

User Manual

1.1 for

**SUGAM e-Governance solution Online Forms
Submission**

Cell and Gene Therapeutic

by

Central Drugs Standard Control Organization (CDSCO)



**Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India**

**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 Block-B, Sector-62, Noida-201309

Phone: 91-120-2210800 Website: <http://www.cdac.in>

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Table Contents

Figure Index

Figure 1: Applicant Dashboard

Figure 2: Select from the Drop-down (Cell and Gene Therapeutic)

Figure 3: Select Form from the drop-down

Figure 4: Data field purpose of application

Figure 5: Data field purpose of application

Figure 6: Data field Finish Formulation

Figure 7: Data field Pack presentation

Figure 8: Data field Storage condition

Figure 9: Data field List of Ingredients

Figure 10: Data field Stability Data of Drug

Figure 11: Data field Manufacturer of Drug Product. (Test)

Figure 12: Data field Manufacturer of Drug Substance. (Ingredient).

Figure 13: Data field Regulatory Status of the Investigational Product in other countries, as appropriate (Test)

Figure 14: Data field Animal Toxicology Status

Figure 15: Data field CT Study Details

Figure 16: Data field Comparator Drug Details (Optional)

Figure 17: Data field Disease Under Investigation

Figure 18: Data field CT Site Details

Figure 19: Data field Protocol Details

Figure 20: Data field Local Clinical Laboratory Details

Figure 21: Data field Central Clinical Laboratory Details

Figure 22: Documents to be uploaded in the checklist

Figure 23: Address Details

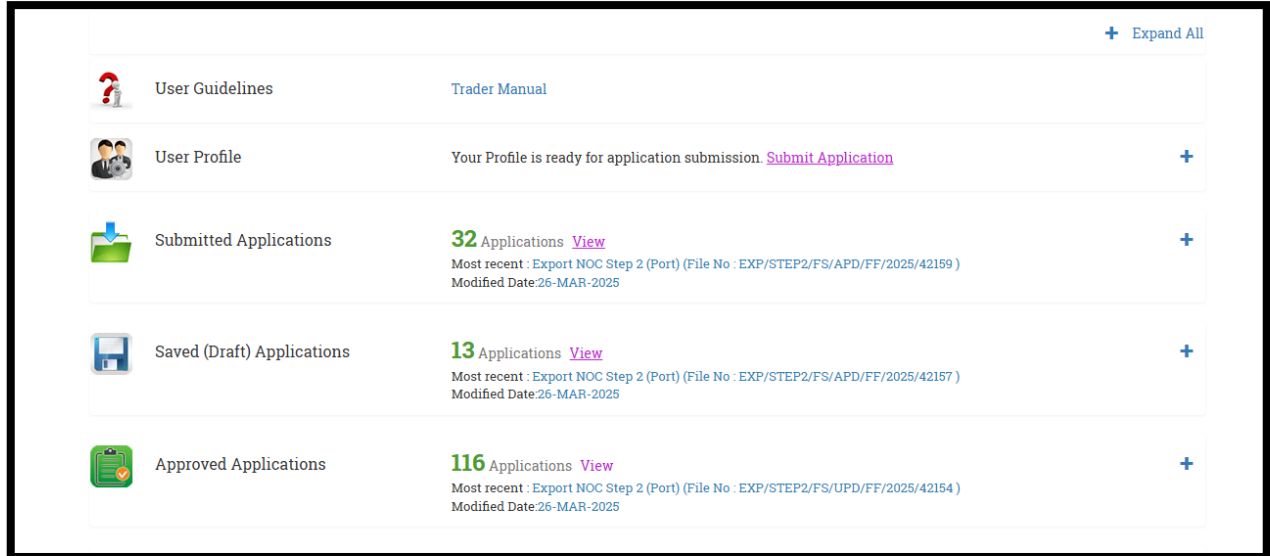
Figure 24: Proceed to Checklist

Figure 25: Checklist page

Figure 26: Payment page

1.SUGAM Applicant Dashboard

After successful login from the homepage of the portal, applicant will be directed to the dashboard depending upon his default role as shown in the below Figure.



The dashboard interface includes a '+ Expand All' link in the top right corner. It features five main sections:

- User Guidelines**: Includes a 'Trader Manual' link.
- User Profile**: States 'Your Profile is ready for application submission' with a 'Submit Application' link.
- Submitted Applications**: Shows '32 Applications' with a 'View' link. The most recent application is 'Export NOC Step 2 (Port)' (File No: EXP/STEP2/FS/APD/FF/2025/42159) modified on 26-MAR-2025.
- Saved (Draft) Applications**: Shows '13 Applications' with a 'View' link. The most recent application is 'Export NOC Step 2 (Port)' (File No: EXP/STEP2/FS/APD/FF/2025/42157) modified on 26-MAR-2025.
- Approved Applications**: Shows '116 Applications' with a 'View' link. The most recent application is 'Export NOC Step 2 (Port)' (File No: EXP/STEP2/FS/UPD/FF/2025/42154) modified on 26-MAR-2025.

