



## **USER GUIDE FOR ONLINE IMPORT / EXPORT APPLICATIONS SOFTWARE**

**Document No:** MISC/GL/IE/001  
**Document History:** 1st Edition  
**Effective Date:** 23-Dec-2021

**Drug Regulatory Authority of Pakistan**  
Islamabad – Pakistan.

## **HISTORY**

This is the first edition of this user guide.

## **APPLICATION- Guidance for industry**

This user guide is applicable to the manufacturers, importers and exporters that intends to import or exports of therapeutic goods in the country including raw materials and finished drugs, biologicals, medical devices and alternative medicines. This document will aid following: -

- i. Manufactures and Importers of therapeutic goods;
- ii. Researchers, investigators or institutions intends to import investigational drugs products for clinical trials.

## **PURPOSE**

This use guide is aimed at provision of assistance for submission of application, through electronic platform, for imports and exports of products to the Drug Regulatory Authority of Pakistan in compliance with the legal and regulatory requirements for all therapeutic goods including finished pharmaceutical and biological drug products, active pharmaceutical ingredients (APIs) and drug substances (DS), Medical Devices, and Health & OTC Product (e.g. nutraceuticals, herbals, ayurvedic and homeopathic products, biochemic and Chinese products) and their raw materials.

## **INTRODUCTION**

In line with the vision of Prime Minister of Pakistan, and to facilitate the therapeutic goods' industry for ease of business and provision of conducive environment for compliance to regulatory requirement, Drug Regulatory Authority of Pakistan (DRAP) has introduced an electronic application management system which will enable applicants and regulators to communicate electronically for enhance provision of quality assured, safe and efficacious therapeutic goods.

This document is intended to provide step wise guidance to the users for submission of applications using this software and will assist in provision of applicable documentation. In case, applicants need any further technical assistance or have any query(s) with regard to use of this software, they may contact Division of Management Information System, DRAP @ [addl-directormis@dra.gov.pk](mailto:addl-directormis@dra.gov.pk) or call at 051-9107414 / 051 9107412.

