



USER GUIDE FOR ONLINE IMPORT / EXPORT APPLICATIONS SOFTWARE

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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 or call at 051-9107414 / 051 9107412.

Step-1: Login Screen

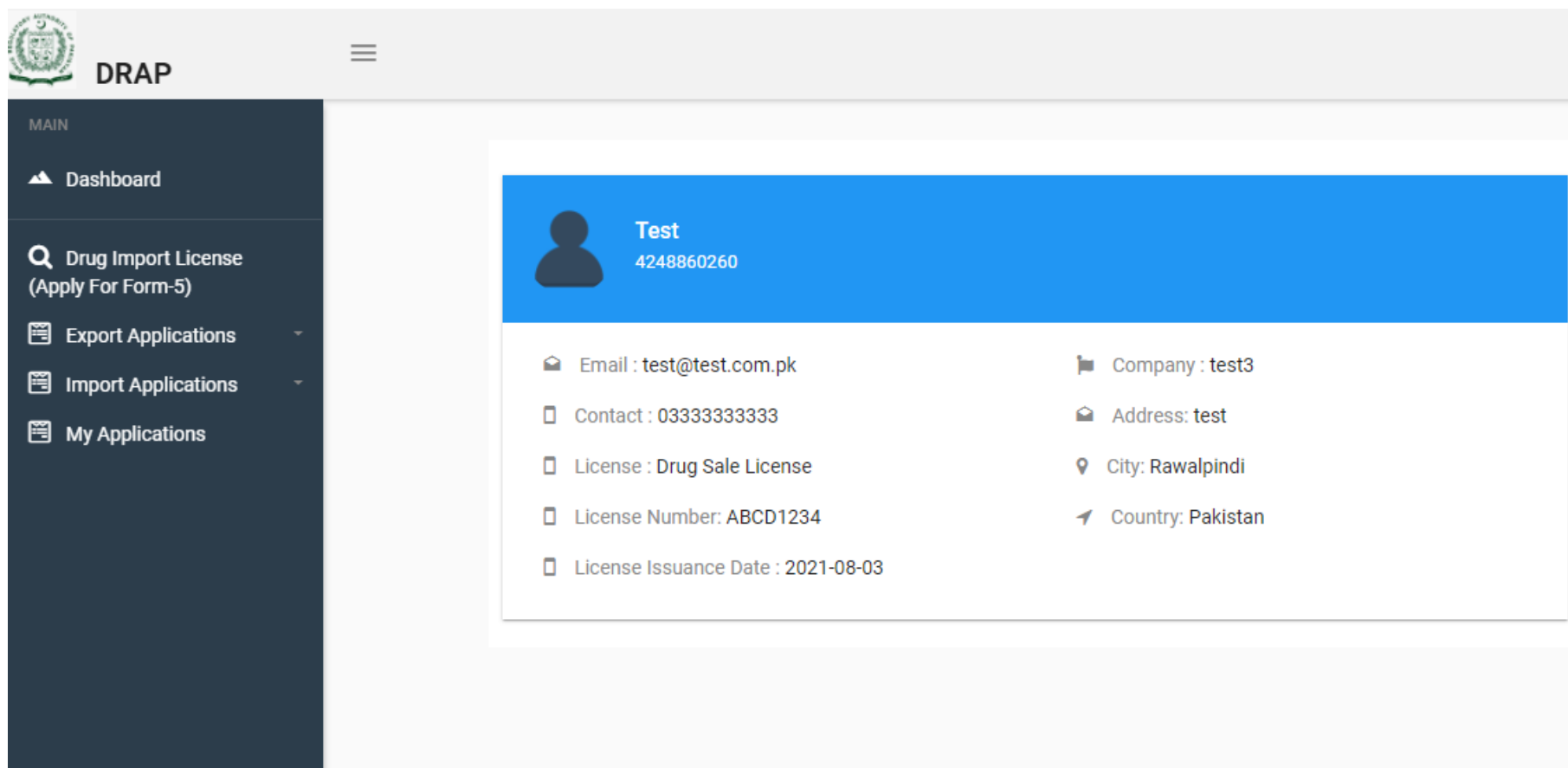
- (i) Access the software application using: ie.dra.gov.pk
- (ii) Please use same user and password provided for online fee challan system.



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, flanked by two horizontal green lines. Underneath, the title 'Online Import / Export Application System' is centered in a large, bold font. The login form consists of two input fields: 'Username' with the text 'test@test.com.pk' and 'Password' with a masked password '.....'. At the bottom of the form, there are three buttons: a blue 'Register' button, an orange 'Reset Password' button, and a green rounded 'Sign In' button.