Figure1: Applicant Dashboard

1.1 Dashboard Options

Following are the options available on the Applicant dashboard of SUGAM portal

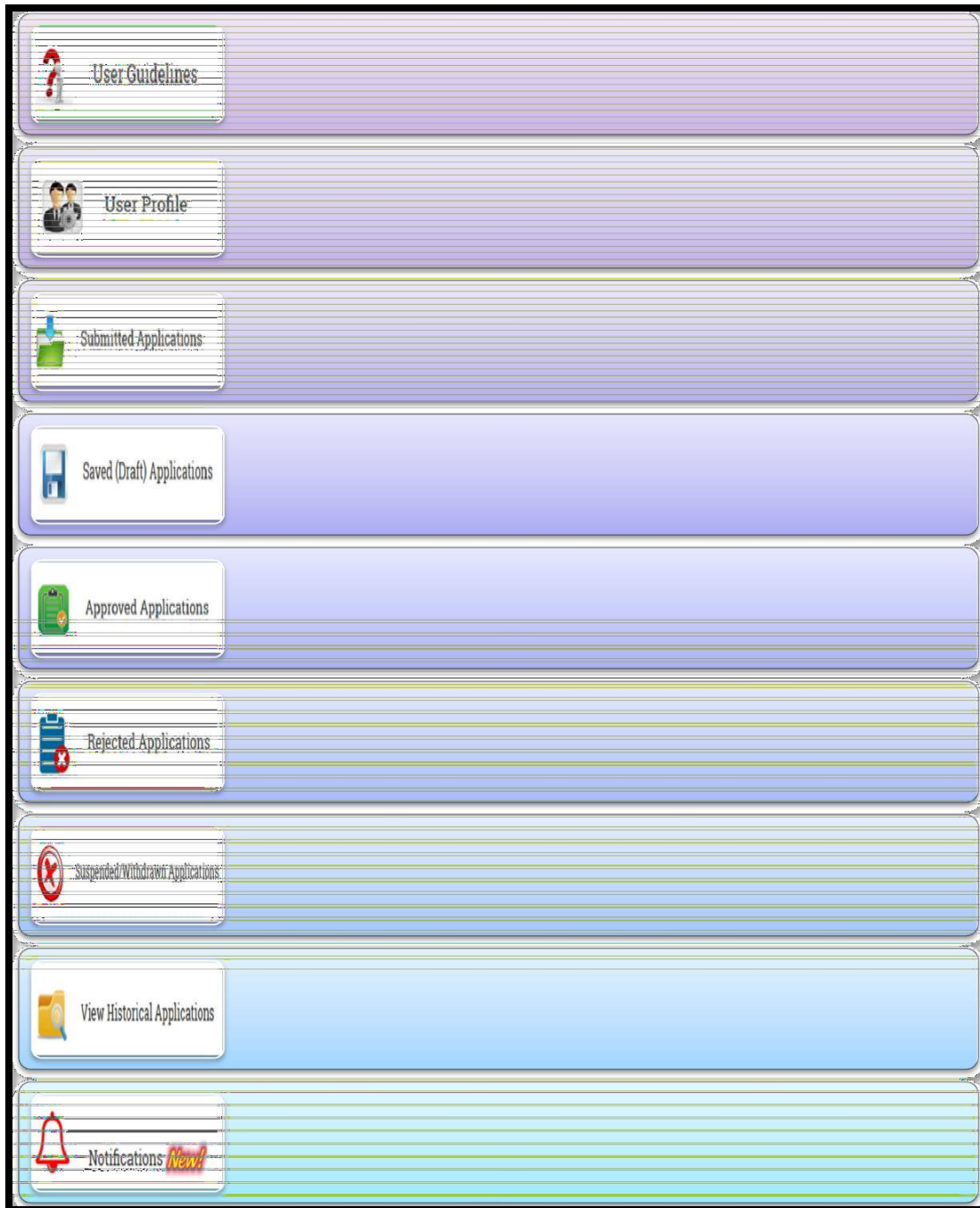


Figure 2

1.2 Form Submission



To submit a form, user must have valid login credentials and should fill up the basic details in User profile section like member details & contact details. If the user is approved by the CDSCO authorities he/she can login to the portal and submit the form.

As shown in the figure below, after login user will be redirected to the dashboard and then click on submit application link to proceed further for submission of application.

