

User Manual

for

SUGAM- An e-Governance solution

Periodic Safety Update Report (PSUR) Module

for Historical

by

Central Drugs Standard Control Organization (CDSCO)



**Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India**

Centre for Development of Advanced Computing
(A Scientific Society of the Ministry of Electronics and Information Technology, Govt. of India)

Anusandhan Bhawan, C-56/1, Institutional Area Block-B, Sector-62, Noida-201309

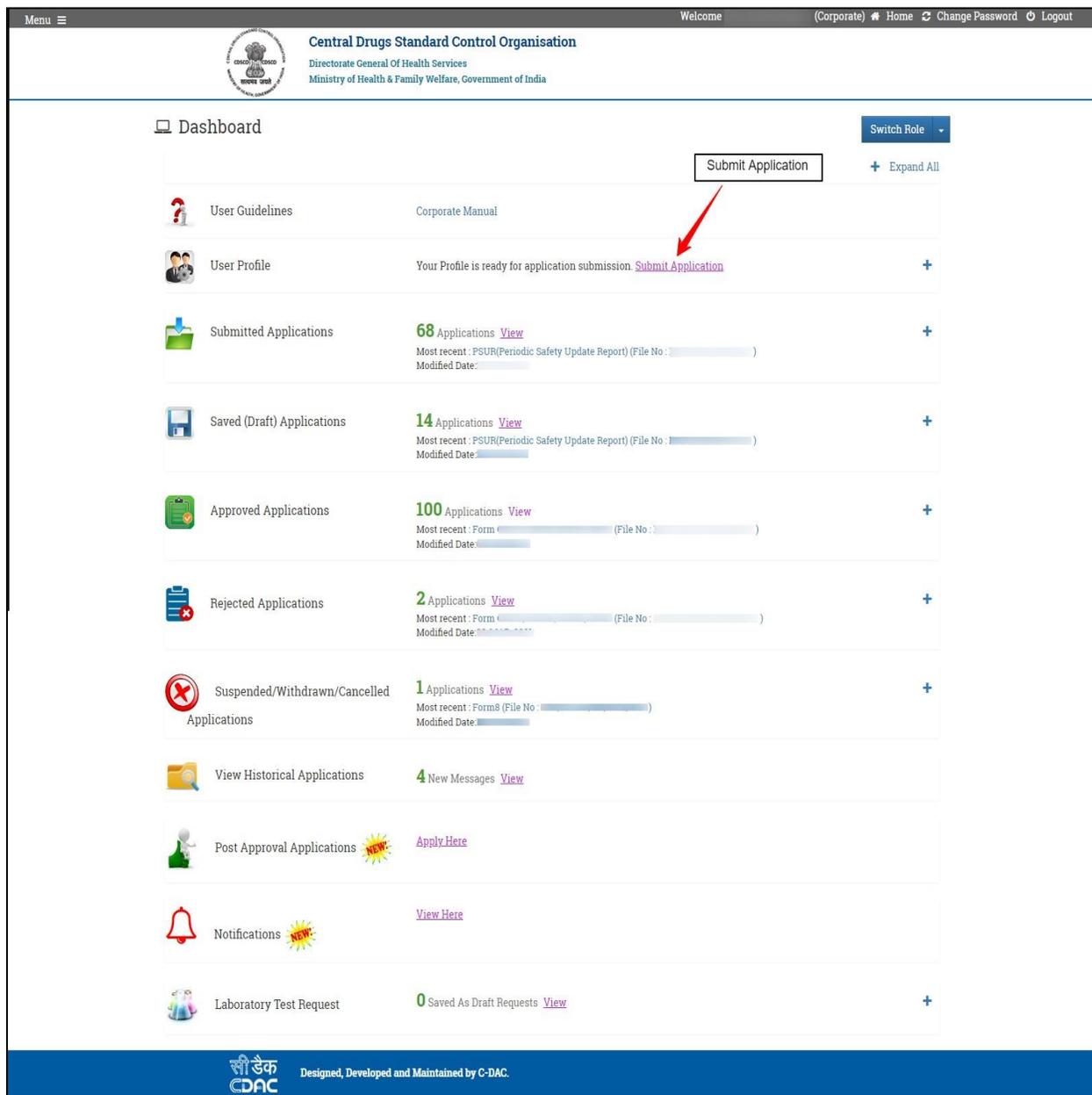
Phone: 91-120-2210800 Website: <http://www.cdac.in>

Periodic Safety Update Report (PSUR) Historical Module for Sugam Portal

A new module i.e. Periodic Safety Update Report has been incorporated in the SUGAM portal.

