Presentation on
e-Governance Initiatives of CDSCO

INTRODUCTION

- E-Governance is one of the component of 12th five year plan
- Centre for Development of Advanced Computing (C-DAC) was nominated for developing online system.
- Work allocated to CDAC in Dec. 2014.
- SUGAM (acronym Suraksha, Gunavatta and Manakta) portal launched in Nov. 2015 by the HFM

Various CDSCO Online portals

- CDSCO and State Licensing Authorities (SLAs) are going to have all activities online
- Application for any purpose to be made online and obtaining of license/ permission/ certificate through online only.
- CDSCO has developed following online portals :
- www.cdscoonline.gov.in for Drugs and Cosmetics
- www.cdscomdonline.gov.in for medical devices (for State and Central)
- www.sugamlabs.gov.in for the laboratories under CDSCO
- www.statedrugs.gov.in National State portal for Licensing

SUGAM CDSCO Online Portal

This portal is used for making application, its processing and issuance of Approval for the following purposes :-

- New Drug approval including Fixed Dose Combination and Subsequent new drug
- Clinical Trials
- BA-BE studies
- Biological products (Vaccines and r-DNA products)
- Import and Registration
- Test Licenses, etc.

Medical Device Online Portal

- Import license
- Manufacturing license
- Test license
- License for Clinical Investigation, etc.

National Sugam Portal for States

- All activities related to manufacturing and sale licenses will be done through this portal uniformly throughout the country so that format of licenses, certificates is uniform and no procurement agencies, buyer , foreign countries get doubt/ or complaint

- Portal for uploading data of manufacturers and their products will be as per Rules.

Structure for filing of Application

- First the company/ or person has to get registered by giving company name and site details
- ID/PAN/Adhar Card
- Undertaking

  and gets login and Password to get the access to apply & get licenses/ certificates
- Under Application, firm has to fill the data of their company and product in the space/ fields provided precisely as they fill in hard copies

- Then as supportive documents which need to be attached/ uploaded against checklist for each type of Form like
  - List of products,
  - constitution of firm,
  - list of equipments,
  - Site Master file,
  - Layout plan of premises,
  - Details of Technical Staff, etc.....
- After filling the Form, you can take print, check its correctness, sign it (digitally wherever required) and upload
- Then you will have to pay the fees through bharatkosh, or challan and upload the receipt.
- Finally submit the Application Form
- All above processes can be done from anywhere in the world, if you have login ID and Password.
- Once this application is submitted, you can check the status of your application online, whether it is ‘under process’, ‘approved’ or any ‘query’ is issued.

FORM- 24

[See Rule 69]

Application for the grant of or renewal of a licence to manufacture for sale or for distribution of drugs other than those specified in [Schedule C, C (1) and X]

I/We of..... hereby apply for the grant/renewal of a license to manufacture on the premises situated at..... the following drugs being drugs other than those specified in Schedules C, C(1) and X to the Drugs and Cosmetics Rules, 1945.

Names of Drugs categorized according to Schedule M.....

Names, qualifications and experience of technical staff employed for manufacture and testing.....

A fee of rupees has been credited to Government under the head of account.....

Date:.....

signature.....

Note: The application should be accompanied by a plan of the premises.

Checklist for approval of new drug e.g. FDC

Checklists No	Item Description	Item Type
1	Covering letter	File Upload
2	Rationale for new proposed claim(s) along with therapeutic justification with supporting literature.	File Upload
3	Copy of valid manufacturing license in Form 25/28.	File Upload
4	Copy of valid Test license in Form 29	File Upload
5	Source of bulk drugs along with current regulatory status of the source with copy of Form 46A in case of new drug.	File Upload
6	Information on active ingredients:	Label
6.1	Brief Chemical & pharmaceutical data for API including specification, Method of Analysis, and Certificate of Analysis	File Upload
7	Data on Formulation:	Label
7.1	Master Manufacturing Formula	File Upload
7.2	Details of the formulation (including inactive ingredients)	File Upload
7.3	Finished Product Specification	File Upload
7.4	In process quality control check	File Upload
7.5	Drug excipient compatibility study	File Upload
7.6	Process validation Report	File Upload
7.7	Validation of analytical method report	File Upload
7.8	Certificate of analysis including identification, pH, content uniformity, impurities, assay etc.	File Upload
7.9	Comparative evaluation with international brand(s) or approved Indian brands, if applicable.	File Upload
7.10	Dissolution data in case of oral dosage forms as appropriate	File Upload
7.11	Stability study evaluation as per requirements of schedule Y	File Upload
8	Clinical trials data showing safety and efficacy of the FDC with the proposed new claims including published data.	File Upload
9	Regulatory status of the drug with the proposed new claims in other countries, as appropriate:	Label
9.1	Names of the countries where the drug is marketed/approved alongwith package insert circulated in those countries.	File Upload
9.2	Names of the countries where the drug is withdrawn, if any, with reasons	File Upload
10	BE study protocol and /or Clinical study protocol as per Appendix X of Schedule Y, as appropriate	File Upload
11	Toxicity data as per Schedule Y, as appropriate. In case of injectable formulation, sub-acute toxicity data generated with the applicants product has to be provided).	File Upload

