TAMIL NADU SINGLE WINDOW PORTAL

APPLICANT MANUAL

Test 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.
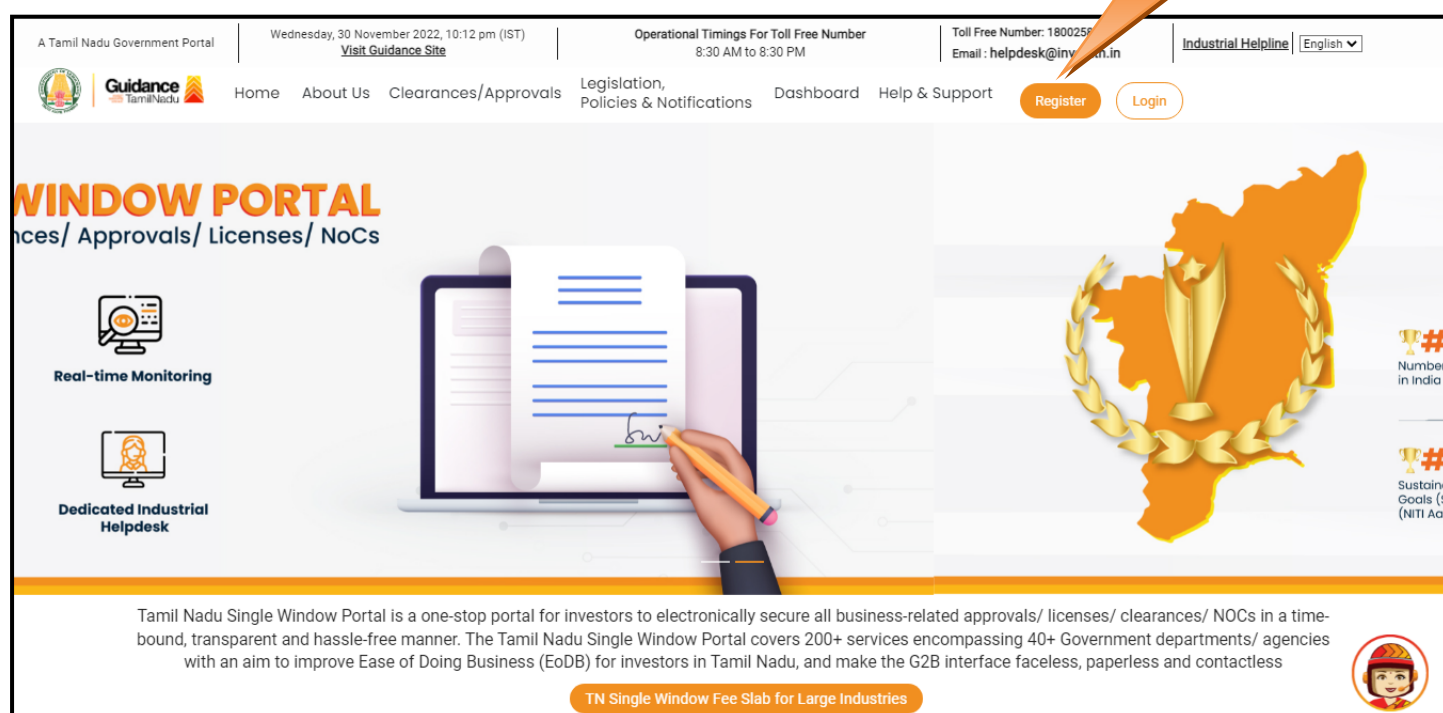
Figure 2. Register

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 ⓘ 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.

o **Mobile Number Verification**

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

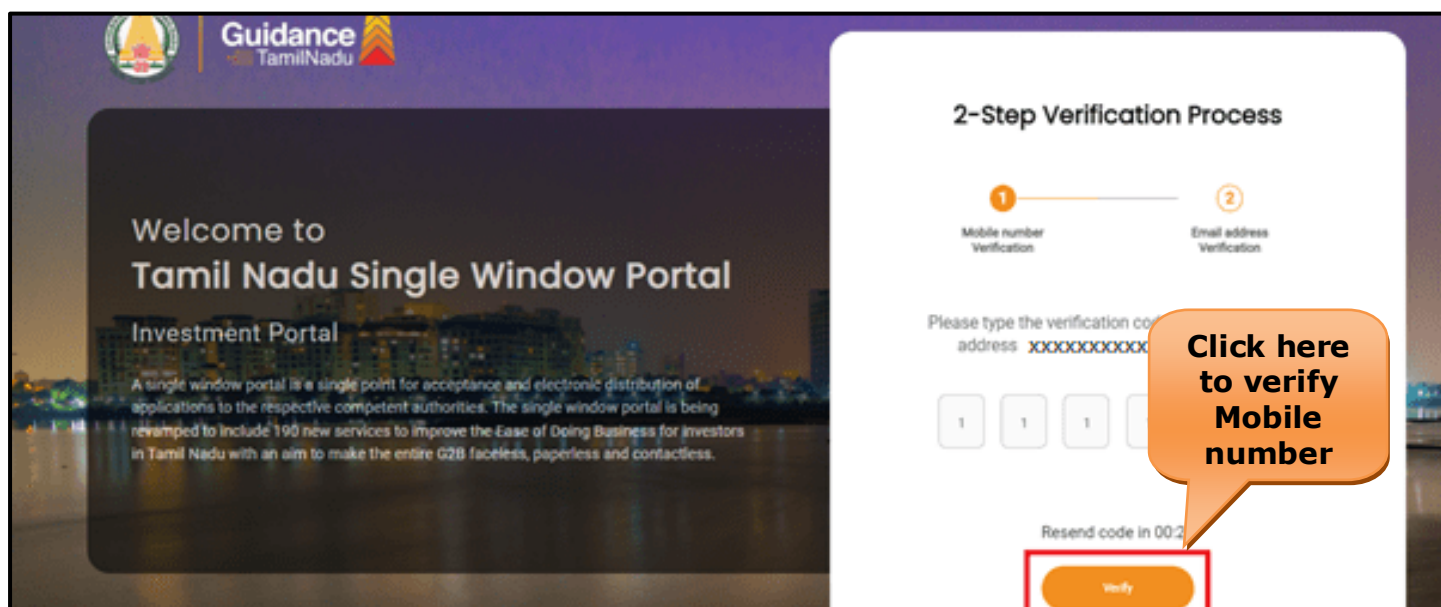2) Enter the verification code and click on the **'Verify'** button.