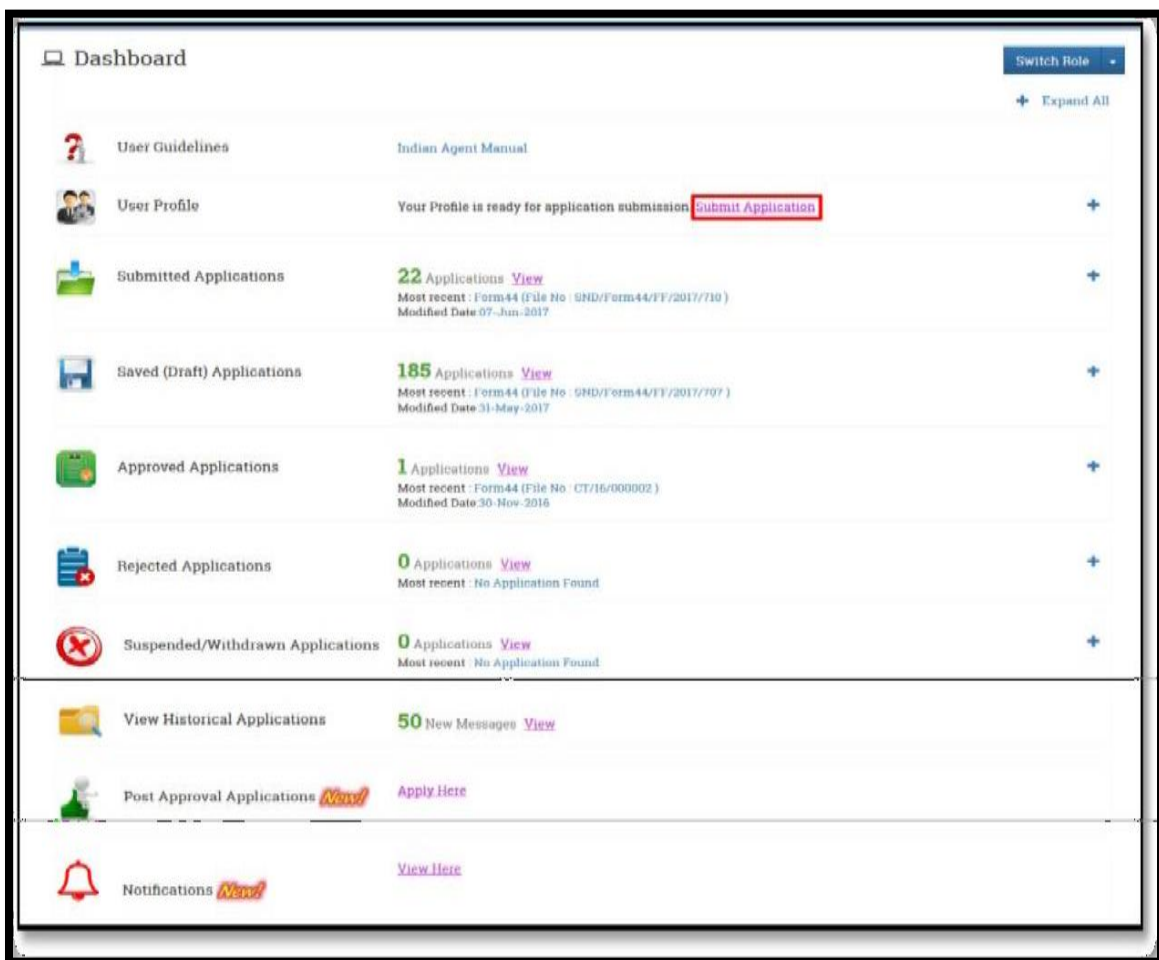


Figure 3: Submit application option

After clicking on “Submit Application” user will be redirected to a new page where he/she will select the department followed by the selection of the form. User should also read the general instruction provided on the same page and click on the declaration box before clicking on proceed to form as shown in the figure below.

User has to select Department and form and click on proceed. After clicking on proceed a new page will open where user has to fill details for Purpose of application

Select Department: ? Cell and Gene Therapeutic

Select Form: Form CT-04

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

Figure 4: Select Department and Form from the drop-down

Submission of form involves 6 steps:

1: Filling of the form: user will fill all the details required for the form. For example, for CT-04 filling of form is further divided into 3 parts. Part 1 captures the purpose application and basic details of the drugs. Part 2 captures more details of the drugs entered in part 1. Part 3 captures details related to CT (Clinical trial) study.

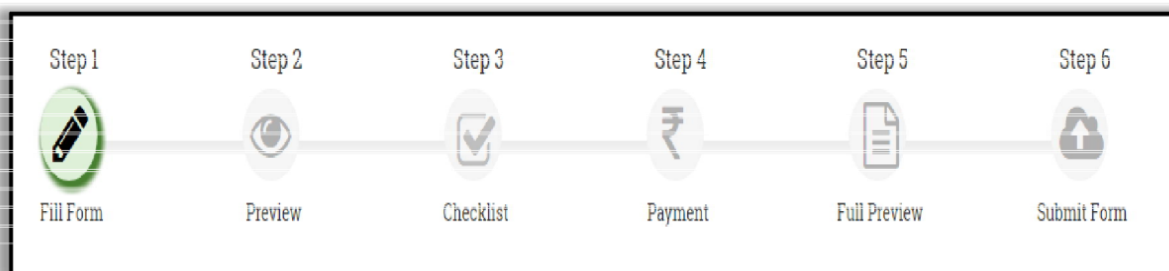
2: First Preview: Based on the details filled by the applicant first preview of the legal form is generated. If the user has any issue with the details, he/she can modify it at this stage. User should ensure all the details are filled correctly because after this step the details cannot be edited.

3: Checklist: Once the preview is verified by the user, they will proceed further to upload the documents required for the form they are filling. Every form has a different checklist of documents based on the form type. User is allowed to upload a PDF document of size not more than 50MB

4: Payment: After uploading the checklist user will be redirected to the payment page. User can make the payment either by uploading a challan or by doing in online.

5: Final Preview: Once payment is done user can view the complete legal form with payment details and download the system generated form for signature.

6: Submit Form: After signing the form user will scan the signed copy and upload the document after which the form will be submitted and a file number will be generated. The status of the file can be tracked using the same file number.



. Figure 5: Application steps

There are five parts in Step-1

In Part 1 Fill the following details of the Purpose of Application

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

Fill Form Preview Checklist Payment Full Preview Submit Form

APPLICATION FOR GRANT OF PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

Purpose of Application

Purpose Of Application:*	To Undertake Clinical Trial (FORM CT-04)
Category of new Cell and Gene Therapeutic Product (CGTP):*	Cell and Gene Therapeutic Product (CGTP)
Type of Application:*	Stem Cell Derived Products
Application applied for:*	<input checked="" type="radio"/> Finished Formulation
Do you have simultaneously applied for Form CT-16 ? *	No
Do you have simultaneously applied for Form CT-10 ? *	No
Do you have simultaneously applied for Form CT-12 ? *	No
Do you have simultaneously applied for Form CT-13 ? *	No
Select CT: *	Clinical Trials (phase I)
Generic/INN Name(s) of Drug(s) * 	Test
Intended Use *	For Human
pH value of Drug	6.4

[Save and Continue](#)

Figure6: Data field purpose of application

Purpose of Application

Purpose Of Application:*	To Undertake Clinical Trial (FORM CT-04) ▼
Category of new Cell and Gene Therapeutic Product (CGTP):*	Cell and Gene Therapeutic Product (CGTP) ▼
Type of Application:*	Stem Cell Derived Products ▼
Application applied for:*	<input checked="" type="radio"/> Finished Formulation
Do you have simultaneously applied for Form CT-16 ? *	No ▼
Do you have simultaneously applied for Form CT-10 ? *	No ▼
Do you have simultaneously applied for Form CT-12 ? *	No ▼
Do you have simultaneously applied for Form CT-13 ? *	No ▼
Select CT: *	Clinical Trials (phase 1) ▼

Generic/INN Name(s) of Drug(s) * ⓘ

Intended Use * ▼

pH value of Drug

[→Next](#)

Figure7: Data field purpose of application

In Part 2 Fill the following details:

Finish Formulation

Pack presentation

Storage condition

List of Ingredients/Impurities for Dose

Finished Formulation

Proprietary, Commercial, or Trade Name of Drug Product *

Dosage Form *

Route of Administration of Cell and Gene Therapeutic *

Pharmacological Classification of Cell and Gene Therapeutic *

Indication for which proposed to be used *

Show entries Search:

Indication	Delete
Indication for which proposed to be used	<input type="button" value="Delete"/>

Showing 1 to 1 of 1 entries Previous Next

Figure 8: Data field of Finish Formulation

Pack Presentation of Cell and Gene Therapeutic Product (CGTP)

Presentation *

Primary Packaging Material *

Pack Size *

Show entries Search:

Presentation	Primary Packaging Material	Pack Size	No. of Dose	Delete
Injectors	Glass	Single Dose	0	<input type="button" value="Delete"/>

Showing 1 to 1 of 1 entries Previous Next

Figure 9: Data field Pack presentation

Storage Condition

Temperature *

Humidity *

Light *

Proposed Shelf Life of Cell and Gene Therapeutic *

Dose * Unit *

Show entries Search:

Dose	Delete
= 10.000 gram (g)	

Showing 1 to 1 of 1 entries Previous Next

Figure 10: Data field Storage condition

List of Ingredients/Impurities for Dose

Add atleast one active ingredient

Ingredient * Pharmacopoeial Monograph * Strength * Unit *

Field is required

Category *

Show entries Search:

Ingeridient Name	Monograph	Stregnth	Category	Delete
Ingredient	I.P.	= 20.0000 mg/ml	Active	

Showing 1 to 1 of 1 entries Previous Next

Figure11: Data field List of Ingredients.

In Part 3 Fill the following details:

Stability Data of Drug

Manufacturer of Drug Product. (Test).

Manufacturer of Drug Substance. (Ingredient).

Regulatory Status of the Investigational Product in other countries, as appropriate (Test)

Animal Toxicology Status

Stability Data of Drug

Batch * Duration(months) * Orientation *

Batch No. * Batch Size * Presentation *

Date of Initiation of Stability * Manufacturing Date * Proposed ShelfLife * months

Stability Condition * Temperature/RH *

Storage Condition

Parameters	Specification	Result	Remarks
Assay(ingredient)	= 20.0000 mg/ml	<input type="text"/>	<input type="text"/>
Water Content	<input type="text"/>	<input type="text"/>	<input type="text"/>
Cell Viability	<input type="text"/>	<input type="text"/>	<input type="text"/>
Cell Count	<input type="text"/>	<input type="text"/>	<input type="text"/>
Endotoxin	<input type="text"/>	<input type="text"/>	<input type="text"/>
Sterility	<input type="text"/>	<input type="text"/>	<input type="text"/>
Phenotype	<input type="text"/>	<input type="text"/>	<input type="text"/>
Others	<input type="text"/>	<input type="text"/>	<input type="text"/>
Others	<input type="text"/>	<input type="text"/>	<input type="text"/>
Others	<input type="text"/>	<input type="text"/>	<input type="text"/>
Others	<input type="text"/>	<input type="text"/>	<input type="text"/>
Others	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Others	<input type="text"/>	<input type="text"/>	<input type="text"/>
Others	<input type="text"/>	<input type="text"/>	<input type="text"/>
Others	<input type="text"/>	<input type="text"/>	<input type="text"/>
Others	<input type="text"/>	<input type="text"/>	<input type="text"/>
Others	<input type="text"/>	<input type="text"/>	<input type="text"/>
Others	<input type="text"/>	<input type="text"/>	<input type="text"/>

Show entries Search:

A	Batch	Duration	Batch No.	Stability Date	Batch Size	Orientation	Temperature	Manufacturing Date	ShelfLife	Stability Condition	Delete
+	Batch 1	0 Month	Batch No	01-Jan-2025	Batch Size	Horizontal	-20°C ± 5°C	31-May-2025	30	Accelerated	🗑️

Showing 1 to 1 of 1 entries Previous Next

Figure12: Data field Stability Data of Drug

Manufacturer of Drug Product.(Test)

Site Type *

Unit Name *

Address Line 1 *

Country *

State/Province/Region *

City *

Zip/Postal Code *

Landline No. (Please include Country code - State code - Landline Number) *

Fax (Please include Country code - State code - Fax Number) *

Show entries Search:

Site Type	Site Name	Site Address	Telephone No.	Fax	Delete
Manufacturing Site	Assay	Assay, 45859608574, FDA bhawan, Delhi, delhi, India, 110002	45859608574	45859608574	

Showing 1 to 1 of 1 entries Previous Next

Figure13: Data field Manufacturer of Drug Product. (Test).

Manufacturer of Drug Substance.(Ingredient)

Site Type *

Unit Name *

Address Line 1 *

Country *

State/Province/Region *

City *

Zip/Postal Code *

Landline No. (Please include Country code - State code - Landline Number) *

Fax (Please include Country code - State code - Fax Number) *

Show entries Search:

Site Type	Site Name	Site Address	Telephone No.	Fax	Delete
Formulation Site	Unit Name	Unit Name, 45859608574, Address Line 1, City, Default, Anguilla, 11111	45859608574	45859608574	

Showing 1 to 1 of 1 entries Previous Next

Figure14: Data field Manufacturer of Drug Substance. (Ingredient).

Regulatory Status of the Investigational Product in other countries, as appropriate(Test)

Regulatory Status *

Show entries Search:

Regulatory Status	Date	Country	Approved Indication	Reason/Remarks	Copy of Approval	Delete
Approval Pending	2024-12-11T00:00:00	France		NA	No Document	<input type="button" value="Delete"/>

Showing 1 to 1 of 1 entries Previous Next

Figure15: Data field Regulatory Status of the Investigational Product in other countries, as appropriate (Test)

In Part 4 Fill the following details:

CT Study Details

CT Study Details

Clinical Trial

Scope/Objective of Trial *

Study Design *

Sponsor Details

Sponsor * Self Sponsored Sponsored by Others

Figure16: Data field CT Study Details

In Part 5 Fill the following details:

- CT Study Details
- Comparator Drug Details (Optional)
- Disease Under Investigation
- CT Site Details
- Protocol Details
- Local Clinical Laboratory Details
- Central Clinical Laboratory Details

Comparator Drug Details (Optional)

