TAMIL NADU SINGLE WINDOW PORTAL

APPLICANT MANUAL

Licence to Manufacture Allopathic Drugs

Food Safety and Drug Administration

Table of Contents

1. Home Page

1) The journey of the new applicant starts with Tamil Nadu Single Window Portal (TNSWP) homepage that can be accessed through **https://tnswp.com** website wherein it gives various information's, useful links, and functionalities about TNSWP.

2) **Applicant can reach the helpdesk Toll free number – 1800-258-3878 and Helpdesk Email.**

TNSWP website (www.tnswp.com)
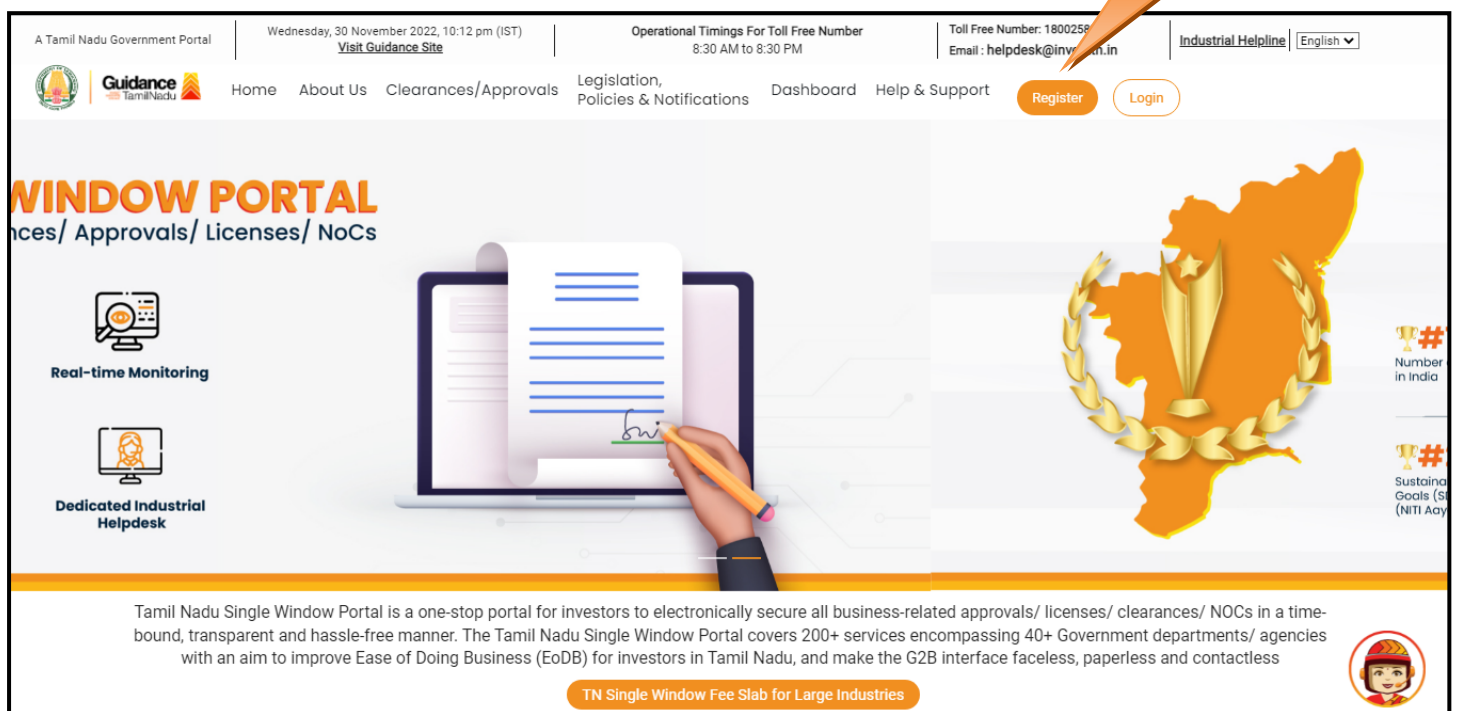
Toll free number and Mail Id

Figure 1. Single Window Portal Home Page

2. Registration

To access the TNSWP and to apply for various clearances the applicant must complete the Registration process.

1) Click on **'Register'** button on TNSWP.

Figure 2. Register

2) New Investor Registration page will appear (Refer Figure 3 & 4)

3) Select the **'Investor'** option and continue with the Registration process.

4) Only for applying Government to Citizen (G2C) fire clearances, click on option **'G2C clearances of Tamil Nadu fire and rescue clearances under the category Individual/Small enterprise'**.

5) The information icon (i) gives a brief description about the fields when the applicant hovers the cursor on these icons.
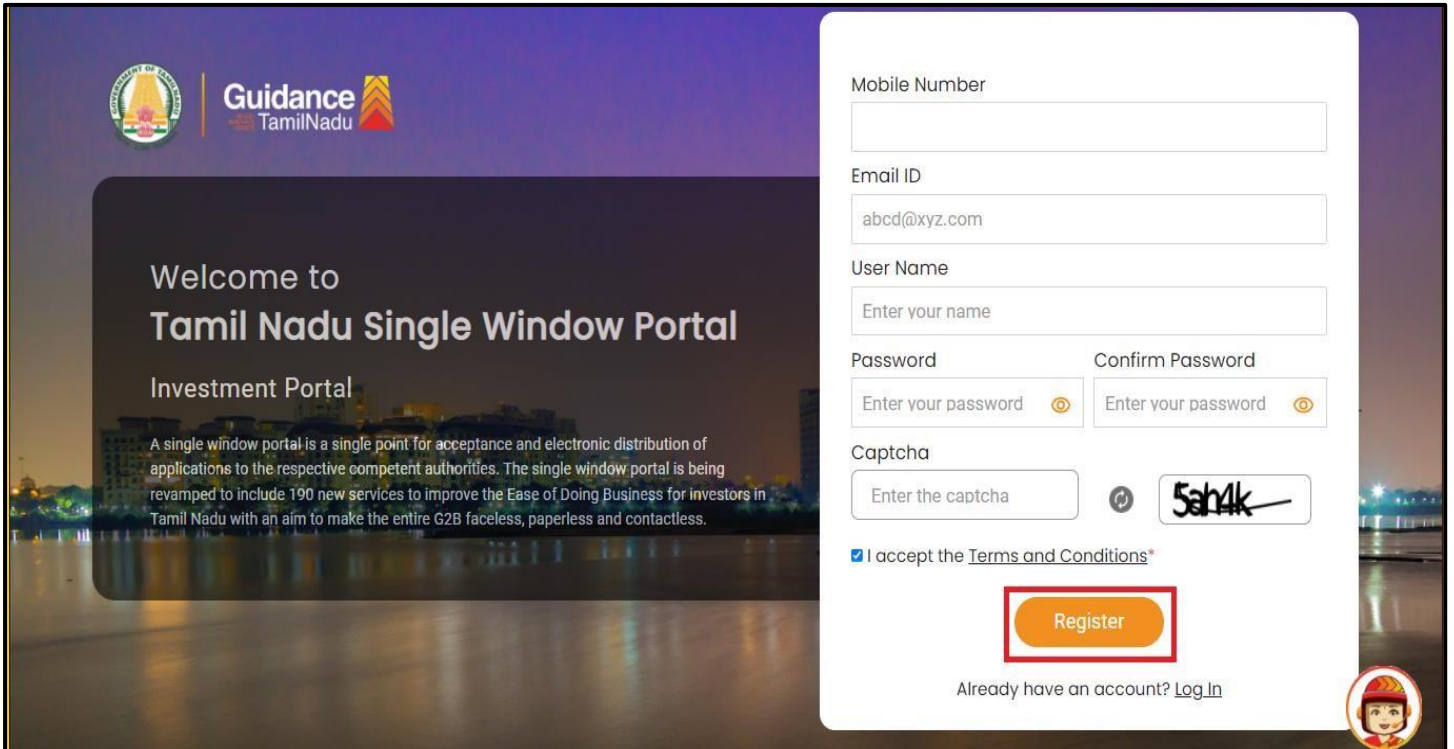
Figure 3. Registration Form

Figure 4. Registration Form Submission

6) The Email ID would be the Username to login the TNSWP.

7) Future communications would be sent to the registered mobile number and Email ID of the applicant.

8) Create a strong password and enter the Captcha code as shown.

9) The applicant must read and accept the terms and conditions and click on **'Register'** button.

3. Mobile Number / Email ID – 2-Step Verification Process

- **'2-Step Verification Process'** screen will appear when the applicant clicks on 'Register' button.

○ **Mobile Number Verification**

1) For verifying the mobile number, the verification code will be sent to the given mobile number.