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.
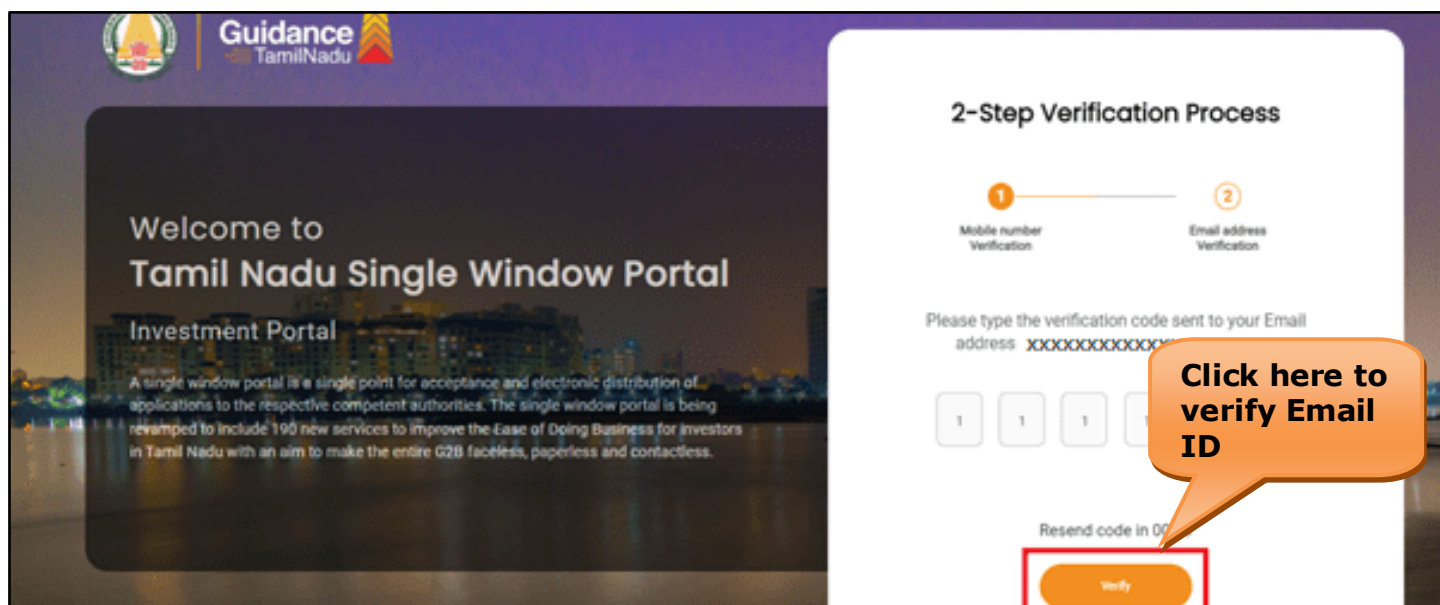

Figure 6. Email ID Verification

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

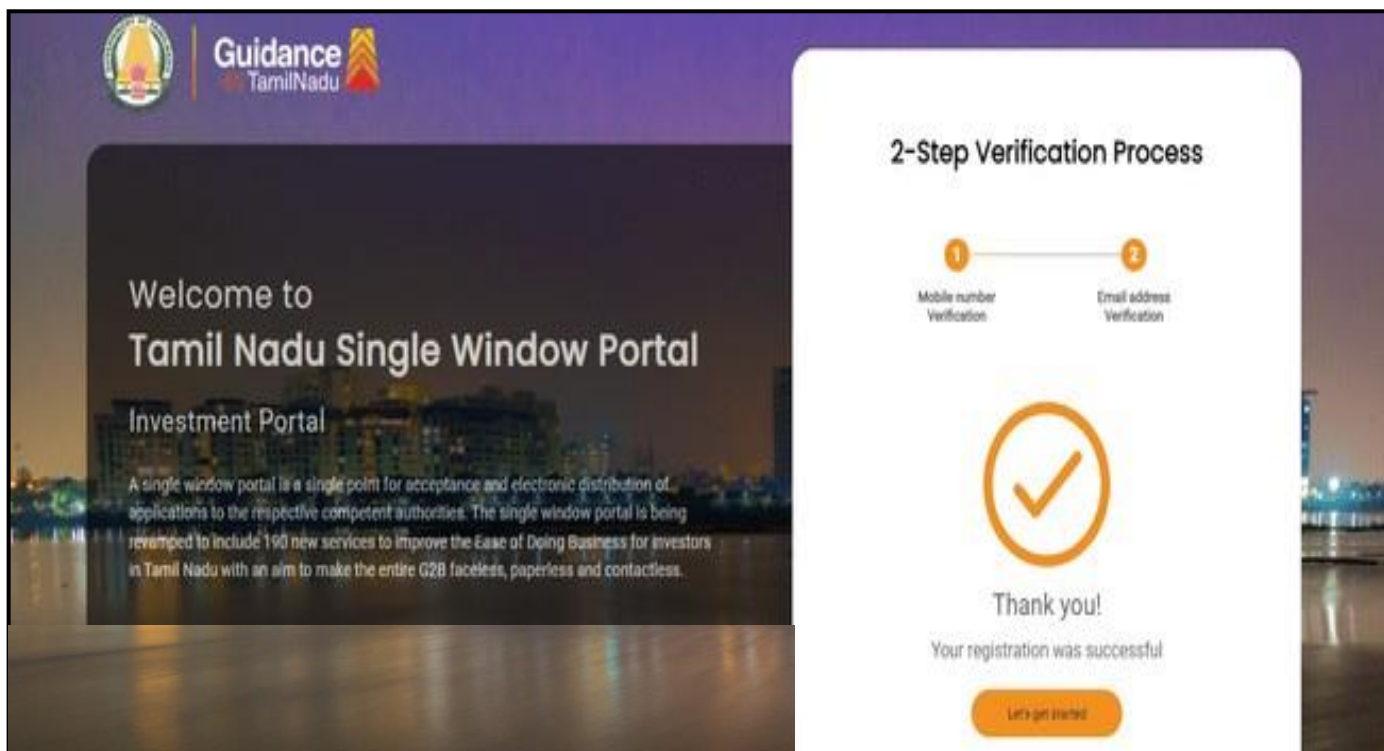4) Registration process is completed successfully.

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.
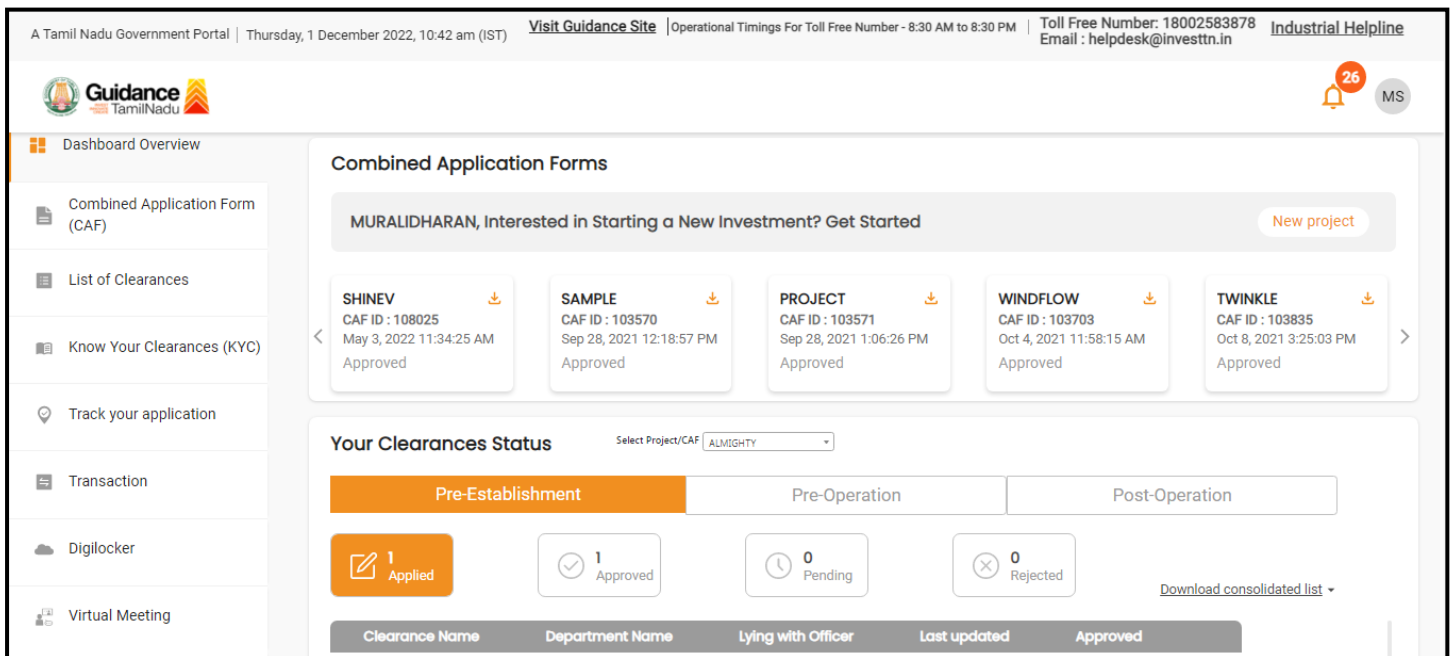
2) Click on login button to enter TNSWP.