Step: II

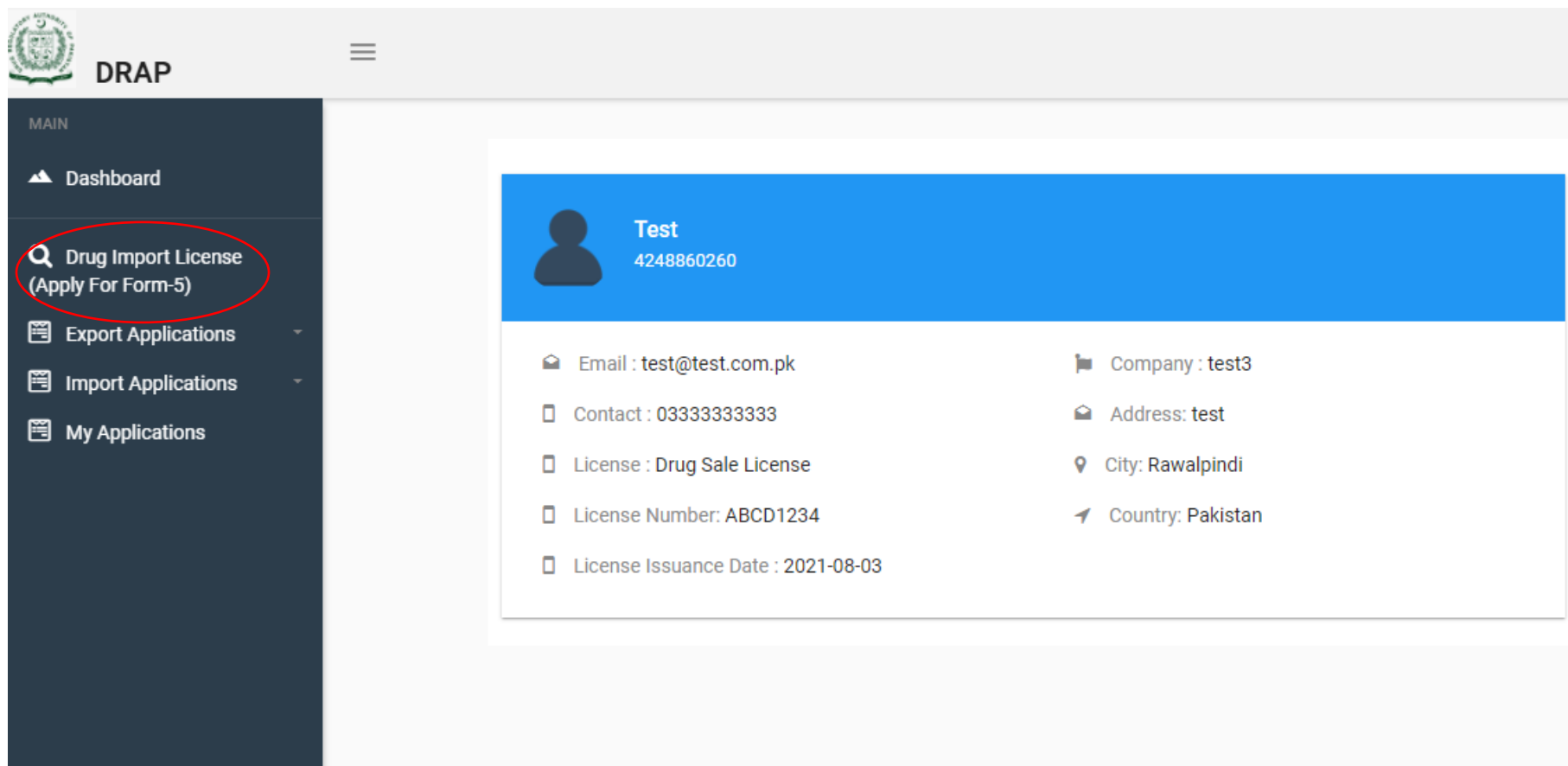
After Login following screen will appear.



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. The top header features the DRAP logo and a hamburger menu icon. The left sidebar, labeled 'MAIN', 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 *
DRAP online paid fee challan number then click verify. After verification information will be shown in next box

Verify Challan

Challan Status:
You have not verified the challan yet.

Application Information

Application Ref No: K-1702601746
App Date: 2021-12-23 10:01:46

Automated generated application ref number and date time.