Comparator Drug Name *

Proprietary, Commercial or Trade name of Drug Product

Drug Composition

Dosage Form *

Route of Administration *

Name of Manufacturing Company *

Name of Country where drug is Manufactured *

Comparator Details

Show entries Search:

Comparator Drug Name	Drug Product	Drug Composition	Dosage Form	Route Administration	Manufacturing Company	Name of Manufacturing Country	Delete
Comparator Drug Name	Proprietary, Commercial or Trade name of Drug Product	25	Capsules	External	Name of Manufacturing Company	France	

Showing 1 to 1 of 1 entries Previous Next

Figure17: Data field Comparator Drug Details (Optional)

Disease Under Investigation

Disease Name *

Is Rare Disease *

Disease Details

Show entries Search:

Disease Name	Is Rare Disease	Delete
Disease Name	No	

Showing 1 to 1 of 1 entries Previous Next

Figure18: Data field Disease Under Investigation

CT Site Details

Hospital *(Select "Others" option if desired hospital is not available in drop-down list)

No. of Beds in Hospital*

Institutional Ethics Committee (IEC) *

Investigator Details

Name of Investigator * **Designation *** **Qualification ***

Medical Council Registration No. * **Specialization *** **No. of CT Completed**

GCP Trained *

CT Site Details

Show entries Search:


*	Hospital	Ethics Committee	Investigator	Delete
	Sir Ganga Ram Hospital Ethics Committee, Room No 1496. IV Floor , Old Building ,Old Rajinder Nagar, , New Delhi, Not Available, Delhi	Ganga Hospital Ethics Committee (ECR/1915/Inst/TN/2024)	Name of Investigator	

Showing 1 to 1 of 1 entries Previous Next

Figure19: Data field CT Site Details

Protocol Details

Protocol No. *
 Version No. *
 Amendment No.

Protocol Date * 
 Dosing *
 No. of Volunteers *

No. of Patients *
 Planned No. of Subjects To Be Included In India *
 Type of Population *



Protocol Title *

Study Design *

Gender *
 Proposed Study period *
 Age Group *

Protocol Details

Show entries Search:

	Protocol No.	Version No.	Protocol Date	Dosing	No. of Healthy Volunteers	Delete
	4444	123	04-FEB-2025	Single Dose	10	

Showing 1 to 1 of 1 entries Previous Next

Figure20: Data field Protocol Details

Local Clinical Laboratory Details

Principal Investigator * **Laboratory Name ***

Address Line * **Country ***

State * **District *** **City ***

Zip/Postal code * **Landline No. *** (Please include Country Code - State Code - Landline Number) **Fax** (Please include Country Code - State Code - Fax Number)
Multiple Contact Numbers can be added with comma separation. Multiple Fax Numbers can be added with comma separation.

E-mail * **Whether NABL/Accredited by other Agency ***

Local Clinical Laboratory Details

Show entries Search:

Principal Investigator	Laboratory Name	Address	Whether NABL/Accredited by other Agency	Delete
Name of Investigator	Laboratory Name	Address : Address Line, Country : India, State : Delhi, District : Central Delhi, City : Delhi, Pincode : 110001, Landline No. : 1111111111, Fax : 1111111111, Email : abc@test.com	Yes	

Showing 1 to 1 of 1 entries Previous Next

Figure21: Data field Local Clinical Laboratory Details

Central Clinical Laboratory Details

Laboratory Name * **Whether NABL/Accredited by other Agency ***

Address Line * **Country ***

State/Province/Region * **City *** **Zip/Postal code ***

Landline No. * (Please include Country Code - State Code - Landline Number) **Fax *** (Please include Country Code - State Code - Fax Number) **E-mail***

Multiple Contact Numbers can be added with comma separation. Multiple Fax Numbers can be added with comma separation.

Central Clinical Laboratory Details

Show entries Search:

Laboratory Name	Whether NABL/Accredited by other Agency	Address	Delete
Laboratory Name	Yes	Address : ABC, Country : Austria, State : Austria, City : Austria, Pincode : 252458, Landline No. :1111111111, Fax : 1111111111, Email : abc@test.com	

Showing 1 to 1 of 1 entries Previous Next

Activate Windows
Go to Settings to activate Windows.

Figure22: Data field Central Clinical Laboratory Details

After completed all 5 parts pages will appear regarding documents to be uploaded

Part 3

Documents to be uploaded in the checklist

Note: You will be required to upload below listed documents in the checklist section for successful submission of application.

- 1 Test specification:
- 2 Test specification:
 - Active Ingredients:
 - Active Ingredients:
 - Inactive Ingredients:
 - Inactive Ingredients:
- Permission to market a new drug:
- Permission to market a new drug:
 - Chemical and Pharmaceutical Information :
 - Chemical and Pharmaceutical Information :
 - Bio-availability, dissolution and stability study Data :
 - Bio-availability, dissolution and stability study Data :
 - Marketing information:
 - Marketing information:
 - Proposed product monograph :
 - Proposed product monograph :
 - Drafts of label and cartoons:
 - Drafts of label and cartoons:
 - Application for test license :
 - Application for test license :
- Subsequent approval/permission for manufactur of already approved new drug:-
- Subsequent approval/permission for manufactur of already approved new drug:-
 - Formulation:
 - Formulation:
 - Raw material (bulk drug substances):
 - Raw material (bulk drug substances):
- Approval/permission for fixed dose combination:-
- Approval/permission for fixed dose combination:-
- Subsequent approval or approval for new indication-new dosage form:
- Subsequent approval or approval for new indication-new dosage form:

I hereby declare that I will enclosed the above listed documents in the Checklist and I will be solely responsible for any false or inaccurate document provided to the division.

[← Previous](#) [→ Continue](#)

Figure23: Documents to be uploaded in the checklist

After clicking on continue, Address details has to be added as shown in the below image

Address Details

Note: Kindly select below listed addresses for required in section 3 of Form CT-XX as per new Drugs & CT rules 2019
Addresses in this section are fetched from [Add Address Details](#) tab added under User Profile.

