

# TAMILNADU SINGLE WINDOW PORTAL

**APPLICANT MANUAL** 

Application for Change in Constitution-Allopathic Drug Sale Licence

# Food Safety and Drug Administration





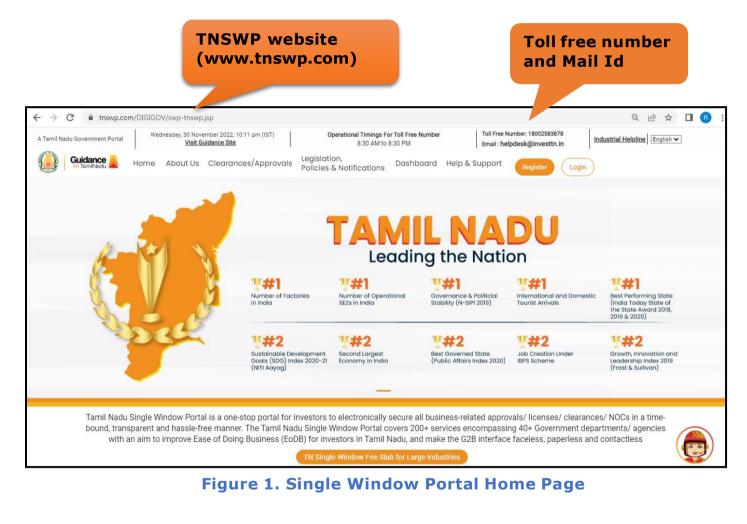
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# Guidance

# 1. Home Page

- The journey of the new applicant starts with Tamil Nadu Single Window Portal (TNSWP) homepage that can be accessed through <u>https://tnswp.com</u> website wherein it gives various information's, useful links, and functionalities about TNSWP.
- Applicant can reach the helpdesk Toll free number 1800-258-3878 and Helpdesk Email.





**Register on** 

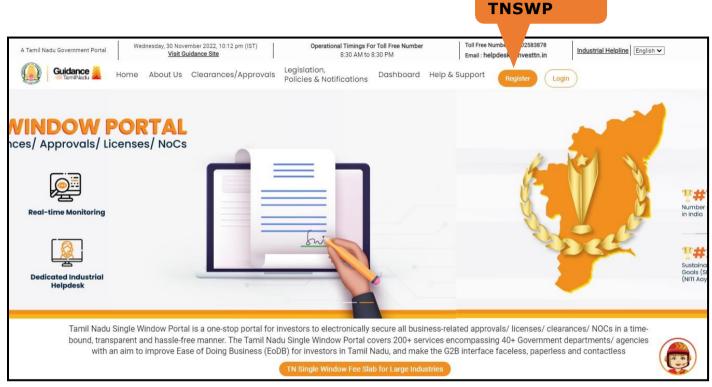
TNSWP – Application for Change in Constitution - Allopathic Drugs Sale Licence

#### 2. Registration

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

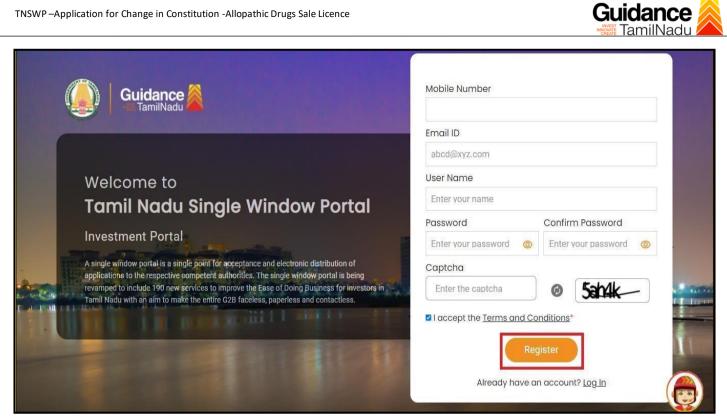
#### Steps for Registration is given below:

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.
- 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.



**Figure 3. Registration Form** 

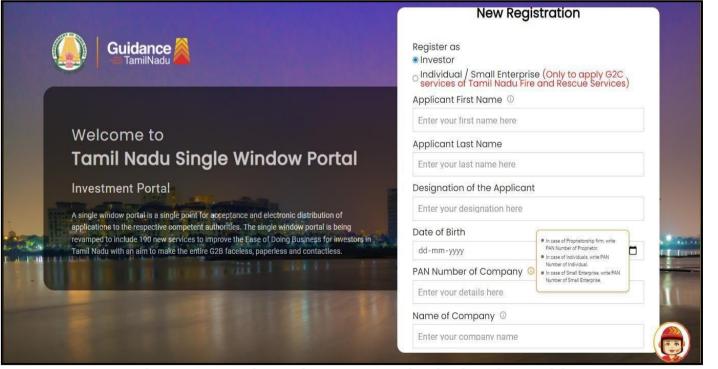


Figure 4. Registration Form Submission (Contd.)