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.
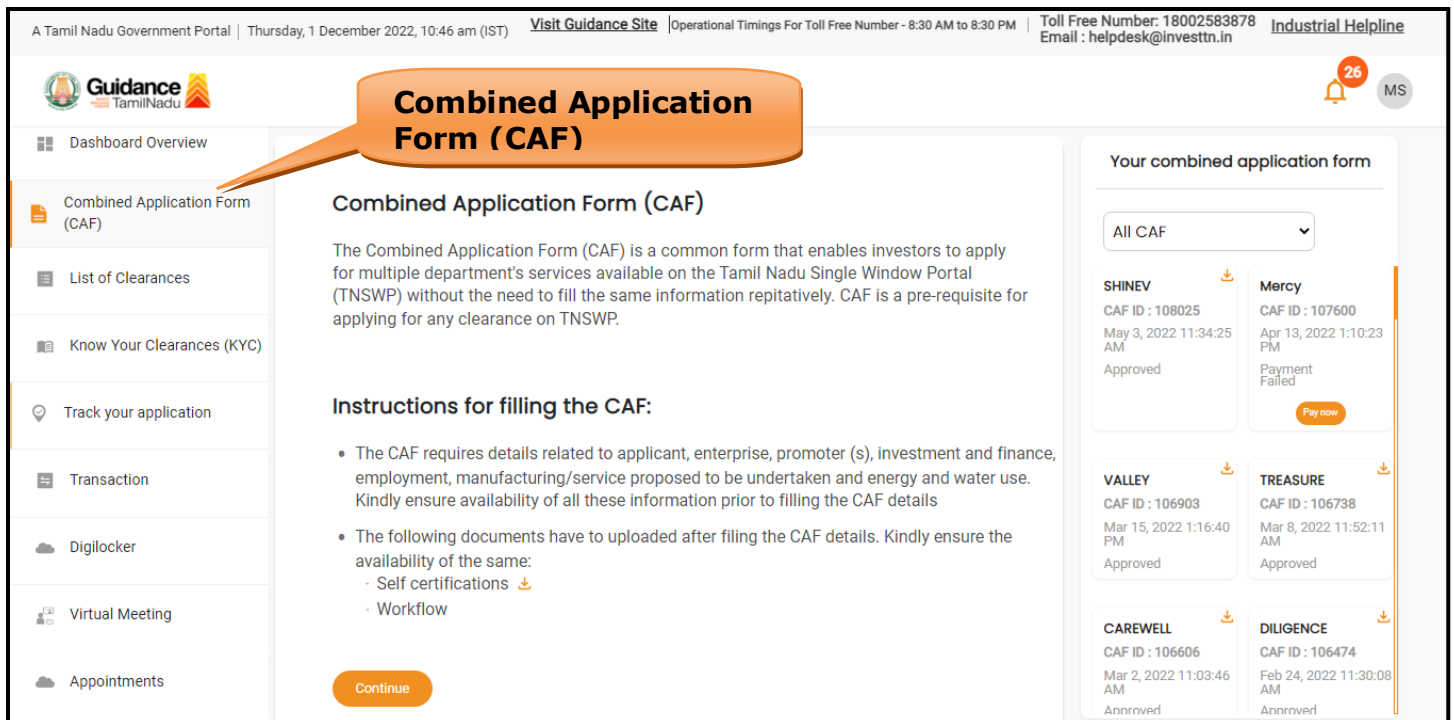

Figure 9. Dashboard Overview

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)
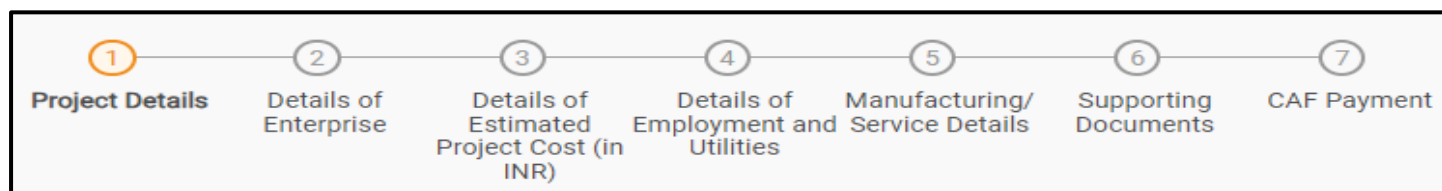
Figure 11. Section of Combined Application Form (CAF)