2) Enter the verification code and click on the **'Verify'** button.
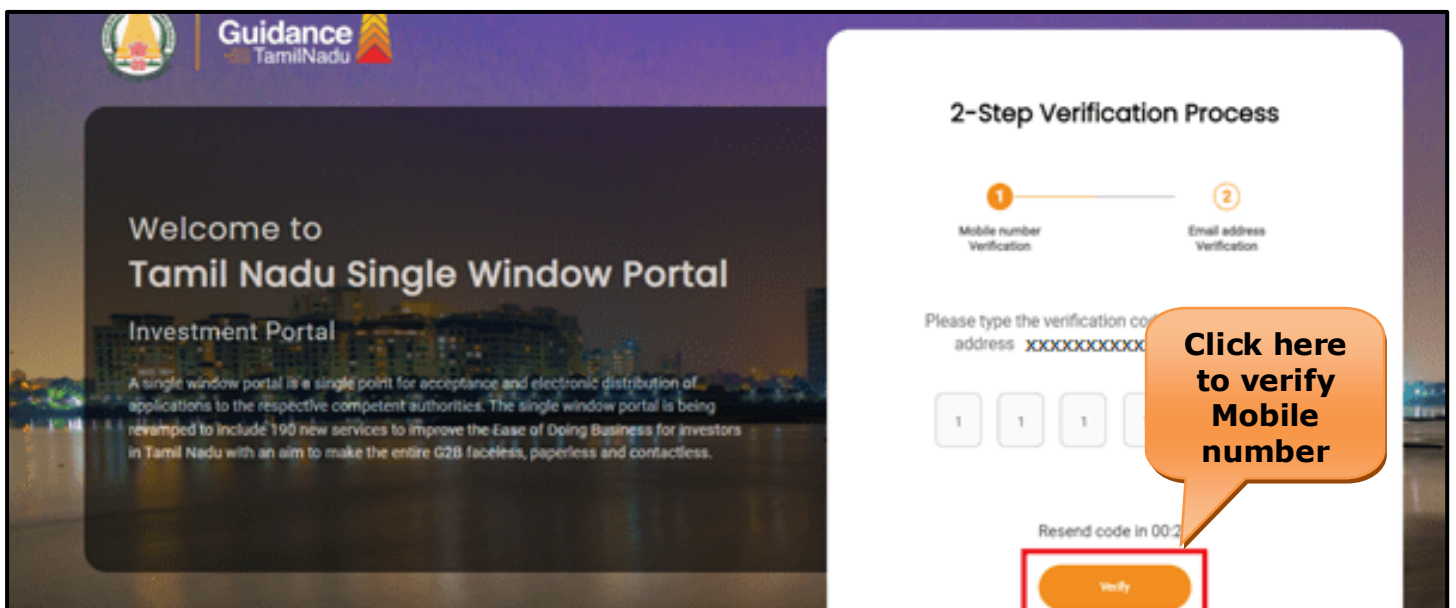
Figure 5. Mobile Number Verification

o **Email ID Verification**

1) For verifying the Email ID, the verification code will be sent to the given Email ID.

2) Enter the verification code and click on the **'Verify'** button.
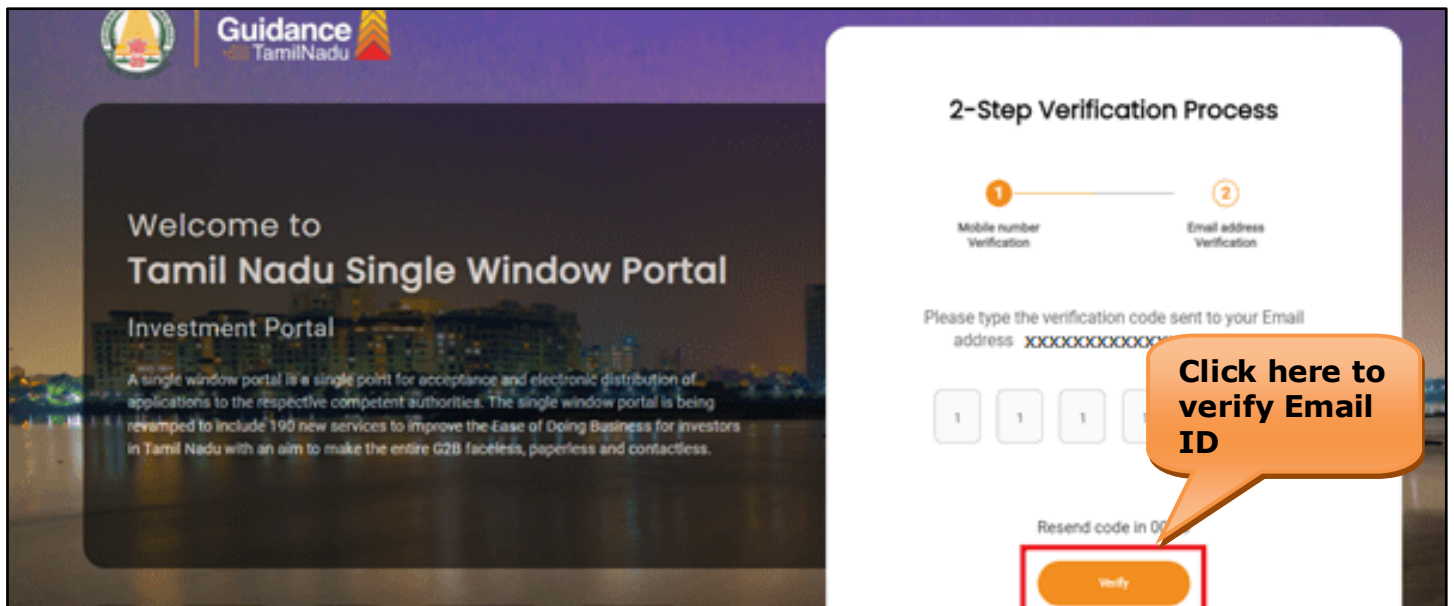
Figure 6. Email ID Verification

3) After completion of the 2-Step Verification process, registration confirmation message will pop-up stating as **'Your registration was successful'** (Refer Figure 7).

4) Registration process is completed successfully.
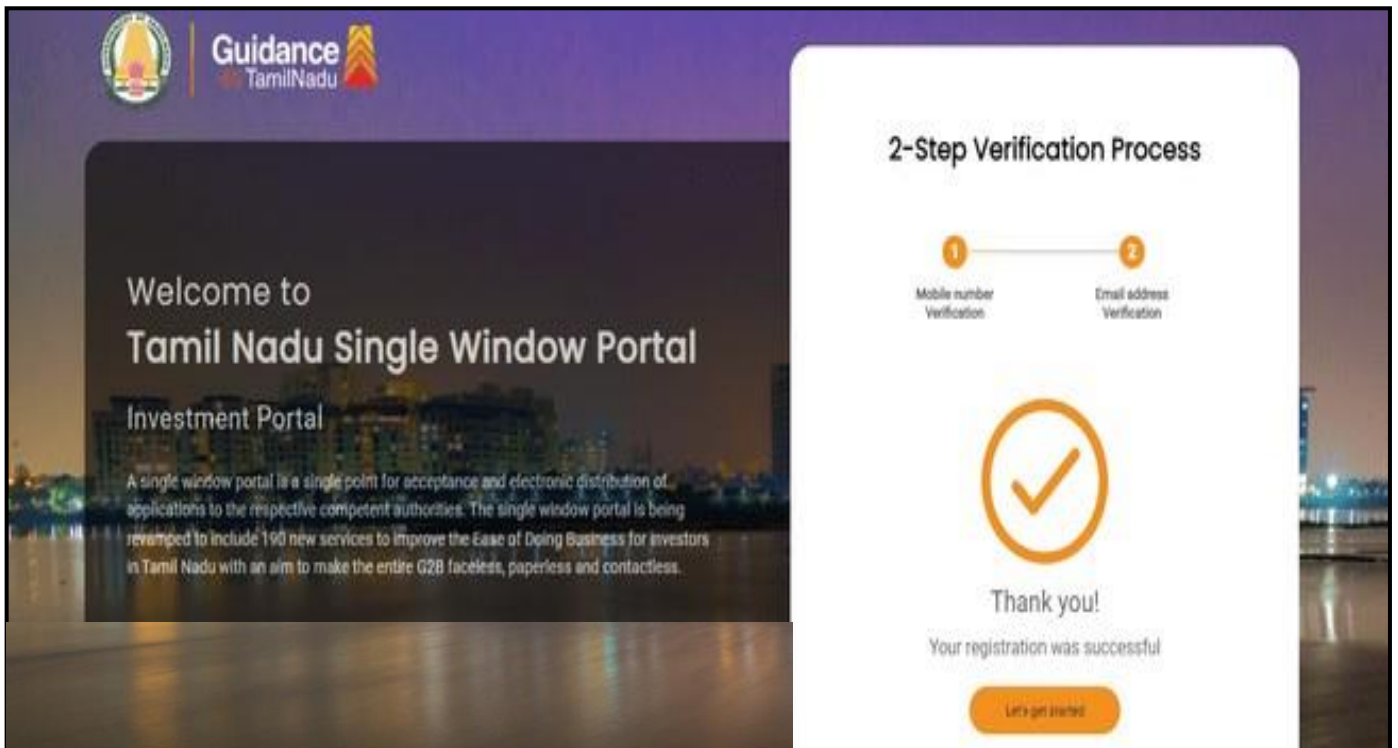
Figure 7. Registration Confirmation Pop-Up

4. Login

1) The Applicant can login to TNSWP with the Username and Password created during the registration process.

2) Click on login button to enter TNSWP.

