

Health & Family Welfare:

Drug Manufacturing License

Provided as a service through 'SilpaSathi', the Online Single Window portal of the State (West Bengal)

User Manual

Drug Manufacturing License

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Introduction

This document is intended to serve as a User Manual for grant of the service "Drug Manufacturing License" by Health and Family Welfare Department, Govt. of West Bengal through Single window of the State, 'SilpaSathi'. The service is integrated with the Single Window (SilpaSathi) and can be accessed through the SilpaSathi portal. This document has been designed as a user-friendly guide to assist applicants in filling their application forms. It will help them to familiarise with the entire procedure in a seamless manner for successful submission of application and download final Approval certificate from the SilpaSathi portal without the requirement of physical visit to the Department(s).

Salient Features of Silpasathi Portal:

- The Single Window Portal of the State of West Bengal (SilpaSathi) allows seamless integration with portals of different government departments thereby providing single login credential for various applications, eliminating the need to provide common information multiple times in different forms of various Departments, and ensuring all clearances are available from a single portal.
- It serves as a digital gateway for providing the necessary statutory compliances under the applicable Acts, Rules, Policies and Schemes of the Govt of West Bengal from a single portal.
- Business Entrepreneurs can get certificates and licences required for setting up and operating business in the State
 in a smooth and time-bound manner, smooth and time-bound manner, without the need to visit any government
 department or office.

About the Service

Drug Manufacturing License – H&FW aims to ensure production facility adheres to the standards set by the regulatory authorities, guaranteeing the safety, efficacy, and quality of the medicines produced. A drug manufacturing license is a regulatory requirement for companies that produce pharmaceuticals. The primary purpose of this license is to ensure that the manufacturing process meets strict safety and quality standards, thereby protecting public health. The online system has the following features without the requirement of physical visit to the Department: 1) Submission of Application 2) Online Payment of fees 3) Track Status of Application 4) Online Download of final approval certificate 5) Third Party Verification.

Comprehensive Checklist of Documents to be submitted online

The applicant is required to submit the following documents in order to apply for the service:

#		Documents Required	Detailed Description
	1.	Power of Attorney (if any) of applicant in non-judicial stamp paper as per proforma	A power of attorney (POA) is a legal document that gives someone the authority to act on another person's behalf.

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#	Documents Required	Detailed Description
2.	Trade License / Trade Enlistment Certificate, mentioning nature of Trade	A Trade License or Trade Enlistment Certificate is a mandatory document that establishes a business entity's legitimacy and compliance with local regulations
3.	Profession documents of the premises: Current house Tax Receipt/Consolidated Rate Bill/ Registered deed of Conveyance/ Consent letter from the owner/NOC in the form of Affidavit before First Class Judicial magistrate/ Rent Bill signed by owner or Authorized signature as the case related to Porcha / Khajna , Dakhila from BL and L.R.O.	official papers or records related to a business or property's occupation, trade, or use
4.	In case of partnership firms, registered partnership deed along with firm registration receipt in case of limited or pvt limited company, copy of memorandum and Articles of Association. In case of LLP (Limited Liability/ Partnership Firm) Copy of Memorandum and Articles of Association	registered partnership deed along with firm registration receipt in case of limited or pvt limited company, copy of memorandum and Articles of Association. In case of LLP (Limited Liability/ Partnership Firm) Copy of Memorandum and Articles of Association
5.	Copy of resolution of the Board Meeting along with list of Present Board of Directors with respect to Limited or pvt Ltd companies	certified copy of a board resolution is a document that verifies the resolution passed at a board meeting
6.	Sketch map of proposed land / premises with location and surrounding (CAD mode)	A sketch map of a proposed land or premises is a visual representation of the properties' layout, boundaries, and features

Timeline (WBRTPS)

Drug Manufacturing License has an WBRTPS timeline of 90 days till approval by the authorities.

Instructions related to the application form

SI. No.	Field Name	Instructions		
Firm Details				
1.	Application Type	Select Application Type (Old / New)		
2.	Type of Firm	Select Type of Firm (Retail / Wholesale)		
3.	Name of Firm	Enter Name of Firm		
4.	Nature of Firm	Select Nature of Firm (Partnership / Private / etc)		
Firm Address				

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SI. No.	Field Name	Instructions
1.	Building No/ Holding No/ Daag Number	Enter details
2.	Street Name	Enter Street Name
3.	Address Line 1	Enter Address
4.	Police Station	Enter name of the police station
5.	Post Office	Enter name of the post office
6.	City/Village	Enter name of city/village
7.	Pin Code	Enter pincode
8.	Local Authority	Enter local authority name
Contract Details of Establishment		
1.	Trade License	Enter trade license permit
2.	Actual Floor Space	Enter details
3.	Nature of Ceiling	Enter Nature of Ceiling
4.	Working hours	Enter number of hours
5.	Email	Enter email id
6.	Landline	Enter landline number
7.	Mobile	Enter mobile number
8.	Enter details of pharmacist	Enter qualification details a long with registration certificate, date of joining, years of experience, etc
Owner Details		
1.	Owner Name	Enter Full Name of the owner
2.	Owner Signature	Add signature
3.	Owner Photo	Add photo