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).
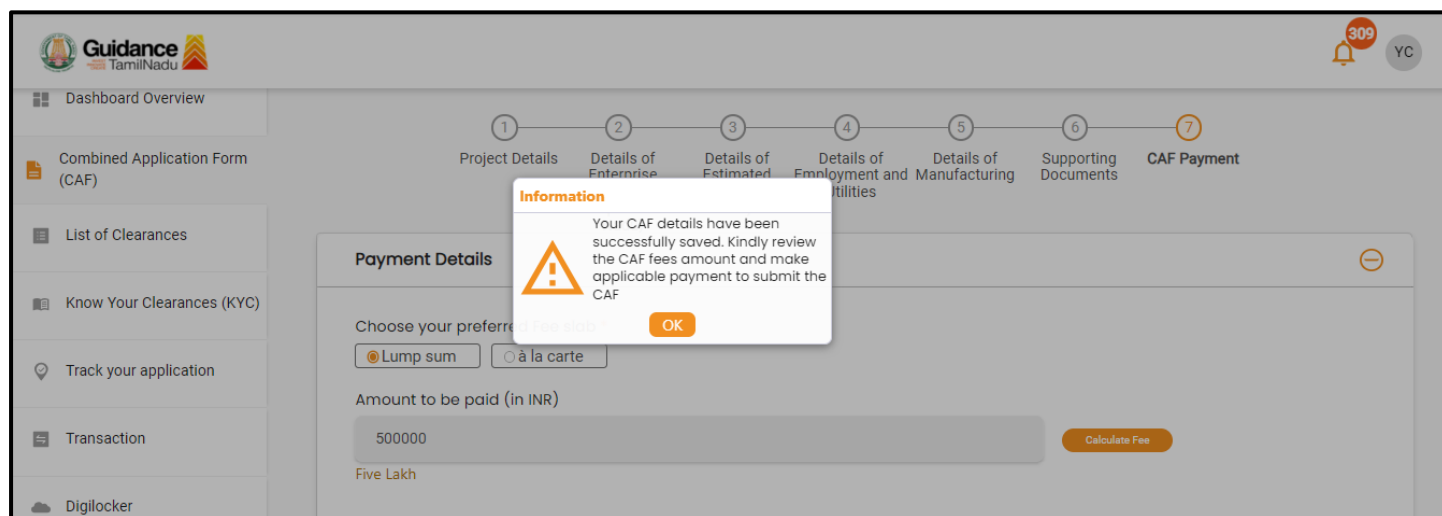
Figure 12. Combined Application Form (CAF)- Confirmation Message
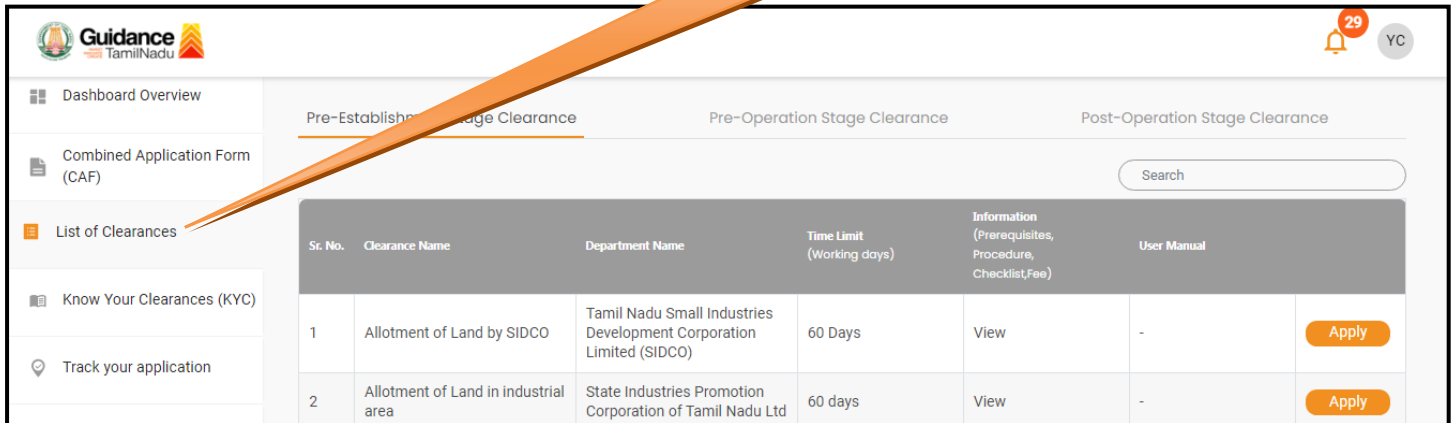
Note:

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 Test 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 '**Test 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 1 section to complete the application.

A. Application Form Details
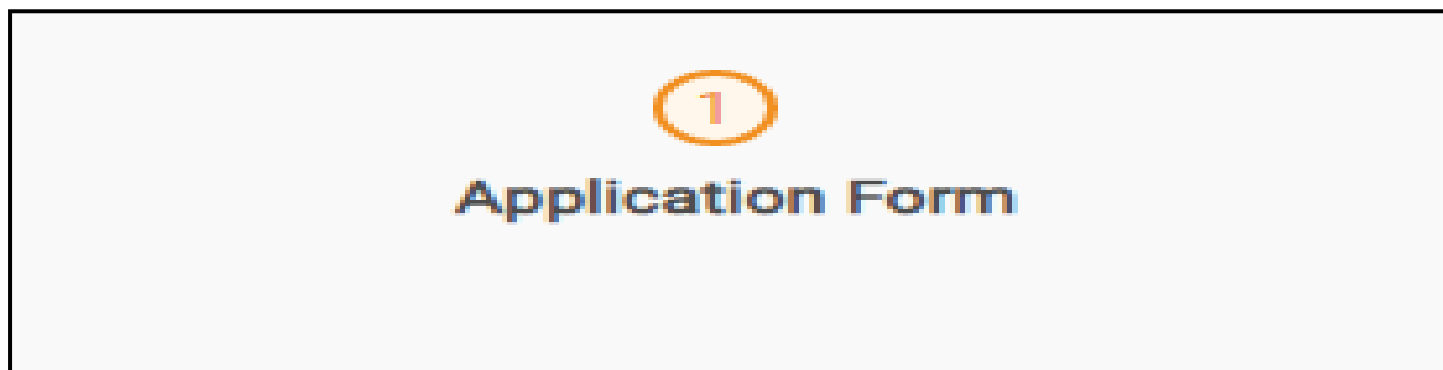
Figure 16. One Section of Applicant Details

Contact Details

Figure 17. Contact Details

Token ID generated

1) After click on **'Save'** button a unique **'Token Id'** would be generated with a pop-up message.
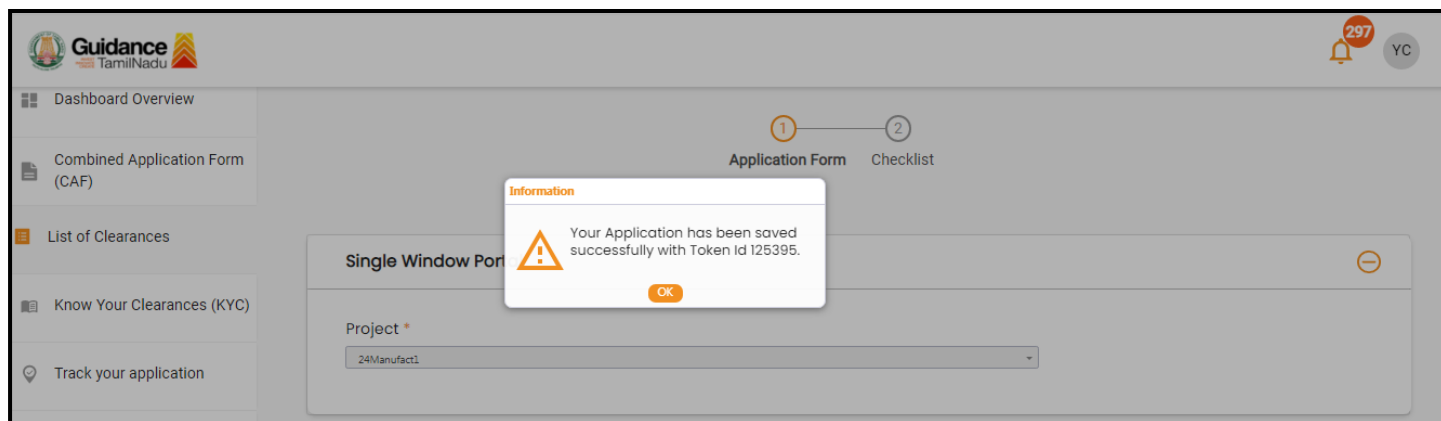
Figure 18. Token ID Generated

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 in zip format.