Application Status

New Application

Company Profile

Company Name test3	Company Address test	Company City Rawalpindi	Company Country Pakistan
Issued License Drug Sale License	License Number ABCD1234	License Issue Date 2021-08-03	

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 5MB size)

Document Submitted

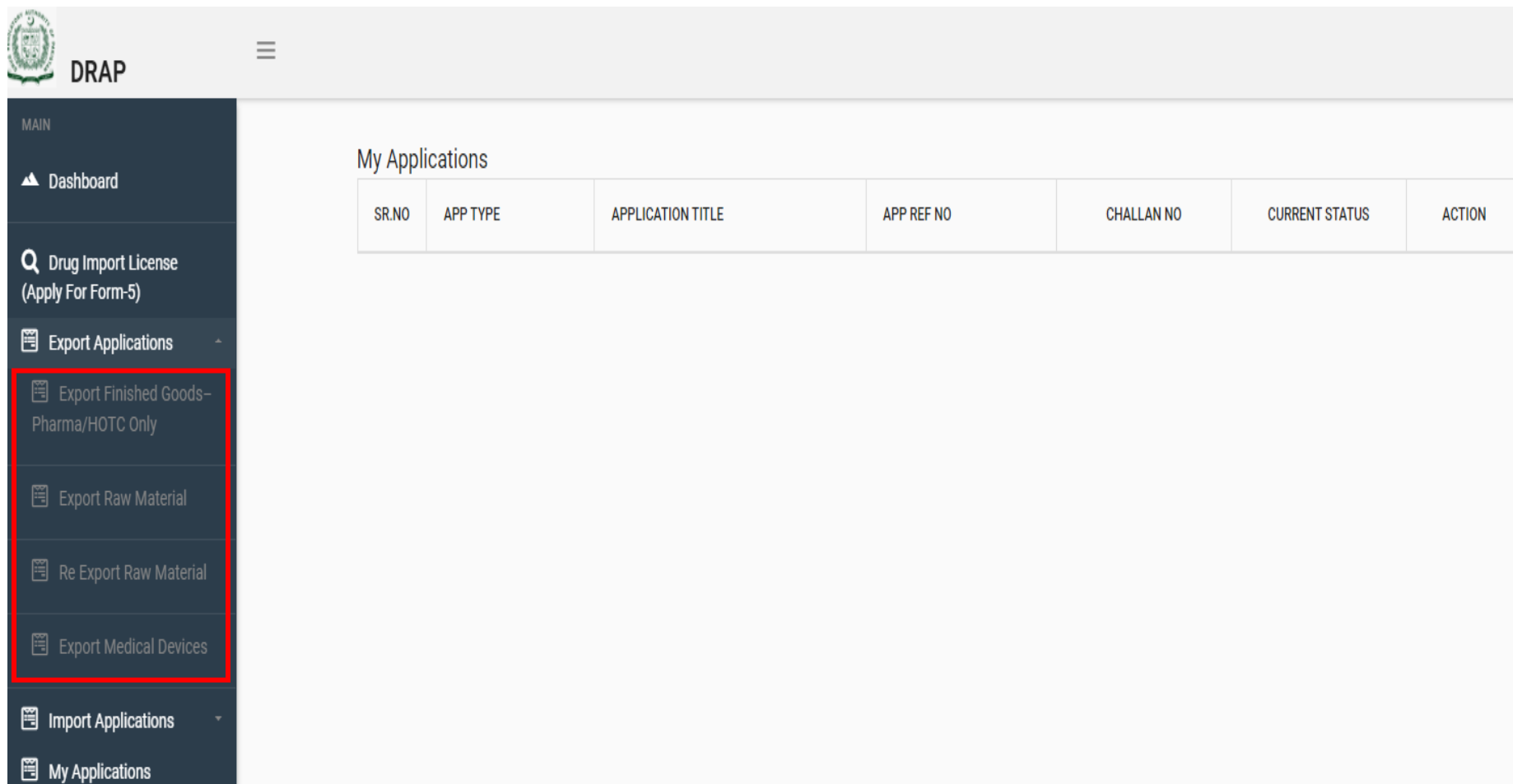
API Requirement Data / Stability Report *	Certificate of Analysis / Specifications *	Clinical Trial Approved *
<input type="button" value="Choose File"/> No file chosen	<input type="button" value="Choose File"/> No file chosen	<input type="button" value="Choose File"/> No file chosen
Copy of Paid DRAP 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.