Sponsor Address i *

Clinical Trial Site Address i *

Correspondence Address i *

Name & address of person responsible for payment of compensation (if any) i

Person Name *

Address *

Country * **State** * **Pincode** *

Contact No. * (Please include STD Code - Phone Number) **Email Id** *

Multiple Contact Numbers can be added with comma separation

Figure24: Address Details

A preview page will appear after address details added as shown in the below image:

Form CT-04

(APPLICATION FOR GRANT OF PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG)

I/We Applicant of M/s. Testing, Testing Enclave Tester Group Mumbai -123123 Telephone No: 1212121212 Fax : 3434343434 E-Mail TMPSANJEEVSOAM@GMAIL.COM hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information/data is given below:

Name of the Drug : Test

Stability Details

Show entries

Search:

	Batch	Duration	Batch No.	Stability Date	Batch Size	Orientation	Temperature	Manufacturing Date	ShelfLife	Stability Condition
	Batch 1	6 Month	Batch No	01-Jan-2025	Batch Size	Horizontal	-20°C ± 5°C	31-May-2025	36	Accelerated

Showing 1 to 1 of 1 entries

Previous Next

Manufacture Details (Drug Product)

Show entries

Search:

Site Type	Site Name	Site Address	Telephone No.	Fax
Manufacturing Site	Assay	Assay, 45859658574, FDA bhawan, Delhi, delhi, India, 110002	45859658574	45859658574

Showing 1 to 1 of 1 entries

Previous Next

Manufacture Details (Drug Substance for Ingredient Ingredient)

Show entries

Search:

Site Type	Site Name	Site Address	Telephone No.	Fax
Formulation Site	Unit Name	Unit Name, 45859658574, Address Line 1, City, Default, Anguilla, 111111	45859658574	45859658574

Showing 1 to 1 of 1 entries

Previous Next

Figure25: Preview (Continue)

Animal Toxicology

Study	Status
Single-dose Toxicity Studies	Study Not Required
Repeated-dose Systemic Toxicity Studies	Study Not Required
Female Reproduction and Developmental Toxicity Studies	Study Not Required
Local Toxicity	Study Not Required
Allergenicity/Hypersensitivity	Study Not Required

Composition of Formulation

Show 10 entries

Search:

Ingerident Name	Monograph	Stregnth	Category
Ingredient	I.P.	= 20.0000 mg/ml	Active

Showing 1 to 1 of 1 entries

Previous 1 Next

Regulatory Status in Other Countries

Show 10 entries

Search:

Regulatory Status	Date	Country	Approved Indication	Reason/Remarks
Approval Pending	2024-12-11T00:00:00	France		NA

Showing 1 to 1 of 1 entries

Previous 1 Next

Clinical Trial Study Details

Clinical Trial

Scope/Objective of Trial	Study Design
Therapeutic	Single Arm Trial

Sponsor Details

Sponsor

Self Sponsored

Comparator Drug Details

S.No.	Comparator Drug Name	Name of Company	Name of Country
1	+ Comparator Drug Name	Name of Manufacturing Company	France

Figure26: Preview (Continue)

Disease Under Investigation

S.No. ⌵	Disease Name ⌵
1	+ Disease Name

CT Site Details

S.No. ⌵	Hospital ⌵	No. of Beds ⌵	Ethics Committee ⌵	Laboratory Details ⌵
1	+ Sir Ganga Ram Hospital Ethics Committee Room No 1496. IV Floor , Old Building ,Old Rajinder Nagar, New Delhi, Not Available, Delhi	30	Ganga Hospital Ethics Committee	Laboratory Name Address Line, null Delhi, Central Delhi Delhi -110001(India) Whether GLP/ISO/NABL/Other Certified: Yes

Protocol Details


S.No. ⌵	Protocol No. ⌵	Version No. ⌵	Date of Protocol ⌵	Dosing ⌵	Subject Details ⌵	Age Group ⌵	Proposed Period ⌵	Study
1	+ 4444	123	04-Feb-2025	Single Dose	Male	Pregnant Women(below 37 Weeks)	24 Weeks	

Centralized Laboratory Details

S.No. ⌵	Lab Name ⌵	Lab Address ⌵	Email ⌵
1	+ Laboratory Name	ABC, , Austria Austria -252458 (Austria)	abc@test.com

Place
Date 09-Jun-2025

Signature
Designation

 Edit Form


 Proceed To Checklist

Figure 27: First Preview of the CT-04

Checklist to upload the documents

Upload Essential Documents CT-04

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/alterd under the Saved Application link available on the Dashboard
4. [Click here to view Guidelines for PDF documents](#)

<input checked="" type="checkbox"/> 1. SECTION A GENERAL INFORMATION
<input checked="" type="checkbox"/> 1.1 Enclosure Sheet
1.2.Covering letter
<input checked="" type="checkbox"/> 1.2.1 Includes name of CGTP drug, its strength, dose, dosage form, indication, route of administration, phase of clinical trial proposed, precise manufacturing site, address where the product will be manufactured, rationale for the application, etc.
<input checked="" type="checkbox"/> 1.3 Name of Applicant
<input checked="" type="checkbox"/> 1.4 Name of CGTP Drug
1.5.Dosage form, Composition and packing details
<input checked="" type="checkbox"/> 1.5.1 Quantitative containing list of active and inactive ingredients) and packing details
1.6.Form CT-10/CT-16 and Fees (Challan details)
<input checked="" type="checkbox"/> 1.6.1 Refer Sixth Schedule of New Drugs and Clinical Trials Rules, 2019
1.7.Application in Form CT-04
<input checked="" type="checkbox"/> 1.7.1 Refer Sixth Schedule of New Drugs and Clinical Trials Rules, 2019
<input checked="" type="checkbox"/> 1.8 Introduction about company
<input checked="" type="checkbox"/> 1.9 Administrative Headquarters
<input checked="" type="checkbox"/> 1.10 Manufacturing Facilities
<input checked="" type="checkbox"/> 1.10.1 Vector, Plasmid and Cells along with license and GMP accreditation
1.10.2.Drugs Substance (Name(s), address(es) and responsibilities of all site(s) involved in cell/tissue procurement site
<input checked="" type="checkbox"/> 1.10.2.1 E.g. apheresis site, tissue bank), product manufacturing, quality control testing (e.g. sterility testing laboratory) and storage including activity wise building, floor, block/suite specific details including Valid and relevant accreditation certificates or licences
<input checked="" type="checkbox"/> 1.10.3 Valid and relevant accreditation certificates or licences
<input checked="" type="checkbox"/> 1.10.3.1 CGTP Drug Product: Name(s), address(es) and responsibilities of all site(s) involved in development and proposed production
<input checked="" type="checkbox"/> 1.10.4 Details whether dedicated or campaign-based manufacturing facility.
<input checked="" type="checkbox"/> 1.10.4.1 Valid and relevant accreditation certificates or licences for Drug product manufacturing facility
1.11.Information about Test license
1.11.1.Form CT-11 or Form- CT-17
<input checked="" type="checkbox"/> 1.11.1.1 Issued by Central Licensing Authority for clinical trial, Bioavailability or Bioequivalence study or for Examination, Test and Analysis
<input checked="" type="checkbox"/> 1.11.2 Form 29 as issued by State Licensing Authority