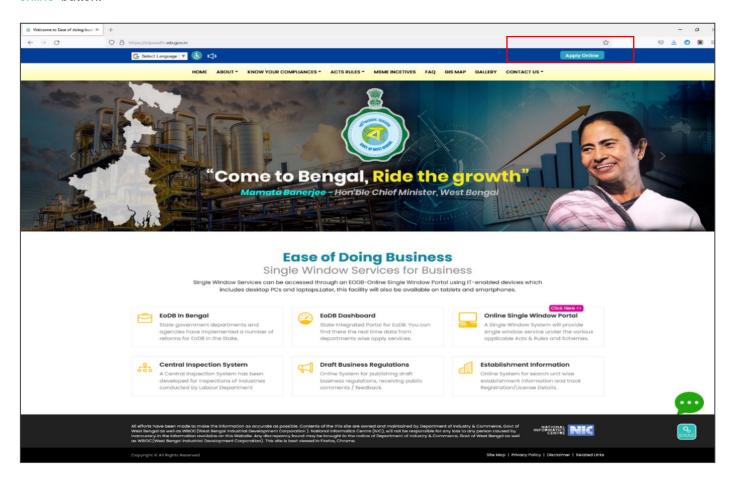
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Application Process through SilpaSathi

1. Online Application submission along with online submission of documents

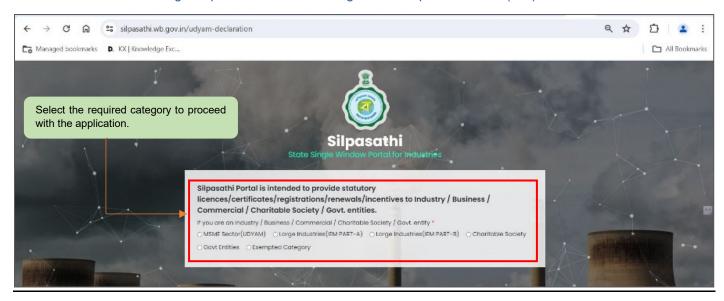
In order to complete the user registration, the applicant has log on to https://silpasathi.wb.gov.in/ and click on 'Apply online' button.



<u>Applicant Log-in</u>: The applicant needs to **select the required category** as illustrated in the screenshot below and **proceed for registration**.

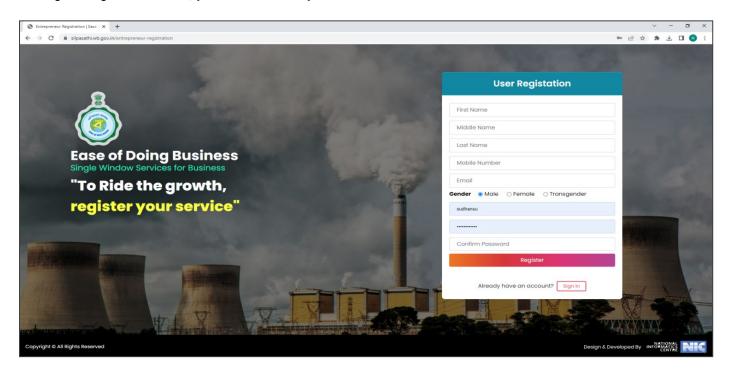
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A sign-up window appears on the screen. The user has to select 'Create New' if he is a new user. An already registered user in SilpaSathi portal can fill in the username and password and login to the SilpaSathi portal.

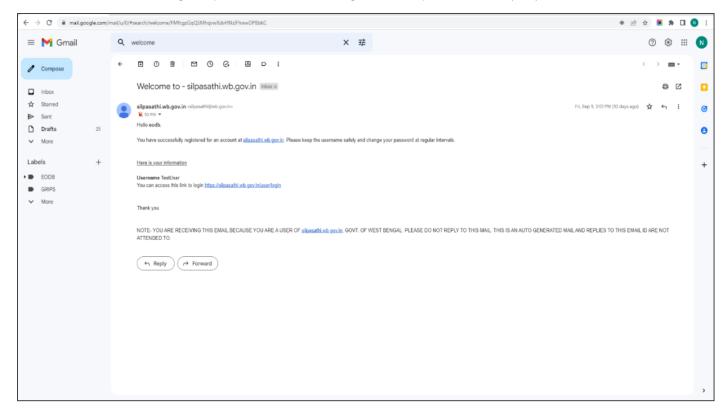
The <u>'User Registration'</u> window will appear with the relevant fields that the applicant needs to fill accurately and click on <u>'Register'</u> as shown by the below screenshot. In case the applicant already has an account, click on the <u>'Sign In'</u> button and login using valid **User ID**, **password and Captcha**.



Applicants will receive email confirmation after registering into the single window portal. Please refer to the screenshot below:

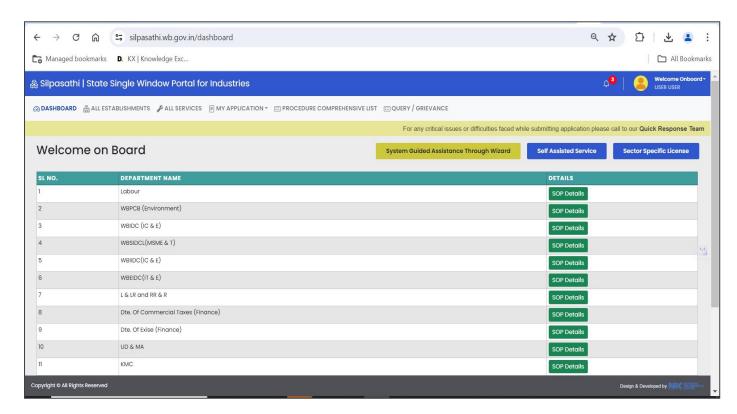
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Online Application submission