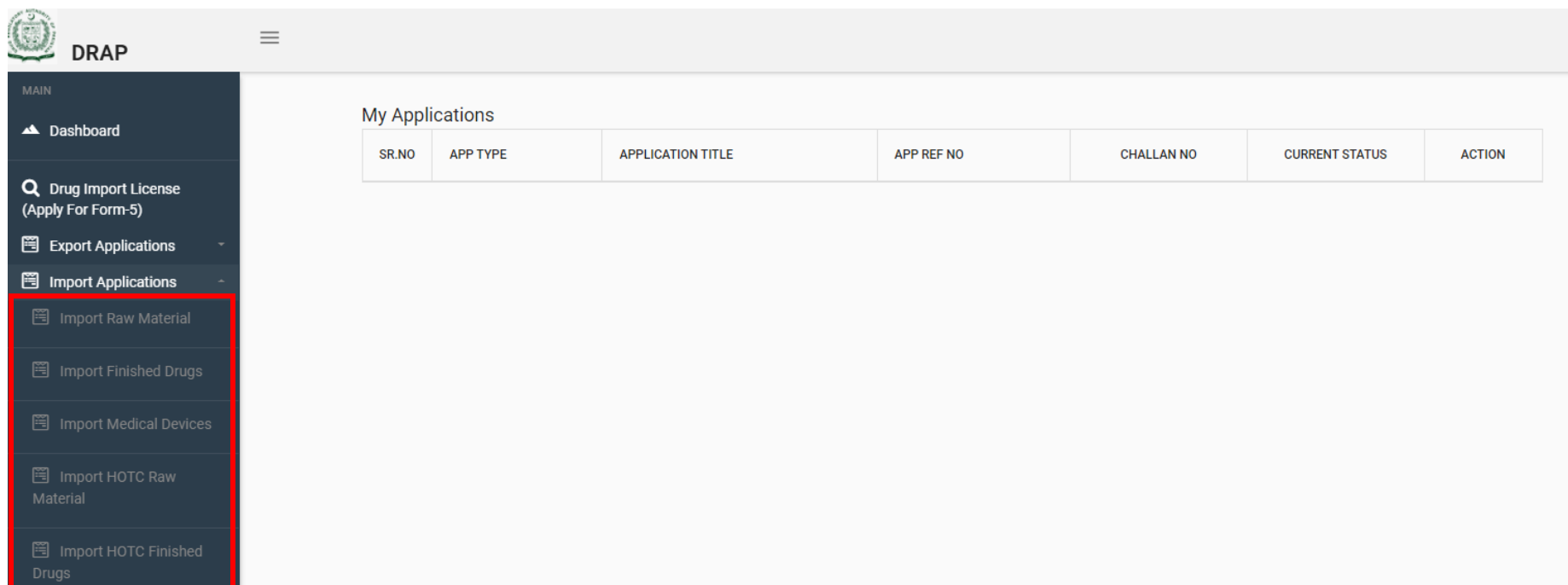


The screenshot displays the DRAP web application interface. On the left is a dark sidebar menu with the following items: MAIN, Dashboard, Drug Import License (Apply For Form-5), Export Applications (highlighted with a red box), Export Finished Goods- Pharma/HOTC Only, Export Raw Material, Re Export Raw 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 is a dark sidebar menu 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' item is highlighted with a red box. 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. The table is currently empty.

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.

The screenshot shows the DRAP web application interface. On the left, there is a dark sidebar with a menu. The 'My Applications' option is highlighted with a red rectangular box. 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

-Rejected application means DRAP office has rejected your application because of some misleading/falsified information and applicant will submit new application with new electronic reference number.

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.

Application History

2021-Dec-22 (11:57 Hrs)

Draft

Draft by: Muhammad Ahmed against application ref no:A-19752219726

Remarks :

2021-Dec-22 (12:03 Hrs)

Submitted

Submitted by: Muhammad Ahmed against application ref no:A-19752219726

Remarks :

2021-Dec-22 (12:22 Hrs)

by: admin against application ref no:A-19752219726

Remarks : Registration certificate uploaded by applicant is not readable please provide the fresh copy of registration of products certificate.

Comments from DRAP officer

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 form interface. On the left, there is a large text input area with the placeholder text "Enter Your Reply Here". To the right of this area, there is a section for document attachment. It features a label "Attach the documents mentioned" above a file selection interface. This interface includes a "Choose File" button and the text "No file chosen". Below the file selection area, there is a prominent green button labeled "Re-Submit", which is highlighted with a red rectangular border. The entire form is enclosed in a light blue 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
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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

Telecom Foundation Complex, G-9/4, Islamabad, Pakistan

Email: saqeb@dra.gov.pk Phone:92-51-9107412

www.dra.gov.pk