## Step-1: Login Screen

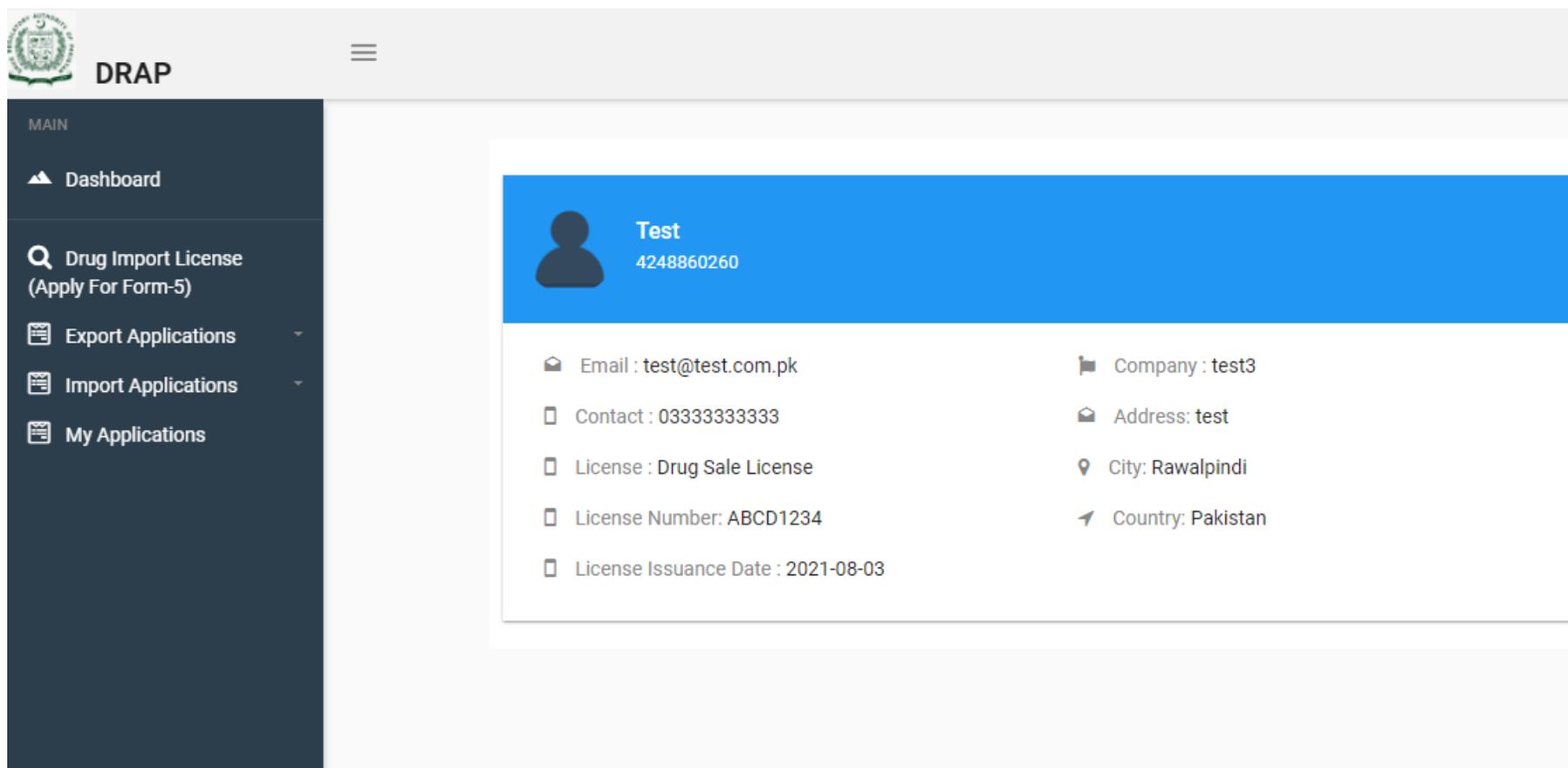
- (i) Access the software application using: ie.dra.gov.pk
- (ii) Please use same user and password provided for online fee challan system.



The screenshot displays the login interface for the Drug Regulatory Authority of Pakistan (DRAP) Online Import / Export Application System. At the top center is the DRAP logo, which features a circular emblem with a crescent moon and star, surrounded by the text 'DRUG REGULATORY AUTHORITY OF PAKISTAN'. Below the logo, the text 'Drug Regulatory Authority Of Pakistan' is centered, followed by 'Online Import / Export Application System'. The login form includes a 'Username' field with the text 'test@test.com.pk' and a 'Password' field with masked characters '\*\*\*\*\*'. At the bottom, there are three buttons: 'Register' (blue), 'Reset Password' (orange), and 'Sign In' (green).

## Step: II

After Login following screen will appear.



