

TAMIL NADU SINGLE WINDOW PORTAL

APPLICANT MANUAL

Issuance of Certificate (without product) not covered under Drugs and Cosmetics Act 1940. Issue of Validity Certificate, Issue of Good Manufacturing Practice Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non-Conviction Certificate, Issue of Performance Certificate, Quality & Capacity Certificate, Good Laboratory Practice Certificate, Others

Food Safety and Drug Administration





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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.

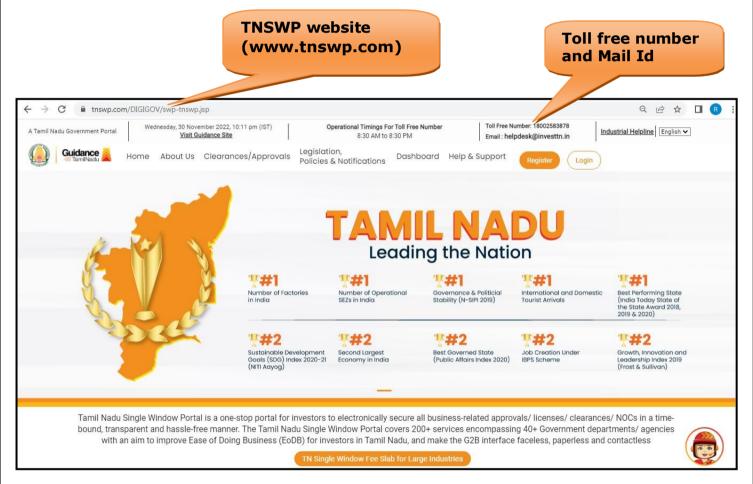


Figure 1. Single Window Portal Home Page



2. Registration

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



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 brief description about the fields when the applicant hovers the cursor on these icons.

TNSWP – Issuance of Certificate (without product) not covered under Drugs and Cosmetics Act 1940. Issue of Validity Certificate, Issue of Manufacturing Practice Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non - Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non - Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non - Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non - Conviction Certificate, Issue of Manufacturing Action (Non - Conviction Certificate) (Non Performance Certificate, Quality & Capacity Certificate, Good Laboratory Practice Certificate, Others



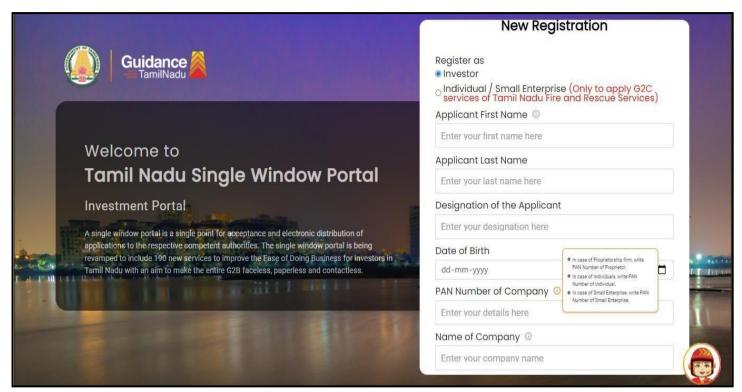


Figure 3. Registration Form

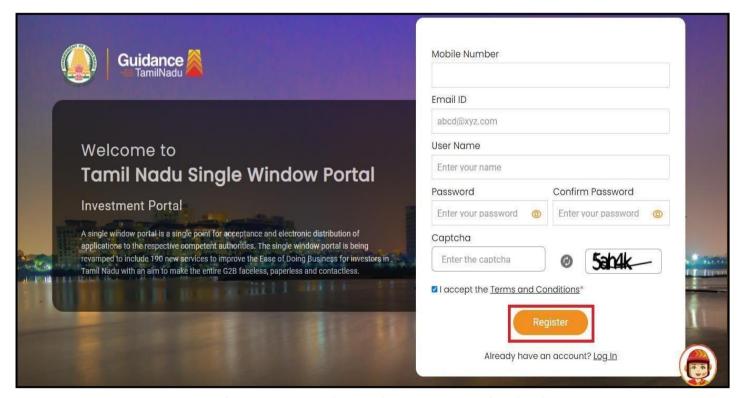


Figure 4. Registration Form Submission



- 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.
- Enter the verification code and click on the 'Verify' button.