In order to submit a PSUR report, the applicant needs to follow the below-mentioned steps:

1. Login with applicant credentials and click on “Submit Application”. The following dashboard will appear as shown below in the figure.



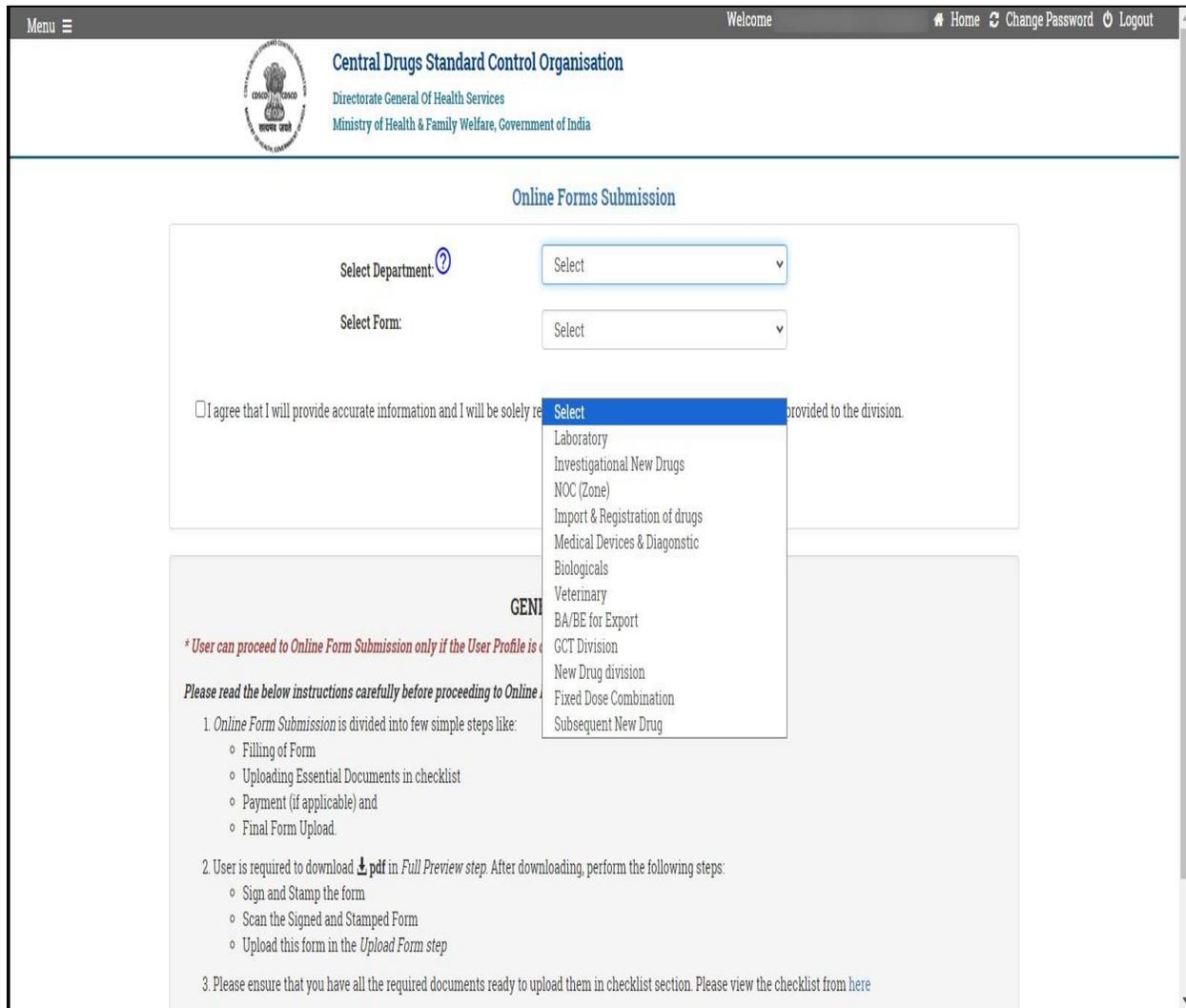
The screenshot shows the Applicant Dashboard for the SUGAM portal. The dashboard is titled "Dashboard" and is part of the "Central Drugs Standard Control Organisation" system. The header includes the organization's name, "Directorate General Of Health Services", and "Ministry of Health & Family Welfare, Government of India". The dashboard contains several cards representing different application statuses:

- User Guidelines**: Corporate Manual
- User Profile**: Your Profile is ready for application submission. [Submit Application](#) (highlighted with a red arrow)
- Submitted Applications**: 68 Applications [View](#). Most recent: PSUR(Periodic Safety Update Report) (File No.:) Modified Date:
- Saved (Draft) Applications**: 14 Applications [View](#). Most recent: PSUR(Periodic Safety Update Report) (File No.:) Modified Date:
- Approved Applications**: 100 Applications [View](#). Most recent: Form (File No.:) Modified Date:
- Rejected Applications**: 2 Applications [View](#). Most recent: Form (File No.:) Modified Date:
- Suspended/Withdrawn/Cancelled Applications**: 1 Applications [View](#). Most recent: Form (File No.:) Modified Date:
- View Historical Applications**: 4 New Messages [View](#)
- Post Approval Applications** **NEW!** [Apply Here](#)
- Notifications** **NEW!** [View Here](#)
- Laboratory Test Request**: 0 Saved As Draft Requests [View](#)

The footer of the dashboard includes the "सी डैक CDAC" logo and the text "Designed, Developed and Maintained by C-DAC".

Figure 1: Applicant Dashboard

2. Once the user clicks on “Submit Application” link, the following screen will appear as shown below. The applicant needs to select the respective department of approved file/license for which he/she wants to submit PSUR application for.



Menu Welcome [Home](#) [Change Password](#) [Logout](#)

 **Central Drugs Standard Control Organisation**
Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Online Forms Submission

Select Department:

Select Form:

I agree that I will provide accurate information and I will be solely responsible for the information provided to the division.

GENERAL INSTRUCTIONS

** User can proceed to Online Form Submission only if the User Profile is complete*

Please read the below instructions carefully before proceeding to Online Form Submission

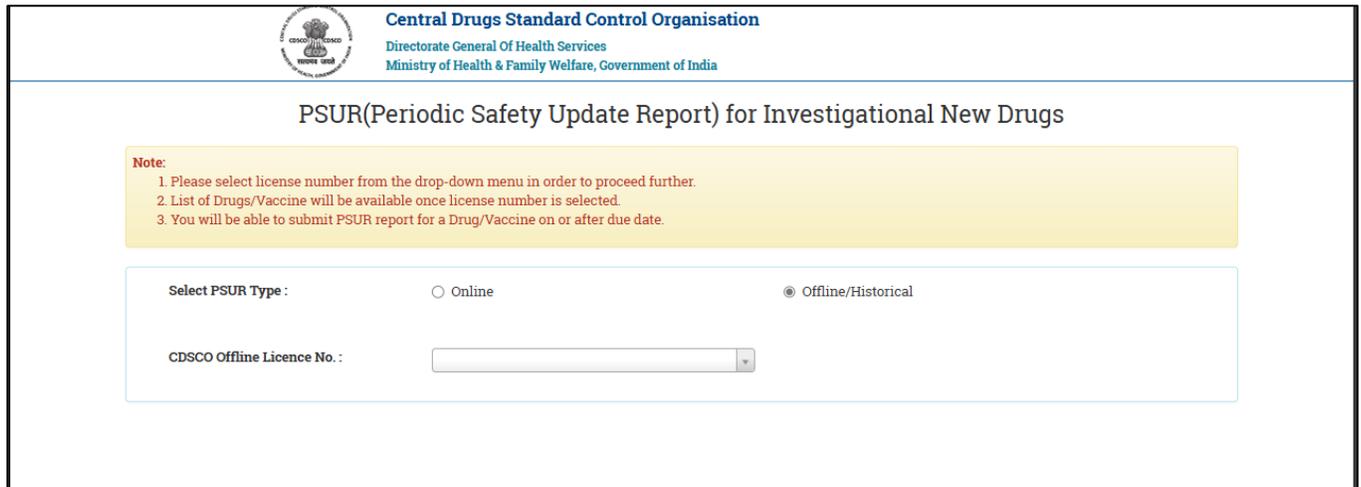
- Online Form Submission is divided into few simple steps like:
 - Filling of Form
 - Uploading Essential Documents in checklist
 - Payment (if applicable) and
 - Final Form Upload.
- User is required to download [pdf](#) in *Full Preview step*. After downloading, perform the following steps:
 - Sign and Stamp the form
 - Scan the Signed and Stamped Form
 - Upload this form in the *Upload Form step*
- Please ensure that you have all the required documents ready to upload them in checklist section. Please view the checklist from [here](#)