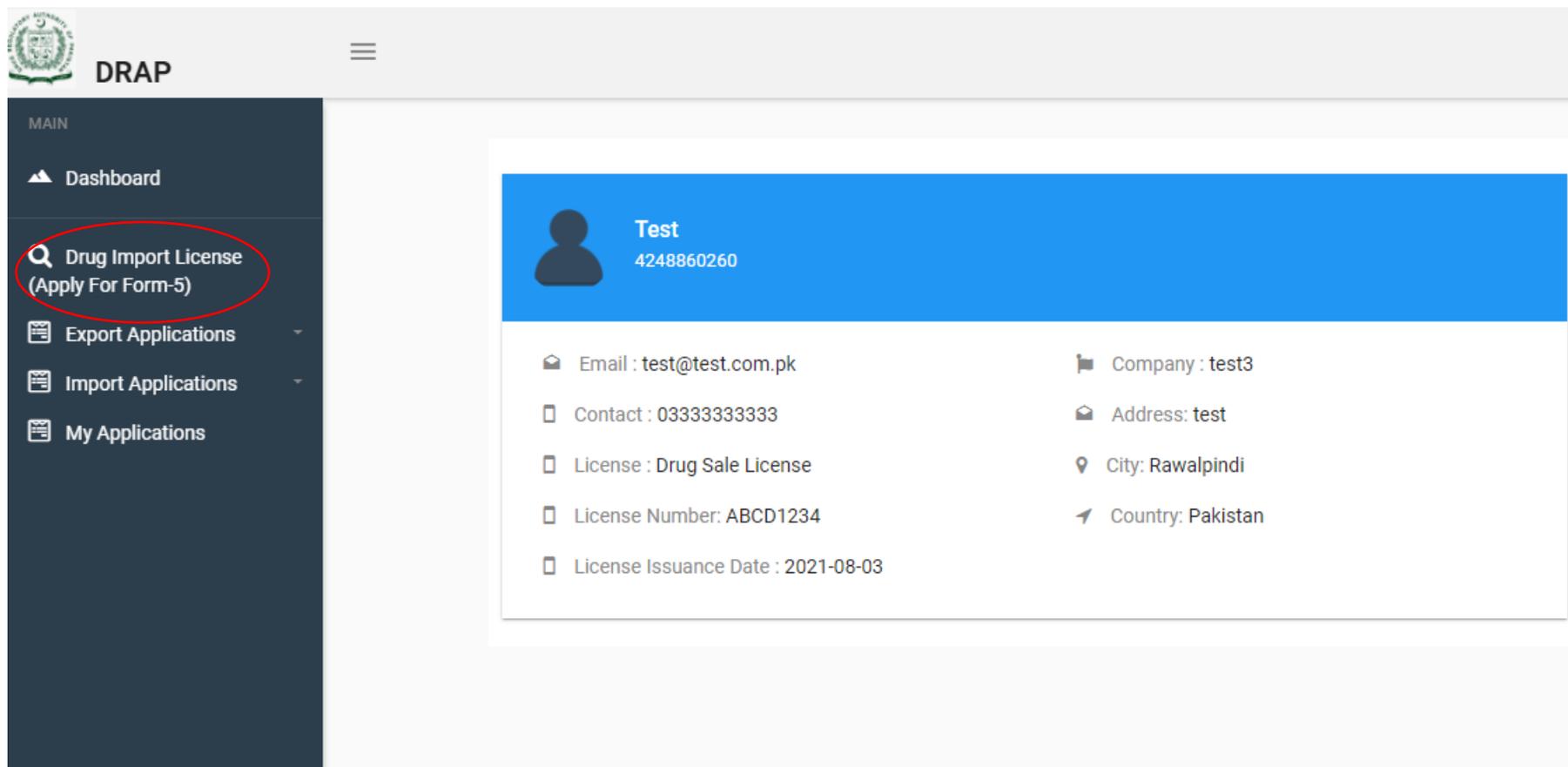
The screenshot displays the DRAP (Drug Regulatory Authority of Pakistan) user interface. At the top left, there is a logo and the text "DRAP". Below this, a dark sidebar menu is visible with the following items: "MAIN", "Dashboard", "Drug Import License (Apply For Form-5)", "Export Applications", "Import Applications", and "My Applications". The main content area shows a user profile for "Test" with the ID "4248860260". Below the profile, there are several fields of user information:

Email : test@test.com.pk	Company : test3
Contact : 03333333333	Address: test
License : Drug Sale License	City: Rawalpindi
License Number: ABCD1234	Country: Pakistan
License Issuance Date : 2021-08-03	

Left Panel showing different types of tabs such as application for Drug Import License, Export Applications, Import Applications, My Applications.

## 1. Application for Drug Import License

Click on Drug Import License (as indicated below)



The screenshot displays the DRAP (Division of Management Information System) web application interface. On the left, a dark sidebar contains a navigation menu with the following items: 'Dashboard', 'Drug Import License (Apply For Form-5)', 'Export Applications', 'Import Applications', and 'My Applications'. The 'Drug Import License (Apply For Form-5)' item is circled in red. The main content area shows a user profile for 'Test' with ID '4248860260'. Below the profile, a list of user details is displayed:

Email : test@test.com.pk	Company : test3
Contact : 03333333333	Address: test
License : Drug Sale License	City: Rawalpindi
License Number: ABCD1234	Country: Pakistan
License Issuance Date : 2021-08-03	

The following form will open and fill the information carefully prior to submit the application.

