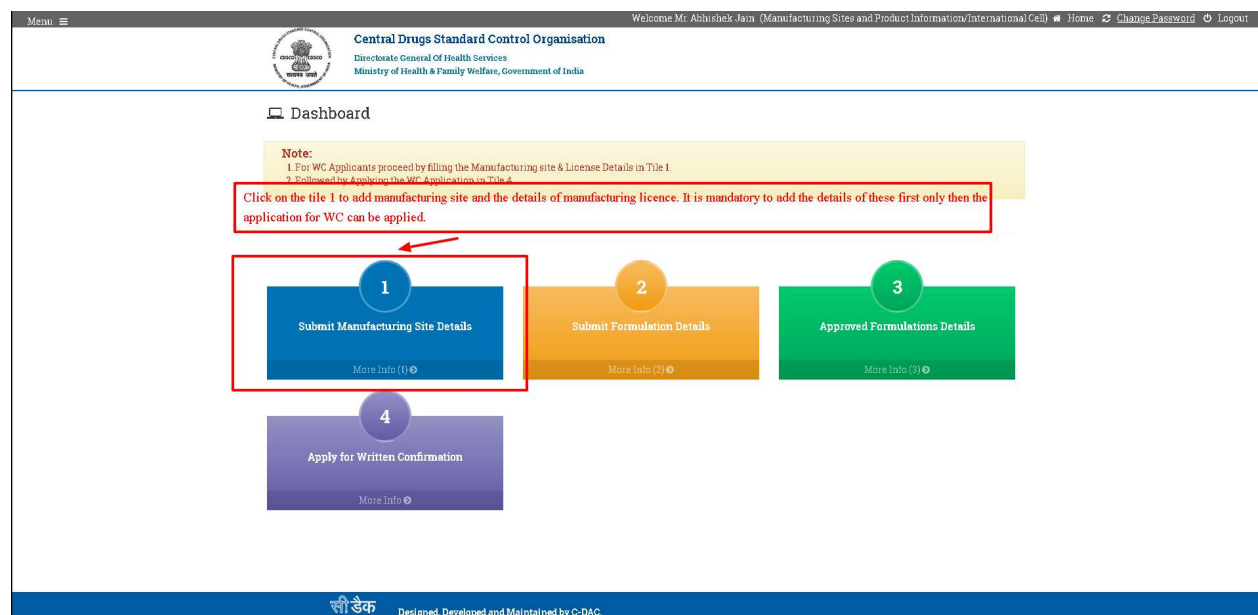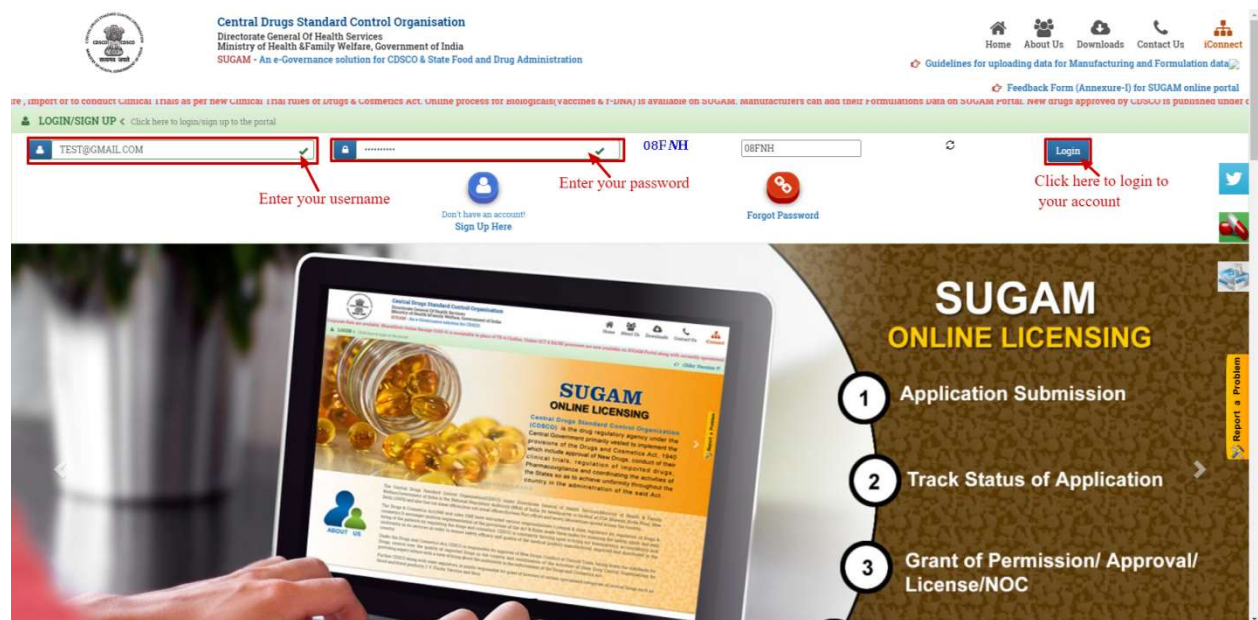
GALLERY