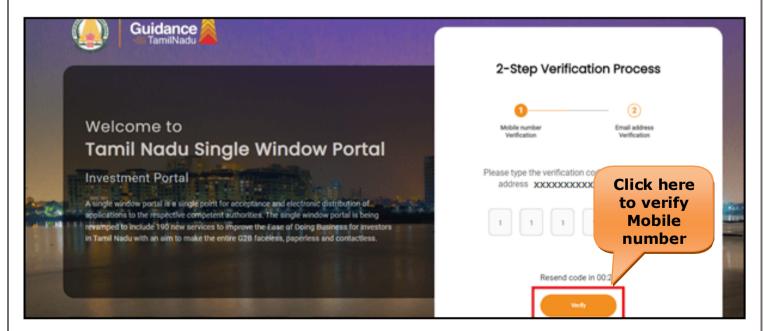


Figure 5. Mobile Number Verification



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.

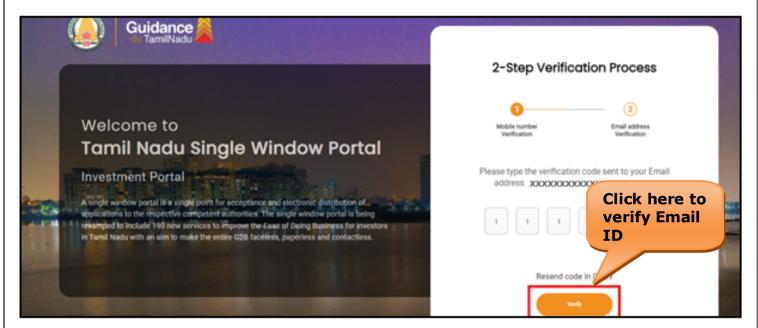


Figure 1. Email ID Verification



- 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.

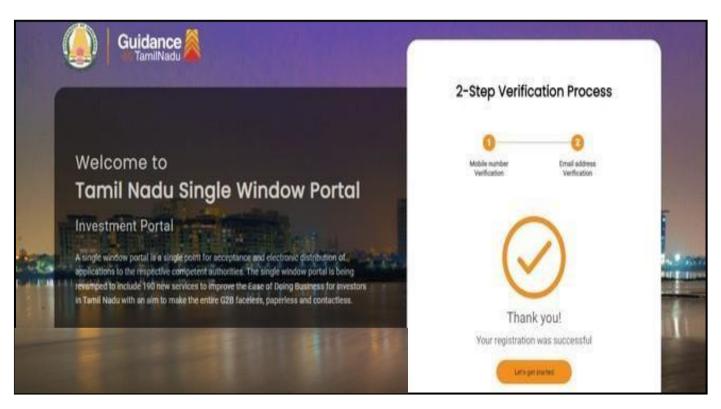


Figure 7. Registration Confirmation Pop-Up

TNSWP – Issuance of Certificate (without product) not covered under Drugs and Cosmetics Act 1940. Issue of Validity Certificate, Issue of Manufacturing Practice Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non - Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non - Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non - Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non - Conviction Certificate, Issue of Manufacturing Action (Non - Conviction Certificate) (Non Performance Certificate, Quality & Capacity Certificate, Good Laboratory Practice Certificate, Others



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.

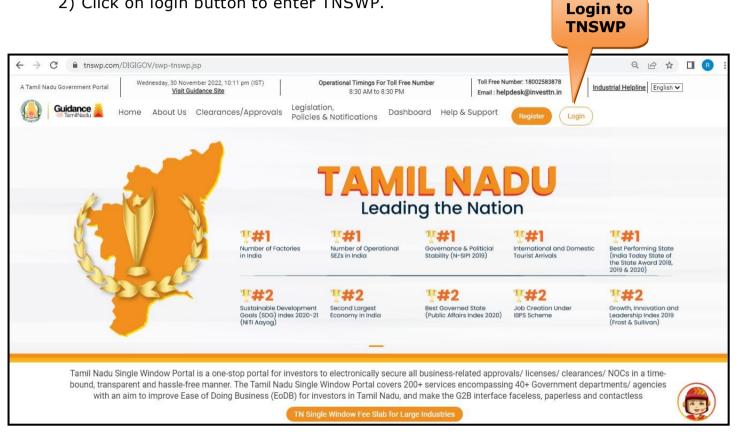


Figure 8. Login



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.