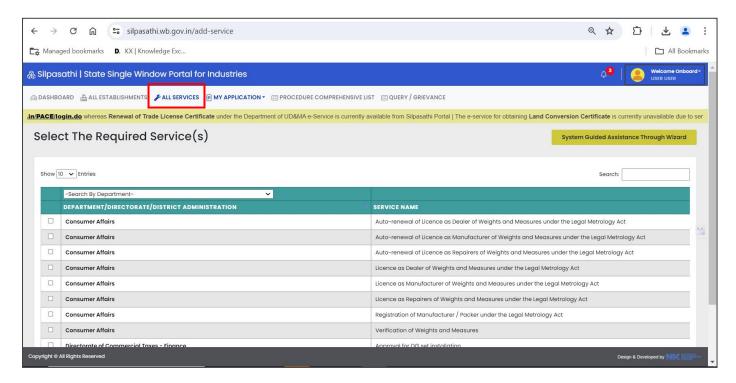
Applicants will now be directed to the user dashboard for completing the further procedures. The following screenshots below illustrate the same.



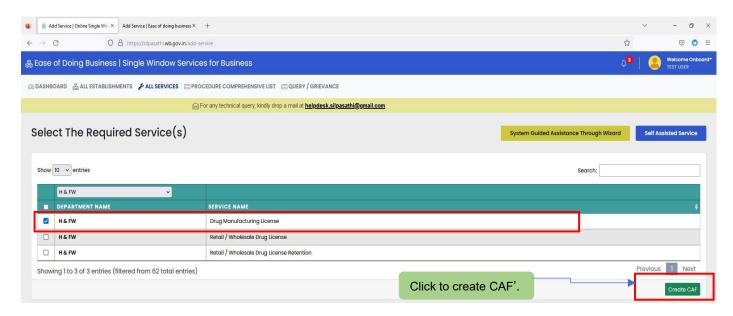
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The applicant has to click on 'ALL SERVICES' to view the list of all services mapped with their corresponding departments.



Once done, a list of services will appear. Applicants need to click on <u>the checkbox</u> adjacent to the service named <u>Drug</u> <u>Manufacturing License – H&FW.</u>

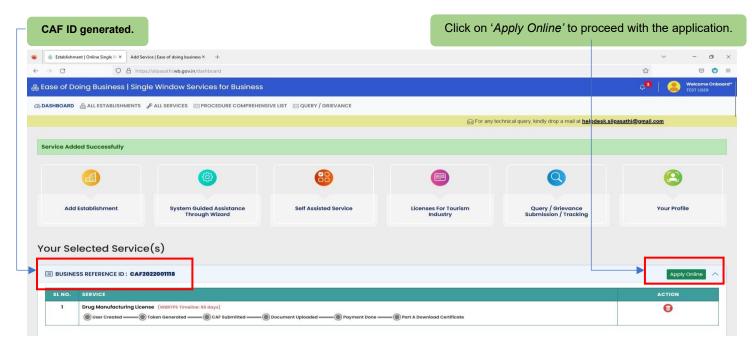


After selecting the service **Drug Manufacturing License – H&FW**, the applicant has to click on <u>'Create CAF'</u>. Applicant's CAF ID will be created. The unique CAF ID is referred to as the common application form.

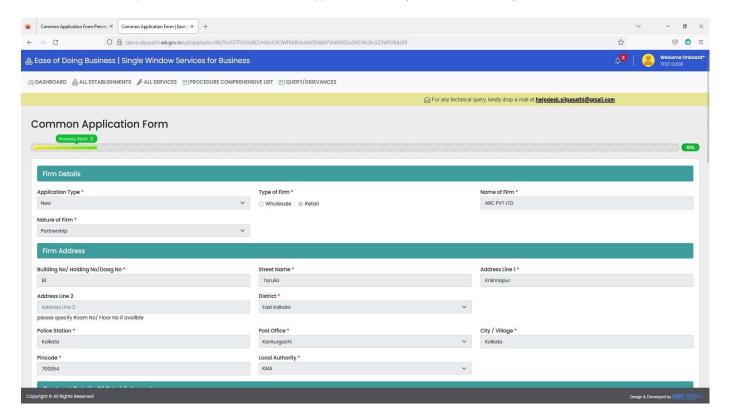
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Applicant's Dashboard