CONTACT US

ADDRESS
Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health and Family Welfare,Government of India
FDA Bhavan, ITO,Kotla Road, New Delhi - 110002

Online Help
📞 P : 011-23502918(CDSCO)
📠 F: 91-11-23236973

Assistance
IT Related : ithelpdesk.sugam[at]cdsco[dot]nic[dot]in
helpdesidcell.sugam[at]cdsco[dot]nic[dot]in

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Visitor Count 177

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 & State Food and Drug Administration

Guidelines for uploading data for Manufacturing and Formulation data

Feedback Form (Annexure-I) for SUGAM online portal

LOGIN/SIGN UP Click here to login/sign up to the portal

TEST@GMAIL.COM

08F**NH**

08FNH

Login

Enter your username

Enter your password

Click here to login to
your account

Don't have an account!
Sign Up Here

Forgot Password

SUGAM
ONLINE LICENSING

1 Application Submission

2 Track Status of Application

3 Grant of Permission/ Approval/
License/NOC

Report a Problem

Menu ≡

Welcome Mr. Abhishek Jain (Manufacturing Sites and Product Information/International Cell) Home Change Password Logout

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

🖥 Dashboard

Note:
1. For WC Applicants proceed by filling the Manufacturing site & License Details in Tile 1.
2. Followed by Applying the WC Application in Tile 4.

Click on the tile 1 to add manufacturing site and the details of manufacturing licence. It is mandatory to add the details of these first only then the
application for WC can be applied.

1
Submit Manufacturing Site Details
More Info (1) ⊘

2
Submit Formulation Details
More Info (2) ⊘

3
Approved Formulations Details
More Info (3) ⊘

4
Apply for Written Confirmation
More Info ⊘

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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).
4. For WC Applicants kindly add the address of Manufacturing Site which is to be mentioned on the certificate to be issued.
5. Please make sure that Address Added is correct as once added cannot be corrected.
6. Added manufacturing site license can be deleted if no Formulation data has been added against License.

Kindly add the manufacturing site address after login to the dashboard. This address can be added only once and cannot be edited. This address will be visible on th WC certificate.

* All fields are mandatory

Address Details

Unit Name		Unit No.	
Address Line 1		Address Line 2	
State	Select	District	Select
Taluka/Mandal /Tahsil		Village/Town/City	
Pin Code	0	E-mail Id	@com
Contact No.	+91 STD Code - Phone Number	Fax No.	+91 STD Code - Fax Number

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

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

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	

Fill the licence details corresponding to the manufacturing site details added above.

🖫 Save Details

After adding the details click on 'Save Details' and the details will be visible in the table below.

Manufacturing Site Details

License Type ⇕	Premises Name ⇕	Address ⇕	License No ⇕	License Type ⇕	Licence ⇕	Status ⇕	Loan Premises Name ⇕	Action ⇕
No Records Found								

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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.
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4. For WC Applicants kindly add the address of Manufacturing Site which is to be mentioned on the certificate to be issued.
5. Please make sure that Address Added is correct as once added cannot be corrected.
6. Added manufacturing site license can be deleted if no Formulation data has been added against License.

* All fields are mandatory

Address Details

Unit Name	Test Unit Name	Unit No.	123
Address Line 1	Test Address Line 1	Address Line 2	Test Address Line 2
State	delhi	District	East Delhi
Taluka/Mandal /Tahsil	sagar	Village/Town/City	kl
Pin Code	110024	E-mail Id	gytty@yty;jk
Contact No.	+91 9999999999	Fax No.	+91 999999999999

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

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

Licence Details

Issuing Authority	Delhi Licensing Autority	Form No	Form 25
Licence No	AD-1234	Date of First Issue of Licence	01/25/2021
Valid From	01/26/2021	Valid Upto	01/26/2021
Upload Licence Document	Browse... 40_Cover_Letter_13525.pdf	Certificate Held	× USFDA

🖫 Save Details

click on save details after filling the details

Manufacturing Site Details

License Type ⇕	Premises Name ⇕	Address ⇕	License No ⇕	License Type ⇕	Licence ⇕	Status ⇕	Loan Premises Name ⇕	Action ⇕
No Records Found								

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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).
4. For WC Applicants kindly add the address of Manufacturing Site which is to be mentioned on the certificate to be issued.
5. Please make sure that Address Added is
6. Added manufacturing site license can b

* All fields are mandatory

Address Details
Name of the Company :
Address :

⚠

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]

Licence Details

Click on 'OK' if the data is correct else click on 'Cancel'.