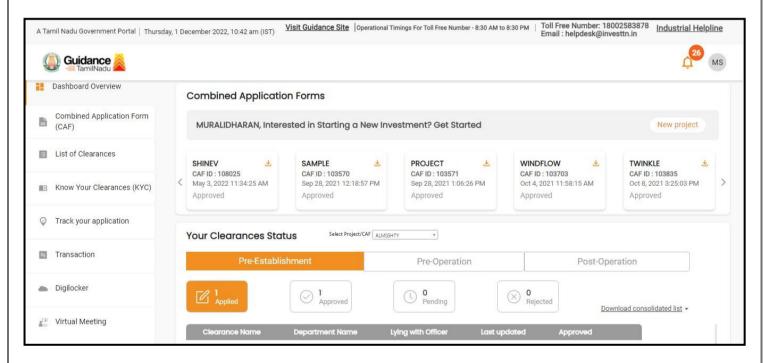


Figure 9. Dashboard Overview



6. Combined Application Form (CAF)

- 1) Prior to applying for various clearances on TNSWP, the Applicant must create a project by filling 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) are mentioned in the below Figure.
- 5) Click on 'Continue' button to fill in the Combined Application Form.

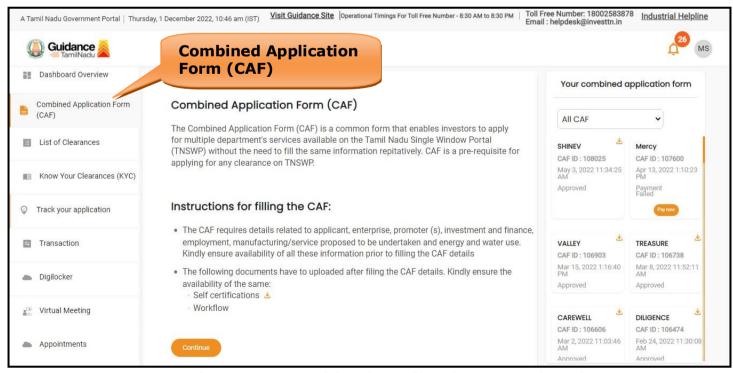


Figure 10. Combined Application Form (CAF)



6.1 Sections of Combined Application Form

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

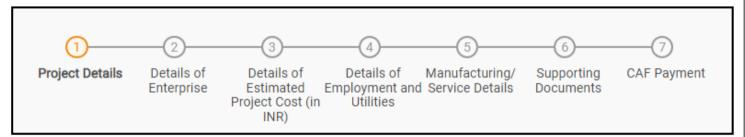


Figure 11. Section of Combined Application Form (CAF)

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

• Self-Certification:

- Download the template.
- Prepare the self-certification documents as per the instructions givenin the template and upload.

Workflow:

- 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).

TNSWP – Issuance of Certificate (without product) not covered under Drugs and Cosmetics Act 1940. Issue of Validity Cartificate, Issue of Manufacturing Practice Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non- Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non- Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non- Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non- Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non- Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non- Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non- Conviction Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non- Conviction Certificate, Issue of Market Standing Certificate, Issue of Market St Performance Certificate, Quality & Capacity Certificate, Good Laboratory Practice Certificate, Others



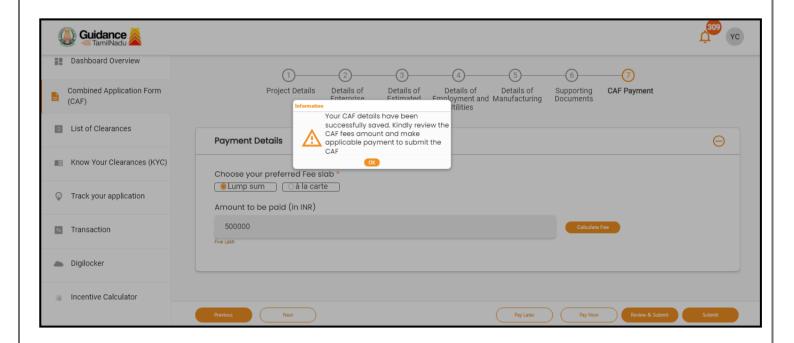


Figure 12. Combined Application Form (CAF) - Confirmation Message

Note:

If the applicant belongs to large industry, 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 Issuance of Certificate (without product) not covered under Drugs and Cosmetics Act 1940. Issue of Validity Certificate, Issue of Good Manufacturing Practice Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non-Conviction Certificate, Issue of Performance Certificate, Quality & Capacity Certificate, Good Laboratory Practice Certificate, Others
- 1) Click on "List of Clearances".