Checklists No	Item Description	Item Type
12	Copy of proposed Package Insert which should include generic name of all active ingredients; composition; dosage form/s, indications; dose and method of administration; use in special populations; contraindications; warnings; precautions; drug interactions; undesirable effects; overdose; pharmacodynamics and pharmacokinetic properties; incompatibilities; shelf-life; packaging information; storage and handling instructions.	File Upload
13	Draft specimen of the label and carton	File Upload
14	Upload Justification for Quantity applied in Form-12, if applicable	File Upload
15	Upload duly signed Form-12 generated through this system , if applicable	Form Upload
16	Application in Form 44	Form Upload
17	TR-6 Challan	Form Upload
18	Details of the approval of the FDC in the country	Label
18.1	Approved Dosage Form	File Upload
18.2	Approved composition	File Upload
18.3	Approved indication	File Upload
18.4	Copy of earlier approval obtained from CDSCO (if any)	File Upload
19	Details of non-clinical (Pharmacological & Toxicological) studies on Applicants Product	File Upload
20	Report of BE study and /or Clinical trial conducted in the country as appropriate(In case the application is for marketing authorisation)	Label

DOCUMENTS FOR GRANT OF LICENCE

S. No	Document type	Format
1	A) Application In Form 24 & 27 (FOR ALLOPATHIC MEDICINE)	File upload
2	Covering letter (with brief of company, categories of products, dosage forms proposed to manufacture)	File upload
3	B) Application In FORM 24-B (FOR LICENCE TO REPACK)	File upload
4	Application In FORM 24D (FOR AYUVERDIC MEDICINE)	File upload
5	Application In FORM 31 (FOR COSMETICS)	File upload
6	Application In Form 24 c (For Homoeopathic Medicine)	File upload
7	Challan Of Fees Paid	File upload
8	Specific Power Of Attorney In Favor Authorized Signatory For Submitting Application On Behalf Of The Company	File upload
9	Site Plan and layout of the building with name, address, scale, measurements of the Area	File upload

DOCUMENTS FOR GRANT OF LICENCE Contd..

S. No	Document type	Format
10	Self attested copies of documents pertaining to the possession of premises such as, Register ownership / rent / lease / allotment letter / Possession Letter, Tax Receipt	File upload
11	Consent to establish from Pollution Control Board.	File upload
12	List of Directors, Partners, Trustees ,along with ROC Copy Registered Partnership deed, Trust deed (As applicable)	File upload
13	List Of Competent Technical Staff, With Their Qualification, Registration, Experience, Previous FDA Approvals, etc.	File upload
14	Appointment/Acceptance Letter Of Competent Technical Staff Of Manufacturing Section.	File upload
15	Appointment/Acceptance Letter Of Competent Technical Staff Of Testing Section.	File upload
16	Section Wise List of Plant And Machineries	File upload
17	Plan Layout of The Premises Approved By The Licensing Authority	File upload
18	State Pollution Control Board NOC	File upload
19	NOC Of Department Of Industrial Safety & Health	File upload

DOCUMENTS FOR GRANT OF LICENCE Cont d..

S. No	Document type	Format
20	Details Of Manufacturing Process, Process Flow Chart (For Bulk Drug)	File upload
21	AHU Installation And Validation Certificate (Wherever Necessary)	File upload
22	Water System Installation And Validation Certificate (Wherever Necessary)	File upload
23	Site master file	File upload
24	Form 29 licensed issued by SLA	File upload
25	Form 10 issued by CDSCO where required	File upload
26	Constitution details of firms	File upload
27	A copy of New Drug permission if applicable. If not, justification	File upload
28	Supporting data for BA/BE study where required	File upload
29	Stability studies data	File upload

Documents required fro grant/ Revalidation of COPPS

Document Typle	Format
Application from Manufacturer	File upload
Site Master file (as specified under WHO TRS)	File upload
Copy of Manufacturing License	File upload
List of Approved Products	File upload
List of products applied for issuance of COPPs	File upload
List of SOPs and STPs	File upload
Stability Data (3 batches)Accelerated / Real Time	File upload
List of equipment and Instruments	File upload
List of Technical staff, their qualification, experience and approval status	File upload