Figure 28: Checklist to upload the documents

1.11.3.RCGM/GEAC Permission issued to conduct toxicology studies
<input checked="" type="checkbox"/> 1.11.3.1 For Gene Therapeutics and r- DNA products
<input checked="" type="checkbox"/> 1.12 Regulatory and intellectual property status in other countries
1.12.1.Countries where the CGTP is
<input checked="" type="checkbox"/> 1.12.2 Marketed (supporting documents)
<input checked="" type="checkbox"/> 1.12.3 Approved (supporting documents)
<input checked="" type="checkbox"/> 1.12.4 Approved as IND(supporting documents)
<input checked="" type="checkbox"/> 1.12.5 Withdrawn, if any, with reasons
<input checked="" type="checkbox"/> 1.13 Patent information status in India & other countries
<input checked="" type="checkbox"/> 1.14 Sponsors name and Authorization letter
<input checked="" type="checkbox"/> 1.15 Study details
<input checked="" type="checkbox"/> 1.15.1 Protocol Title
<input checked="" type="checkbox"/> 1.15.2 Protocol Number
<input checked="" type="checkbox"/> 1.15.3 Phase of the study
<input checked="" type="checkbox"/> 1.15.4 Number of subjects to be enrolled
<input checked="" type="checkbox"/> 1.16 Executive Summary (as per the prescribed attached format)
<input checked="" type="checkbox"/> 1.17 Protocol Synopsis
1.18.Clinical development for proposed indication and any other Indication (including earlier study in humans)
<input checked="" type="checkbox"/> 1.18.1 Part I
<input checked="" type="checkbox"/> 1.18.2 Part II (Optional)
<input checked="" type="checkbox"/> 1.18.3 Part III (Optional)
<input checked="" type="checkbox"/> 1.18.4 Part IV (Optional)
2. Section B: CMC DATA
2.1.Product Description
<input checked="" type="checkbox"/> 2.1.1 Name of the product
2.1.2.Generic name / INN name
<input checked="" type="checkbox"/> 2.1.2.1 Generic name / International Non-proprietary Name (INN), The United States Adopted Names (USAN), proprietary name or common name of that is given to the product or an active substance.
<input checked="" type="checkbox"/> 2.1.3 Route of administration
<input checked="" type="checkbox"/> 2.1.4 Dosage of strength
<input checked="" type="checkbox"/> 2.1.5 Qualitative and Quantitative Composition
2.2.Information on CGTP Drugs Substance
2.2.1.General Information
2.2.1.1.Nomenclature

Figure 29: Checklist to upload the documents(continue)