[💾 Save Details]

Manufacturing Site Details

⇅	License Type ⇅	Premises Name ⇅	Address ⇅	License No ⇅	License Type ⇅	Licence ⇅	Status ⇅	Loan Premises Name ⇅	Action
1	— Manufacturing Site	Test Unit Name	Test Address Line 1, Test Address Line 2, ,,kl, Delhi, India, 110024	AD-1234	NA	Own License	01/26/2021	Submitted to StateFDA	-

Contact No: 9999999999
Fax No: 9999999999999
Form No: Form 25
Issuing Authority: ⬇
Certificates: Delhi Licensing Autority
Issue Date: USFDA
Expiry Date: 01/26/2021

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

🖥 Dashboard

Note:
1. For WC Applicants proceed by filling the Manufacturing site & License Details in Tile 1.
2. Followed by Applying the WC Application in Tile 4.

1
Submit Manufacturing Site Details
More Info (1) ❯

2
Submit Formulation Details
More Info (2) ❯

3
Approved Formulations Details
More Info (3) ❯

4
Apply for Written Confirmation
More Info ❯

After adding manufacturing site and licence details apply for written confirmation by clicking on tile 4.

Central Drugs Standard Control Organisation
Directorate General Of Health Services
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🖥 Dashboard

✚ Expand All

User Guidelines

User Profile   Your Profile is ready for application submission **Submit Application** ✚

Click here to fill the application

Submitted Applications   **16** Applications View
Most recent : Written Confirmation (File No : WC/HIS/2021/267)
Modified Date:22-Jan-2021   ✚

Saved (Draft) Applications   **38** Applications View
Most recent : Written Confirmation (File No : WC/HIS/2021/266)
Modified Date:22-Jan-2021   ✚

Approved Applications   **3** Applications View
Most recent : Written Confirmation (File No : No Result found)
Modified Date:22-Jan-2021   ✚

Rejected Applications   **0** Applications View
Most recent : No Application Found   ✚

Suspended/Withdrawn Applications   **0** Applications View
Most recent : No Application Found   ✚

View Historical Applications   **0** New Messages View

Post Approval Applications NEW!   Apply Here

Notifications NEW!   View Here

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Online Forms Submission

Select Department: International Cell ⌄

Select Form: Written Confirmation ⌄   → *Select the respective division and form*

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

➲ Proceed

Click on Proceed to fill the application

GENERAL INSTRUCTIONS

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

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

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

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Written Confirmation

| 1. Written Confirmation Form | 2. Drug Details | 3. Written Confirmation Preview |

Premises Details

Manufacturing Unit:	**CDAC** Cdac, Noida, Noida -123456, Uttar Pradesh, India **Phone:** 0-9801236789, **Fax:** 0-9876345670, **Email:** _____C.IN

→ This Address will be displayed on the WC Certificate Issued.

Purpose	Choose purpose ▼

→ Chose the purpose or type of application from the drop down

→ Next

Click on Next button to proceed further.

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Ministry of Health & Family Welfare, Government of India

Written Confirmation

| 1. Written Confirmation Form | 2. Drug Details | 3. Written Confirmation Preview |

Premises Details

Manufacturing Unit:	
Purpose	Fresh ✔
Select Licenses :	✔

→ Select your respective license against which WC is to applied and then fill the drug details respectively

Drug Details

Purpose of Drug:	Select Purpose ▼	Drug Type ❓	Bulk Drug ▼
Generic name ❓	Enter Generic Name	Pharmacological classification of Drug (Optional)	Select classification ▼
Pharmacopoeial Monograph ❓	Choose pharmacopia	Shelf Life	
Drug Approval Status in India	Select ▼		

🖫 Add Drug Details

→ Then click on Add Drug Details Button to add the drug.