Document Type	Format
Manufacturing Layout Plan	File upload
Process validation for 3 batches of each product	File upload
Schematic diagram of Water system specifying circulation loop and MOC (Material of Construction)	File upload
Schematic diagram of HVAC system specifying terminal filter configuration	File upload
Export data of last 2 years in case of revalidation	File upload
Product Summery sheet	File upload

Processing of Application

- Application once submitted goes to respective Authority and you can check the status, whether it is under process or query generated or approved.
- This process helps to monitor timelines which brings transparency and gives comfort to see it from anywhere in the world.
- The file goes to assigned officer (generally called as Nodal officer) who forwards it to Drugs inspector (called as Reviewing officer) who after review/ inspection upload his comments and submit online to next Authority (which may be called as ADC or Licensing Authority) who then again checks it and issues permission or ask query.

- The same process of Registration, making application with fees by the applicants, their processing by the regulators and issuing query or approval is followed in all kind of Sugam processes. Therefore, Sugam is extremely simple with regard to its operation once you are acquainted with it.

Steps involved in Portal

Registration (Corporate/Company etc.)

Submission of application as per the required application forms

Processing of applications depending on the type of application.

Issuance of Licenses/Certificates


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
Home
About Us
Downloads
Contact Us
iConnect
Guidelines for uploading data for Manufacturing and Formulation data
Feedback Form (Annexure-I) for SUGAM online portal
nical Trial rules of Drugs & Cosmetics Act. Online process for Biologicals(Vaccines & r-DNA) is available on SUGAM. Manufacturers can add their Formulations Data on SUGAM Portal. New drugs approved by CDSCO is publishe
LOGIN/SIGN UP
Click here to login/sign up to the portal
username or email
password
Z9CZG
Enter Captcha
Login
Don't have an account!
Sign Up Here
Forgot Password
SUGAM
ONLINE LICENSING
Application Submission
Track Status of Application
Grant of Permission/Approval/ License/NOC
APPROVED
Report a Problem

CDSCO Officer Dashboard

Dashboard

Home > Dashboard

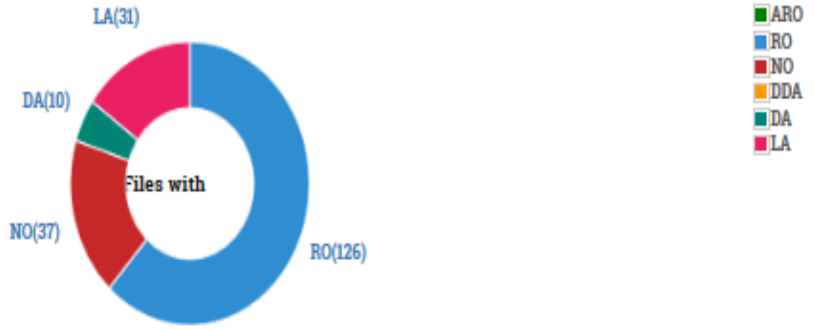
New Applications

29
Total Applications

13
New Applications

16
Query Responded

Inprocess Applications



View All In Process Applications: 204

944
Approved Applications
More info

2
Letter Under Issuance
More info

45
Rejected Applications
More info

109
Query Raised
More info

0
Suspended/Withdrawn Applications
More info

Notifications
Post Submission/Approval
Change Request
More info

2 New Post Approval Applications
55 Total Post Approval Applications
More info

8 New Historical Applications
1761 Total Historical Applications
More info

Laboratory Test Request

CDSCO

Benefits

Timeliness in Drug Regulatory System

- Reduced Application filing time
- Auto generated required Legal forms.
- Online Essential Document upload status

Process Re-engineering

- Inbuilt Pre Screening of Application .
- Inbuilt e-Office

Streamlined Scrutinizing of Application

- Ease in Application Scrutinizing coz no need to carry bulky files as the files are readily available within the system.
- Online query management

Increased Transparency

- Application Status will be available to the Applicant as well as CDSCO Officials at every level.
- National portal will monitor the status of clearances

Automation

- Auto Alerts will prompt the Officials to adhere to time lines for Application Scrutinizing.
- Permissions and Licenses will be generated automatically by system and instantly available to the Applicant.
- Legal Application forms will be generated automatically as prescribed in Drug Act.

e-Governance Implementation in Indian Drug Regulations

2015

CDSCO: Online Regulatory Processes of Drugs/Devices/Vaccines/Blood Products/Cosmetics

2017

MDR 2017

CDSCO & State Food & Drug Administration

Online Regulatory Processes of Medical Devices

2018

Government Laboratories : 7
CDSCO Labs

Lab automation software for testing of medical products

2019…….2022

National e-Gov Portal for States

CDSCO & State Drug Controllers

SUGAM 2.0: Enhancements

SUGAM 2.0

Thank you