List of

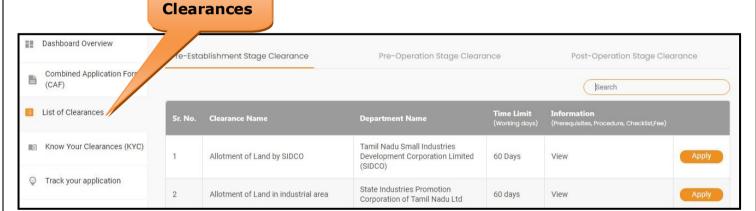


Figure 13. List of Clearances

- 2) The list of clearances is segregated into three stages.
 - Pre-Establishment Stage Clearance
 - Pre-Operation Stage Clearance
 - Post-Operation Stage Clearance



3) Select 'Post-Operation Stage Clearance' and find the clearance 'Issuance of Certificate (without product) not covered under Drugs and Cosmetics Act 1940. Issue of Validity Certificate, Issue of Good Manufacturing Practice Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non-Conviction Certificate, Issue of Performance Certificate, Quality & Capacity Certificate, Good Laboratory Practice Certificate, Others' by using Search option as shown in the figure given below.

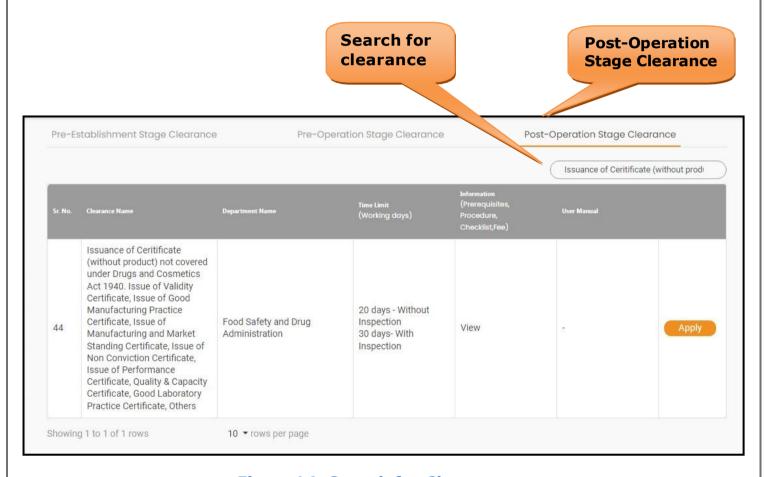


Figure 14. Search for Clearance



- 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) he 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.

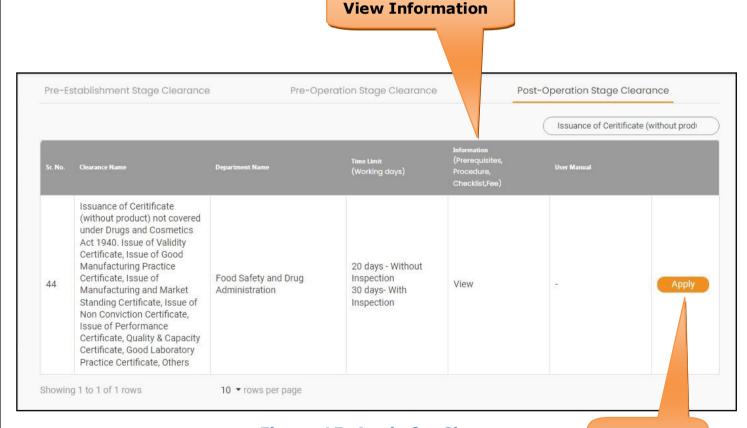


Figure 15. Apply for Clearance

Apply for Clearance



8. Filling the Application Form

- 1) Applicant needs to fill all the details under the following 2 sections to complete the application.
 - A. Application Details
 - **B. Document Checklist**

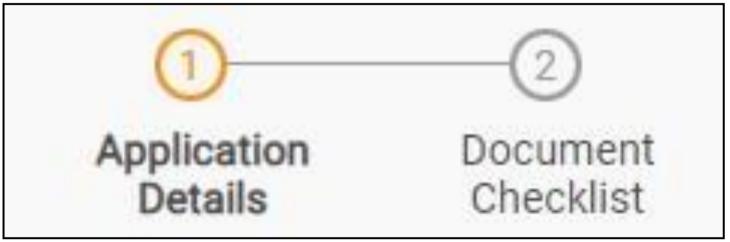


Figure 16. Two Section of Application Form

A. Document 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.
- 4) After Uploading all the supporting document click on 'Next' to go Payment details' screen.

