



## **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

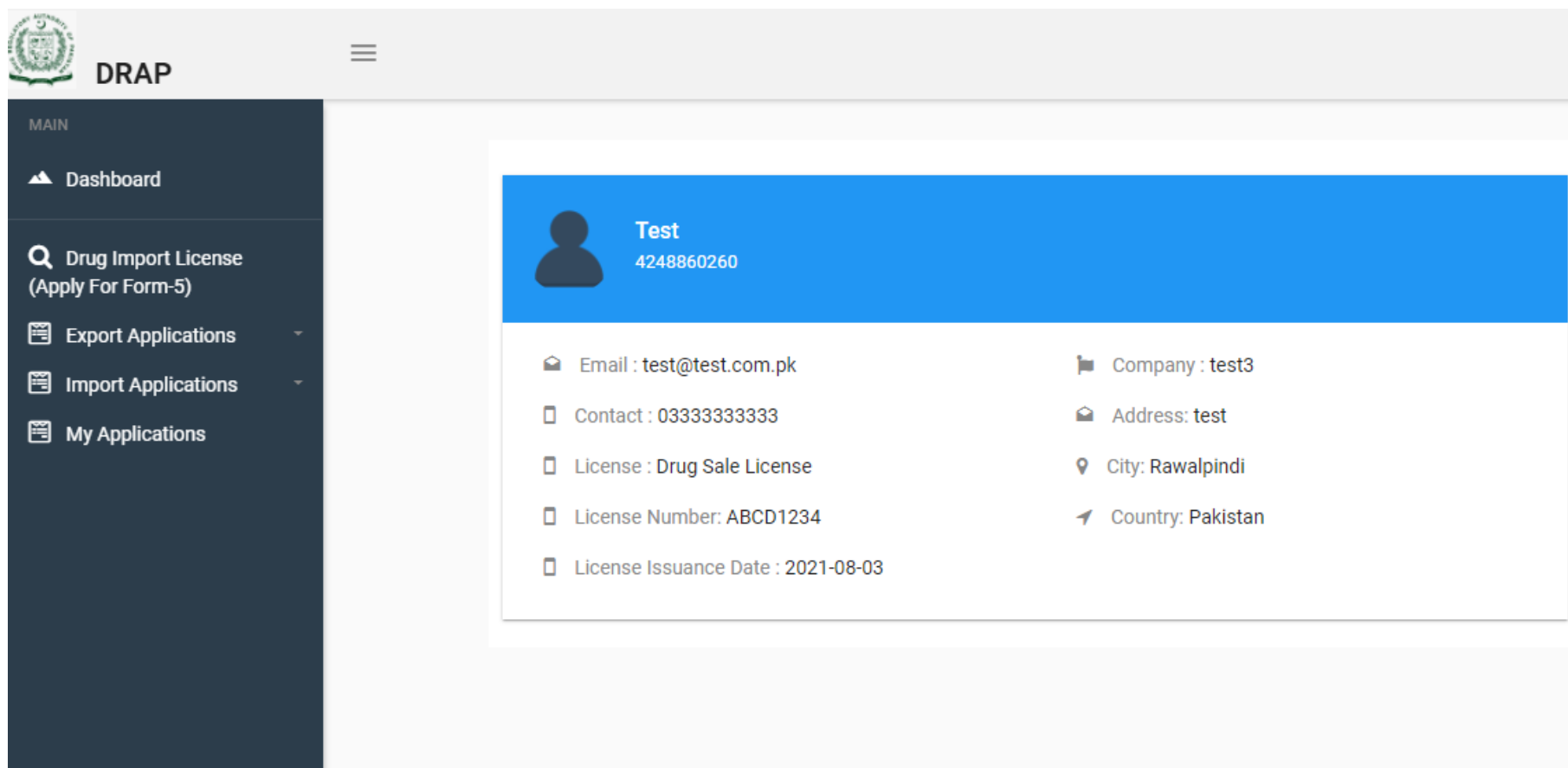
- (i) Access the software application using: ie.dra.gov.pk
- (ii) Please use same user and password provided for online fee challan system.