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

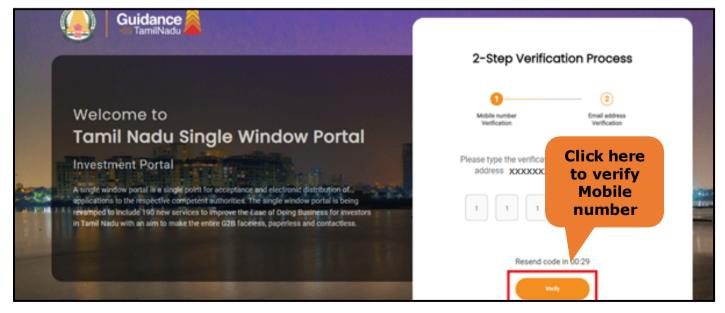
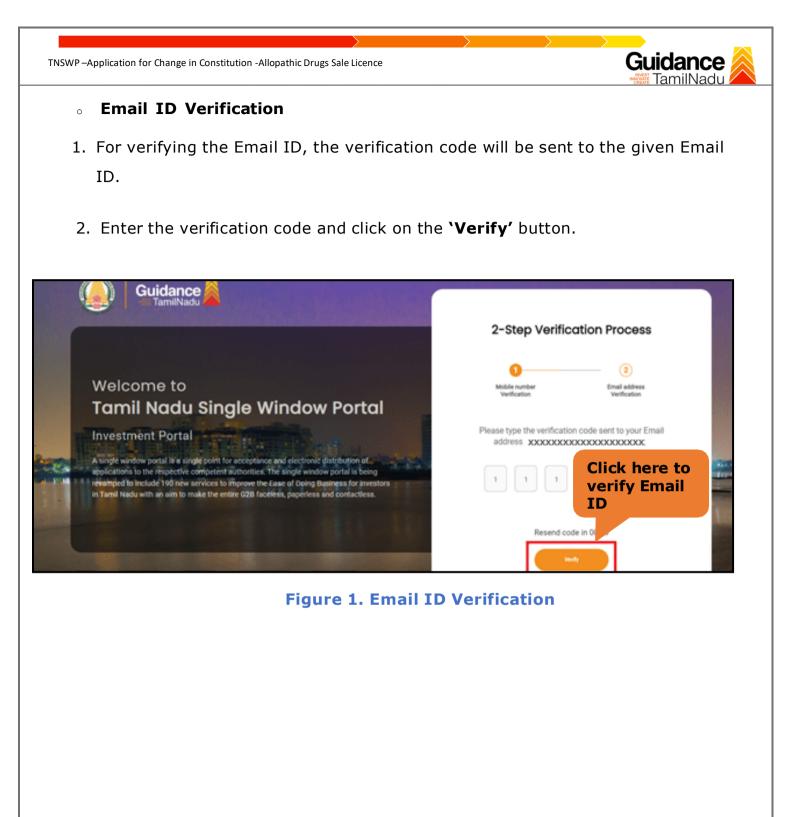
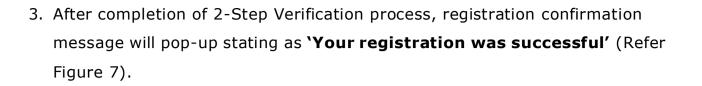


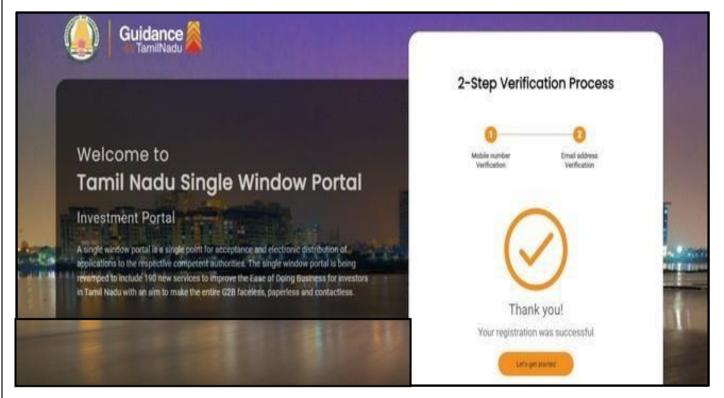
Figure 5. Mobile Number Verification

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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** Q 🖻 🏠 🔲 🖪 C 4  $\rightarrow$ tnswp.com/DIGIGOV/swp-tnswp.jsp Wednesday, 30 November 2022, 10:11 pm (IST) Visit Guidance Site Toll Free Number: 18002583878 Operational Timings For Toll Free Number A Tamil Nadu Government Portal Industrial Helpline English 🗸 8:30 AM to 8:30 PM Email: helpdesk@investtn.in Legislation, Policies & Notifications Dashboard Help & Support Guidance Home About Us Clearances/Approvals Leading the Nation **##1 ##1** ##1 \*#1 **##1** International and Domestic Tourist Arrivals Number of Factories in India Governance & Politicial Stability (N-SIPI 2019) Number of Operational SEZs in India Best Performing State (India Today State of the State Award 2018, 2019 & 2020) **##2 ##2** ##2 ##2 ##2 Growth, Innovation and Leadership Index 2019 (Frost & Sullivan) Job Creation Unde IBPS Scheme Second Largest Economy in India Best Governed State (Public Affairs Index 2020) Goals (SDG) Index 2020-21 (NITI Aayog) Tamil Nadu Single Window Portal is a one-stop portal for investors to electronically secure all business-related approvals/ licenses/ clearances/ NOCs in a timebound, transparent and hassle-free manner. The Tamil Nadu Single Window Portal covers 200+ services encompassing 40+ Government departments/ agencies with an aim to improve Ease of Doing Business (EoDB) for investors in Tamil Nadu, and make the G2B interface faceless, paperless and contactless
  - Figure 8. Login

## 5. Dashboard Overview

- 1. When the applicant logs into TNSWP, the dashboard overview page will appear.
- 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.