> **Login to TNSWP**

Figure 8. Login

5. Dashboard Overview
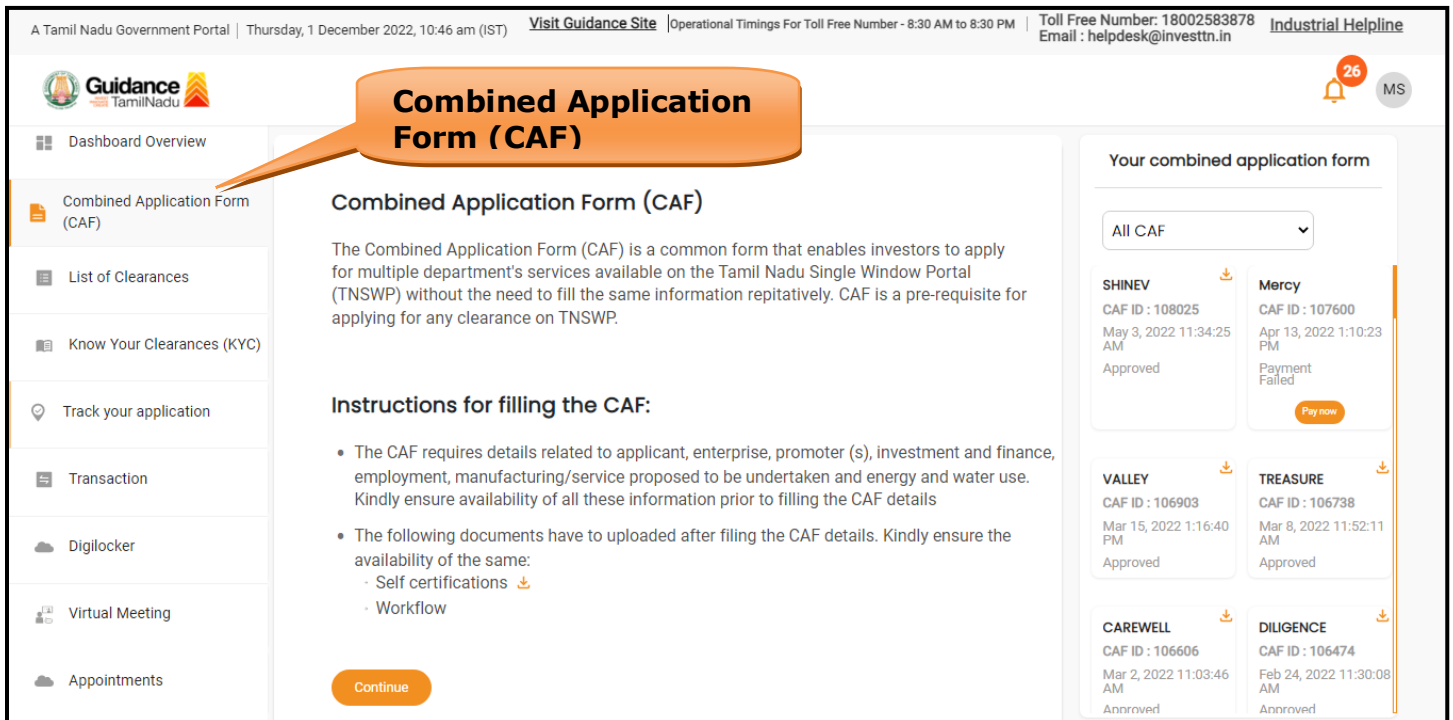
1) When the applicant logs into TNSWP, the dashboard overview page will appear.

2) Dashboard overview is applicant-friendly interface for the applicant's easy navigation and to access various functionalities such as Menu bar, Status whether the application is Approved, Pending, Rejected and Data at-a glance on a unified point.
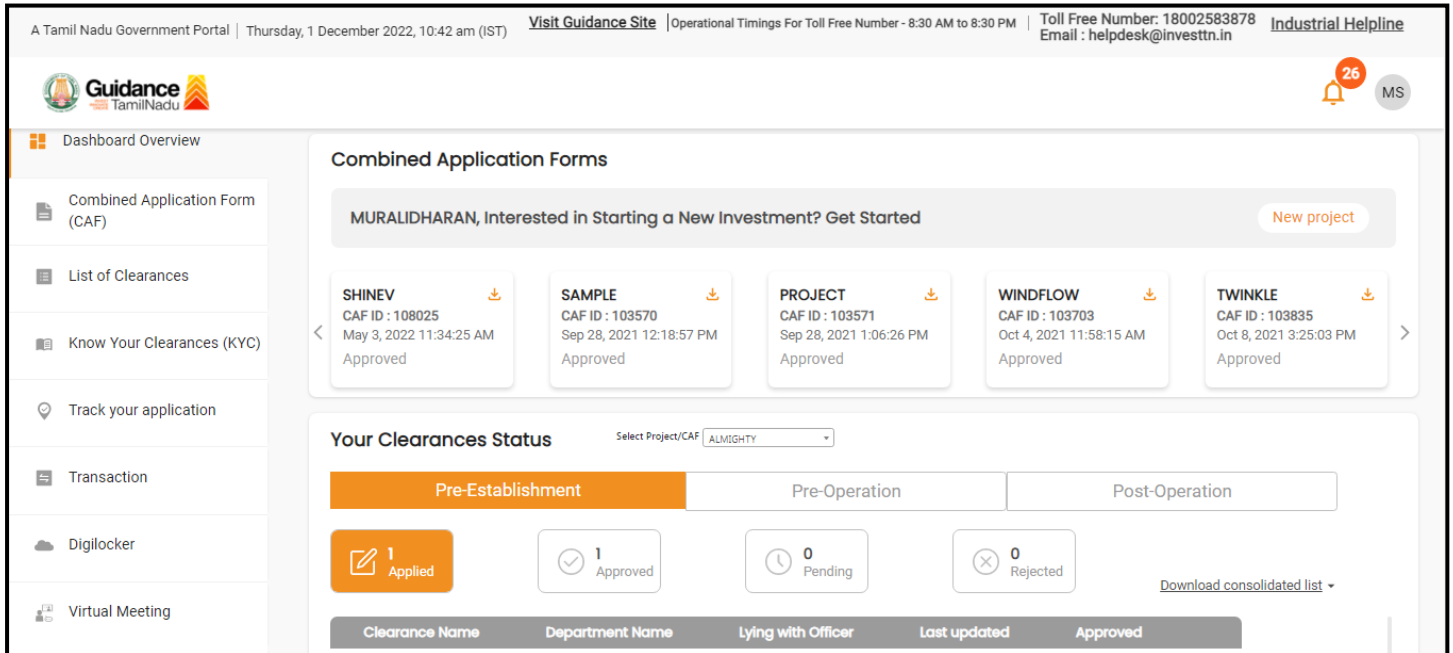
Figure 9. Dashboard Overview

6. Combined Application Form (CAF)

1) Prior to applying for various clearances on TNSWP, the applicant has to create a project by filling in the combined application form (CAF).

2) Click on Combined Application Form (CAF) from the menu bar on the left.

3) The details which are commonly required for applying various clearances are stored in Central Repository through CAF. So, whenever the applicant applies for various clearances for a specific project, the details stored in CAF gets auto populated in the application form which minimizes the time spent on entering the same details while filling multiple applications.

4) The Overview of the Combined Application Form (CAF) and the instructions to fill in the Combined Application Form (CAF) is mentioned in the below Figure.

5) Click on **'Continue'** button to fill in the Combined Application Form.

Figure 10. Combined Application Form (CAF)

6.1 Sections of Combined Application Form

1) To complete the combined application form (CAF) the applicant has to fill in 7 Sections of CAF as displayed in Figure 11. (CAF payment tab will be displayed only for large enterprise)

| ① Project Details | ② Details of Enterprise | ③ Details of Estimated Project Cost (in INR) | ④ Details of Employment and Utilities | ⑤ Manufacturing/ Service Details | ⑥ Supporting Documents | ⑦ CAF Payment |
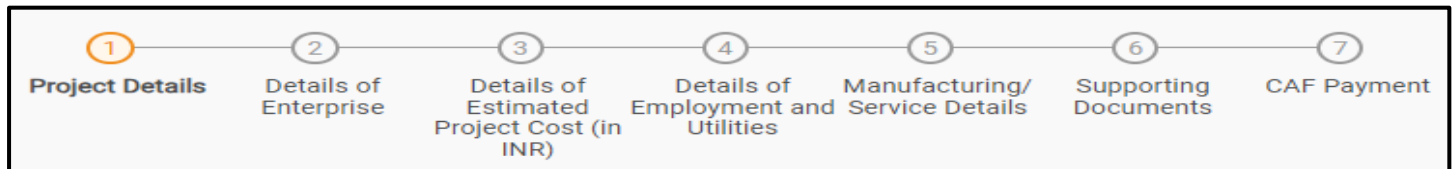
Figure 11. Section of Combined Application Form (CAF)

2) After filling the CAF details, the applicant has to upload the requisite supporting documents under 'Section 6: Supporting Documents'

- **Self-Certification:**

  o Download the template.

  o Prepare the self-certification documents as per the instructions given in the template and upload.

- **Workflow**:

  o Prepare and upload the business process flow chart.

3) After filling all the sections in combined application form (CAF), the applicant can submit the form.