The screenshot displays the login interface for the Drug Regulatory Authority of Pakistan (DRAP) Online Import / Export Application System. At the top, the DRAP logo is centered, featuring a circular emblem with a crescent and star, surrounded by the text 'DRUG REGULATORY AUTHORITY OF PAKISTAN'. Below the logo, the text 'Drug Regulatory Authority Of Pakistan' is displayed, followed by 'Online Import / Export Application System'. The login section includes a 'Username' label above a text input field containing 'test@test.com.pk', and a 'Password' label above a text input field filled with asterisks. At the bottom, there are three buttons: a blue 'Register' button, an orange 'Reset Password' button, and a green 'Sign In' button.

## Step: II

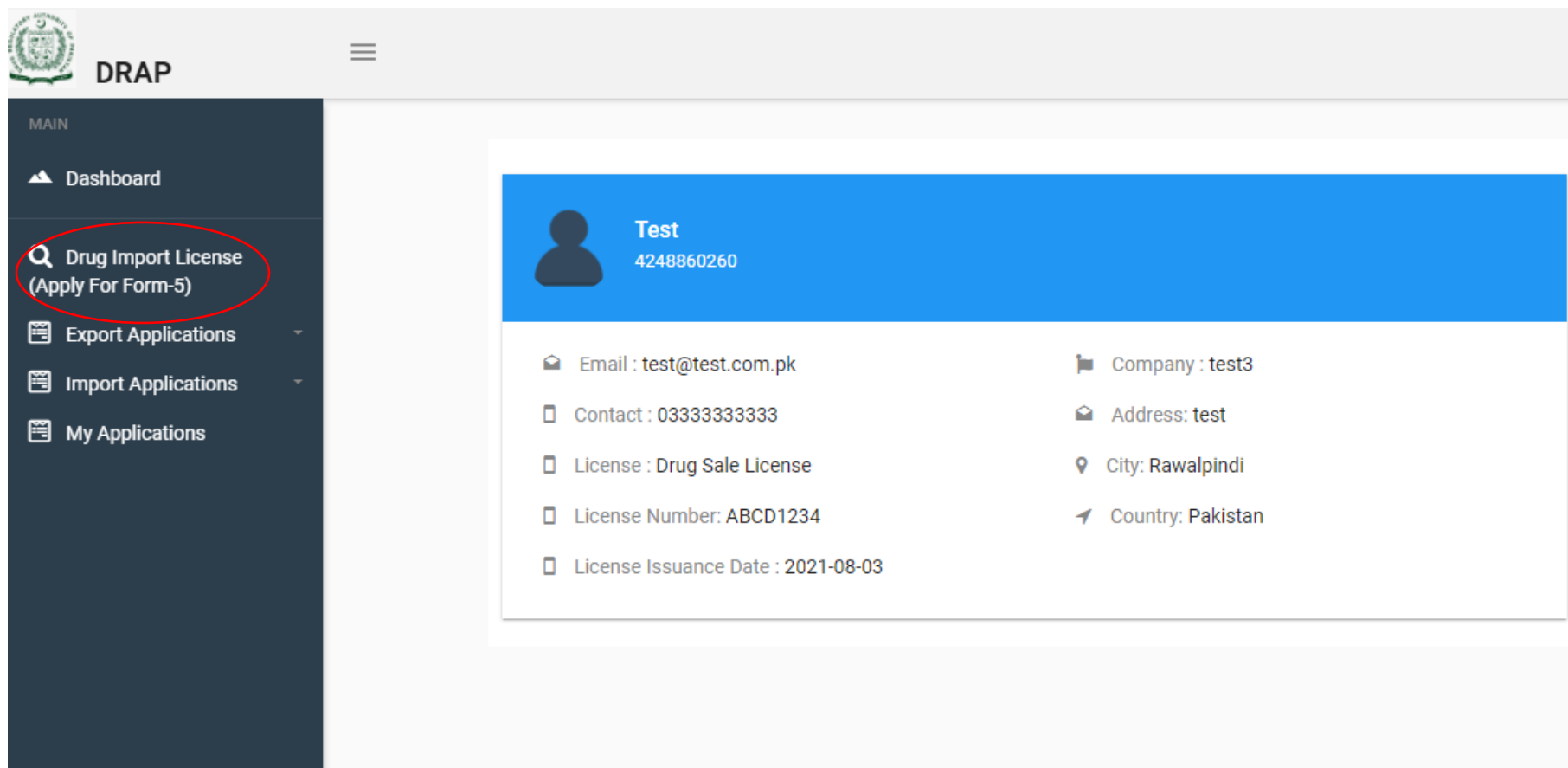
After Login following screen will appear.