A Tamil Nadu Government Portal   Thurs	rsday, 1 December 2022, 10:42 am (IST) Visit Guidance Site Operational Timings For Toll Free Number - 8:30 AM to 8:30 PM   Toll Free Number: 1800/ Email : helpdesk@invest	
Guidance 👗		20 MS
🚦 Dashboard Overview	Combined Application Forms	
Combined Application Form (CAF)	MURALIDHARAN, Interested in Starting a New Investment? Get Started	New project
List of Clearances	SHINEV         SAMPLE         PROJECT         WINDFLOW         Carrow           CAFID:108025         CAFID:103570         CAFID:103571         CAFID:103703	TWINKLE
Know Your Clearances (KYC)	CAP ID: 103023         CAP ID: 10303         CAP ID: 10303         CAP ID: 10303           May 3, 2022 11:34:25 AM         Sep 28, 2021 12:18:57 PM         Sep 28, 2021 11:06:26 PM         Oct 4, 2021 11:58:15 AM           Approved         Approved         Approved         Approved         Approved	Oct 8, 2021 3:25:03 PM >
Track your application	Your Clearances Status Select Project/CAF ALMIGHTY *	
Transaction	Pre-Establishment Pre-Operation Post-Opera	ation
Digilocker	Applied S 1 Approved S 0 Pending S 0 Rejected Downly	oad consolidated list 👻
≟ Virtual Meeting	Clearance Name Department Name Lying with Officer Last updated Approved	

**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) is mentioned in the below Figure.
- 5. Click on 'Continue' button to fill in the Combined Application Form.

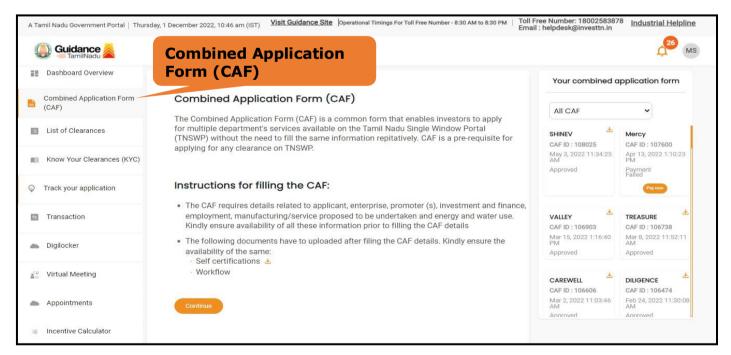
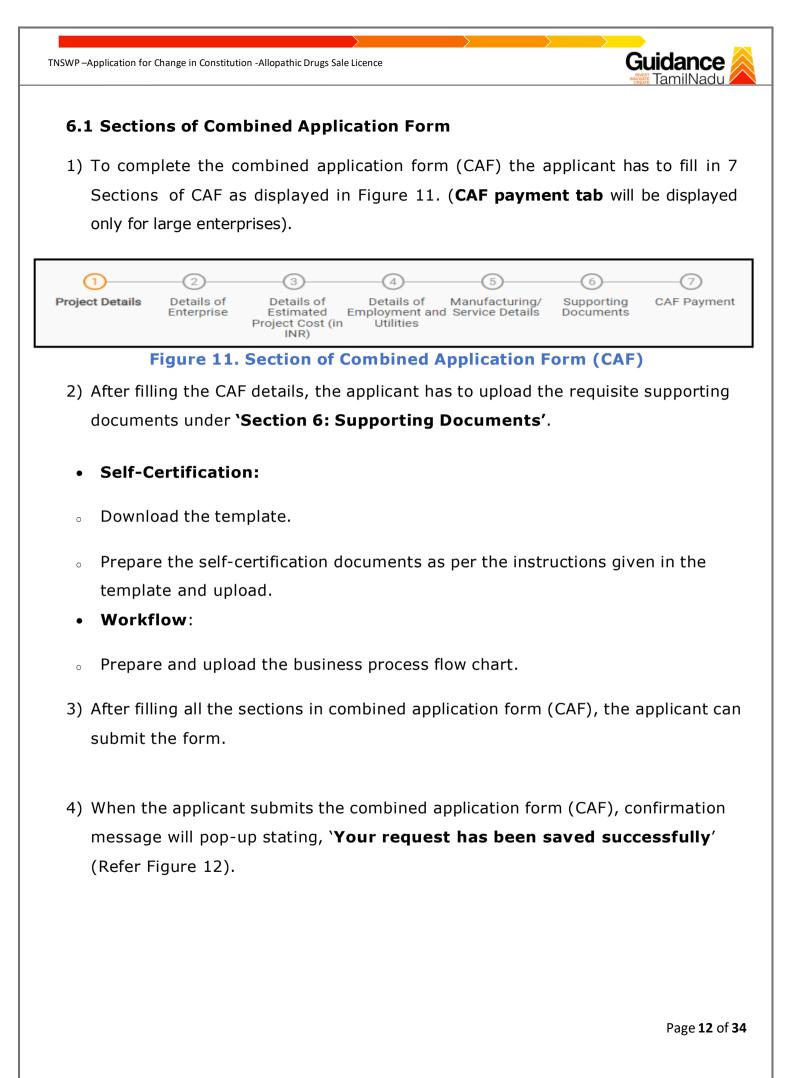


Figure 10. Combined Application Form (CAF)