### L01 – Drug Import License (Apply for Form-5) - Application Form

**Challan Information**

Challan No \*   **Challan Status:** You have not verified the challan yet.

**Application Information**

Application Ref No:  App Date:

**Application Status**

**Company Profile**

Company Name	Company Address	Company City	Company Country
<input type="text" value="test3"/>	<input type="text" value="test"/>	<input type="text" value="Rawalpindi"/>	<input type="text" value="Pakistan"/>
Issued License	License Number	License Issue Date	
<input type="text" value="Drug Sale License"/>	<input type="text" value="ABCD1234"/>	<input type="text" value="2021-08-03"/>	

Automated generated application ref number and date time.

Company information fetched from the online fee challan system user profile.

**Select the license type**

License Details

License Type \*

- Select -

- Select -

Manufacturer

Test Analysis

Clinical Trials

Please select a License Type to proceed

**Upload relevant documents (\* is mandatory uploading and only pdf file not more than 2MB size)**

**Document Submitted**

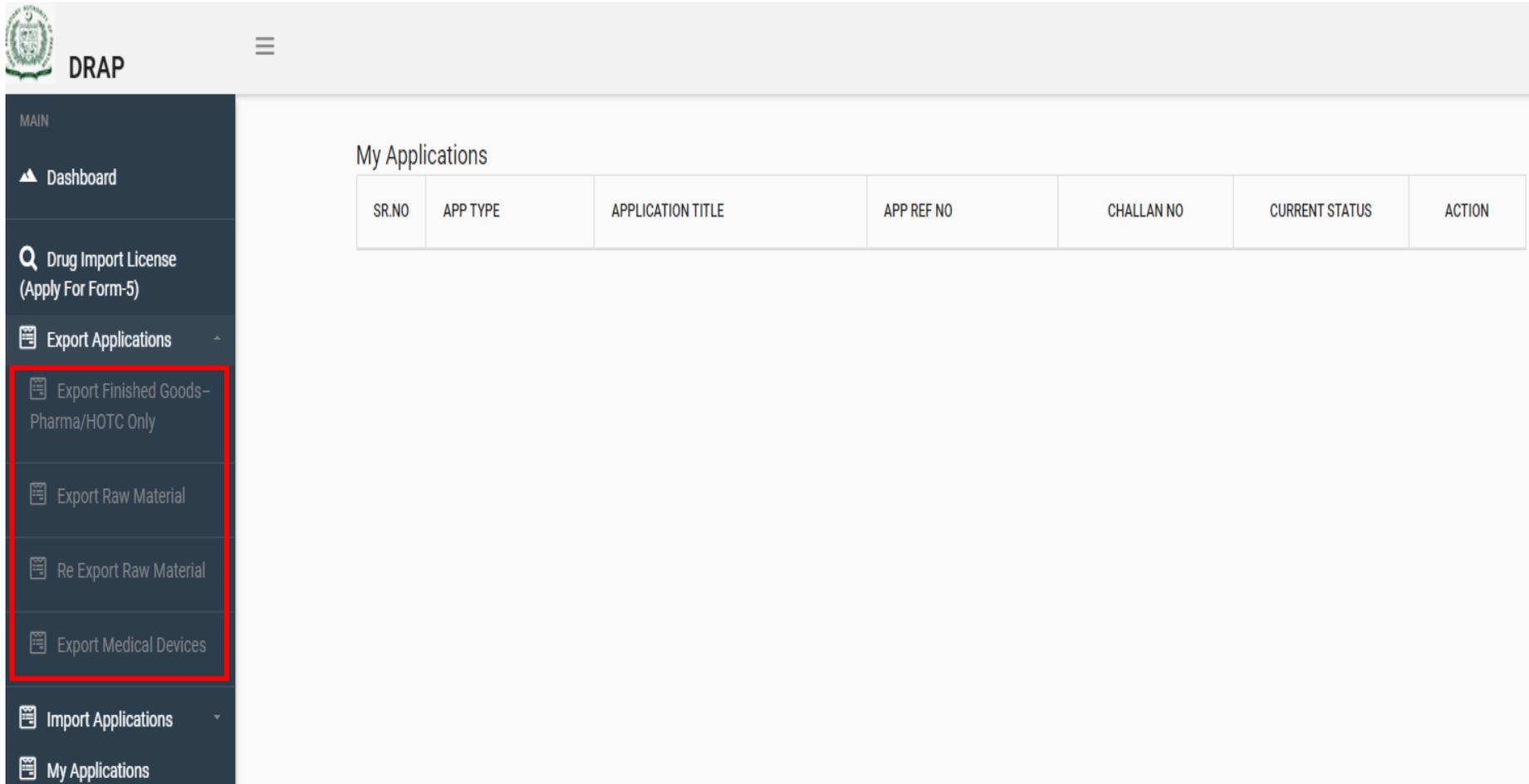
API Requirement Data / Stability Report *	Certificate of Analysis / Specifications *	Clinical Trial Approved *
<input type="button" value="Choose File"/> No file chosen	<input type="button" value="Choose File"/> No file chosen	<input type="button" value="Choose File"/> No file chosen
Copy of Paid DRAP Fee Challan *	Drug Registration Letter / Renewals *	Form 2 *
<input type="button" value="Choose File"/> No file chosen	<input type="button" value="Choose File"/> No file chosen	<input type="button" value="Choose File"/> No file chosen
Form 4 *	GMP Certificate ( Manufacturers ) *	Undertaking on Stamp Paper *
<input type="button" value="Choose File"/> No file chosen	<input type="button" value="Choose File"/> No file chosen	<input type="button" value="Choose File"/> No file chosen
Others		
<input type="button" value="Choose File"/> No file chosen		