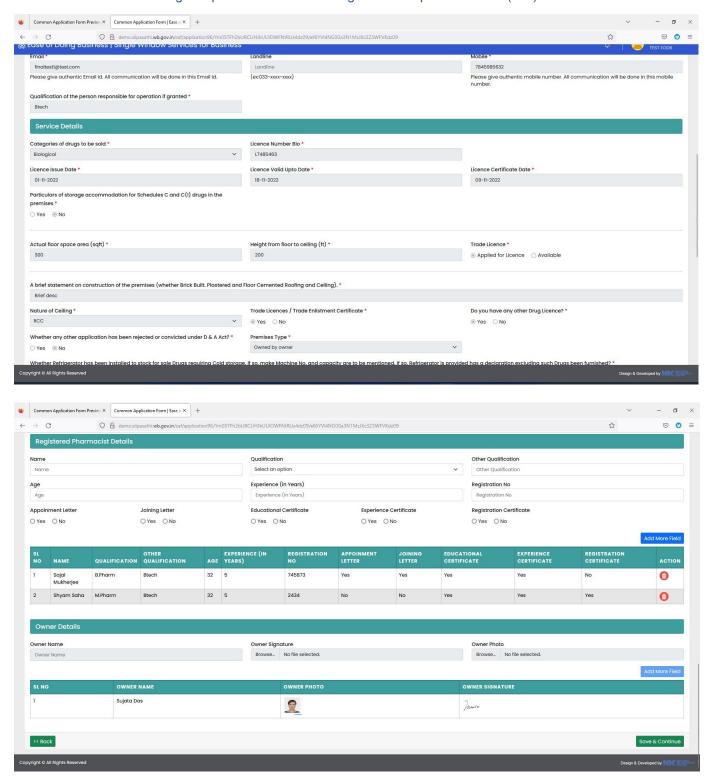


After clicking on '<u>Apply Online'</u> option, the applicant shall be redirected to the main application form. The applicant will have to fill in the required details and review the application form (screenshot below):



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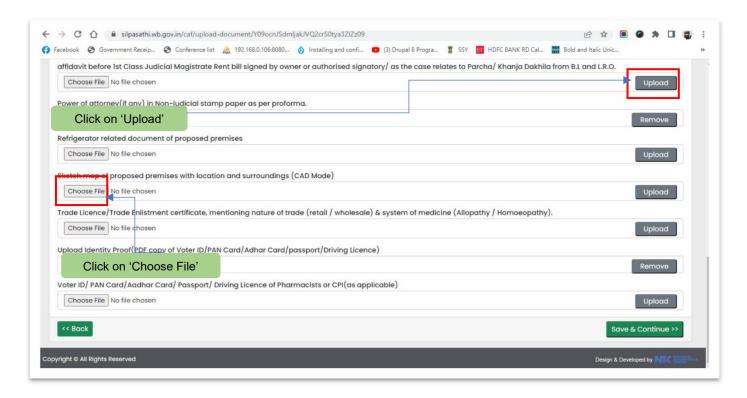


Upon completion of the application process along with document submission, the applicant clicks on the <u>'Submit'</u> button for final submission of the application.

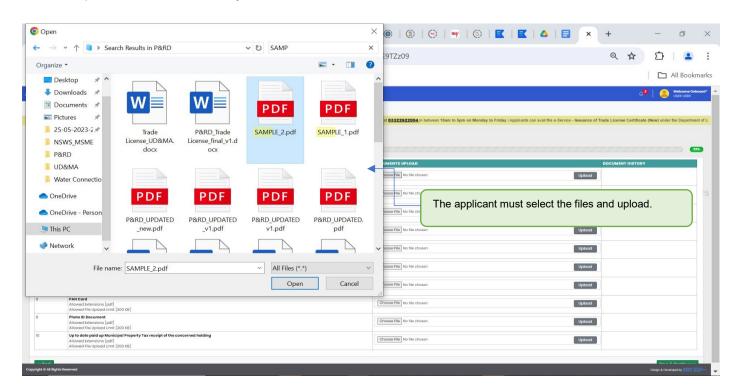
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The document submission process has been described below. Please refer to the screenshots below for detailed illustrations.



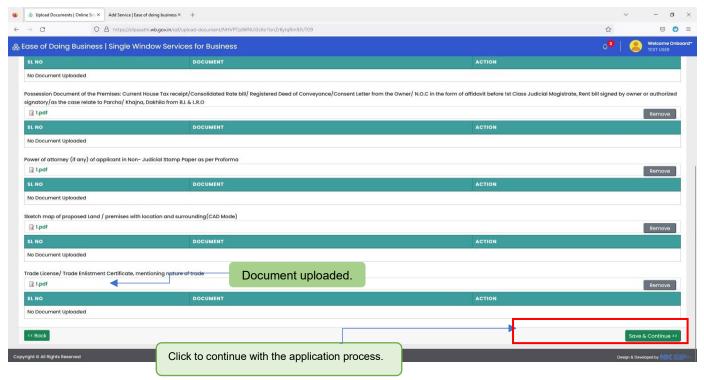
The applicant has to browse the required files in his system and upload them as described in the screenshots. A dialogue box appears after clicking on 'Choose File'. Once the required file is selected, the applicant has to click on 'Upload' button to upload the files successfully.



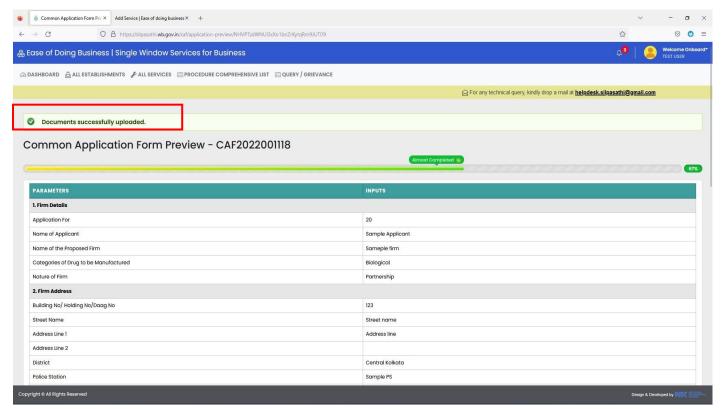
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The applicant is required to upload <u>required documents</u> in <u>pdf format</u> as illustrated in the screenshots. After filling the application form and uploading the required documents the applicant has to click on '<u>Save and Continue</u>' to proceed with the application.