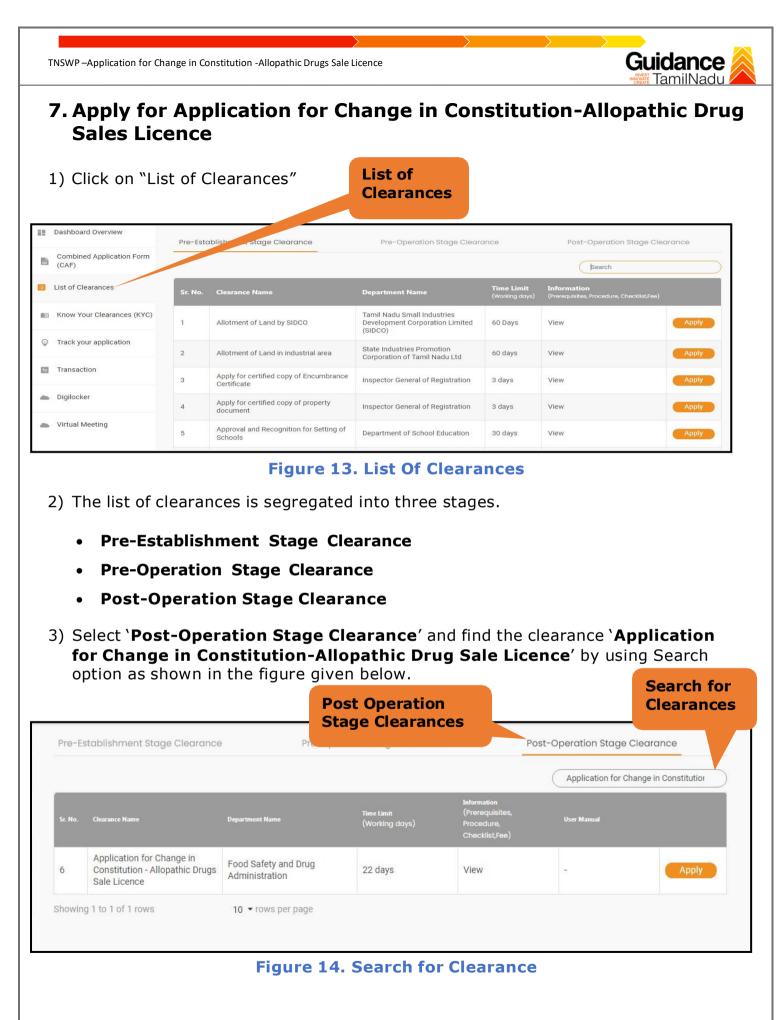


TNSWP – Application for Change in Constitution - Allopathic Drugs Sale Licence						
		ý YC				
Dashboard Overview	1 3 4 5 6 7					
Combined Application Form (CAF)	Project Details of Details of Details of Details of Details of Supporting CAF Payment Enterprise Estimated Employment and Manufacturing Documents Information tillties					
List of Clearances	Your CAF details have been successfully saved. Kindly review the CAF fees amount and make applicable payment to submit the	Θ				
Know Your Clearances (KYC)	CAF Choose your preferred ree slap					
O Track your application	Amount to be poid (in INR)					
Transaction	500000 Calculate Fee					

#### 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. <u>Click here to</u> access the Single Window Fee Slab.



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- 5) 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)
- 6) To apply for the clearance, click on 'Apply' to access the department application form (Refer Figure 15).
- 7) 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

View

Pre-E	stablishment Stage Clearance	Pre-Ope	aration Stage Clearanc	e	Post-Operation Stage	Clearance
					Application for C	Change in Constitution
Sr. No.	Clearance Name	Department Name	Time Limit (Working days)	Information (Prerequisites, Procedure, Checklist,Fee)	User Manual	
6	Application for Change in Constitution - Allopathic Drugs Sale Licence	Food Safety and Drug Administration	22 days	View	-	Apply

#### Figure 15. Apply for Clearance

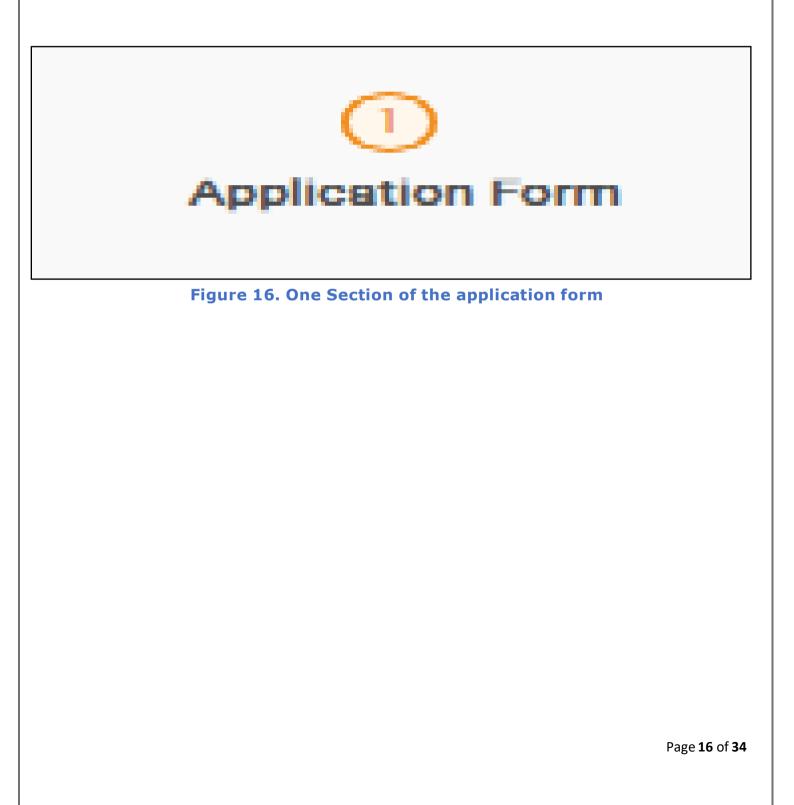
Apply for clearance





# 8. Filling the Application Form

- 1. Applicant to fill the details under the following one section to complete the application.
- 1. Application Form