Figure 2: Online Forms Submission

There are various departments from which the user can choose, however, the PSUR Module is only available for the following departments:

- Biologicals
- Fixed Dose Combination
- Subsequent New Drug
- New Drug Division
- Veterinary
- Investigational New Drugs

- Import and Registration of drugs
- 3. Once the user clicks on the desired department, he needs to select “PSUR” under the **Select Form** section. Now, the Applicant can proceed by clicking on the Proceed button present on the same page.
- 4. On PSUR application, user can select offline/Historical then click on menu to add license number and drug details.



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PSUR(Periodic Safety Update Report) for Investigational New Drugs

Note:

1. Please select license number from the drop-down menu in order to proceed further.
2. List of Drugs/Vaccine will be available once license number is selected.
3. You will be able to submit PSUR report for a Drug/Vaccine on or after due date.

Select PSUR Type : Online Offline/Historical

CDSCO Offline Licence No. :

Figure 3: PSUR for Offline/Historical



User Profile -

- ➔ View Profile
- ➔ Add Member Details
- ➔ Contact Person Details
- ➔ Add Wholesale / Manufacturing License Details
- ➔ Add R&D Site Details
- ➔ Add Address Details
- ➔ Add PSUR Historical License
- ➔ Add PSUR Historical Drugs/Vaccines

Permissions Owned -

Application Submission -

Online Payment -

Raise Ticket For HelpDesk -

Welcome Mr. Applicant (Indian Agent) | Home | Change Password | Logout

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Select PSUR Type : Online Offline/Historical

CDSCO Offline Licence No. :

Figure 2: Add license details

PSUR Historical Module for SUGAM 3.0

5. Add PSUR Historical License from Menu to fill details.

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Note:
1. Please enter the License Details for PSUR
2. You will be able to add drug details once the license details are saved. Click here to add Drug Details. [Add Drug Details](#)

Add License Data for PSUR

PSUR License Details

License Number* (Please upload all endorsement permissions as well)
TEST ✓ **Choose File** TEST.pdf ✓

License Issue Date* 01/01/2024 **Select Issuing Authority*** Central Licensing Authority ✓

Figure 2.1: After fill details click on Add

User Profile -
→ View Profile
→ Add Member Details
→ Contact Person Details
→ Add Wholesale / Manufacturing License Details
→ Add R&D Site Details
→ Add Address Details
→ Add PSUR Historical License
→ Add PSUR Historical Drugs/Vaccines
Permissions Owned -
Application Submission -
Online Payment -
Raise Ticket For HelpDesk -

Menu ☰ Welcome Mr. Applicant (Indian Agent) Home Change Password Logout

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PSUR(Periodic Safety Update Report) for Investigational New Drugs

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3. You will be able to submit PSUR report for a Drug/Vaccine on or after due date.

Select PSUR Type : Online Offline/Historical

CDSCO Offline Licence No. :

Figure 3: Add drug details

PSUR Historical Module for SUGAM 3.0



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Note:

1. Please select license number from the dropdown menu in order to proceed further.
2. Details of Drugs with type "Finished Formulation" can only be added.
3. The license numbers are fetched from the PSUR Historical License detail page in the User Profile Section, if you have not added the license number kindly add. [Add License](#)

Add Drug Data for PSUR

Drug Details Form

Select License Number	<input type="text" value="* Select File"/>
Type of Drug	<input type="text" value="* Finished Formulation"/>
Name of Drug/Formulation	<input type="text" value="Name of Drug"/>
Brand Name	<input type="text" value="Brand Name"/>
Class of Drug	<input type="text" value="Select"/>
Drug Strength	<input type="text" value="Strength"/> <input type="text" value="* Select"/>
Quantity	<input type="text" value="0"/> <input type="text" value="Select"/>
Pack Size	<input type="text" value="Pack Size"/>