4) When the applicant submits the combined application form (CAF), confirmation message will pop-up stating, '**Your request has been saved successfully**' (Refer Figure 12).
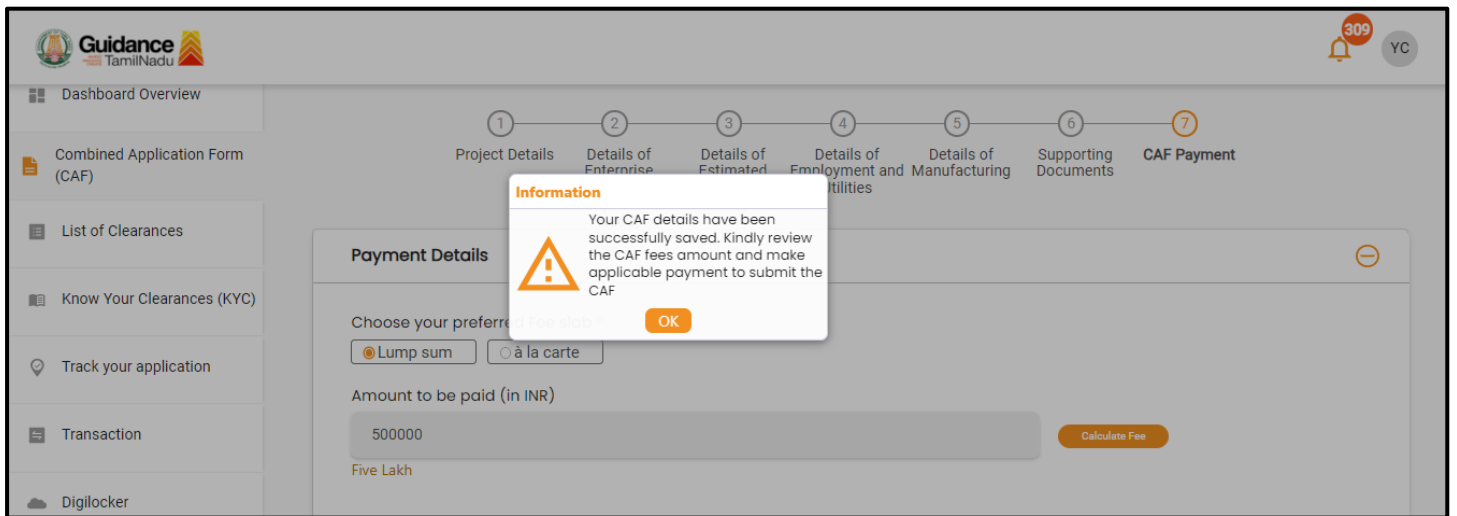
Figure 12. Combined Application Form (CAF)- Confirmation Message

Note:

If the applicant belongs to a large industry, a single window fee would be applicable according to the investment in Plant & Machinery or Turnover amount. Click here *to access the Single Window Fee Slab.*

7. Apply for Licence to Manufacture Allopathic Drugs

1. Click on "List of Clearances"

Figure 13. List of Clearances

2. The list of clearances is segregated into three stages.

- **Pre-Establishment Stage Clearance**
- **Pre-Operation Stage Clearance**
- **Post-Operation Stage Clearance**

3. Select '**Pre-Operation Stage Clearance**' and find the clearance '**Licence to Manufacture Allopathic Drugs'** by using Search option as shown in the figure given below.
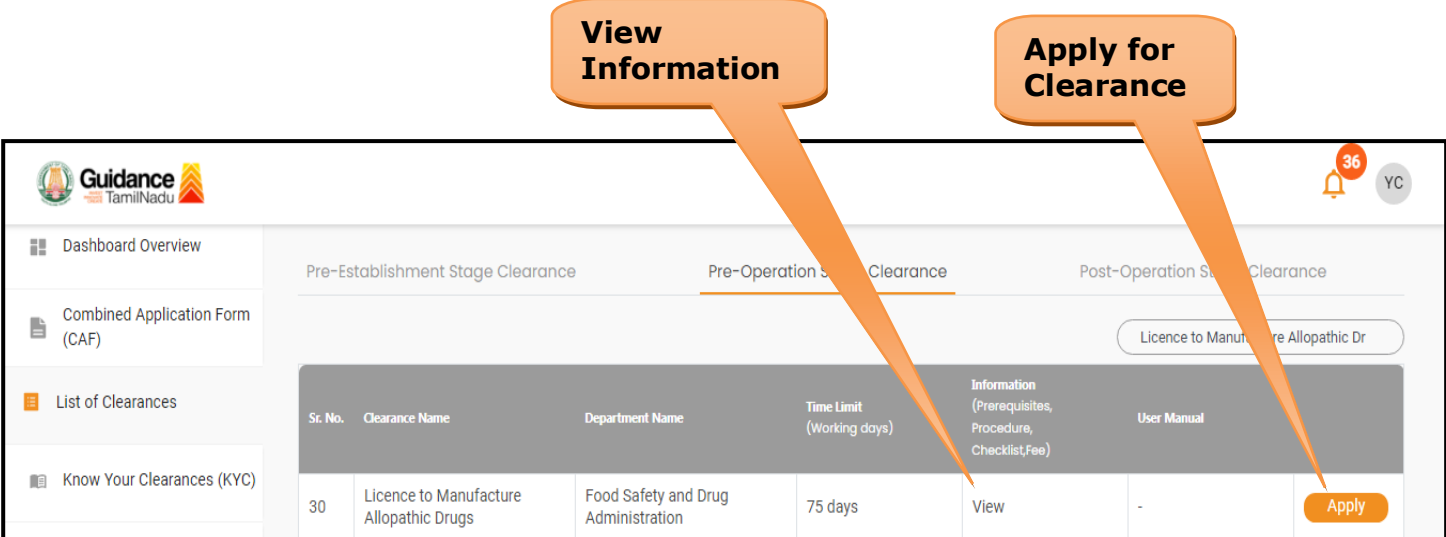

Figure 14. Search for Clearances

4. Applicant can view information on workflow, checklist of supporting documents to be uploaded by the applicant and fee details. Click on 'view' to access the information (Refer Figure 15)

5. To apply for the clearance, click on 'Apply' to access the department application form (Refer Figure 15).

6. The Applicant can apply to obtain license for more than 1 establishment using a single login, but the applicant must create multiple Combined Application Form (CAF) for each of the establishment.