Guidance TNSWP – Application for Change in Constitution - Allopathic Drugs Sale Licence **Contact Details** The contact details auto populated from Combined Application form • **Contact Details** Θ Contact Person \* Phone / Landline No. Primary Mobile Number \* Secondary Mobile Number Email ID \* **Click on** Email ID **`Submit'button** 

#### **Figure 2. Contact Details**

Reset

Next

Save As Draft



#### Information Pop up

 Click on 'Submit' so that the Application gets saved and the screen redirects to Checklist Tab.

		Application Form Checkli	st		
Details of existin	g L				(
Form	Licence Number	Approval Date	From Date	To D: Action	
Form 20	TN/Z04/20/00110	01-01-2022	01-01-2022	31-1: Read	Only

**Figure 18. Token Id Generated** 

#### Checklist

- The following supporting documents need to be uploaded by the Applicant as per the notes given
- Maximum 10 MB Allowed (Only .DOC, .PDF, .XLS, .BMP, .GIF, .JPEG, .PNG, .PPTX, .DOCX, .XLSX, .ZIP, .KML are allowed)
- In case of multiple documents, please upload in zip format
- After Uploading all the supporting document click on 'Next' to go Payment details' screen
- After uploading, click on "Save document" button.
- After Successful Submission, the page gets redirected to Payment gateway.



Attachments Θ 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 Kindly download Form-XX (i.e. 24 / 27 / 24F / 27B - as applicable) from the "Document Download" section below and upload a signed copy of the document here Sr Document Name Attach Document No. Form 24 1 SAMPLE ñ Form 27 2 3 Form 24F Form 27B 4 ✓ Authorization of the signatory of the application form (Board Resolution / Authorisation Letter) 5 SAMPLE Ē Drug manufacturing Licences Copy, if any 6 n Previously issued Form 29 Copy, if any 7 ✓ 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 8 SAMPLE n Society: Registration Certificate, By Laws, Copy of Resolution passed Hindu Undivided Family: HUF deed ✓ 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 Applicants in a single zip file) 9 SAMPLE Î



10	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)	SAMPLE
u	Experience Certificate of the Technical Staff (s) (Kindly upload experience certificates of all Technical Staffs in a single zip file)	SAMPLE
12	✓ 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)	SAMPLE
13	✓ 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)	SAMPLE
14	✓ Ownership document of the premises (Registered Sale Deed / Registered General Power of Attorney / Conveyance Deed / Latest Property Tax Receipt)	SAMPLE
15	Rental agreement of the premises, if applicable	SAMPLE

Guidance TamilNadu

١	16	✓ Plan of the premises- with details of partitions, measurements - Section wise with location of machineries	SAMPLE
1	17	✓ List of machineries and equipment, Air Handling Units, and water system provided Section wise for the manufacturing	SAMPLE
1	18	✓ List of analytical instruments and equipment for analysis	SAMPLE
1	19	Copy of purchase invoices with the details like production capacity, make etc. wherever applicable	SAMPLE
3	20	Product dossier (for each product) (Kindly upload the product dossier for all products in a single zip file)	SAMPLE
3	21	🔽 Form 51/Brand Name affidavit	SAMPLE
2	22	✓ Agreement with Marketer, if applicable	SAMPLE
2	23	✓ Any other relevant details or documents to establish the correctness of the details or documents or claims made with regard to the above items	SAMPLE
Doc	ument Do		Θ
Doc	ument Download	Click on 'Save Document'	
Previou	IS C	Next O	lose Save Document
		Figure 18. Checklist Document	
			Page <b>21</b> of <b>34</b>