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)



DRAP

MAIN

Dashboard

Drug Import License (Apply For Form-5)

Export Applications

Import Applications

My Applications

Test  
4248860260

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.

**MAIN**

- Dashboard
- Drug Import License (Apply For Form-5)
- Export Applications
- Import Applications
- My Applications

### 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

**Application Status**

New Application

**Company Profile**

|                                     |                            |                                  |                             |
|-------------------------------------|----------------------------|----------------------------------|-----------------------------|
| Company Name<br>test3               | Company Address<br>test    | Company City<br>Rawalpindi       | Company Country<br>Pakistan |
| Issued License<br>Drug Sale License | License Number<br>ABCD1234 | License Issue Date<br>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

i

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 \*

Choose File No file chosen

Certificate of Analysis / Specifications \*

Choose File No file chosen

Clinical Trial Approved \*

Choose File No file chosen

Copy of Paid DRAP Fee Challan \*

Choose File No file chosen

Drug Registration Letter / Renewals \*

Choose File No file chosen

Form 2 \*

Choose File No file chosen

Form 4 \*

Choose File No file chosen

GMP Certificate ( Manufacturers ) \*

Choose File No file chosen

Undertaking on Stamp Paper \*

Choose File No file chosen

Others

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.

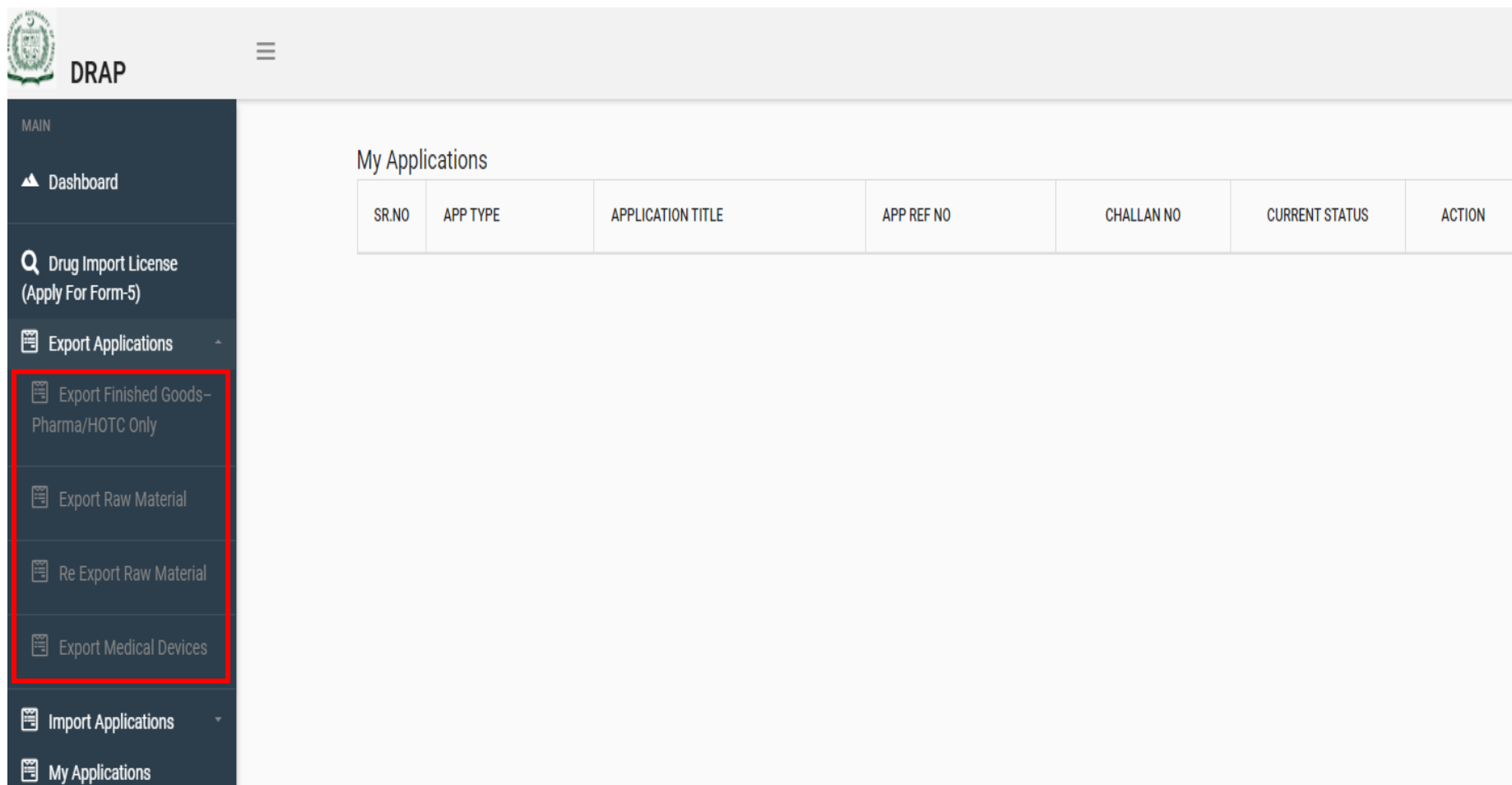
Save & Submit

Save As Draft

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 shows the DRAP web application interface. The left sidebar contains a menu with the following items:

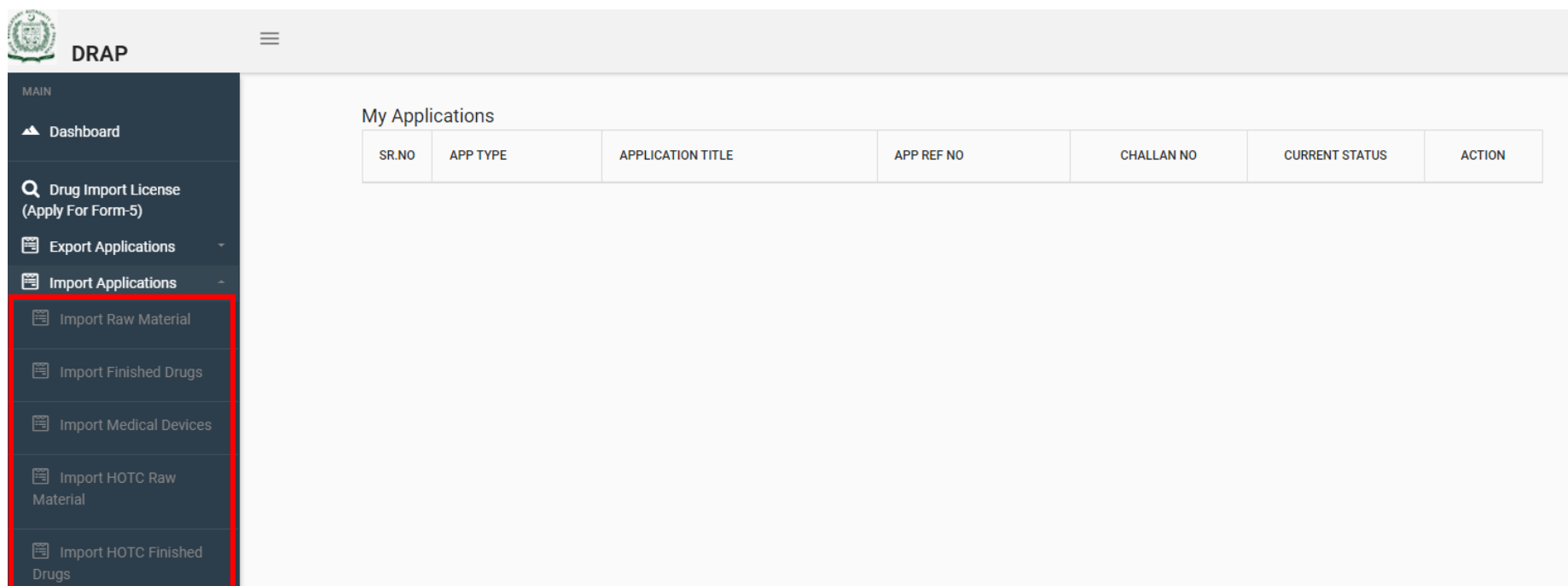
- MAIN
  - Dashboard
  - Drug Import License (Apply For Form-5)
  - Export Applications
    - Export Finished Goods- Pharma/HOTC Only
    - Export Raw Material
    - Re Export Raw Material
    - Export Medical Devices
  - Import Applications
  - My Applications

The main area displays a table titled "My Applications" with the following columns:

| SR.NO | APP TYPE | APPLICATION TITLE | APP REF NO | CHALLAN NO | CURRENT STATUS | ACTION |
|-------|----------|-------------------|------------|------------|----------------|--------|
|-------|----------|-------------------|------------|------------|----------------|--------|

### 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 'Import Applications' section highlighted by a red border. This section contains five sub-options: 'Import Raw Material', 'Import Finished Drugs', 'Import Medical Devices', 'Import HOTC Raw Material', and 'Import HOTC Finished Drugs'. The main content area on the right is titled 'My Applications' and features 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.