Figure 3.1: Fill details and save



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Dashboard

Switch Role -

+ Expand All

	User Guidelines	Indian Agent Manual	
	User Profile	Your Profile is ready for application submission. Submit Application	+
	Submitted Applications	3 Applications View Most recent : Form12 (File No : BABE/Form12/TL/2018/49811) Modified Date:12-APR-2018	+
	Saved (Draft) Applications	322 Applications View Most recent : Form CT-04 / CT-05 / CT-18 / CT-21 (File No : BIO/CT04/FF/2024/45329) Modified Date:10-SEP-2024	+
	Approved Applications	1 Applications View Most recent : Form12 (File No : VET/Form12/TL/2023/132835) Modified Date:04-AUG-2023	+
	Rejected Applications	1 Applications View Most recent : Form8 (File No : IMP/Form8/FF/2019/22673) Modified Date:13-FEB-2024	+
	Suspended/Withdrawn/Cancelled Applications	2 Applications View Most recent : Form8 (File No : IMP/Form8/FF/2019/22673) Modified Date:13-FEB-2024	+
	View Historical Applications	66 New Messages View	

Activate Windows
Go to Settings to activate Windows

Figure 4: Submit application

PSUR Historical Module for SUGAM 3.0



Central Drugs Standard Control Organisation

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Ministry of Health & Family Welfare, Government of India

Online Forms Submission

Select Department:

Investigational New Drugs

Select Form:

PSUR(Periodic Safety Update Report)

I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division.

Proceed

Figure 5: Select Department and Form



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2. List of Drugs/Vaccine will be available once license number is selected.
3. You will be able to submit PSUR report for a Drug/Vaccine on or after due date.

Select PSUR Type :

Online

Offline/Historical

CDSCO Offline Licence No. :

Select Option
HK-26/1996
AS-30/1996
Test Lic
TEST

Figure 6: Click on Offline/Historical and select license no

PSUR Historical Module for SUGAM 3.0



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Select PSUR Type : Online Offline/Historical

CDSCO Offline Licence No. :

[→ Save & Continue](#)

Show entries Search:

	Drug Name	Drug Type	Drug Class	Quantity	Brand Name	Dosage Name	Issue Date
<input type="radio"/>	ewfef	Finished Formulation	Multivitamin	12 mm	ferfer	NA	Jun-04-2024

Showing 1 to 1 of 1 entries Previous Next

Figure 7: Drugs Checklist

The table shown in the image above displays list of all submitted PSUR for a Drug/Vaccine till date.

In case "Apply PSUR" button is disabled it means that new PSUR report is not due yet. Refer to the below figure for better understanding.

NOTE: You will be able to submit PSUR report for a Drug/Vaccine on or after due date.

Drug Name

Note:
 1. Below table displays list of all submitted PSUR for a Drug/Vaccine till date.
 2. In case "Apply PSUR" button is disabled it means that new PSUR report is not due yet.
 3. In order to view all PSUR due dates. Kindly click on **i**.

License Approval Date : Jul-20-2023 First PSUR Due Date : Jan-20-2024 ⓘ

S.NO.	PSUR File No.	Base Psur File No.	Applied Date	File Status
1			Feb-13-2024	Submitted to CDSCO