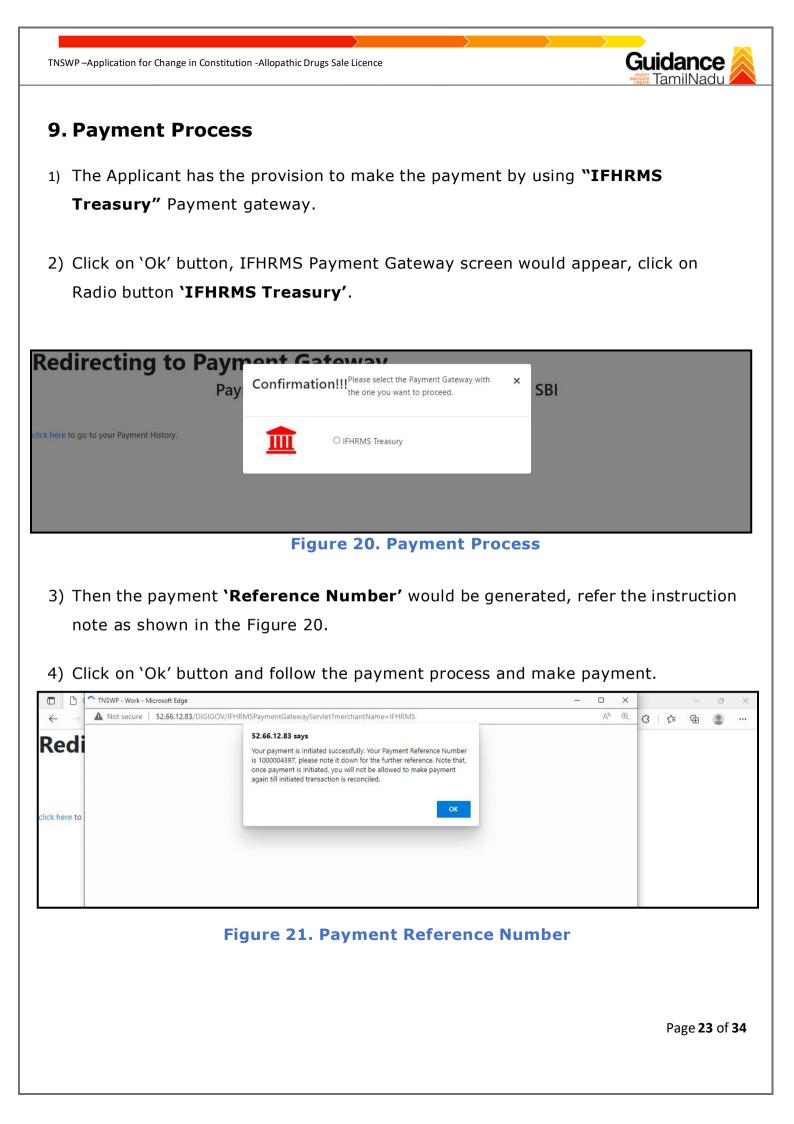


#### Inspection checklist-supporting documents

Note 1: Maxi	mum 10 MB Allowed (Only .DOC, .PDF, .XLS, .BMP, .GIF, .JPEG, .PNG, .PPTX, .DOCX, .XLSX, .ZIP, .KML are allow	ved)
Note 2: In ca	se of multiple documents, please upload in zip format	
Sr. No.	Document Name	Attach Document
1	✓ Inspection Checklist - Supporting Documents - I (Note - Kindly upload the supporting documents for S.No. 1 - 11 of the inspection checklist in a single zip file here. Please name the file as per the S.No. for which it is being submitted e.g. 1.2,1.3 etc.)	SAMPLE
2	✓ Inspection Checklist - Supporting Documents - II (Note - Kindly upload the supporting documents for S.No. 12 - 21 of the inspection checklist in a single zip file here. Please name the file as per the S.No. for which it is being submitted e.g. 1.2,1.3 etc.)	SAMPLE
3	✓ Inspection Checklist - Supporting Documents - III (Note - Kindly upload the supporting documents for S.No. 22 - 29 of the inspection checklist in a single zip file here. Please name the file as per the S.No. for which it is being submitted e.g. 1.2,1.3 etc.)	SAMPLE
Document Document Downlo	Download	(

- After uploading, click on "Save document" button.
- After Successful Submission, the page gets redirected to Payment gateway.

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5) 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.

Dashboard Overview	Trac	k your Ap	plication Se	ect Project/CAF	01feb02				Overvie	W	All Details	
Combined Application Form (CAF)	Filter	15 💌			Status Ch							
List of Clearances		pplication ID 112507	Application F		<b>`Applicat</b> i		mitte		elect	On time/ Select		Apply filter Reset filter
Know Your Clearances (KYC)												
Track your application	Sr No	Application Id	Application Ref No (from dept.)	Applied on	Clearance Name	Last Updated Date	Status	Lying with Officer	Pending Days	On time/ Delayed	Action	Feed
Transaction	1	105949 - 112507	27	Feb 3, 2022 4:24:09 PM	Application for Change in Constitution -	Feb 3, 2022 4:50:34 PM	Application Submitted	Head Quarters	0/22 days	On time	Actions	Feed Appli Proc
		112007		4.24.0511	Allopathic Drugs Sale Licence	4.00.041 M		Tapal	days			Feed Appli Subr

#### **Figure 22. Application Submitted**

# **10. Track Your Application**

- After submitting the application, unique 'token ID' is be generated. Using the 'Token ID' the applicant can track the status of clearances by clicking on 'Track your application' option.'
- 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

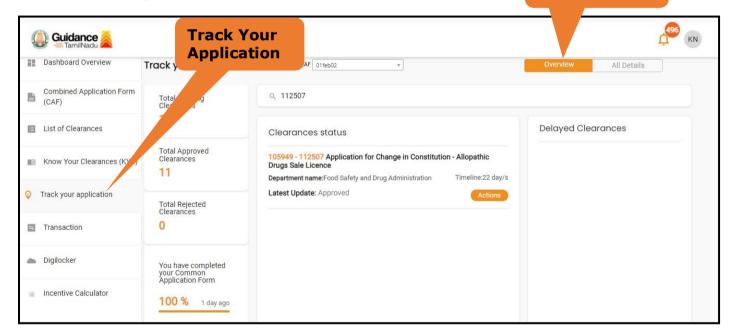


Figure 23. Track your application

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Guidance

**Overview of** 

applications





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

Guidance

Guidance 👗		Д <sup>496</sup> км
Dashboard Overview	Track your Application Select Project/CAF 01feb02 *	Overview All Details
Combined Application Form (CAF)	Filters 🖌	
List of Clearances		Select     Select     Reset filters
Know Your Clearances (KYC)		
Track your application	Sr Application Application Ref No Id No (from dept.) Applied on Clearance Name Last Updated Status Officer Officer	
Transaction	1         105949 - 112507         Feb 3, 2022         Application for Change in 4:24:09 PM         Feb 3, 2022         Approved         Director Drugs Allopathic Drugs Sale           1         105949 - 112507         4:24:09 PM         Application for Change in Allopathic Drugs Sale         Feb 3, 2022         Approved         Director Drugs Control	0/22 days On time Actions Feed
Digilocker	Licence	Appli Subn
Incentive Calculator	٩	,