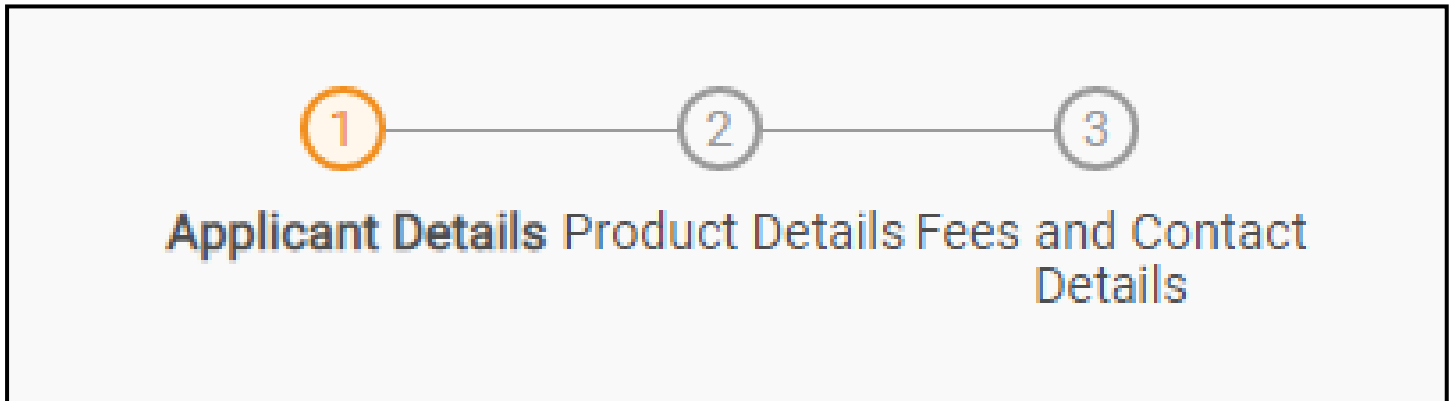**Figure 15. Apply for Clearances**

8. Filling the Application Form

1. Applicant needs to fill all the details under the following 3 sections to complete the application.
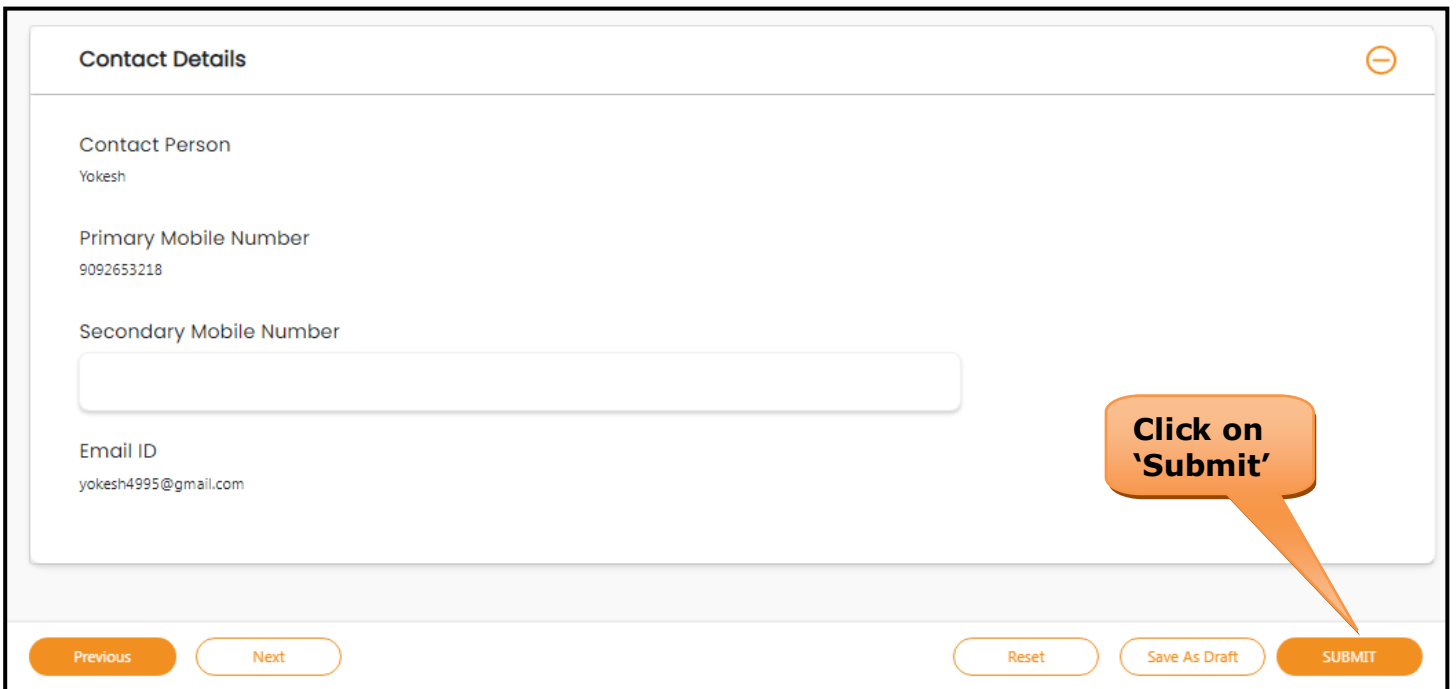
   A. Applicant Details

   B. Product Details

   C. Fees and contact Details

Figure 16. Three Sections of Application From

Contact Details

Figure 17. Contact Details

Token Id Generated

1. Click on **'Submit'** button a unique **'Token Id'** would be generated with a pop-up message.

<div align="center">
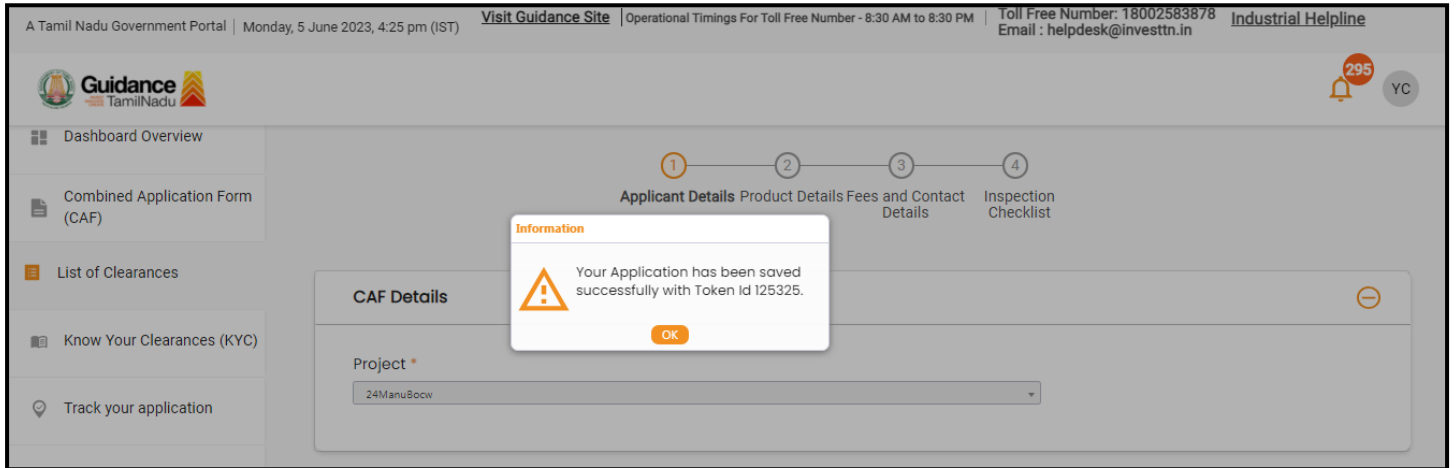
Figure 18. Token Id Generated

</div>

D. Inspection Checklist

1. Enter all Inspection Details

<div align="center">

Figure 19. Four Section of Application Form

</div>

1. Location and surroundings:

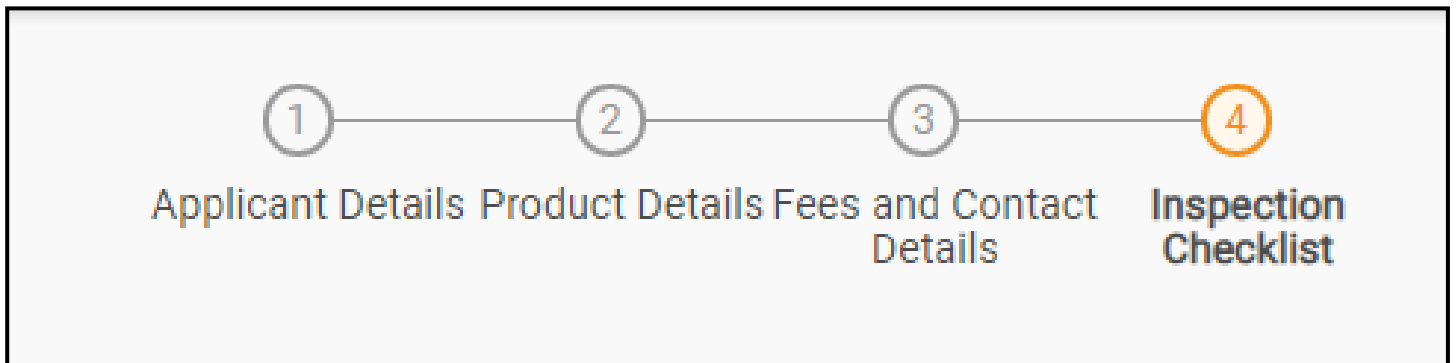| Inspection Criteria	Self-appraisal to be filled by the manufacturer along with all details (Mandatory)	Remarks (if any)
How is the factory building situated and controlled to avoid risk of contamination from external environment including open sewage, drain, public lavatory or any other factory which produces disagreeable or obnoxious, odors, fumes, excessive soot, dust, and smoke, chemical or biological emissions? Please specify industries / establishments adjoining manufacturing site.	grg	hgtr

1.2 Building and premises

Inspection Criteria	Self-appraisal to be filled by the manufacturer along with all details (Mandatory)	Remarks (if any)
How the building has been designed constructed and maintained to suit the manufacturing operations so as to produce drugs under hygienic conditions? Please specify nature of construction used in the facility in respect of its maintenance and hygienic conditions.	tghd	ghrgtr
Whether the building confirm to the conditions laid down in the Factories Act, 1948? Please attach valid factory certificate/ license issued by the competent authority.	Yes x ▾	thrdh
Specify how the premises used for manufacturing operations and testing purpose prevents contaminations and cross contamination is: a) Compatible with other drug manufacturing operations that may be carried out in the same or adjacent area. Please specify any special criteria for the product manufactured. e.g. temperature, humidity, air class requirements maintained for aseptic products, etc.	thfg	ergte
b) Whether adequate working space is provided to allow orderly and logical placement of equipment, materials and movement of personnel so as to avoid risk of mix-up between different categories of drugs and to avoid possibility of the contamination by suitable mechanism? Please specify space left around the machines (in Remarks) Please attach equipment layout, men and material movement, waste movement if applicable (in Supporting Documents)	Yes x ▾	ryer

c) Describe the pest, insects, birds and rodents control system followed in the premises. Attach copy of pest / rodent control schedule along with contract agreement if any.	fdbgdf	trhytrh
d) What measures have been taken to make Interior surface of (walls, floors, and ceilings) smooth and free from cracks, and to permit easy cleaning? Specify material of construction and finish for walls, ceiling, floor, coving etc. i.e. whether Epoxy or PU coated, kota / granite stone with epoxy sealed joints, solid / GI / gypsum / cal. Silicate board ceiling with epoxy, PU or any other pre-fabricated panel (GRP, powder coated SS or Aluminum etc.) paint.	gsdfg	ghrt
e) What measures have been taken so that the production and dispensing areas are well lighted and effectively ventilated, with air control facilities? Please specify the lux level maintained in various parts of the premise.	fdgse	ngnf
Please specify the air handling system used in various areas like stores, production, packing, QC areas etc.	fdbvd	fdbg
f) Specify drainage system which prevents back flow and entry of insects and rodents into the premises. (Please specify number and location of drains installed)	fbgdfg	vbdgh

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29
30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46

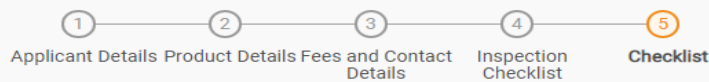**Click on 'Save Inspection Details'**

Previous   Next   Save Inspection Details

Figure 20. Inspection Details

E. Checklist

1) The following supporting documents need to be uploaded by the applicant as per the notes given.

2) Maximum 10 MB Allowed (Only .DOC, .PDF, .XLS, .BMP, .GIF, .JPEG, .PNG, .PPTX, .DOCX, .XLSX, .ZIP, .KML are allowed).