<input checked="" type="checkbox"/>	2.2.1.1.1 International Non-proprietary Name (INN), The United States Adopted Names (USAN), proprietary name or common name of that is given to the product or an active substance.
2.2.1.2. Structure	
<input checked="" type="checkbox"/>	2.2.1.2.1 Physical characteristics of cells e.g. origin, phenotype, cell size, cell surface markers
<input checked="" type="checkbox"/>	2.2.1.2.2 Schematic representation of structural component combined with a CGTP e.g. scaffold, matrices, medical device
<input checked="" type="checkbox"/>	2.2.1.2.3 For viral vectors, to provide schematic representation of regulatory and functional genetic elements (e.g. promoter, enhancer, restriction enzyme sites, transgene and selection markers). Information include but not limited to the composition of viral capsid, envelope structures, molecular weight, particle size, glycosylation sites, nature of the genome (single-stranded, double stranded, DNA or RNA, copy number of genomes per particles), tropism of viral vectors (e.g. specificity of viral vector for particular host tissue).
<input checked="" type="checkbox"/>	2.2.1.2.4 For plasmid vector, to provide schematic representation of regulatory and functional genetic elements (e.g. promoter, enhancer, restriction enzyme sites, transgene and selection markers). Information include but not limited to the physical properties, biochemical, growth characteristics, genetic markers and location (e.g. on plasmid, episomal or chromosomally) of inserted foreign genes.
<input checked="" type="checkbox"/>	2.2.1.2.5 For use of gene editing technology, provide description of the gene(s) edited and gene editing technology that was used.
2.2.1.3. General properties	
<input checked="" type="checkbox"/>	2.2.1.3.1 Physicochemical and biological properties to achieve the defined biological effect.
<input checked="" type="checkbox"/>	2.2.1.3.2 Proposed mechanisms of action.
2.2.2. Manufacture(s)	
<input checked="" type="checkbox"/>	2.2.2.1 Name, Address and responsibilities of all site (s) involved in cell/tissue procurement site (e.g. apheresis site, tissue bank), product manufacturing, quality control testing (e.g. sterility testing laboratory) and storage.
<input checked="" type="checkbox"/>	2.2.2.2 Valid and relevant accreditation certificates or licences
2.2.3. Description of manufacturing process and in-process controls	
<input checked="" type="checkbox"/>	2.2.3.1 A flow diagram of the manufacturing process with in process controls and acceptance criteria (e.g. control limits).
2.2.3.2. Detailed description of the manufacturing steps from:	
<input checked="" type="checkbox"/>	2.2.3.2.1 Human cell/tissue collection (e.g. leukapheresis, biopsy, cord blood bank, tissue bank)
<input checked="" type="checkbox"/>	2.2.3.2.2 Vector production (e.g. viral vectors, bacterial plasmids and mRNA production, purification procedures, vector quality testing and storage conditions)
<input checked="" type="checkbox"/>	2.2.3.2.3 Enzymatic digestion
<input checked="" type="checkbox"/>	2.2.3.2.4 Cell selection (e.g. method, devices and reagents used)
<input checked="" type="checkbox"/>	2.2.3.2.5 Cell expansion (e.g. culture media components, culture flasks/bags/bioreactor)
<input checked="" type="checkbox"/>	2.2.3.2.6 Open or closed culture system, culture temperature, duration)
<input checked="" type="checkbox"/>	2.2.3.2.7 Gene modifications (e.g. transfection, infection, electroporation or gene editing components)
<input checked="" type="checkbox"/>	2.2.3.2.8 Purification, irradiation, process operating parameters (e.g. duration, temperature, centrifugation speed)
<input checked="" type="checkbox"/>	2.2.3.2.9 In-process control tests (e.g. viability, pH, cell number, dissolved oxygen, titre, bioburden, impurities)
<input checked="" type="checkbox"/>	2.2.3.2.10 Hold times, transfer steps, production duration, harvesting, formulation, filling and storage.
<input checked="" type="checkbox"/>	2.2.3.3 Transport procedures for starting material and finished product (e.g. transport temperature, duration and packing information) and hold times of materials to the manufacturing facility and during manufacturing process
<input checked="" type="checkbox"/>	2.2.3.4 Information on batch size, scale of production, quantity of starting materials e.g. volume apheresis materials) and expected yield.
<input checked="" type="checkbox"/>	2.2.3.5 Batch (or lot) identification system

Figure 30: Checklist to upload the documents(continue)

<input checked="" type="checkbox"/> 5.5 Template of the Case Report Form to be used
<input checked="" type="checkbox"/> 5.6 Investigators Brochure as per Table 7 of Schedule III of New Drugs and Clinical Trials Rules, 2019
<input checked="" type="checkbox"/> 5.6.1 Affidavit declaring that the information about study Cell and Gene Therapy Product drug as mentioned in Investigators Brochure is correct and based on available facts
<input checked="" type="checkbox"/> 5.7 List of Participating Sites, along with name and contact details of the Principal Investigators and EC Details
<input checked="" type="checkbox"/> 5.7.1 Details of the contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator
<input checked="" type="checkbox"/> 5.7.2 Undertaking by the Investigators as per Table 4 of Schedule III of NDCT Rules 2019 including List of Investigators with qualification along with CV and MRC
<input checked="" type="checkbox"/> 5.7.3 Ethics committee approval if any
<input checked="" type="checkbox"/> 5.8 Proposed Draft of IMP Label as per New Drugs and Clinical Trials Rules, 2019
<input checked="" type="checkbox"/> 5.9 Valid Copy of the Insurance Certificate (Certificate Only)
<input checked="" type="checkbox"/> 5.10 Assessment of risk versus benefit to the patient (for this proposal)
<input checked="" type="checkbox"/> 5.11 Innovations Vs existing therapeutic option (w.r.t. this proposal)
<input checked="" type="checkbox"/> 5.12 Unmet medical need in the country (of IMP/Trial proposal)
<input checked="" type="checkbox"/> 5.13 Any published literature on the development of the IMP
<input checked="" type="checkbox"/> 5.14 In case of Phase II clinical trial submit the report of Phase I trial
<input checked="" type="checkbox"/> 5.15 Post Marketing (Phase IV) Studies
<input checked="" type="checkbox"/> 5.15.1 Marketing Approval status of the CGTP drug under study
<input checked="" type="checkbox"/> 5.15.2 Product Prescribing Information containing clinical trial results, conclusions, adverse and serious adverse events experienced during the clinical trials in tabular manner as per Table 8 of Schedule III of New Drugs and Clinical Trials Rules, 2019
<input checked="" type="checkbox"/> 5.15.3 Summary of phase I, phase II & Phase III clinical trial studies
<input checked="" type="checkbox"/> 5.16 Clinical trials data generated in Country of Origin and other Countries (for imported CGTP product)
<input checked="" type="checkbox"/> 5.16.1 Part 1 (Optional)
<input checked="" type="checkbox"/> 5.16.1.2 Part 2 (Optional)
<input checked="" type="checkbox"/> 5.16.1.3 Part 3 (Optional)
<input checked="" type="checkbox"/> 5.17 Training procedure of Healthcare Professionals for handling of CGTP product
5.18.Comparability Studies (For Phase II clinical trial):
<input checked="" type="checkbox"/> 5.18.1 Significant manufacturing changes, then comparability studies may be necessary to determine the impact of these changes on the identity, purity, potency, and safety of the product.
<input checked="" type="checkbox"/> 5.18.2 Differences between toxicology lots and clinical lots should be assessed for their impact on product safety.
<input checked="" type="checkbox"/> 5.19 Any other information (optional)

Activate Windows
Go to Settings to activate Windows.

Figure 31: Checklist to upload the documents

Payment for the form

Payment Details

Payment has been calculated as below:

- A fee of Rs 300000 for each product

Head of Account **0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines**

Mode of Payment * Purpose *

Figure 32: Payment page

After payment Final preview of the form with download option will appear.



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. **CGT/CT04/FF/2025/48865** for future correspondence.

Figure 33: Application Submitted Successful