#### Figure 24. 'All details' tab

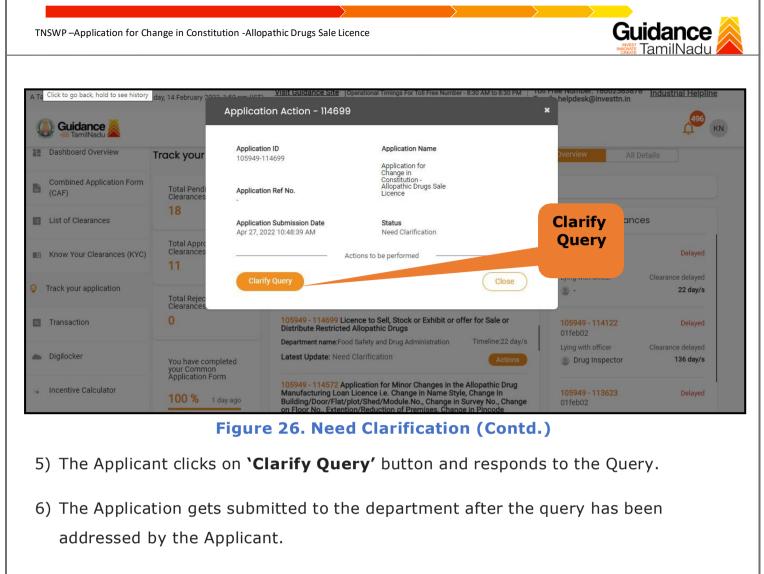
Page **26** of **34** 

## **11. Need Clarification**

- After submitting the application to the Drugs department, the concerned officer Additional 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
- Applicant could go to 'Track your application' option and view the query under action items - 'All Details' Tab
- 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.

Guidance Suidance			495 KN
Dashboard Overview	Track your Application	Select Project/CAF 01feb02 +	Overview All Details
Combined Application Form (CAF)	Total Pending Clearances	Q 112507	
List of Clearances	18	Clearances status	Delayed Clearances
Know Your Clearances (KYC)	Total Approved Clearances 11	105949 - 112507 Application for Change in Constitution - Allopathic         Drugs Sale Licence         Department name:Food Safety and Drug Administration       Timeline:22 day/s	
Orack your application	Total Rejected Clearances	Latest Update: Need Clarification Actions	
Transaction	0		
Digilocker	You have completed your Common Application Form	Need Clarification	
Incentive Calculator	100 % 1 day ago		

#### Figure 25. Need Clarification



7) The Status of the application changes from 'Need clarification' to 'Under Process' after the Applicant submits the query

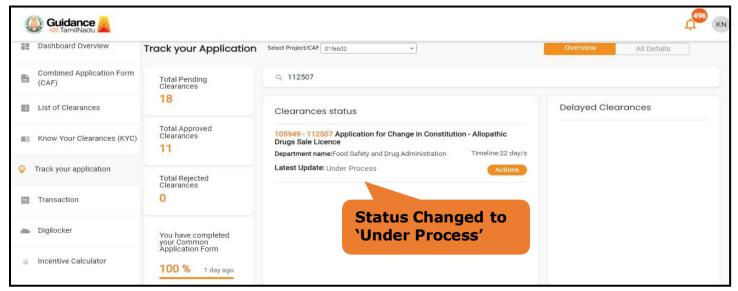


Figure 27. Status of the Application

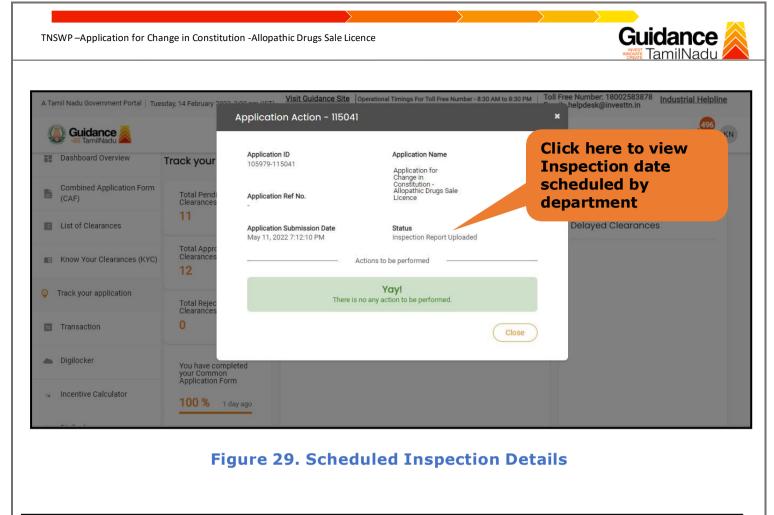
TNSWP-Application for Change in Constitution - Allopathic Drugs Sale Licence **12. Inspection Schedule**The Assistant Director of Drugs Forwards the file for Inspection to the Drug Inspector.