**DRAP**

MAIN

- Dashboard
- Drug Import License (Apply For Form-5)
- Export Applications
- Import Applications
- My Applications**

### My Applications

| 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<br>Print Letter |
| 4     | Export   | Re-Export of Raw Material    | B-18652218516 | 61307208147  | Approved       | View<br>Print Letter |
| 5     | Export   | Export of Raw Material       | C-19252218674 | 381716240558 | Approved       | View<br>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 update cards. The first card, dated 2021-Dec-22 (11:57 Hrs), is titled 'Draft' and notes it was drafted by Muhammad Ahmed against application ref no: A-19752219726. The second card, dated 2021-Dec-22 (12:03 Hrs), is titled 'Submitted' and notes it was submitted by Muhammad Ahmed against the same application ref no. The third card, dated 2021-Dec-22 (12:22 Hrs), notes it was updated by admin against the same application ref no. Its remarks state: 'Registration certificate uploaded by applicant is not readable please provide the freash copy of registration of products certificate.' A blue arrow points from a red-bordered box labeled 'Comments from DRAP officer' to this third card.

**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 :

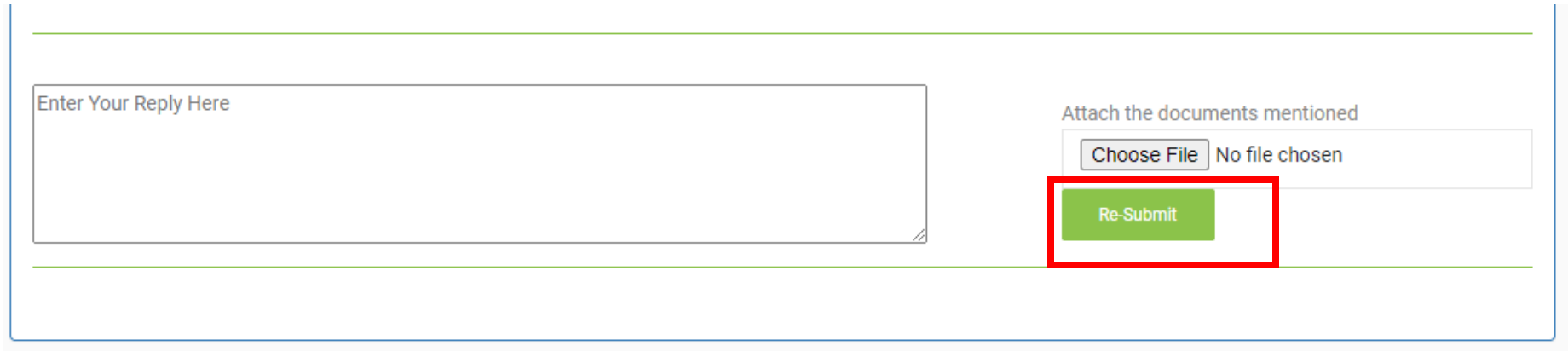
2021-Dec-22 (12:22 Hrs)

by: admin against application ref no:A-19752219726

Remarks : Registration certificate uploaded by applicant is not readable please provide the freash 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 interface for resubmitting an application. It features a large text input area on the left with the placeholder text "Enter Your Reply Here". To the right of this area is a file upload section. At the top of this section is the text "Attach the documents mentioned". Below this text is a button labeled "Choose File" and a status indicator that says "No file chosen". At the bottom of the file upload section is a green button labeled "Re-Submit", which is highlighted with a red rectangular border. The entire interface 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. The left sidebar contains navigation links: Dashboard, Drug Import License (Apply For Form-5), Export Applications, Import Applications, and My Applications. The main content area is titled 'My Applications' and displays a table of application records. A callout box points to the 'Print Letter' button for an approved application.

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

**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<br>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**

Prime Minister National Health Complex, Park Road,

Islamabad, Pakistan

Email: [addl-directormis@dra.gov.pk](mailto:addl-directormis@dra.gov.pk) Phone: 92-51-9262142

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