3) In case of multiple documents, please upload them in zip format.

7	☐ Previously issued Form 29 Copy, if any	Drag & Drop (Browse Files) (DigiLocker)
8	☑ Document relating to constitution of concerned firm/ Company/ LLP and others. **Proprietorship:** *Declaration Form* **Partnership Firm:** *Partnership Deed* **Limited Liability Partnership:** *LLP deed, Registration Certificate of ROC* **Pvt. Ltd. / Ltd:** *Memorandum and articles of association, Registration Certificate of ROC, Copy of Board resolution* **Trust:** *Trust deed* **Society:** *Registration Certificate, By Laws, Copy of Resolution passed* **Hindu Undivided Family:** *HUF deed*	PDF 🗑 Registration.pdf
9	☑ Bio-data (with photograph) of the Applicant(s) *To be enclosed for each applicant separately, in case there are multiple applicants.*	PDF 🗑 Registration.pdf
10	☑ Address/ID Proof of the Applicant (s) e.g. Passport, Driving License, Election Commission ID Card, Aadhaar Card/e-Aadhaar letter download from UIDAI website, Income Tax PAN Card *To be enclosed for each applicants in case there are multiple applicants.*	PDF 🗑 Registration.pdf
11	☑ Bio-data (with photograph) of the Technical Staff (s)-(Kindly upload the Bio-data of all Technical Staffs in a single zip file)	PDF 🗑 Registration.pdf
12	☑ Educational qualification certificate(s) of the Technical Staff (s) (Starting from Minimum Educational Qualification as specified in the Drugs Rules, 1945)-(Kindly upload educational qualification certificates of all Technical Staffs in a single zip file)	PDF 🗑 Registration.pdf
13	☑ Experience Certificate of the Technical Staff(s) - (Kindly upload experience certificates of all Technical Staffs in a single zip file)	PDF 🗑 Registration.pdf
14	☑ Digitally Signed Self-Certification by each Technical Staff stating that He / She is a full time employee of the Firm under consideration - (Kindly upload self-certifications of all Technical Staffs in a single zip file)	PDF 🗑 Registration.pdf
15	☑ Address/ID Proof of the Technical Staff(s) e.g. Passport, Driving License, Election Commission ID Card, Aadhaar Card/e-Aadhaar letter downloaded from UIDAI website, Income Tax PAN Card (Kindly upload address / ID proof of all Technical Staffs in a single zip file)	PDF 🗑 Registration.pdf

16	☑ Ownership document of the premises (Registered Sale Deed / Registered General Power of Attorney / Conveyance Deed / Latest Property Tax Receipt))	PDF 🗑 Registration.pdf
17	☐ Rental agreement of the premises, if applicable	Drag & Drop (Browse Files) (DigiLocker)
18	☑ Plan of the premises- with details of partitions, measurements – Section wise with location of machineries	PDF 🗑 Registration.pdf
19	☑ List of machineries and equipment, Air Handling Units, and water system provided Section wise for the manufacturing	PDF
20	☑ List of analytical instruments and equipment for analysis	PDF 🗑 Registration.pdf
21	☑ Copy of purchase invoices with the details like production capacity, make etc. wherever applicable	PDF 🗑 Registration.pdf
22	☑ Product dossier (for each product)-(Kindly upload the product dossier for all products in a single zip file)	PDF 🗑 Registration.pdf
23	☑ Form 51/ Brand Name affidavit	PDF 🗑 Registration.pdf
24	☐ Agreement with Marketer, if applicable	Drag & Drop (Browse Files) (DigiLocker)
25	☐ Any other relevant details or documents to establish the correctness of the details or documents or claims made with regard to the above items	Drag & Drop (Browse Files) (DigiLocker)
26	☐ Inspection Checklist	Drag & Drop (Browse Files) (DigiLocker)

Inspection Checklist – Supporting Documents
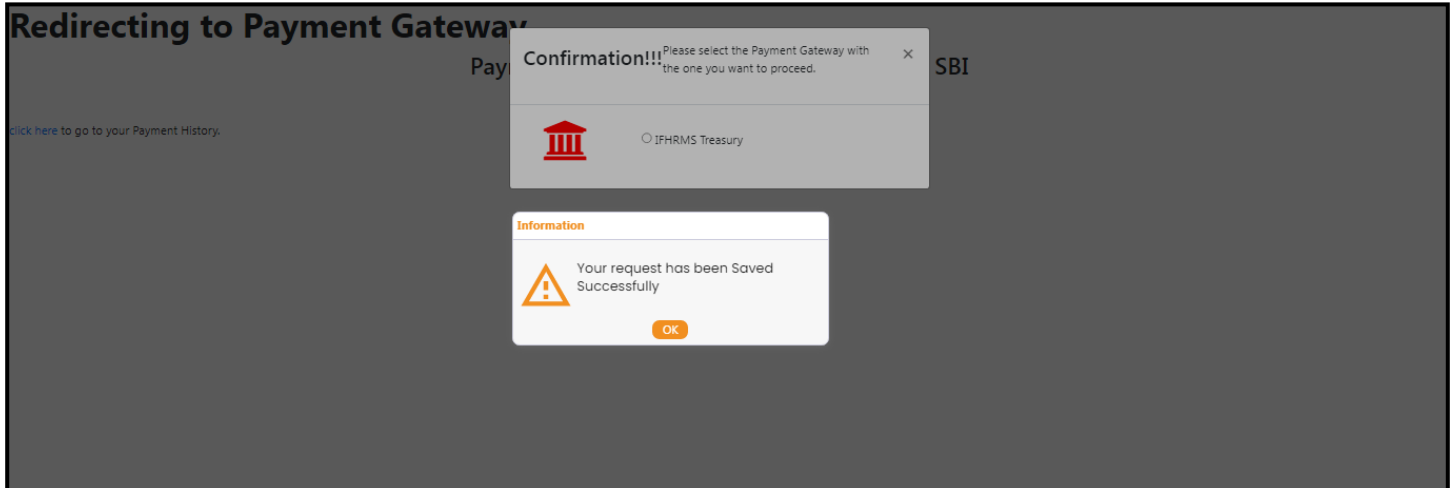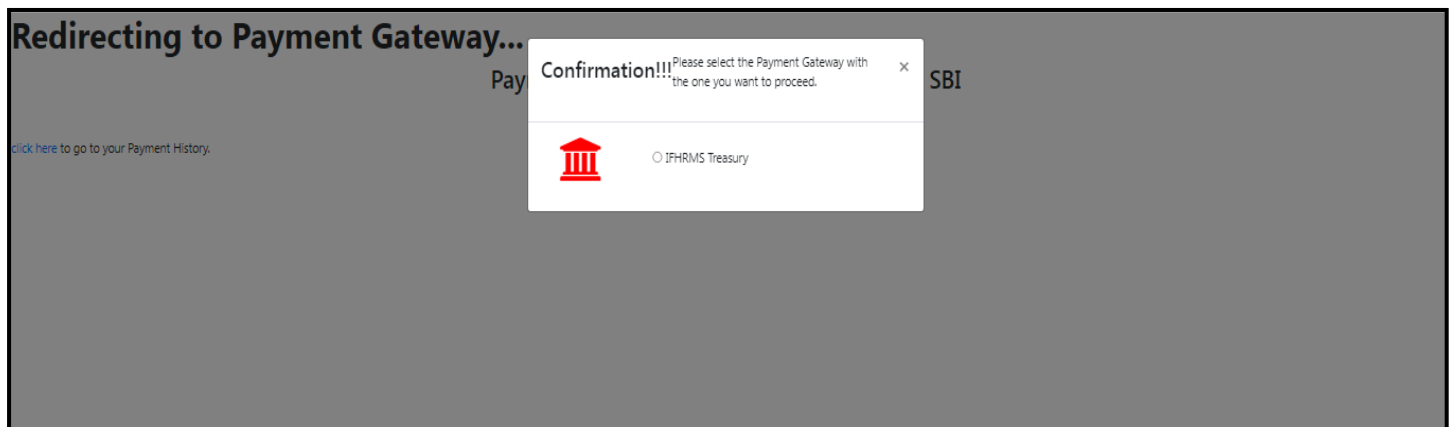

Figure 21. Checklist

9. Payment Process

1) Click on **'Submit'** button a unique **'Token Id'** would be generated with a pop-up message.

Figure 22. Request Saved Successfully

2) The Applicant has the provision to make the payment by using **"IFHRMS Treasury"** Payment gateway.