Show [10 ▼] entries   Search: [____]

S.No ⇅	License No ⇵	Generic Name ⇵	Approval Status of Drug ⇵	Action ⇵
		No data available in table		

Showing 0 to 0 of 0 entries   Previous Next

🖫 Save

→ Then Click on Save button to save the drug & proceed further

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Ministry of Health & Family Welfare, Government of India

Written Confirmation

| 1. Written Confirmation Form | 2. Drug Details | 3. Written Confirmation Preview |

Premises Details

Manufacturing Unit:	**CDAC** Cdac, Noida, Noida -123456, Uttar Pradesh, India **Phone:** 0-9801236789, **Fax:**0-9876345670, **Email:** ABHISHEKJAIN@CDAC.IN
Purpose	Fresh ✔
Select Licenses :	AD-1234 - (Form 25) ✔

Drug Details

Purpose of Drug:	Both (Domestic & Export) ✔	Drug Type ❓	Bulk Drug
Generic name ❓	Test Drug Name ✔	Pharmacological classification of Drug (Optional)	Antibacterial ✔
Pharmacopoeial Monograph ❓	✕ I.P. ✕ U.S.P.	Shelf Life	12 months ✔
Drug Approval Status in India	Approved ✔		

🖫 Add Drug Details

Click here to add the drugs entered

Show [10 ▼] entries   Search: [ ]

S.No ↕	License No ↕	Generic Name ↕	Approval Status of Drug ↕	Action ↕
		No data available in table		

Showing 0 to 0 of 0 entries   Previous   Next

🖫 Save

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

Written Confirmation

| 1. Written Confirmation Form | 2. Drug Details | 3. Written Confirmation Preview |

Premises Details

Manufacturing Unit:	**CDAC** Cdac, Noida, Noida -123456, Uttar Pradesh, India **Phone:** 0-9801236789, **Fax:**0-9876345670, **Email:** ABHISHEKJAIN@CDAC.IN
Purpose	Fresh ✔
Select Licenses :	Select ▼ *Click here to select the licence to add more drugs against it*

🖫 Add Drug Details   *Click here to add the drug after selecting the licence and filling the drug details*

Show [10 ▼] entries   Search: [ ]

S.No ↕	License No ↕	Generic Name ↕	Approval Status of Drug ↕	Action ↕
⊕ 1	AD-1234 - (Form 25)	Test Drug Name	Approved	⊘ Delete ✎ Edit

Click here to Edit or Delete the drugs added

Showing 1 to 1 of 1 entries   Previous   **1**   Next

🖫 Save   *Click here to save the drugs and proceed further if drug addition is complete*

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

Written Confirmation Preview

| 1. Written Confirmation Form | 2. Drug Details | 3. Written Confirmation Preview |

Premises Details

Manufacturing Unit:	**CDAC**	
	Cdac, Noida, Noida -123456, Uttar Pradesh, India	
	Phone: 0-9801236789, **Fax:**0-9876345670, **Email:** ABHISHEKJAIN@CDAC.IN	
Purpose:	Fresh	

Show 10 ⌄ entries   Search: [ ]

S.No	License No	Generic Name	Activity(ies)
⊕ 1	AD-1234 - (Form 25)	Test Drug Name	Manufacturing & Packing

Showing 1 to 1 of 1 entries   Previous **1** Next

Proceed To Checklist   **Modify Form**

Click here to proceed the checklist   Click here to modify the form if any change is required

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Written Confirmation Preview

| 1. Written Confirmation Form | 2. Drug Details | 3. Written Confirmation Preview |

Premises Details

Manufacturing Unit:

Purpose:

Show 10 ⌄ entries

⚠

Are you sure?

Do you want to proceed checklist? You will be no longer to modify Form

OK   Cancel

S.No	License No		Activity(ies)
⊕ 1	AD-1234 - (Form 25)		Manufacturing & Packing

Showing 1 to 1 of 1 entries   Previous **1** Next

Click here to proceed further   Click here to cancel

Proceed To Checklist   Modify Form

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Ministry of Health & Family Welfare, Government of India

Upload Essential Documents For Written Confirmation

Note:
1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/altered under the Saved Application link available on the Dashboard
4. Click here to view **Guidelines for PDF documents**

☐ 1. Covering Letter/Application from Manufacture ⟵ Click here to upload the document against the checklist

☐ 2. Site master file (as specified under WHO TRS 961, Annexure 14)

☐ 3. An Authorization letter in original issued by the Director/Company Secretary/Partner of thefirm

☐ 4. Copy of GMP certificate issued as per WHO GMP, USFDA, EDQM, etc., if any

☐ 5. Copy of Manufacturing License

☐ 6. List of Approved APIs

☐ 7. List of APIs applied for issuance of WC

☐ 8. List of SOPs and STPs

☐ 9. List of Technical Staff, their Qualification, Experience and approval status & Organogram