I hereby certify that the documents and information provided herein is correct and if found incorrect /misrepresent it shall lead to legal action under the Drug Regulatory Authority of Pakistan act, 2012 and the rules made there under.

1. After uploading documents check the box to certify the information which you have provided is correct after that there are two options Save as Draft (means your application is saved at your own dashboard) and save & submit (means your application has been submitted to DRAP for further proceedings).
2. Once application submitted to DRAP, applicant cannot change any information

## 2. Export Applications

There are 4 options for export purpose as indicated below, applicant can apply to click on the desired tab.

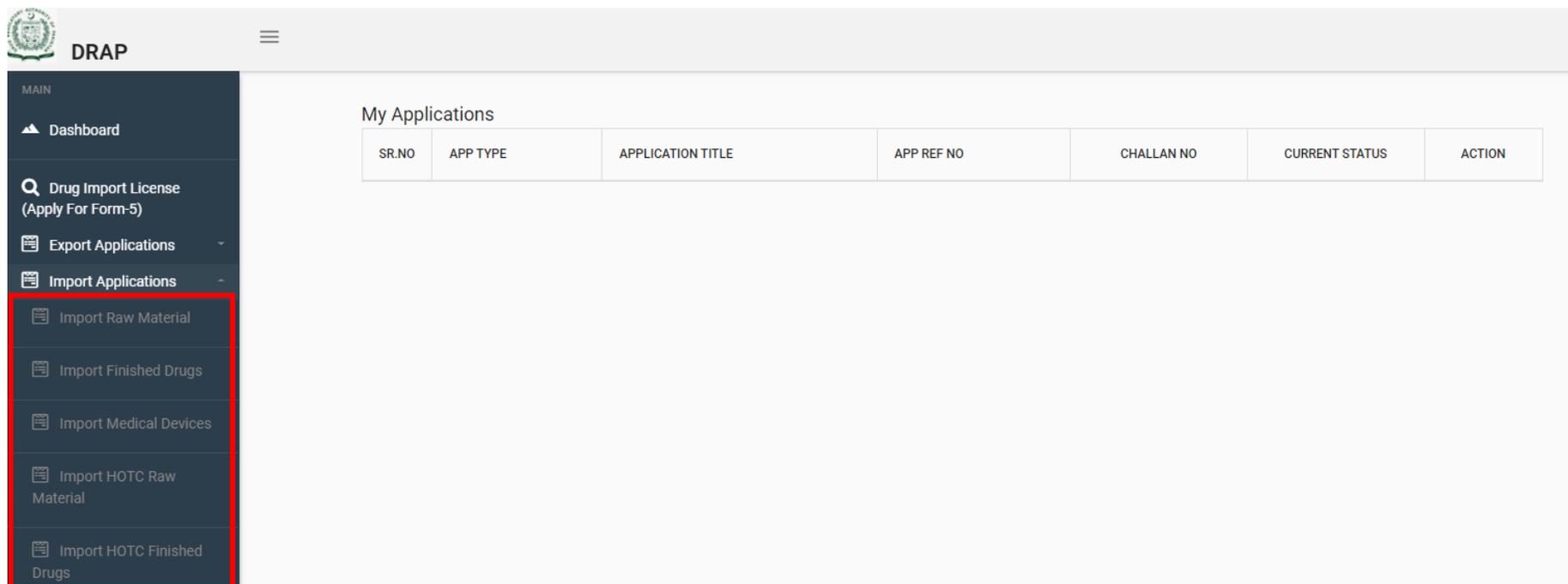


The screenshot displays the DRAP web application interface. On the left is a dark sidebar menu with the following items: MAIN, Dashboard, Drug Import License (Apply For Form-5), Export Applications (highlighted with a red box), Export Finished Goods- Pharma/HOTC Only, Export Raw Material, Re Export Raw Material, Export Medical Devices, Import Applications, and My Applications. The main content area is titled 'My Applications' and contains a table with the following columns: SR.NO, APP TYPE, APPLICATION TITLE, APP REF NO, CHALLAN NO, CURRENT STATUS, and ACTION.

SR.NO	APP TYPE	APPLICATION TITLE	APP REF NO	CHALLAN NO	CURRENT STATUS	ACTION
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### 3. Import Applications

There are 05 types of options available as indicated below, applicant can apply to click on the desired tab.