2) The Drug Inspector schedules the Inspection date.
3) After the Inspection gets completed, the Drug Inspector submits the Inspection report to the Assistant Director of Drugs.

4) The Applicant has the provision to view the Scheduled Inspection details.

5	Guidance 👗			Lange KN						
	Dashboard Overview	Track your Application	Select Project/CAF 01feb02 *	Overview All Details						
iii	Combined Application Form (CAF)	Total Pending Clearances	Q 112507							
	List of Clearances	18	Clearances status	Delayed Clearances						
UII	Know Your Clearances (KYC)	Total Approved Clearances <b>11</b>	105949 - 112507 Application for Change in Constitution - Allopathic         Drugs Sale Licence         Department name:Food Safety and Drug Administration       Timeline:22 day/s							
0	Track your application	Total Rejected	Latest Update: Inspection Scheduled Actions							
	Transaction	0	Status changed to							
4	Digilocker	You have completed your Common	'Inspection Schedu	led'						
10	Incentive Calculator	Application Form								

Figure 28. Inspection Schedule



Guidance 👗		224 MS
Dashboard Overview		
Combined Application Form	Inspection Details : 117870	
CAF)	Inspection Scheduled Date (DD/MM/YYYY): date scheduled	ed
List of Clearances	27/09/2022 by departme	
Know Your Clearances (KYC)	Inspection Remarks:	
Orack your application		
Transaction		
Digilocker		
Jula Provide the set of the set		
	Figure 30. Scheduled Inspection De	etails (Contd.)

5) After the Inspection schedule is done, the Drugs inspector uploads the inspection report and submits to the department. The status would reflect as "Inspection Report uploaded".

Cuidance     TamiiNadu     Dashboard Overview	Track your Application	Select Project/CAF 01feb02 +	Overview All Details
Combined Application Form (CAF)	Total Pending Clearances	Q 112507	
List of Clearances	18	Clearances status	Delayed Clearances
Know Your Clearances (KYC)	Total Approved Clearances <b>11</b>	105949 - 112507 Application for Change in Constitution - Allopathic Drugs Sale Licence Department name:Food Safety and Drug Administration Timeline:22 day/s	
Track your application	Total Rejected Clearances	Latest Update Inspection Report Uploaded Actions	
Transaction	0		
Digilocker	You have completed your Common	Inspection Report Uploaded	
Incentive Calculator	Application Form 100 % 1 day ago		

Figure 31. Inspection Report Uploaded

# **13. Application Processing**

a) The Department Scrutinizes and reviews the application and updates the status as
 "Approved" or "Rejected".

Dashboard Overview	Trac	k your Ap	plication Se	ect Project/CAF	01feb02				Overvie	ew	All Details		
Combined Application Form (CAF)	Filter	rs 🕶						prove	d				
List of Clearances		pplication ID 112507	Application F		iied on mm-yyyy 🗖	Clearance N		atus	s Select	On time/ Select		Apply filter	
Know Your Clearances (KYC)													
Track your application	Sr No	Application Id	Application Ref No (from dept.)	Applied on	Clearance Na	me Las Dat	: Updated Stat	tus Lying w Officer	ith Pending Days	On time/ Delayed	Action	Feed	
Transaction	1	105949 - 112507	<b>1</b> .	4:04:00 PM	Application for Change in Feb 3, 2 Constitution - 4:50:34		34 PM Approved	Diugs	Drugs days	On time	Actions	Feed Appli Proc	
Digilocker					Licence			Control				Appli Subr	

#### Figure 32. Application Processed

b) 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 33)

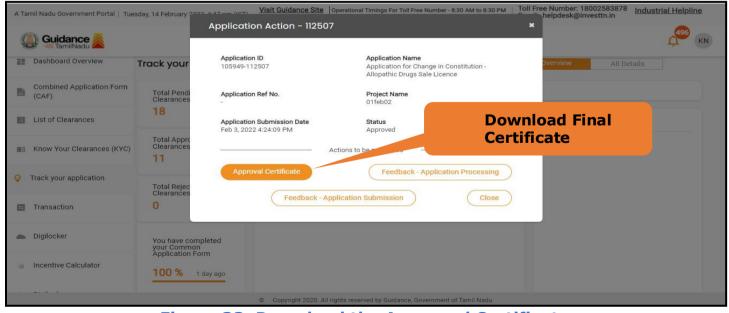


Figure 33. Download the Approved Certificate

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c) 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 34)

TNSWP – Application for Change in Constitution - Allopathic Drugs Sale Licence

Dashboard Overview	Track your Ap	plication Se	lect Project/CAF		Overview All Details						
Combined Application Form (CAF)	Filters 👻										
List of Clearances	Application ID 112507	Application I Search		lied on mm-yyyy 🗖	Clearance Name Search	Reje	cted	elect	On time/ Select	Delayed	Apply filter Reset filter
Know Your Clearances (KYC)						State	us				
Track your application	Sr Application No Id	Application Ref No (from dept.)	Applied on	Clearance Nam	e Last Updated Date	Status	Lying with Officer	Pending Days	On time/ Delayed	Action	Feed
Transaction	1 105949 - 1 112507	2 90	Feb 3, 2022 Chang	Application for Change in Constitution - Allopathic Drugs S	Feb 3, 2022 4:50:34 PM	Rejected	Director Drugs Control	0/22 days	On time	Actions	Feed Appli Proc
Digilocker				Licence			Control				Appli Subr

Figure 34. Rejected Status

200

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