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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. **Document Name** Attach Document No. Covering letter addressed to the Director of Drugs Control stating the reason for applying for the concerned application SAMPLE SUPPORTING Ô \checkmark Authorization of the signatory of the application (Board Resolution / 2 Authorisation Letter) SAMPLE SUPPORTING Copy of Licences/ Renewal Certificate / Challan (Kindly upload all relevant 3 documents in a single zip file) SAMPLE SUPPORTING Ô Scanned copy of WHO GMP Certificate/Renewal Certificate SAMPLE SUPPORTING Ô ✓ Tender Document for which certificate is requested 5 SAMPLE SUPPORTING \Box

TNSWP – Issuance of Certificate (without product) not covered under Drugs and Cosmetics Act 1940. Issue of Validity Manufacturing Practice Certificate, Issue of Manufacturing and Market Standing Certificate, Issue of Non-Conviction Performance Certificate, Quality & Capacity Certificate, Good Laboratory Practice Certificate, Others





Click on 'Submit' button token id get generated.



Figure 18. Token id generated

Click on **`Submit'**



9. Payment Process

- 1) The Applicant has the provision to make the payment by using **"IFHRMS Treasury"** Payment gateway.
- Click on 'Ok' button, IFHRMS Payment Gateway screen would appear, click on Radio button 'IFHRMS Treasury'.

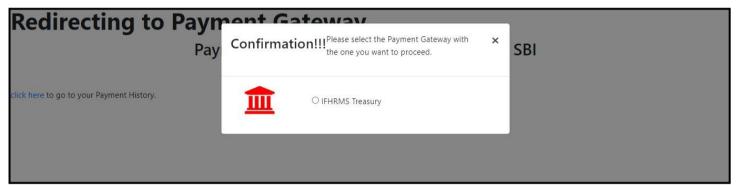


Figure 19. Payment Process

- 3) Then the payment 'Reference number' would be generated, refer to theinstruction note as shown in the below figure.
- 4) Click on 'Ok' button, follow the payment process and make the payment.

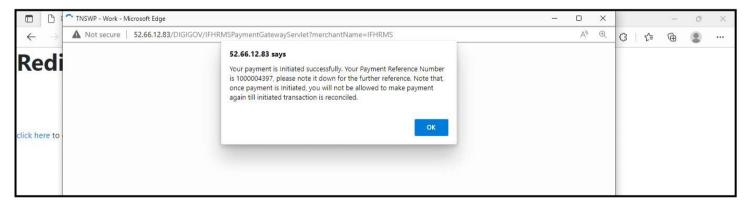


Figure 20. Payment Reference Number

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Application Submitted

1) 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 \rightarrow Select the CAF from the Dropdown \rightarrow All details

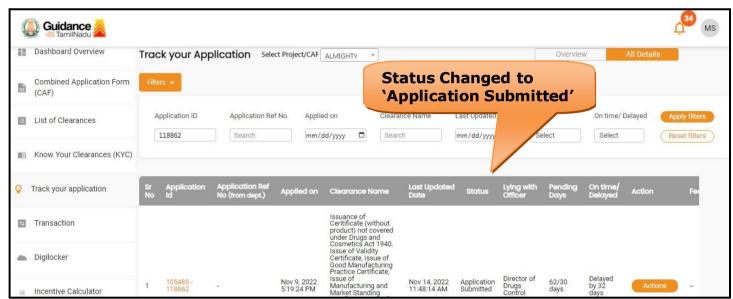


Figure 21. Status of the Application



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 Track Your** Overview of **Application** applications Guidance Dashboard Overview Select Project/CAF AAA your Application Combined Application Form Total Pending Q 119007 (CAF) List of Clearances Delayed Clearances Clearances status Total Approved Clearances 101981 - 119007 Application for Minor Changes in the Allopathic Drugs M Know Your Clearance Timeline:60 day/s Department name:Food Safety and Drug Administration Track your application Latest Update: Approved Total Rejected Clearances 0 ■ Transaction