The screenshot displays the DRAP web application interface. On the left, a dark sidebar menu is visible with the following items: MAIN, Dashboard, Drug Import License (Apply For Form-5), Export Applications, Import Applications, Import Raw Material, Import Finished Drugs, Import Medical Devices, Import HOTC Raw Material, and Import HOTC Finished Drugs. The 'Import Applications' section is highlighted with a red border. The main content area shows a table titled 'My Applications' with the following columns: SR.NO, APP TYPE, APPLICATION TITLE, APP REF NO, CHALLAN NO, CURRENT STATUS, and ACTION.

SR.NO	APP TYPE	APPLICATION TITLE	APP REF NO	CHALLAN NO	CURRENT STATUS	ACTION
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After completion of desired forms save and submit the application then you will get electronic reference number for future record.

## 4. Status of all applications

Applicants can check the status of all applications to click on the option “My Applications” as indicated below in left panel.

SR.NO	APP TYPE	APPLICATION TITLE	APP REF NO	CHALLAN NO	CURRENT STATUS	ACTION
1	Export	Export Finished Drugs / HOTC	A-19752219726	61307208147	Returned	Update
2	Export	Export Medical Devices	D-18352213692	61307208147	Rejected	View
3	Export	Export of Raw Material	C-18552213247	61307208147	Approved	View Print Letter
4	Export	Re-Export of Raw Material	B-18652218516	61307208147	Approved	View Print Letter
5	Export	Export of Raw Material	C-19252218674	381716240558	Approved	View Print Letter

-Rejected application means DRAP office has rejected your application because of some misleading/falsified information.  
-Applicant will require fresh application to reconsider the case.