①————②
Application Form   Checklist

Checklist ⊖

Note 1: Maximum 10 MB Allowed (Only .DOC, .PDF, .XLS, .BMP, .GIF, .JPEG, .PNG, .PPTX, .DOCX, .XLSX, .ZIP, .KML are allowed)

Note 2: In case of multiple documents, please upload in zip format

| Sr. No.	Document Name	Attach Document
1	☑ Form-30 *(Kindly download Form-30 from the "Document Download" section below and upload a signed copy of the document here)*	🗎 PDF 🗑 sample.pdf
2	☑ Board Resolution/ Authorization Letter for the Authorized Signatory	🗎 PDF 🗑 sample.pdf
3	☑ Drug manufacturing licences copy *(Kindly upload all the Licences in a single document)*	🗎 PDF 🗑 sample.pdf
4	☐ Previously issued Form 29 copy, if any	Drag & Drop (Browse Files) (DigiLocker)
5	☐ Copy of valid DSIR (Department of Scientific and industrial research) approval certificate (if any)	Drag & Drop (Browse Files) (DigiLocker)
6	☑ Product dossier (for each product) *(kindly upload the product dossier of all the products in a single zip file)*	🗎 PDF 🗑 sample.pdf
7	☐ 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)
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*	Drag & Drop (Browse Files) (DigiLocker)

9	Bio-data (with photograph) of the Applicant(s) *To be enclosed for each applicant separately, in case there are multiple applicants.* *(Kindly upload the Bio-Data of all the applicants in a single zip file)*	Drag & Drop (Browse Files) (DigiLocker)
10	Address / ID Proof of the Applicant (s) e.g. Passport, Driving License, Election Commission ID Card, Aadhaar Card/e-Aadhaar letter downloaded from UIDAI website, Income Tax PAN Card *To be enclosed for each applicant in case there are multiple applicants.* *(Kindly upload the Address / ID Proof of all the applicants in a single zip file)*	Drag & Drop (Browse Files) (DigiLocker)
11	Bio-data (with photograph) of the Technical Staff(s) *(Kindly upload the Bio-data of all the Technical Staffs in a single zip file)*	Drag & Drop (Browse Files) (DigiLocker)
12	Educational qualification certificate(s) of the Technical Staff(s) (Starting from Minimum Educational Qualification as specified in the Drugs Rules, 1945) *(Kindly make a single document for all educational qualification certificates of each technical staff and upload the educational qualification certificates of all the Technical Staffs in a single zip file)*	Drag & Drop (Browse Files) (DigiLocker)
13	Experience Certificate of the Technical Staff(s) *(Kindly make a single document for all educational experience of each technical staff and upload the experience certificates of all the Technical Staffs in a single zip file)*	Drag & Drop (Browse Files) (DigiLocker)
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 the digitally signed self-certification of all the Technical Staffs in a single zip file)*	Drag & Drop (Browse Files) (DigiLocker)
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 *To be enclosed for each applicant in case there are multiple applicants.* *(Kindly upload the Address / ID Proof of all the Technical Staffs in a single zip file)*	Drag & Drop (Browse Files) (DigiLocker)
16	Ownership document of the premises *(Registered Sale Deed / Registered General Power of Attorney / Conveyance Deed / Latest Property Tax Receipt))*	Drag & Drop (Browse Files) (DigiLocker)

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	Drag & Drop (Browse Files) (DigiLocker)
19	☐ List of machineries and equipments, AHUs, and water system provided Section wise for the manufacturing	Drag & Drop (Browse Files) (DigiLocker)
20	☐ List of analytical instruments and equipments for analysis	Drag & Drop (Browse Files) (DigiLocker)
21	☐ The photocopies of purchase invoices with the details like production capacity, make etc. wherever applicable	Drag & Drop (Browse Files) (DigiLocker)

Document Download ⊖

[Download Form 30]

[Previous] [Next]

Click on 'Save Document'

[Save Document]

Figure 19. Checklist

9. Payment Process

1) Click on **'Save'** button a unique **'Token Id'** would be generated with a pop-up message.
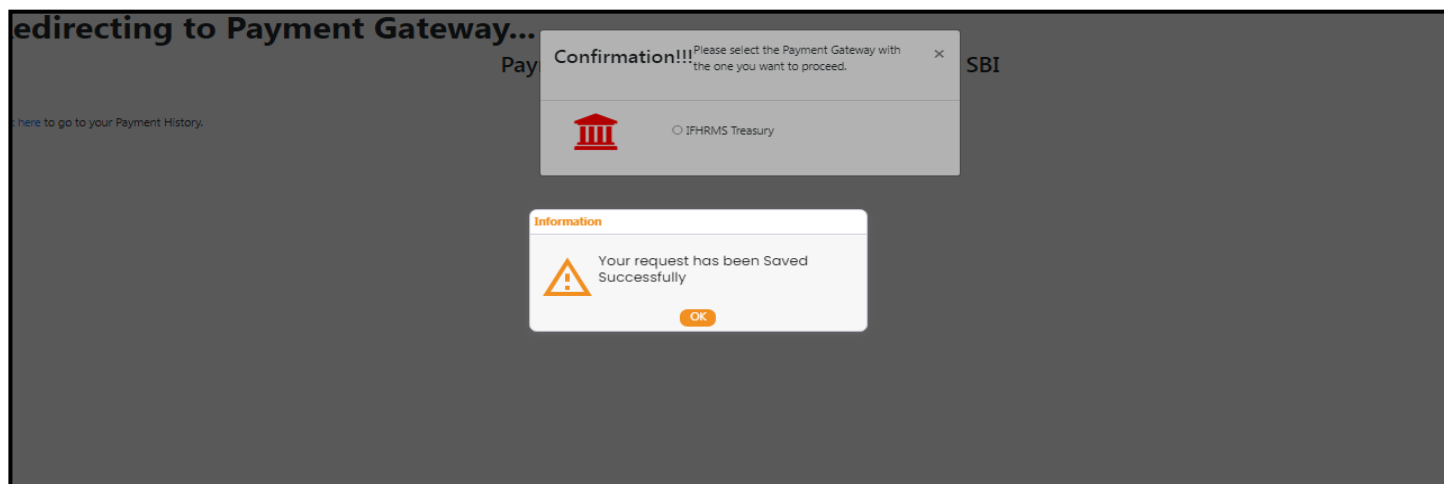
Figure 20. Request Saved Successfully