📄 File PSUR Report ✕ Close

Figure 8: File PSUR button disabled

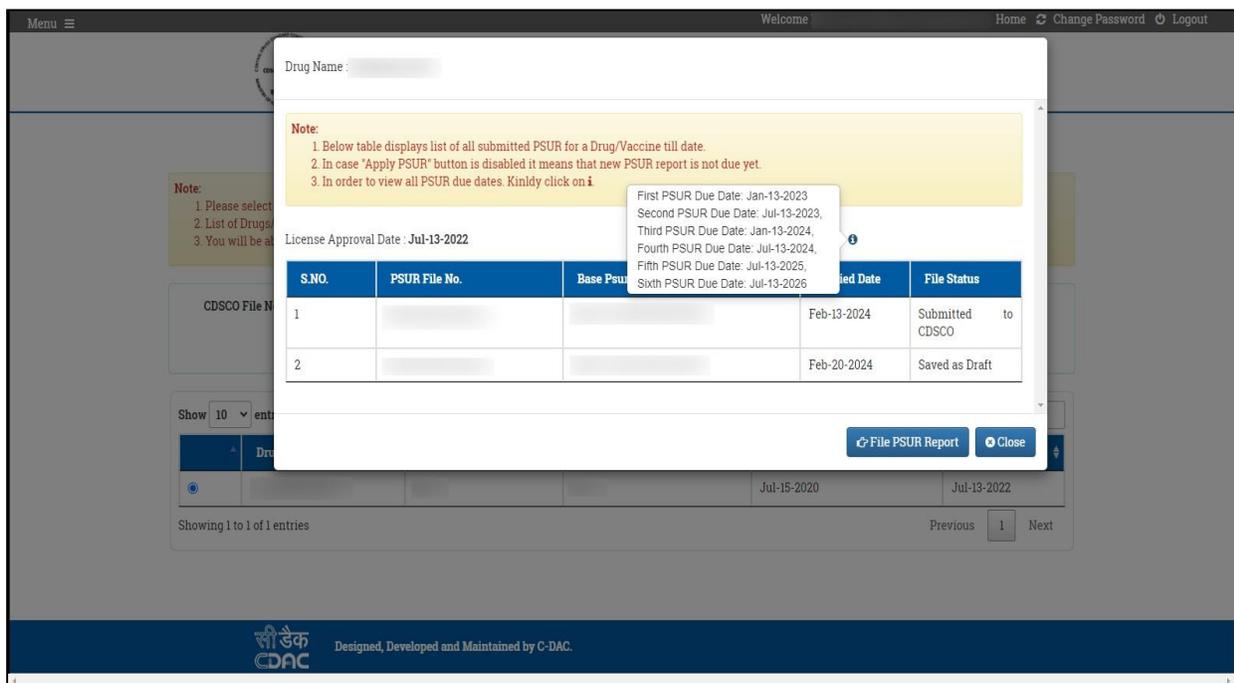
In order to view all PSUR due dates, applicant can click on the "i" icon present on the

PSUR Historical Module for SUGAM 3.0

screen.

The “i” button will show all the dates which are due in the first, second, third, fourth, fifth and sixth PSUR.

For better understanding, please refer to the below image.



The screenshot displays the PSUR Historical Module interface. A confirmation window is open, titled "File PSUR Report". The window contains a "Note" section with three points: 1. Below table displays list of all submitted PSUR for a Drug/Vaccine till date. 2. In case 'Apply PSUR' button is disabled it means that new PSUR report is not due yet. 3. In order to view all PSUR due dates. Kindly click on **i**. Below the note is a table with columns: S.NO., PSUR File No., Base Psur, and File Status. The table has two rows: Row 1: S.NO. 1, PSUR File No. [redacted], Base Psur [redacted], File Status Submitted to CDSCO. Row 2: S.NO. 2, PSUR File No. [redacted], Base Psur [redacted], File Status Saved as Draft. Below the table are buttons for "File PSUR Report" and "Close". A tooltip is visible over the "i" icon, listing due dates: First PSUR Due Date: Jan-13-2023, Second PSUR Due Date: Jul-13-2023, Third PSUR Due Date: Jan-13-2024, Fourth PSUR Due Date: Jul-13-2024, Fifth PSUR Due Date: Jul-13-2025, Sixth PSUR Due Date: Jul-13-2026. The background shows a list of PSUR entries with a "License Approval Date" of Jul-13-2022. The footer includes the CDAC logo and text: "Designed, Developed and Maintained by C-DAC".

Figure 9: PSUR Due Dates

Once the user clicks on **File PSUR Report**, a confirmation window will open as shown below.