Figure 22. Track Your Application



All Details

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

Options 🕽 Guidance 🎉 MS Dashboard Overview Track your Application Select Project/CAF ALMIGHTY Overview Combined Application Form (CAF) Application ID Application Ref No. Applied on On time/ Delayed Clearance Name Last Updated Date List of Clearances 118862 mm/dd/yyyy 🗖 Search Select Reset filters M Know Your Clearances (KYC) Track your application Issuance of Ceritificate (without product) not covered under Drug sand Cosmetics Act 1940. Issue of Validity Certificate, Issue of Good Manufacturing Practice Certificate, Issue of Transaction Digilocker Director of Drugs 105485 118862 Nov 9, 2022 5:19:24 PM Nov 14, 2022 11:48:14 AM Incentive Calculator

Figure 23. 'All Details' tab



11. Need Clarification

- After submitting the application to the Drugs department, the concerned officer – **Director of Drugs control** reviews the application and if there are any clarifications required, the 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 '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.

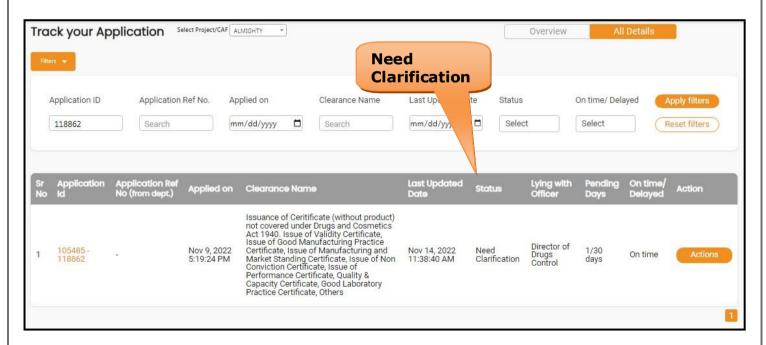


Figure 24. Need Clarification

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Figure 25. 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.

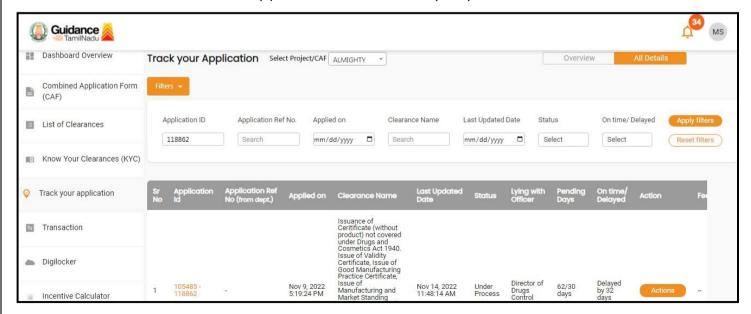


Figure 26. Status changed to 'Under Process'



12. Application Processing

1) The Department scrutinizes and reviews the application and updates the status as "Approved" or "Rejected".

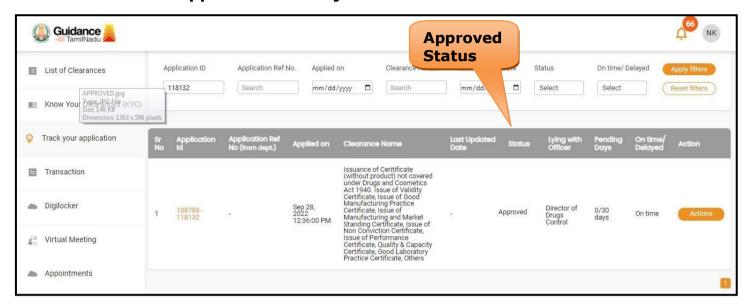


Figure 27. Application Processed

2) If the application is 'Approved' by the Department, the applicant can download the Approval Certificate under 'Track your application - > 'Action' button -> Approval Certificate (Refer Figure 28)



Figure 28. Download the Approved Certificate

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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 29)

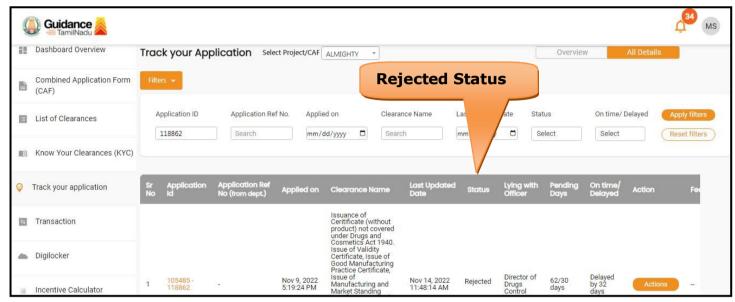


Figure 29. Rejected Status