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

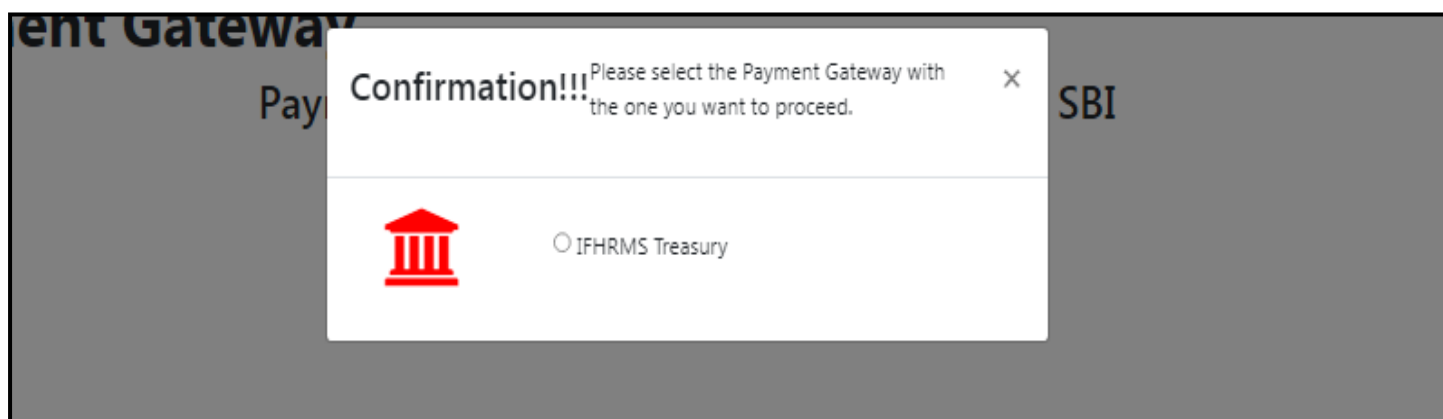3) Click on 'Ok' button, IFHRMS Payment Gateway screen would appear, click on Radio button **'IFHRMS Treasury'**.

Figure 21. 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.
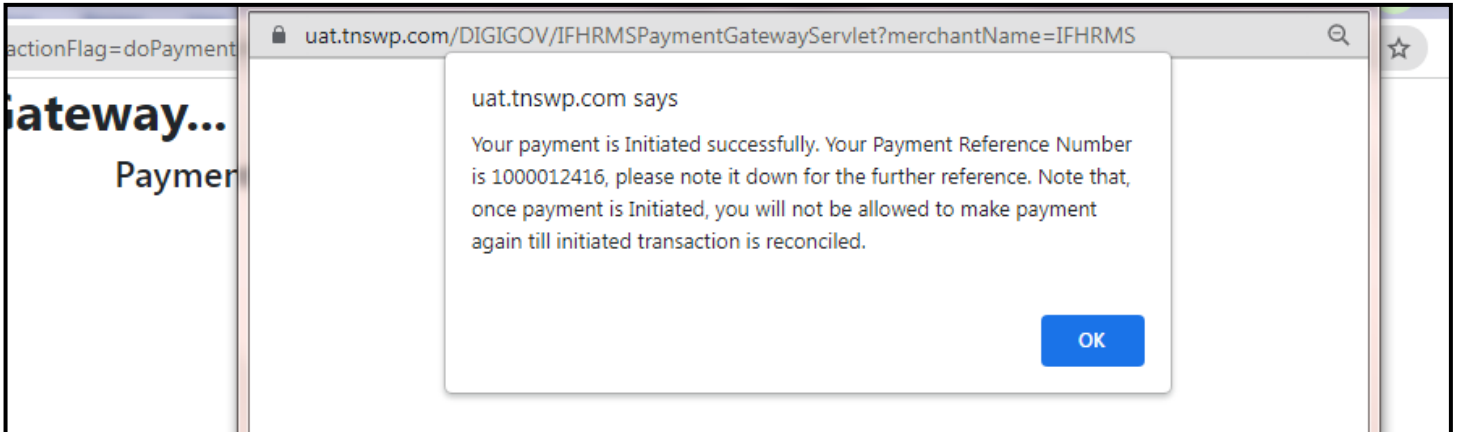
Figure 22. Payment Reference Number

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**
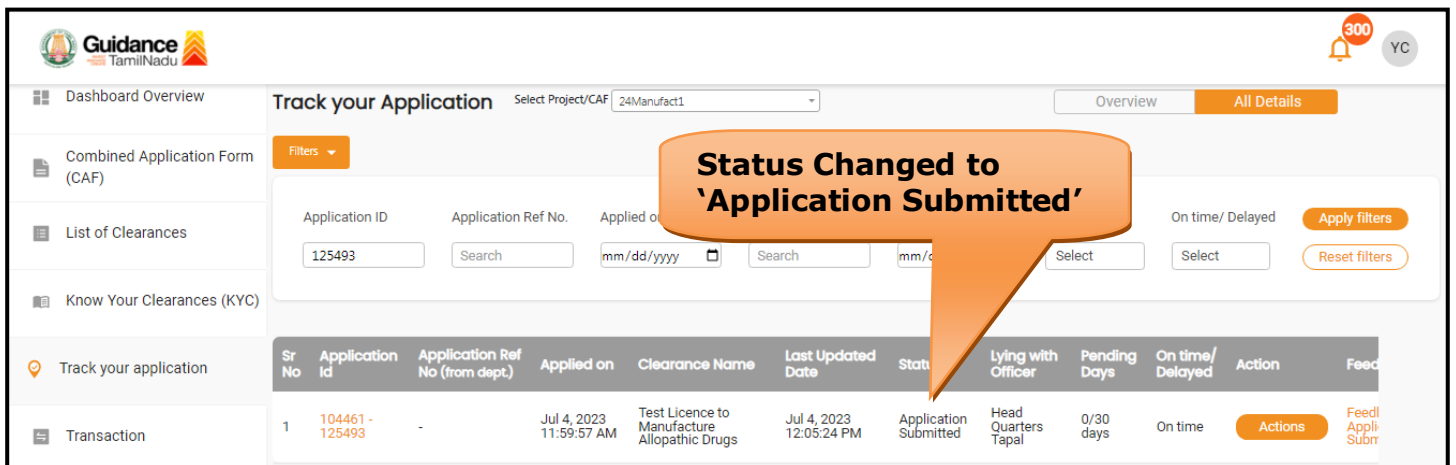
Figure 23. Application Submitted

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.'
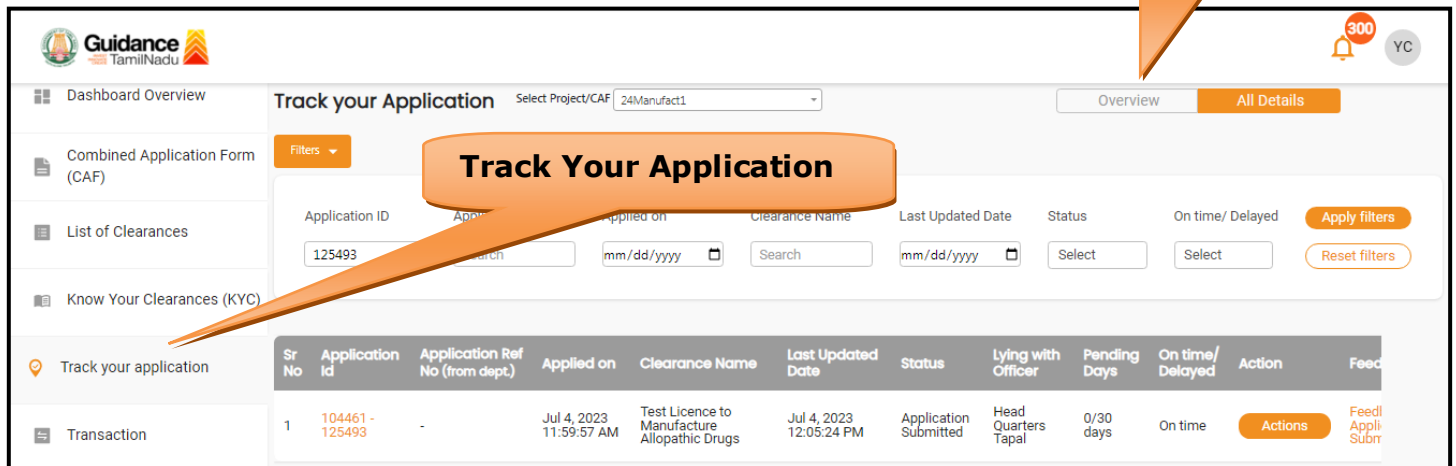
2) Applicant to choose the name of the project created during CAF from the dropdown 'Select project / CAF' displayed at the top of the page.