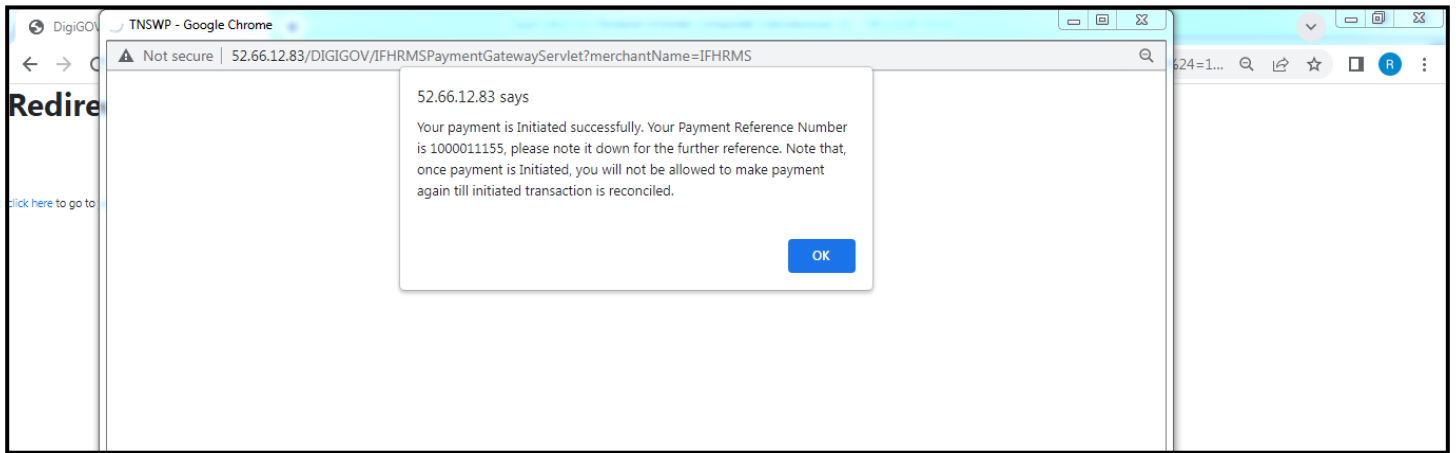3) Click on 'Ok' button, IFHRMS Payment Gateway screen would appear, click on Radio button **'IFHRMS Treasury'**.


Figure 23. Payment Process

4) Then the payment **'Reference number'** would be generated, refer to the instruction note as shown in the below figure.

5) Click on 'Ok' button, follow the payment process and make the payment.

Figure 24. Payment Reference Number

6) After the applicant has completed the payment process, the application is submitted successfully to the Department for further processing. The applicant can view the status of the application under **Track your application → Select the CAF from the Dropdown → All details**
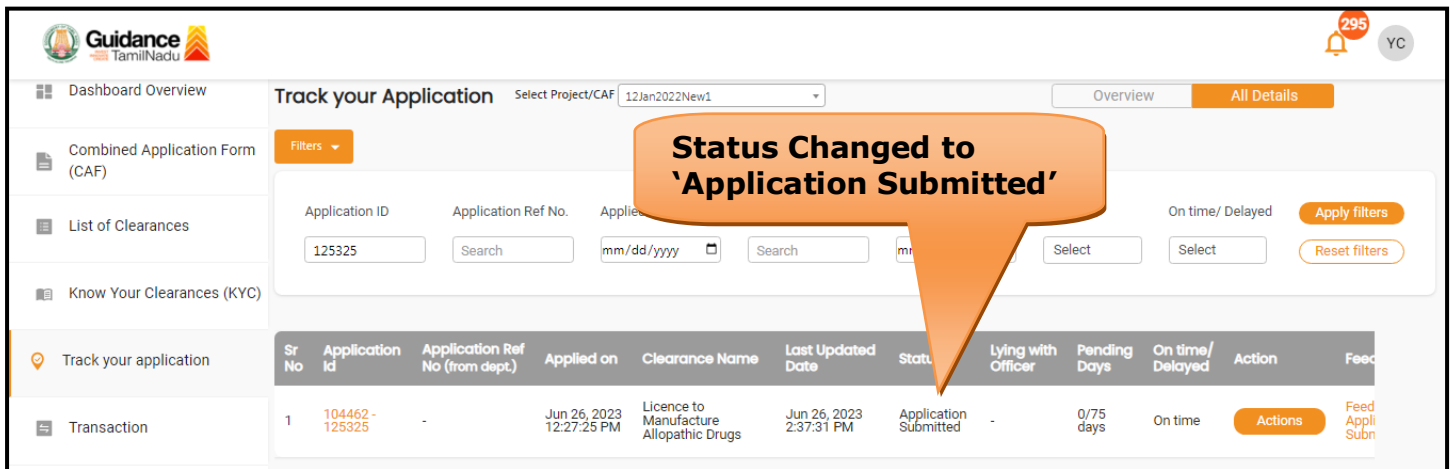
Figure 25. Application Submitted Successfully

10. Track Your Application

1) After submitting the application, a unique 'token ID' would be generated. Using the 'Token ID' the Applicant can track the status of clearances by clicking on 'Track your application' option.'
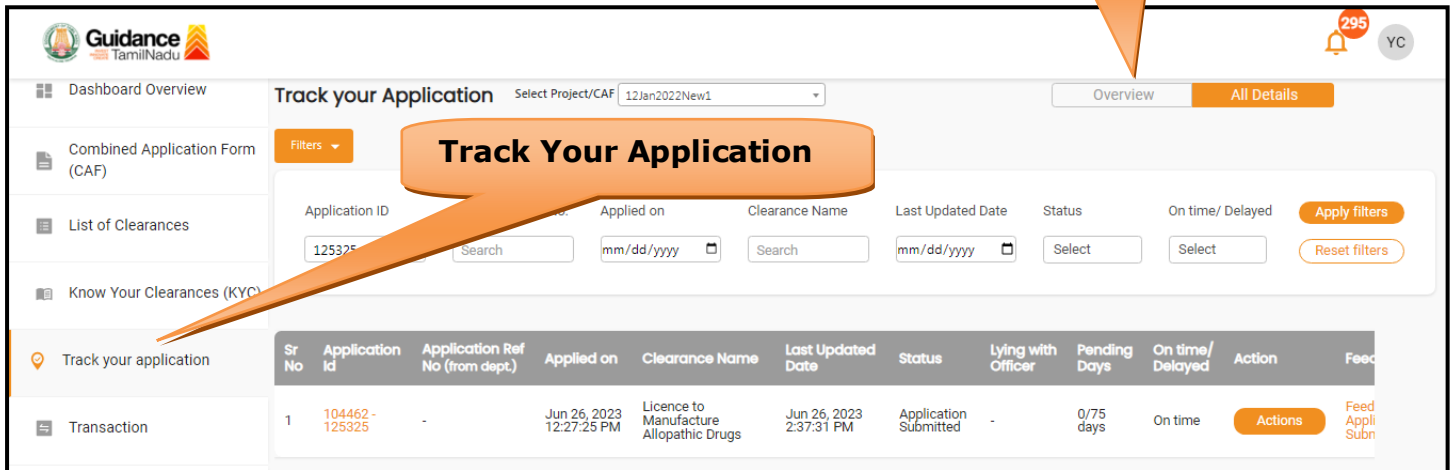
2) Applicant to choose the name of the project created during CAF from the dropdown 'Select project / CAF' displayed at the top of the page.

- **Track your application– Overview option**

   By clicking on 'Overview' tab, Applicant can view the count of various clearance statuses as follows.
   - **Total Pending Clearances**
   - **Total Approved Clearances**
   - **Total Rejected Clearances**
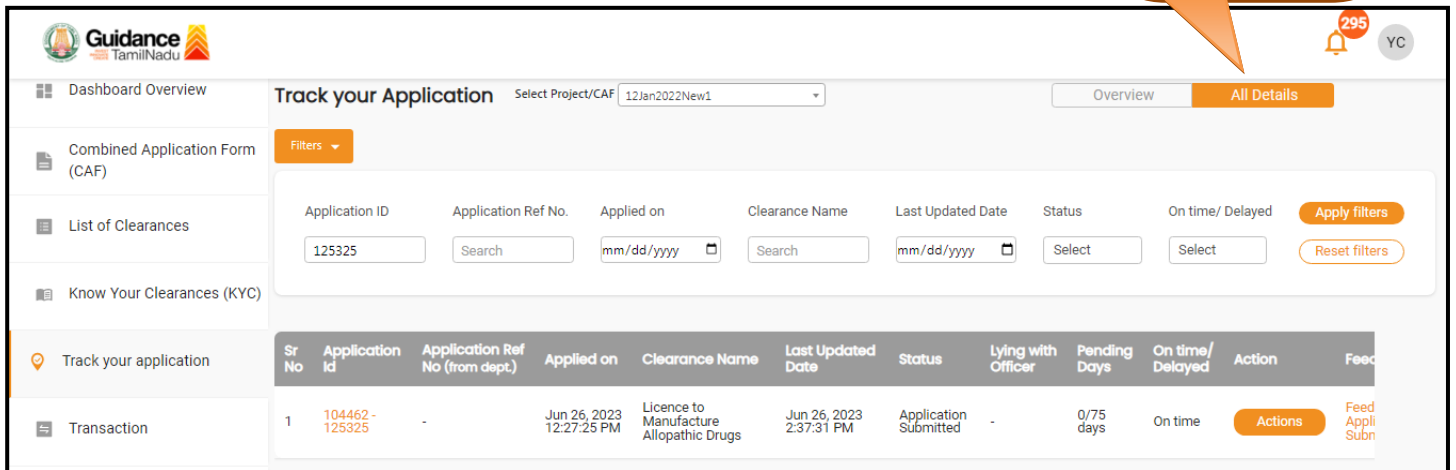
Figure 26. Track your application

- **Track your application– 'All details' option**

  By clicking on **'All details'** tab, Applicant can view the following statuses of the list of clearances applied for the specified project.

  - **Applied on**
  - **Last updated date**
  - **Status of the application**
  - **Lying with officer**
  - **Pending days**
  - **On time / Delayed Action**

  All Details Options

Figure 27. 'All details' tab

11. Query Clarification

1) After submitting the application to the Drugs department, the State Licensing Authority officer reviews the application and if there are any clarifications required, the State Licensing Authority officer would raise a query to the applicant.