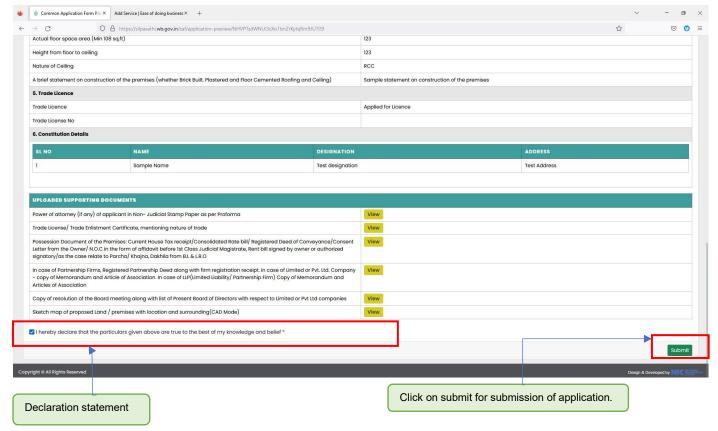


The applicant shall review the filled in application form and proceed for final submission of application. Once reviewed, the applicant shall also be required to click on the Declaration checkbox on the bottom left of the application page before proceeding to 'Submit' button, as illustrated in the screenshots below.

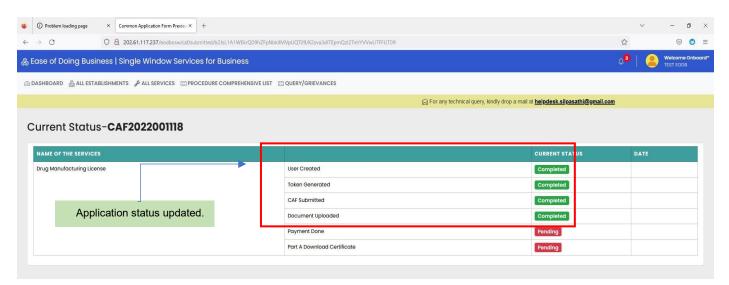


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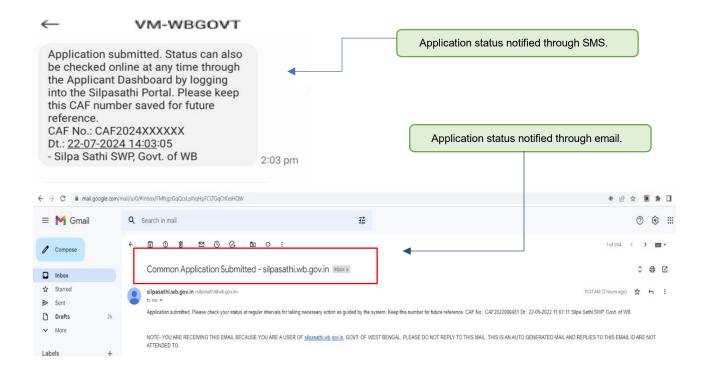
On clicking on 'Submit' link, the following webpage appears post submission of application with updated Status.



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The applicant /user shall be notified via SMS and email on his registered phone number and email id respectively. The applicant receives notifications at different stages of the application - application submission, application approval, etc.



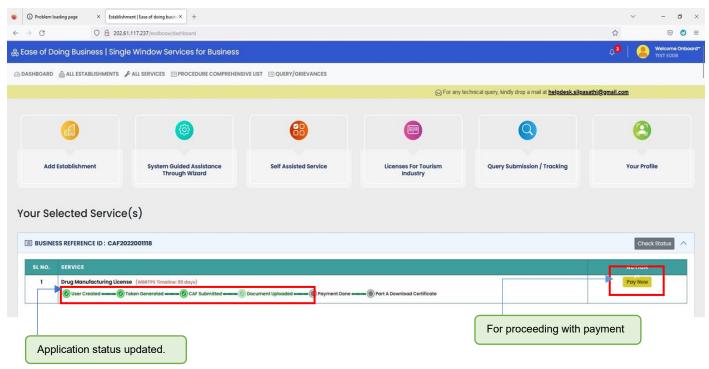
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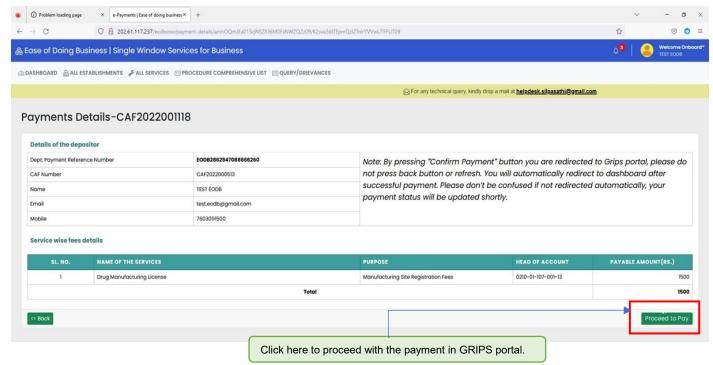
2. Online Payment of fees