- **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 24. 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**

Figure 25. '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 26. Need Clarification
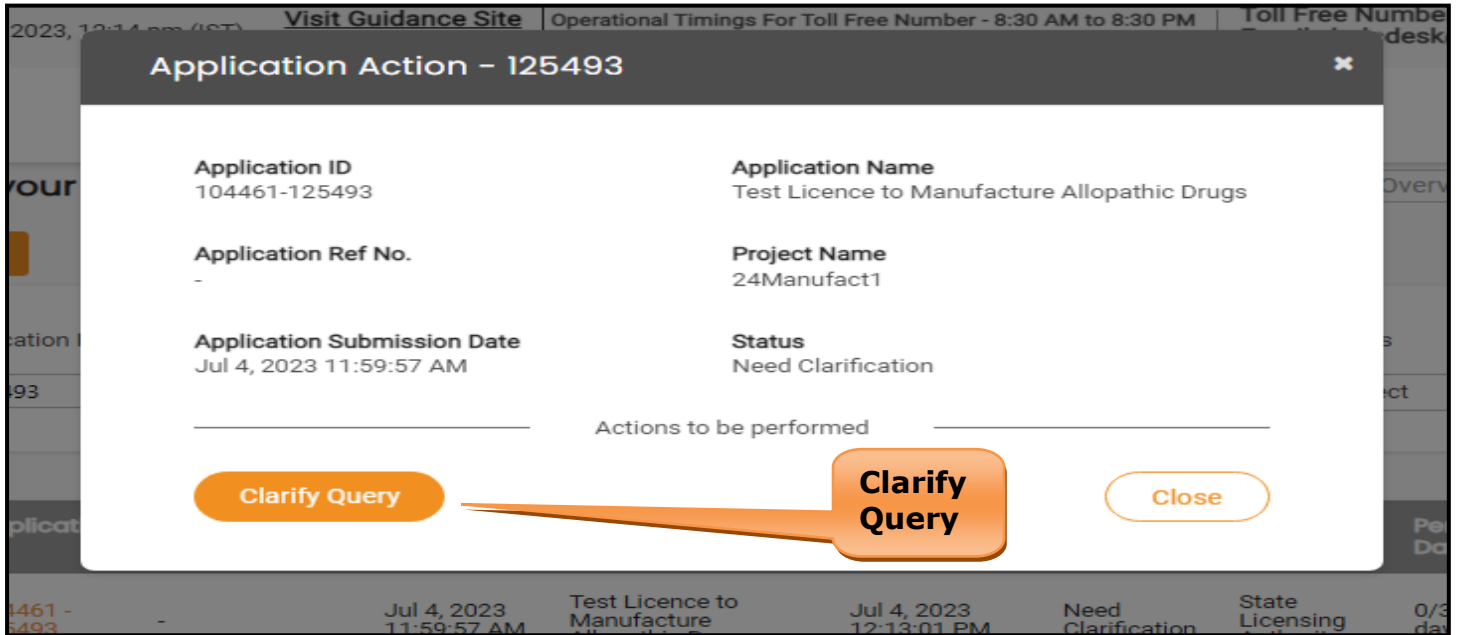
Figure 27. Clarify Query

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.
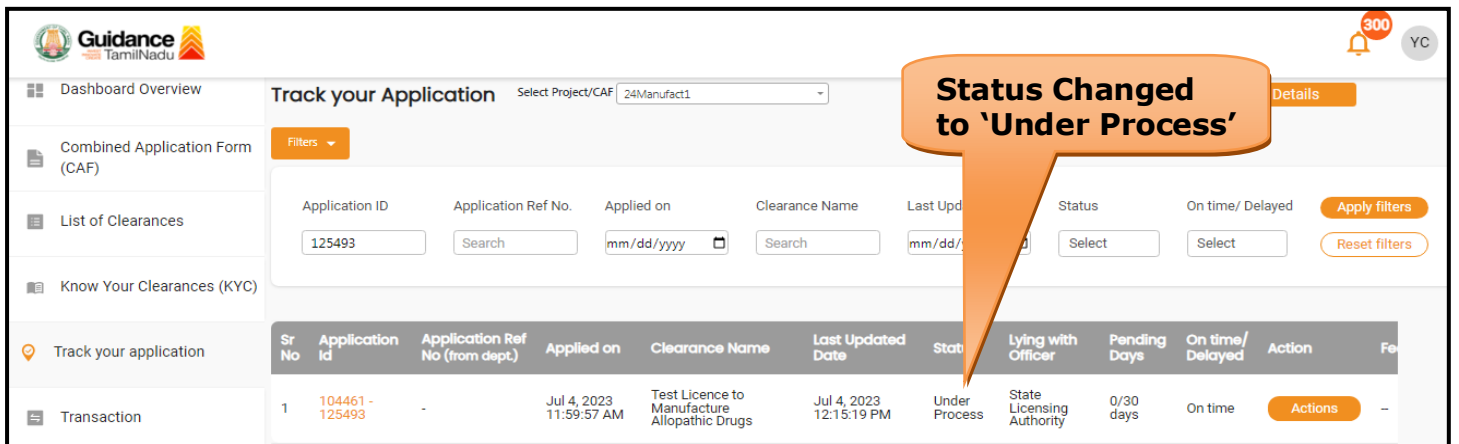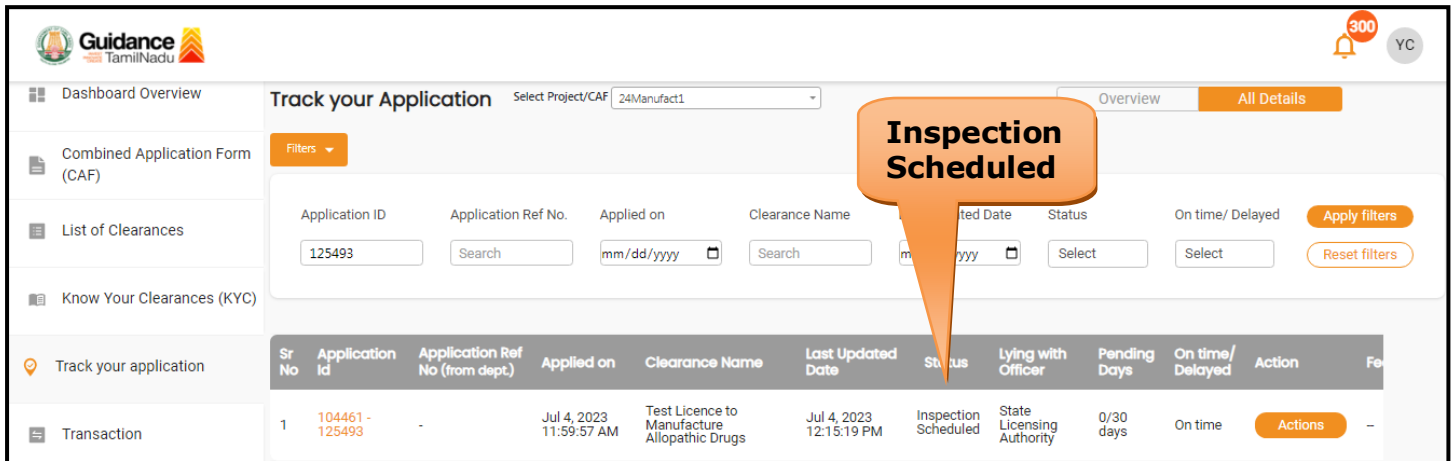