☐ 10. List of Equipment and Instruments

☐ 11. Manufacturing Plant layout

☐ 12. Validation Master Plan

☐ 13. Good Distribution Practices followed by the firm

➡ 14 . Legal Undertaking and Form

☐ 14.1 Legal undertaking

15(1) . Product Permission   Click + to view document list ⊕

16(1) . Stability studies of 3 batches for minimum 06 months for accelerated and real time studies along with stability protocol and commitment   Click + to view document list ⊕

17(1) . Process Validation for 3 batches of each Product   Click + to view document list ⊕

18(1) . Annual Product Review for last 3 years   Click + to view document list ⊕

19(1) . Export data for last 3 years   Click + to view document list ⊕

20(1) . Analytical Method Validation   Click + to view document list ⊕

21(1) . Market Complaint Review   Click + to view document list ⊕

22(1) . Data of impurity profiling   Click + to view document list ⊕

23(1) . NSQ reports, if any   Click + to view document list ⊕

Click on + sign to see checklist item and upload the docmunets

⬆ Submit   ⟵ Click on Submit button when complete checklist is filled

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Note: Please write NA, in case you do not have any remarks to enter.

Upload Certificate

Covering Letter/Application from Manufacture	Choose File No file chosen ⟵ Click here to upload the document
Remarks	Enter Remarks ⟵ Enter your remarks here

⬆ Submit   ⟳ Reset

Click here to upload it against the respective cheklist   *Click here to reset it to blank*

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

Upload Essential Documents For Written Confirmation

Note:
1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/altered under the Saved Application link available on the Dashboard
4. Click here to view **Guidelines for PDF documents**.

Once document is uploaded against the checklist then it turns green

☑ 1. Covering Letter/Application from Manufacture
☑ 2. Site master file (as specified under WHO TRS 961, Annexure 14)
☑ 3. An Authorization letter in original issued by the Director/Company Secretary/Partner of the firm
☑ 4. Copy of GMP certificate issued as per WHO GMP, USFDA, EDQM, etc., if any
☑ 5. Copy of Manufacturing License
☑ 6. List of Approved APIs
☑ 7. List of APIs applied for issuance of WC
☑ 8. List of SOPs and STPs
☑ 9. List of Technical Staff, their Qualification, Experience and approval status & Organogram
☑ 10. List of Equipment and Instruments
☑ 11. Manufacturing Plant layout
☑ 12. Validation Master Plan
☑ 13. Good Distribution Practices followed by the firm
➡ 14 . Legal Undertaking and Form
☑ 14.1 Legal undertaking
15(1) . Product Permission   [Click + to view document list] ⊕
16(1) . Stability studies of 3 batches for minimum 06 months for accelerated and real time studies along with stability protocol and commitment   [Click + to view document list] ⊕
17(1) . Process Validation for 3 batches of each Product   [Click + to view document list] ⊕
18(1) . Annual Product Review for last 3 years   [Click + to view document list] ⊕
19(1) . Export data for last 3 years   [Click + to view document list] ⊕
20(1) . Analytical Method Validation   [Click + to view document list] ⊕
21(1) . Market Complaint Review   [Click + to view document list] ⊕
22(1) . Data of impurity profiling   [Click + to view document list] ⊕
23(1) . NSQ reports, if any   [Click - to hide document list] ⊖
☑ 23.1 Test Drug Name -- AD-1234 - (Form 25)

[⬆ Submit] ← Click here to submit the application

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

Written Confirmation Preview

| 1. Written Confirmation Form | 2. Drug Details | 3. Written Confirmation Preview |

Premises Details

Manufacturing Unit:

Purpose: Fresh

Show [10 ▾] entries   Search: [_____]

S.No	License No	Generic Name	Activity(ies)
⊕ 1	(Form 25)	Test Drug	Manufacturing & Packing

Showing 1 to 1 of 1 entries   [Previous] [1] [Next]

Click here to agree →

Declaration

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

Click to here to download the pdf of your application which needs to be uploaded in Next step →

[Download Pdf] [Next] ← Click on next button to proceed further

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

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

Application for Written Confirmation

Upload Written Confirmation

Written Confirmation   Choose File Written Confirmation.pdf ✔

Click here to upload the WC downloaded in previous step

Submit

Click here to Submit the application then the application number will be generated once the file is submitted

---

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

Your Application has been submitted successfully.
Kindly note your file no. WC/FR/2021/2... for future correspondence.

This is the application number generated for your submitted application