The applicant is now required to pay the required fees based on the application filled by the applicant. The applicant has to click on 'Pay Now' option and proceed with the payment procedure. The screenshot below provides an illustration:

Applicant's Dashboard



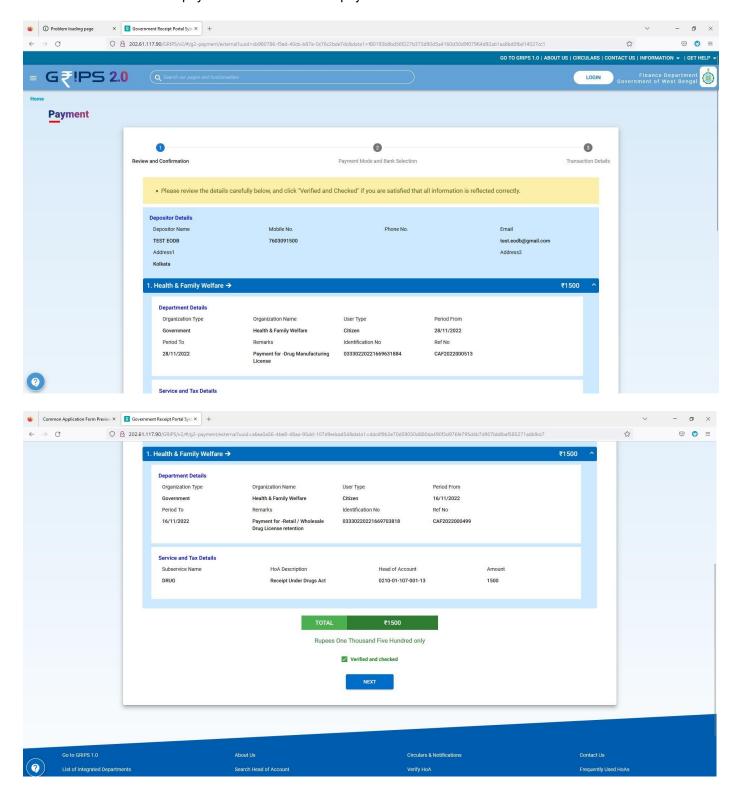
The payment procedure has been illustrated as per the following screenshots. The applicant can proceed with the payment after clicking on the 'Proceed to Pay' option.



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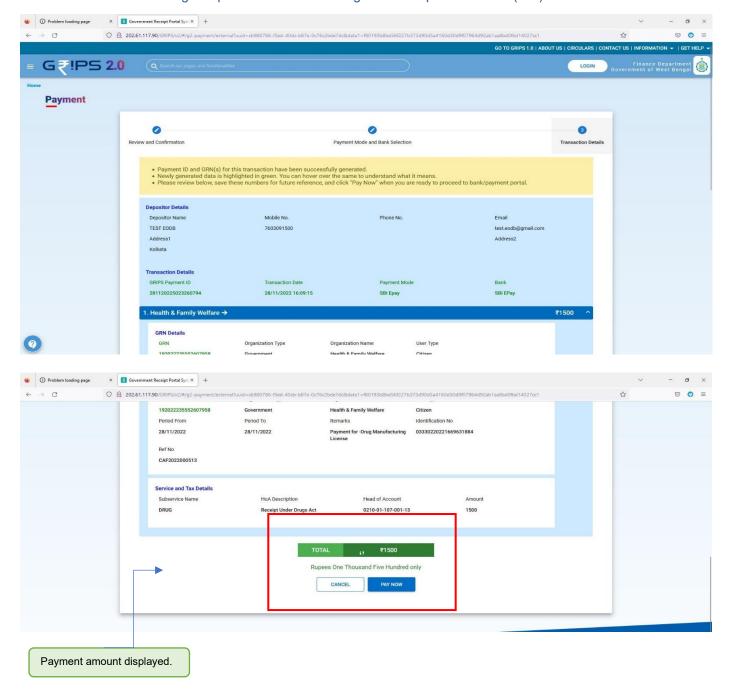
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The applicant is redirected to the **GRIPS portal** to complete the payment process. The applicant shall be able to choose between various modes of payment methods for fees payment.