2) Applicant would receive an alert message through Registered SMS/Email.

3) Applicant could go to 'Track your application' option and view the query under action items under the 'All Details' Tab.

4) Applicant could view the status as '**Need Clarification'** under the 'Status' column. Click on 'Action' button to respond the query as shown in the below figure.

Figure 28. Need Clarification
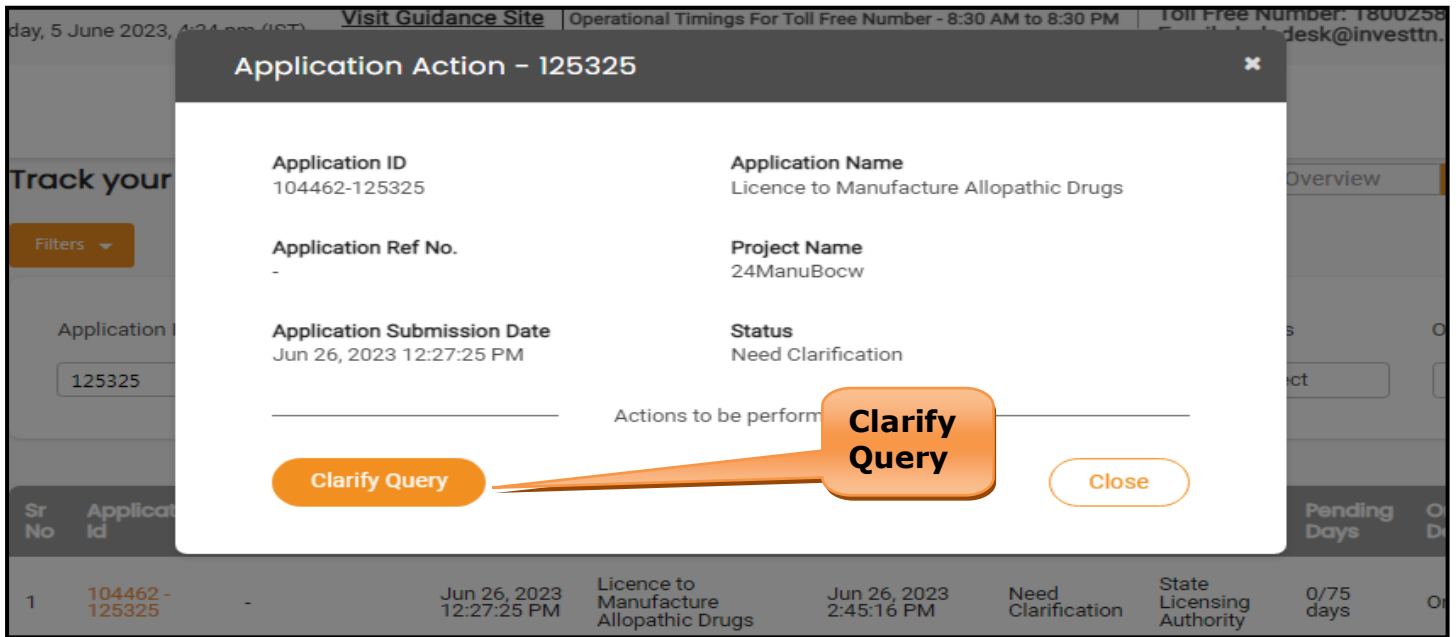
Figure 29. Clarify Query
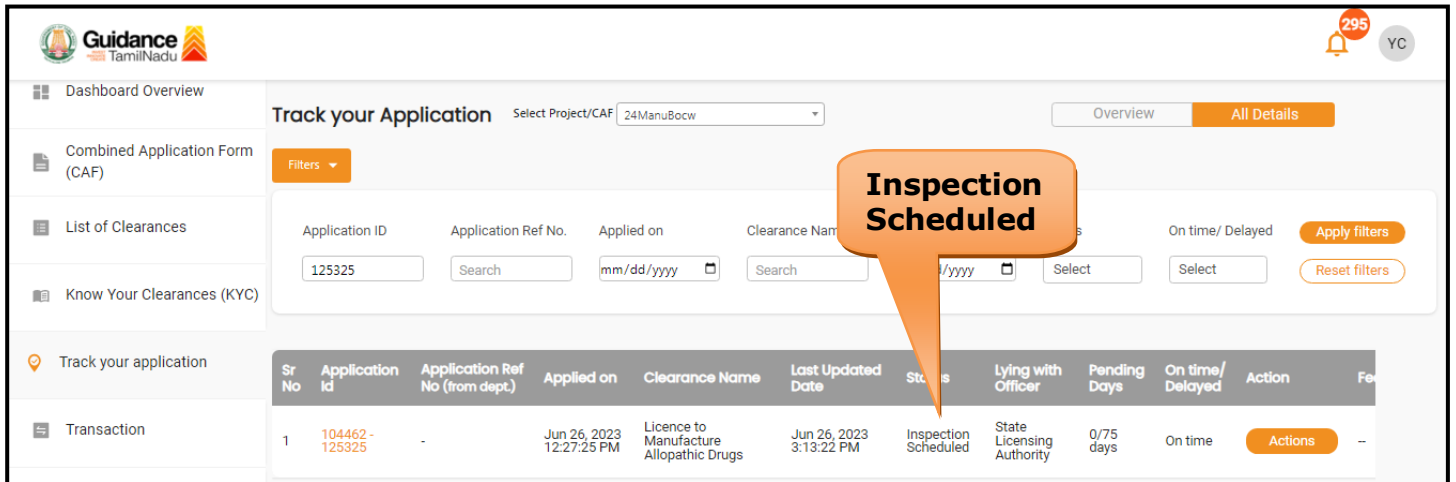
5) The Applicant clicks on **'Clarify Query'** button and responds to the Query.

6) The Application gets submitted to the department after the query has been addressed by the Applicant.

7) The Status of the application changes from 'Need clarification' to **'Under Process'** after the Applicant submits the query.
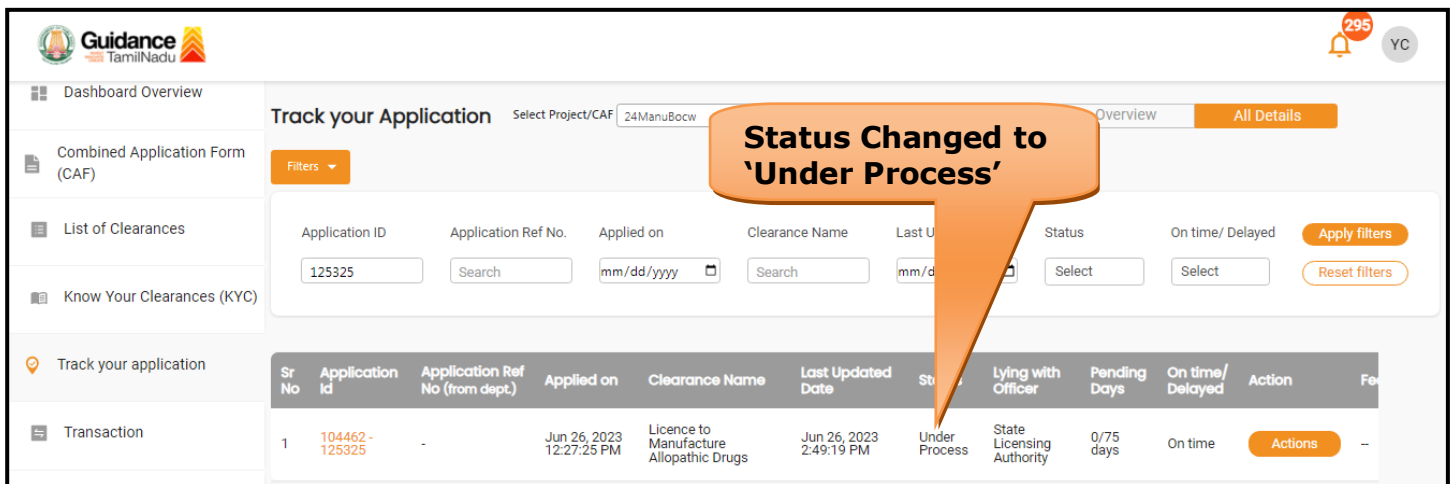
Figure 30. Application under Process

12. Inspection Schedule

1) The Drug Inspector of Drugs schedules the date of appointment for inspection to be done for the specified institution.

2) After the Inspection gets completed, the Drug Inspector submits the Inspection report.

3) The Applicant has the provision to view the Scheduled Inspection details

Figure 31. Inspection Scheduled

Figure 32. Scheduled Inspection Details

Figure 33. Scheduled Inspection Details (Contd.)

13. Application Processing

1) The State Licensing Authority scrutinizes and reviews the application and updates the status as **"Approved" or "Rejected"**.

Figure 34. Application Processed

2) If the application is **'Approved'** by the Department, the applicant can download the Approval Certificate under **'Track your application – > 'Action' button -> Download Certificate** (Refer Figure 35)

Figure 35. Download the Approved Licenses

3) If the application is 'Rejected' by the Department, the applicant can view the rejection remarks under the Actions Tab by the department. Applicant has to create a fresh application if the application has been rejected. (Refer Figure 36)

Figure 36. Rejected Status