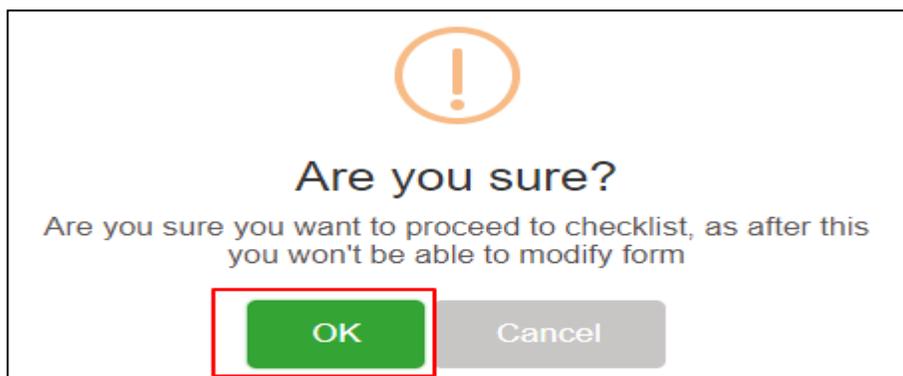


Figure 10: Confirmation window

After clicking on OK, the checklist window will open, wherein the Applicant needs to upload all the essential documents.

NOTE: All checklist items are mandatory. In case of unavailability of document the Applicant needs to give proper justification regarding the unavailability of document and also upload supporting document.

Menu ☰



Central Drugs Standard Control Organisation
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Home Change Password Logout

Upload Essential Documents

Note:

- Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
- All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
- Partially saved checklist can be viewed/alterd under the Saved Application link available on the Dashboard
- Click here to view [Guidelines for PDF documents](#)

- 1. Covering Letter
- 2. Executive Summary
- 3. Marketing status of the proposed product in India
- 4. Licence Information**
- 4.1 CLAA Permission/ Approval letter
- 4.2 Amendments/Post Approval Change approvals (if any)
- 4.3 Product Labels/IFUs
- 4.4 Summary of Product Characteristics (SmPC)
- 5. Dossier**
- 5.1 CTD Module V
- 5.2 Phase III Clinical Trial Report/PMS Report/Phase IV Report
- 5.3 Safety Summary Report
- 6. PSUR Report**
- 6.1 Title Page
- 6.2 Introduction
- 6.3 Current worldwide marketing authorization status
- 6.4 Actions taken in reporting interval for safety reason
- 6.5 Changes to reference safety information
- 6.6 Estimated patient exposure
- 6.6.1 (i) Cumulative and interval subject exposure in clinical trial
- 6.6.2 (ii) Cumulative and interval patient exposure from Marketing Experience from India
- 6.6.3 (iii) Cumulative and interval patient exposure from Marketing Experience from rest of the world
- 6.7 Presentation of individual case histories
- 6.7.1 (i) Reference prescribing information
- 6.7.2 (ii) Individual cases received from India
- 6.7.3 (iii) Individual cases received from rest of the world
- 6.7.4 (iv) Cumulative and interval summary tabulations of serious adverse events from clinical investigations.
- 6.7.5 (v) Cumulative and interval summary tabulations from post-marketing data sources
- 6.8 Studies
- 6.8.1 (i) Summaries of significant safety findings from clinical investigations during the reporting period
- 6.8.2 (ii) Findings from non-interventional Studies
- 6.8.3 (iii) Findings from non-Clinical Studies
- 6.8.4 (iv) Findings from literature
- 6.9 Other information
- 6.9.1 (a) Signal and risk evaluation
- 6.9.2 (b) Risk management plan
- 6.10 Overall Safety Evaluation
- 6.10.1 (i) Summary of safety concerns
- 6.10.2 (ii) Benefit evaluation.
- 6.10.3 (iii) Benefit risk analysis evaluation
- 6.11 Conclusion
- 7. Appendix**
- 7.1 Approved Prescribing Information Leaflet
- 7.2 ICSRs
- 7.3 ICSRs Line listing in xl/E2B R2/R3 format
- 7.3.1 Listed ADRs/AEFIs
- 7.3.2 Non-Listed ADRs/AEFIs
- 7.4 SAE CIOMS
- 8. Warning**
- 8.1 Drug Alert/Recalls if any
- 8.2 Contraindications
- 8.3 Drug Interactions
- 8.4 Box Warning



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Figure 11: Checklist window

6. After uploading all the essential documents, the Applicant needs to submit the application by clicking on the Submit button present at the bottom of the page.

A file number will be created after the submission of the application for future correspondence.

Your Application has been submitted successfully.
Kindly note your file no. [REDACTED] for future correspondence.

Figure 12: Submission confirmation