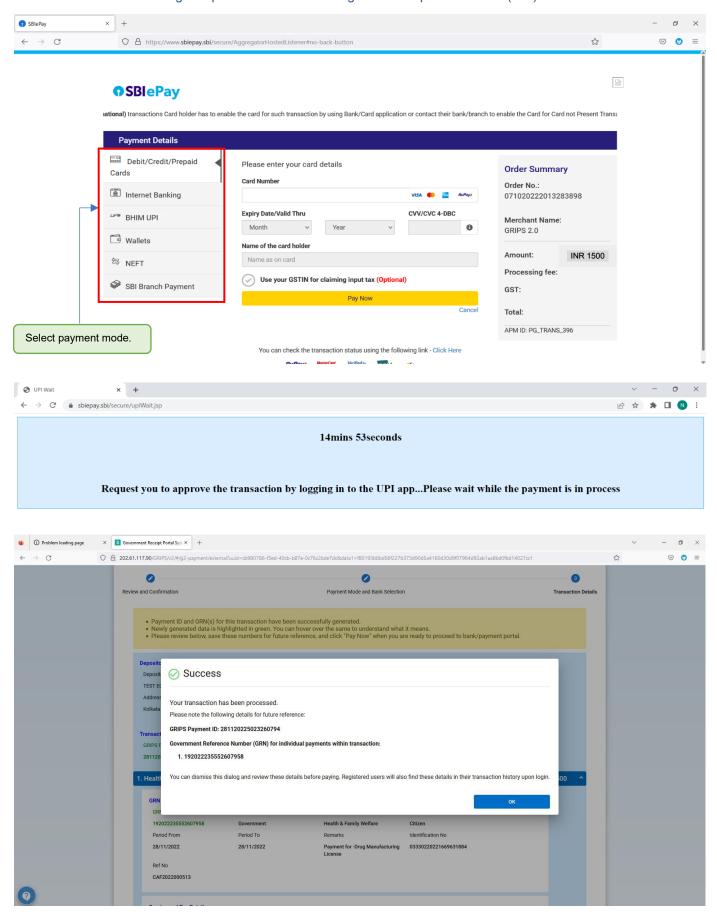
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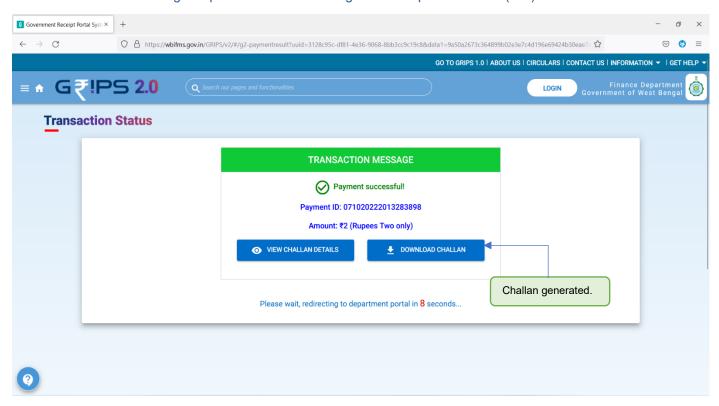
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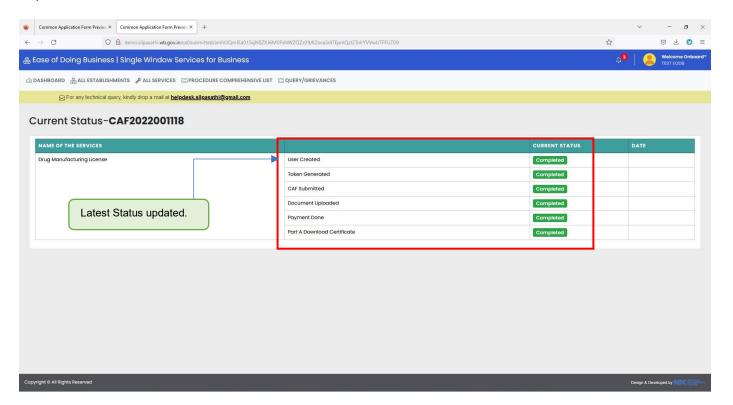


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After subsequent approval by the authority, the applicant will receive in the online system the License approved by the Department.



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3. Track Status of Application

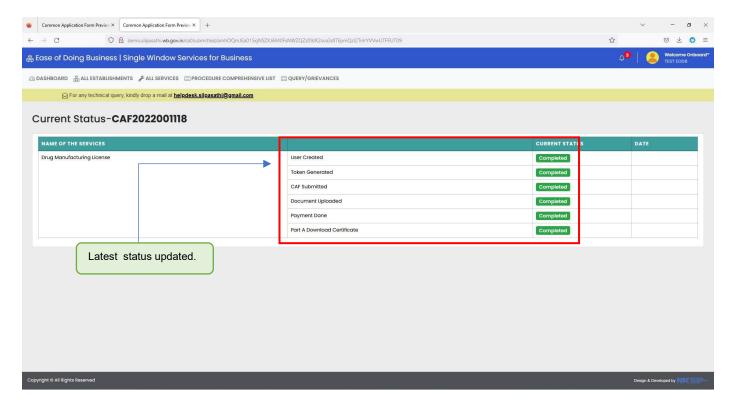
The applicant has to click on 'Check Status' to view the latest status of the application.

Applicant's Dashboard



Note: Latest status can be seen any time through Applicant's Dashboard

Current status appears in the Status Dashboard (Screenshot below).



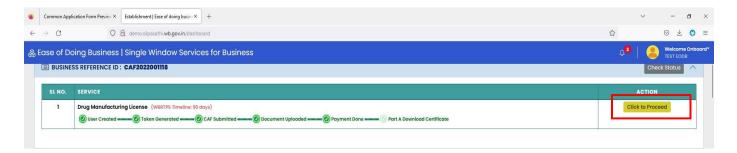
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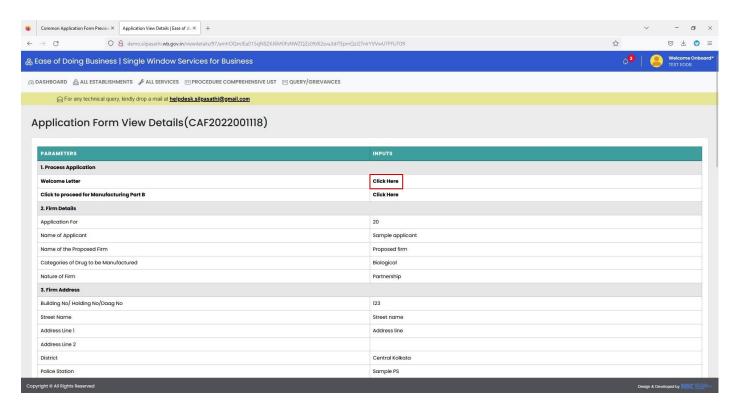
4. Online Download of final approval certificate

The applicant has to click on 'Click to Proceed' to view further.