Figure 28. Application under Process

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 29. Inspection Scheduled

Figure 30. Inspection Details

Figure 31. Inspection Date

13. Application Processing

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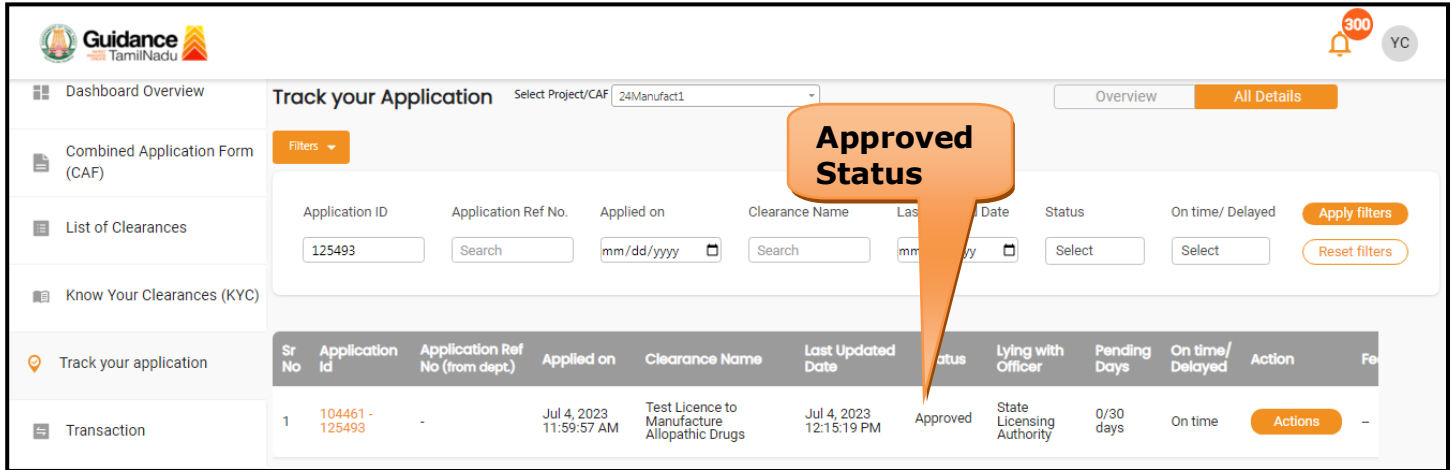

Figure 32. Application Processed

2) If the application is **'Approved'** by the Department, the applicant can download the Approval Certificate under **'Track your application – > 'Action' button -> Download Approval Certificate** (Refer Figure 29)
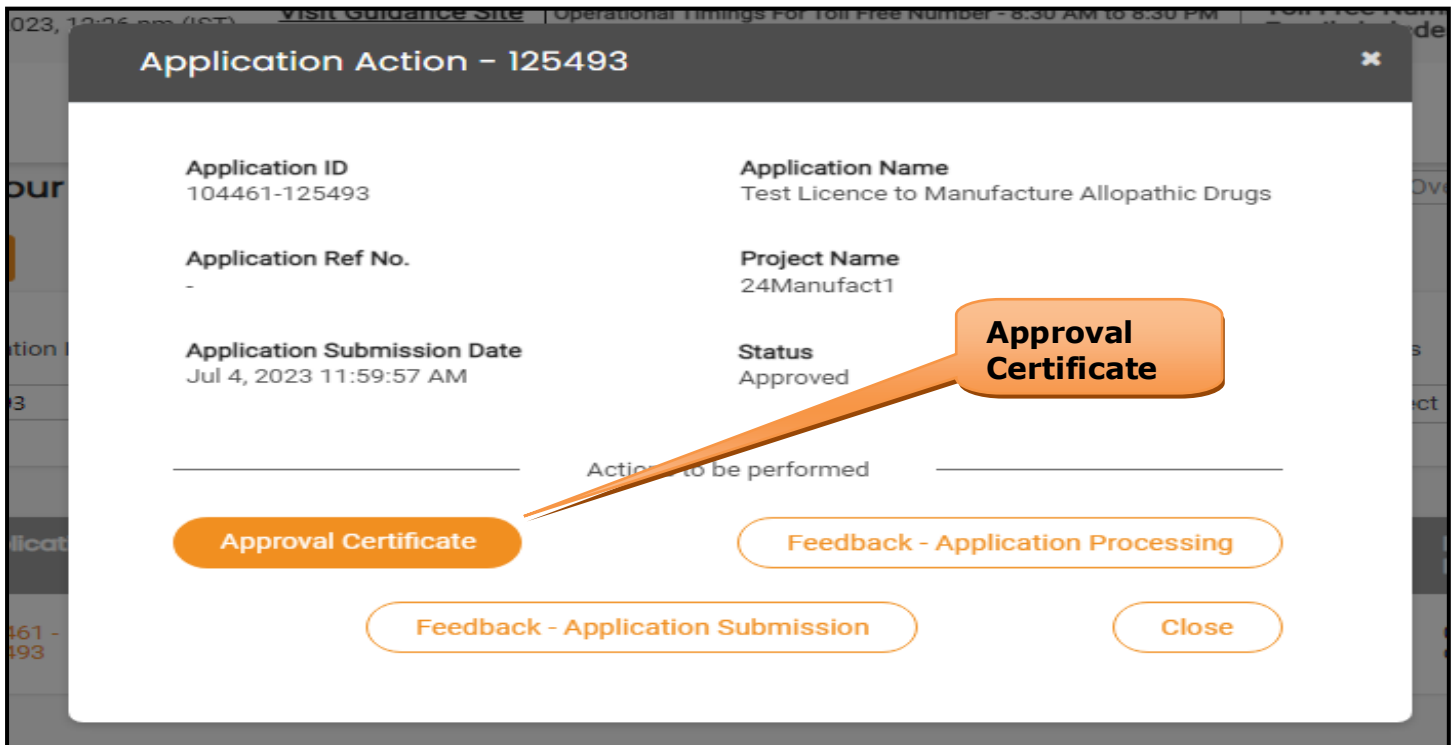

Figure 33. Download the Approved Certificate

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 30)

Figure 34. Rejected Status