Returned application status means that DRAP desired some clarifications from applicant. Click on update button to view the comments from DRAP, after provision of desired information resubmit the application.

## 5. Process of returned Applications

After click on update the following section will appear in the bottom of application under “**Application History**” tab.

The screenshot displays the 'Application History' section with a blue header. A vertical timeline with three green circular markers connects three application status cards. The first card, dated 2021-Dec-22 (11:57 Hrs), is labeled 'Draft' and notes it was created by Muhammad Ahmed. The second card, dated 2021-Dec-22 (12:03 Hrs), is labeled 'Submitted' and also notes it was submitted by Muhammad Ahmed. The third card, dated 2021-Dec-22 (12:22 Hrs), is labeled 'by: admin' and contains a 'Remarks' field with the text: 'Registration certificate uploaded by applicant is not readable please provide the fresh copy of registration of products certificate.' A blue arrow points from a red-bordered box containing the text 'Comments from DRAP officer' to this remarks field.

Applicant can type reply in the following box and upload the desired documents as needed. After upload click on the re-submit button as indicated below. Your application will be resubmitted to DRAP.

The screenshot shows a web interface for resubmitting an application. It features a large text area on the left with the placeholder text "Enter Your Reply Here". To the right of the text area is a file upload section with the heading "Attach the documents mentioned". Below this heading is a "Choose File" button and the text "No file chosen". A green "Re-Submit" button is located below the file upload section and is highlighted with a red rectangular border.

## 6. Printing of Letter (Approved Application)

Approved application means your application had approved and applicant can print the letter using the following button.

The screenshot shows the DRAP web application interface. On the left is a dark sidebar with navigation options: Dashboard, Drug Import License (Apply For Form-5), Export Applications, Import Applications, and My Applications. The main content area is titled 'My Applications' and contains a table with the following data:

SR.NO	APP TYPE	APPLICATION TITLE	APP REF NO	CHALLAN NO	CURRENT STATUS	ACTION
1	Export	Export Finished Drugs / HOTC	A-19752219726	61307208147	Returned	Update
2	Export	Export Medical Devices	D-18352213692	61307208147	Rejected	View
3	Export	Export of Raw Material	C-18552213247	61307208147	Approved	View, Print Letter
4	Export	Re-Export of Raw Material	B-18652218516	61307208147	Approved	View, Print Letter
5	Export	Export of Raw Material	C-19252218674	381716240558	Approved	View, Print Letter

A callout box with a blue border and green text points to the 'Print Letter' button in the 'Approved' status column of the third row.

Note: Copy of Sample Letter shown on next slide.



Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
Drug Regulatory Authority of Pakistan  
TF Complex, Sector G-9/4, Islamabad  
\*\*\*\*\*



SAY NO TO CORRUPTION

Computerized No C-18552213247

Date of issue 2021-Dec-20

Firm Name, Chemonics

Address, 2nd Floor NSTP H12 Islamabad

City, Islamabad

Subject: **NO OBJECTION CERTIFICATE**

Please refer to your application No. C-18552213247 dated 2021-12-20 12:28:15 on the subject cited above. The Drug Regulatory Authority of Pakistan has No Objection in exporting the below mentioned Raw Material to M/s Chemonics 2nd Floor NSTP H12 Islamabad Islamabad Pakistan vide invoice no. 61307208147 dated 2021-Dec-31

Material Name	Batch No.	Mfg Date	Exp Date	Packs	Pack Size	Manufacturer	Quantity	Amount Unit Price (USD)
	TI-3212	2021- Dec-30	2025-Dec- 31	10	20	Chemonics	200	2000

2. However, all other codal formalities may please be compiled at the time of Export.
3. Custom authorities are requested to check the consignment thoroughly at the time of export.

**Muhammad Ishtiaq**

**Assistant Director (I&E)**

This is computer generated document, hence signature is not required. This document can be verified using link XXXXXXXXXXXXXXXX

**DRUG REGULATORY AUTHORITY OF PAKISTAN**

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**[www.dra.gov.pk](http://www.dra.gov.pk)**