Applicant's Dashboard



The applicant shall now be able to download the final certificate after final approval of application. The applicant has to click on 'PDF' icon to download the Final Approval Certificate issued.



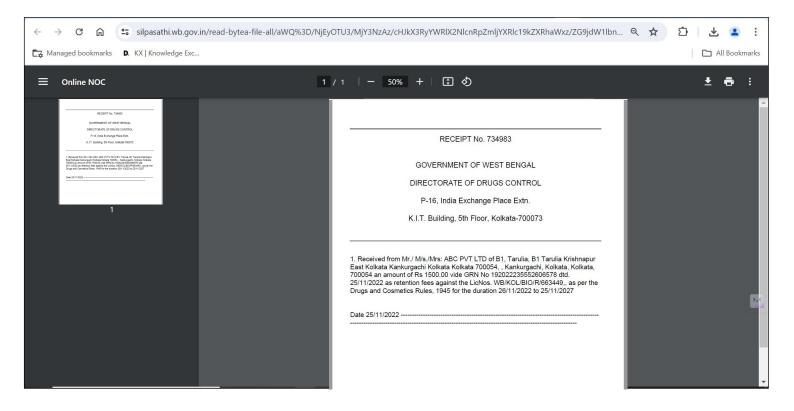
Note: Latest status can be seen any time through Applicant's Dashboard

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The certificate as downloaded has been illustrated in the screenshot below:

The Final Certificate gets downloaded (Screenshot)



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One Approval certificate document has been illustrated below:

RECEIPT No. 734983

GOVERNMENT OF WEST BENGAL DIRECTORATE OF DRUGS CONTROL

P-16, India Exchange Place Extn.

K.I.T. Building, 5th Floor, Kolkata-700073

1. Received from Mr./ M/s./Mrs: ABC PVT LTD of B1, Tarulia, B1 Tarulia Krishnapur East Kolkata Kankurgachi Kolkata Kolkata 700054, , Kankurgachi, Kolkata, Kolkata, 700054 an amount of Rs 1500.00 vide GRN No 192022235552606578 dtd. 25/11/2022 as retention fees against the LicNos. WB/KOL/BIO/R/663449,, as per the Drugs and Cosmetics Rules, 1945 for the duration 26/11/2022 to 25/11/2027

Date 25/11/2022 -----

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5. Third Party verification details

Third party verification is a process by which any independent user / third party verifies an individual's license and registration details online check authenticity of the Certificate, without

Third party verification process

The applicant or any user has to log in to https://silpasathi.wb.gov.in/.

A user (any third party) needs to click on '*Third party Verification*' section in the homepage and enter registration number / license number and then click on 'Search' link, for Verification of Certificate.

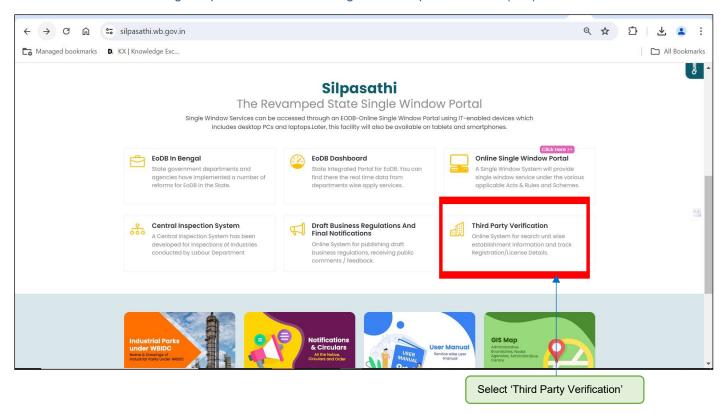
(Screenshots below):

SilpaSathi Homepage

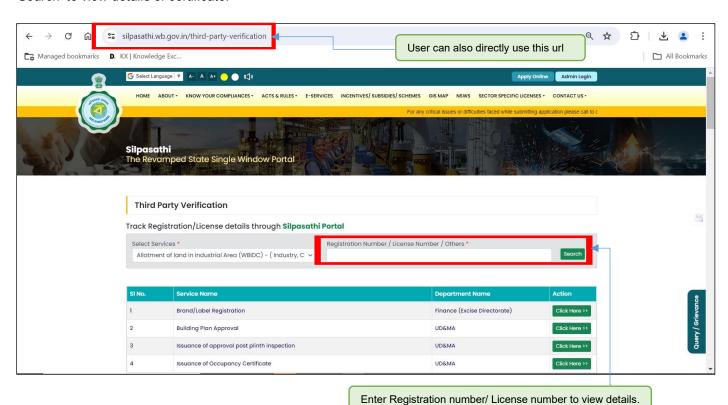


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Applicant selects the service and then enter the Certificate/ Approval number in the text box beside it and clicks on 'Search' to view details of certificate.



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The third party can view the details as illustrated below:

