

**Mechanism for Using the Pharmaceutical Data
Platform (Pharma Data Hub Tool)
Data entry of packaging details / Global Trade Item
Number (GTIN) / Global Location Number (GLN) /
Detailed composition data for products (human or
biological) / Inactive ingredients (excipients).
Year 2026**

Code: EDREX:NP.PPMA.022

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Introduction:

Within the framework of the Egyptian Drug Authority's strategy for digital transformation and the development of the regulatory system, a dedicated electronic tool has been developed to enable pharmaceutical companies to enter packaging data, add the Global Trade Item Number (**GTIN**) for each registered package, enter the Global Location Number (**GLN**) for each licensed facility, and input detailed composition data for their products (human or biological), specifically inactive ingredients (**excipients**), in an organized and automated manner.

This tool serves as an essential step toward updating the central database with accurate and comprehensive information for all company products.

Purpose of the Tool

The tool aims to:

- Complete the technical data for pharmaceutical products, including (item code/GTIN for each package, location code/GLN for each facility, and inactive ingredients/excipients data).
- Establish a unified and accurate database to support evaluation and regulatory activities.
- Pave the way for launching future automation programs based on complete and validated data.
- Accelerate procedures for services provided to companies in the future.

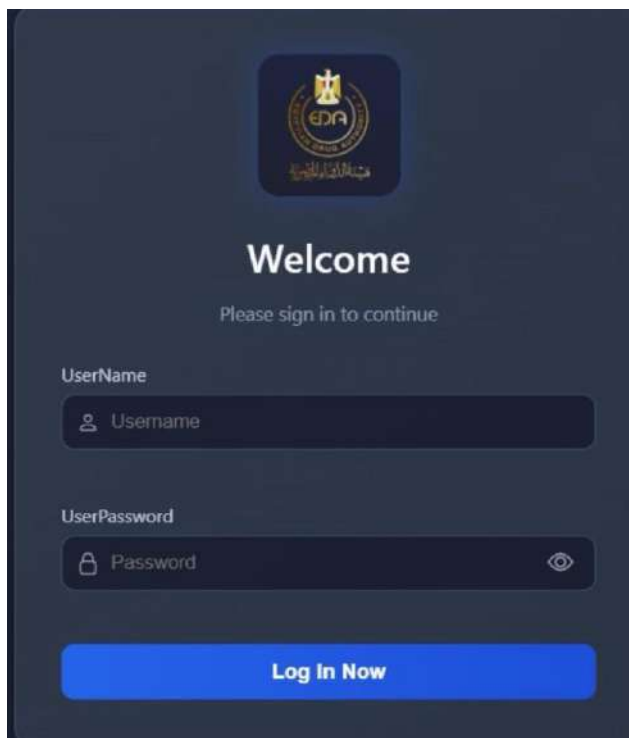
Features of the Tool

The tool offers several advantages, most notably:

- **Data Accuracy:** Direct data entry by the product's owner company minimizes errors.
- **Readiness for Automation:** Enables the Authority to activate fully automated e-services.
- **Transparency and Traceability:** Provides a unified electronic record for each product.
- **Decision Support:** Delivers an analytical database that can be relied upon for regulatory and technical studies.

Workflow Steps on the Tool:

1. Log in via the following link: **Click Here**
2. Access the tool using your username and password through the **Company Profile**.



3. Click on "**LOG IN NOW**" to access the main home page.

Main Home Page:

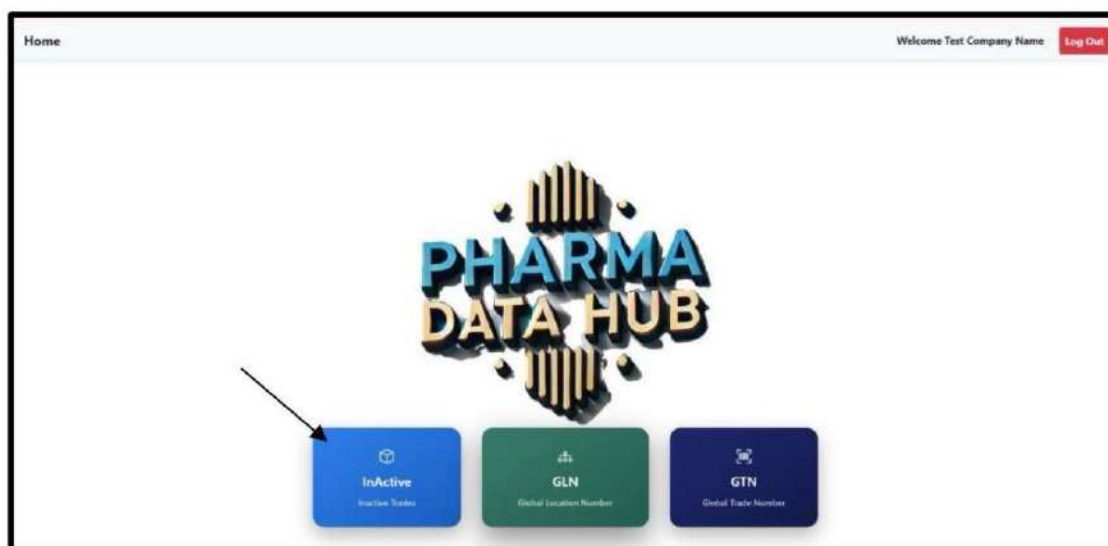
The top menu bar contains:

- Company Name
- Log Out option

PHARMA DATA HUB Sections

First: Steps for Entering Inactive Ingredients (Excipients):

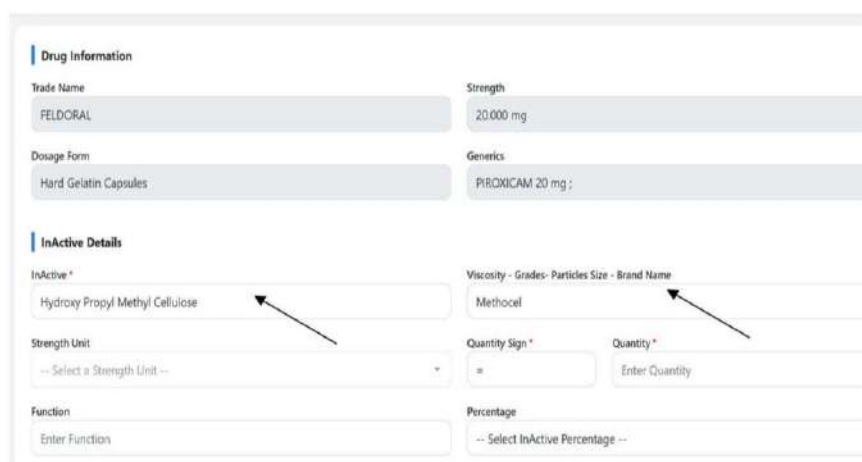
1. Inactive Trades is selected.



2. Select the product for which the inactive ingredients (excipients) are to be entered:
 - Registered products or products under registration belonging to the company can be displayed.
 - Human or biological products belonging to the company can be displayed.

3. Complete the raw materials data for each product:

- Search for and select the required inactive ingredient (**excipient**). Additional specifications may also be entered (if present in the composition statement):
 - **Viscosity - Grades - Particle Size - Brand Name**



- Select the **Strength unit**, with a search field available to facilitate selection.
(A **QS** option is available if present in the composition statement).

InActive Details

InActive *
Hydroxy Propyl Methyl

Viscosity - Grades- Particles Size - Brand Name
15cps/90/methocel/PH101

Strength Unit
Quantity Sufficient

Quantity Sign *
=

Quantity *
0

Percentage
-- Select InActive Percentage --

mg
gm/100mg
mg
mg/0.2ml
mg/0.3ml
mg/0.4ml
mg/0.5ml

In-House
USP
BP

- Select the **Quantity Sign** and enter the **Quantity**.

InActive Details

InActive *
Hydroxy Propyl Methyl

Viscosity - Grades- Particles Size - Brand Name
15cps/90/methocel/PH101

Strength Unit
Quantity Sufficient

Quantity Sign *
≥

Quantity *
10

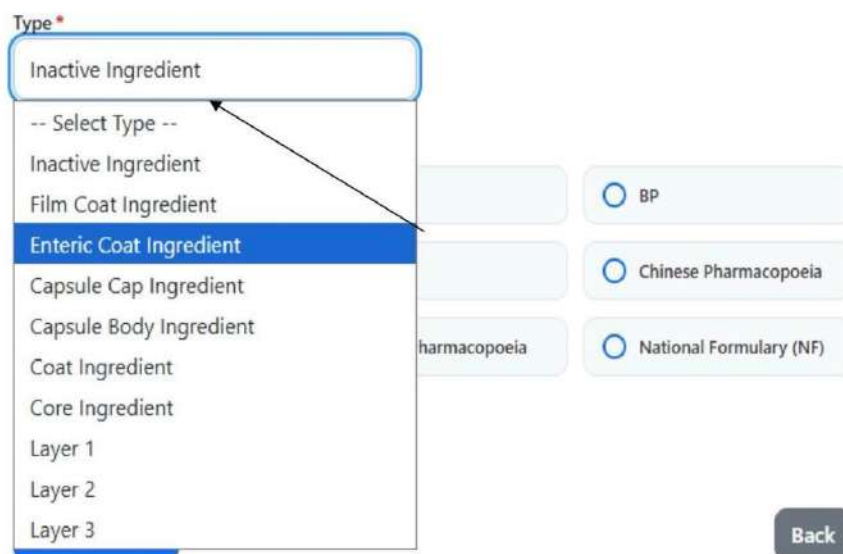
Percentage
-- Select InActive Percentage --

Function
Enter Function

- Select the **Percentage** and enter the **Function** (if specified in the composition statement).



- Select the type of inactive ingredient (**excipient**).



- Select the **Reference** (optional), and multiple references can be added.
- After adding all data, click on **Add**, and enter the remaining inactive ingredients using the same method.

reference

☐ In-House	☐ USP	☐ BP
☐ Eur.Ph.	☐ JP	☐ Chinese Pharmacopoeia
☐ Indian Pharmacopoeia	☐ Korean Pharmacopoeia	☐ National Formulary (NF)
☐ Int.		

- Attach the latest composition statement for the product.

Reference *

☐ In-House	☐ USP	☐ BP
☐ Eur.Ph.	☐ JP	☐ Chinese Pharmacopoeia
☐ Indian Pharmacopoeia	☐ Korean Pharmacopoeia	☐ National Formulary (NF)
☐ Int.		

Inactive Attachment



Inactive PDF

[View Document](#)



No file selected

4- After entering all inactive ingredients for all products (do not forget to check the undertaking/declaration box to submit the entered data for review; if the undertaking box is not checked, the entered data will not be transmitted to the Authority's reviewers).

Drugs Management

☐ I declare (CEO), that all composition sheets attached to the company's products are the most updated composition sheet for the products.
Note: This is in case any variations are made on them. **Confirm**

Type: **Human** **Bio** Status: **Reg** **UnderReg**

Search by Trade Name or RegNo/SoftFileNo

#	RegNo/SoftFileNo	Trade Name	LicStatus	RegStatus	Strength	Dosage	Generics	InActive	Action
1	21705	FEIDORAL	Valid	Registered	20.000 mg	Hard Gelatin Capsules	PIROXICAM 20 mg ;	Trimethyl- 1- Cyclodextrin ,	Manage
2	23469	ANAPLATE	Valid	Registered	75.000 mg	Sugar Coated Tablets	DIPYRIDAMOLE 75 mg ;	2-Ethylhexyl Acrylate-Vinyl Acetate-Aluminum Acrylate Copolymer (For Duro-Tak 87-	Manage

- Entered material data can be edited or deleted.
- In case any modification is made, the undertaking box must be checked again.

-- Select InActive Percentage -- Enter Function

Add **Back**

InActive Attachment

No PDF uploaded yet

Choose PDF No file selected **Upload / Replace**

InActive Name	Reference	Strength Unit	Quantity Sign	Quantity	Percentage	Function
2-Ethylhexyl Acrylate-Vinyl Acetate-Aluminum Acrylate Copolymer (For Duro-Tak 87-2194)	Korian Pharmacopoeia	gm	=	10.000000	%W/W	111 Edit Delete
2-Naphthalenol	Eur.Ph.	gm/100ml	=	10.000000	%W/W	m/m/m Edit Delete

Second: Packaging Data Entry

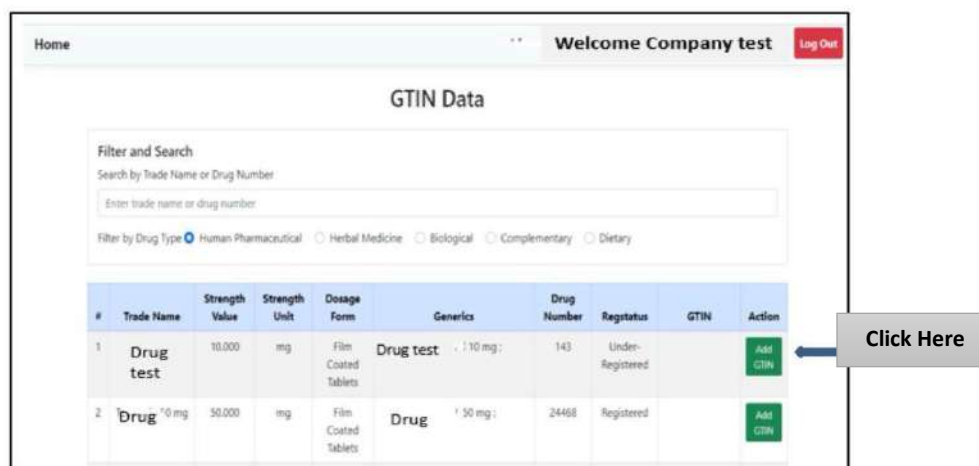
To enter the package identification code, click on **GTIN**.



1- GTIN Data Screen:

This screen displays all registered products and products under registration. You can filter and search by:

- Product name (**Trade Name**), Registration Number, or **Soft File No.**
- Product type: **Human, Biological, Herbal, Complementary, or Dietary Supplement.**



#	Trade Name	Strength Value	Strength Unit	Dosage Form	Generics	Drug Number	Regstatus	GTIN	Action
1	Drug test	10.000	mg	Film Coated Tablets	Drug test ; 10 mg ;	143	Under-Registered		Add GTIN
2	Drug	50.000	mg	Film Coated Tablets	Drug ; 50 mg ;	24468	Registered		Add GTIN

2. Add GTIN: The screen is divided into several sections:

First: Product Data: You can review the product data saved in the Egyptian Drug Authority (EDA) database.

Second: You can enter the package Global Trade Item Number (GTIN) and click **Search**:

- If the entered number is correct, the package details will appear below the search box. Note that these details are for guidance only (in case of any adjustments, please consult the issuing agency for the item identification number), as shown in the image below.
- If the entered number is incorrect, an error message will be displayed (Image 6).

Third: Packaging Details

Example 1: A carton package containing 30 tablets, with 3 strips of 10 tablets each. In this case, enter the following:

- In the **Unit** box: Enter **1**
- In the **Pack unit** box: Enter **Carton**
- In the **Sub unit** box: Enter **3**
- In the **Sub Pack unit** box: Enter **Strip**
- In the **Sub Sub Unit** box: Enter **10**

- In the **Sub Sub Pack unit** box: Enter **Tablet**

Example 2: A carton package containing 3 ampoules. In this case, enter the following:

- In the **Unit** box: Enter **1**
- In the **Pack unit** box: Enter **Carton**
- In the **Sub unit** box: Enter **3**
- In the **Sub Pack unit** box: Enter **Ampoule**

Fourth: Manufacturer Data

When multiple options are available, you can select from the drop-down menu:

- **Manufacturer Batch Releaser**
- **Manufacturer of Bulk**
- **Manufacturer responsible for primary packaging**
- **Manufacturer responsible for secondary packaging**
- **Manufacturer of finished product**
- **Manufacturer in Egypt**

Fifth: Priced Packages

You can select the company's priced package. In case of multiple packages, you can select them repeatedly after completing the entry of the Global Trade Item Number (**GTIN**).

When adding a GTIN for an unpriced package, you can select:

- **Click here in the case of the product not a price (Tender & or Export)**
- **Click on Add GTIN**

Add GTIN for Temocillin 50 mg

Trade Name: Drug Common Name: Dosage Form:

Generic: Drug Type Name: Application:

Registration: Strength:

Search GTIN:

Add Packs

Unit: Pack unit:

Sub-unit: Sub Pack unit:

Sub Sub unit: Sub Sub Pack unit:

Manufacturer Details

Manufacturer: Select Subunit: Manufacturer of Sub:

Manufacturer responsible for primary packaging: Manufacturer responsible for secondary packaging:

Manufacturer of finished product: Manufacturer in Egypt:

Detail	Pharmaceutical	Accessories	Price
1	1 pack / 2 days in Table		20.00

☐ Tick here if you're preparing add without a price

Product Data

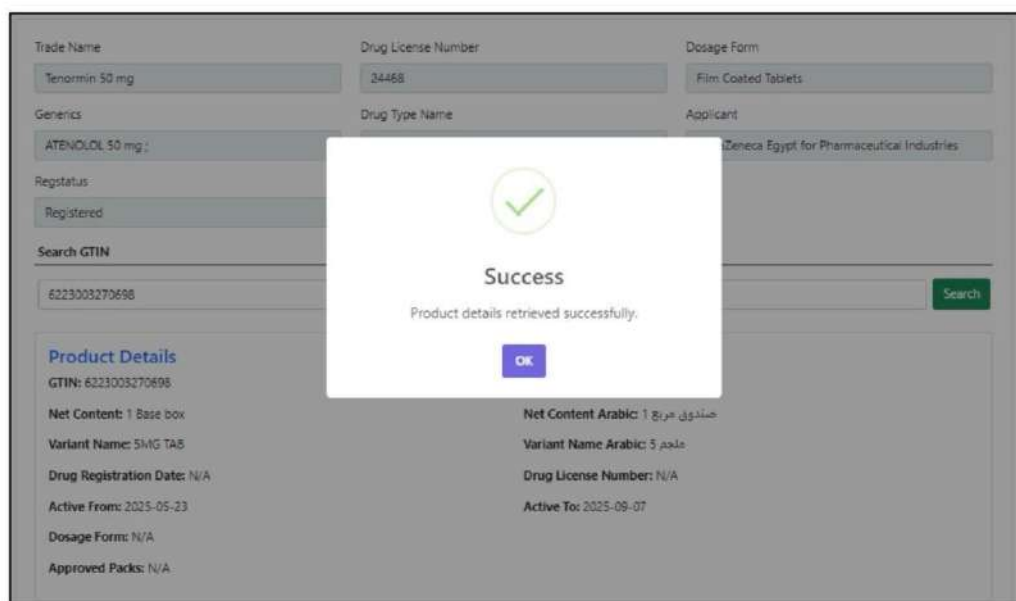
Enter GTIN

Package Details as Issued by the GTIN

Manufacturer Details

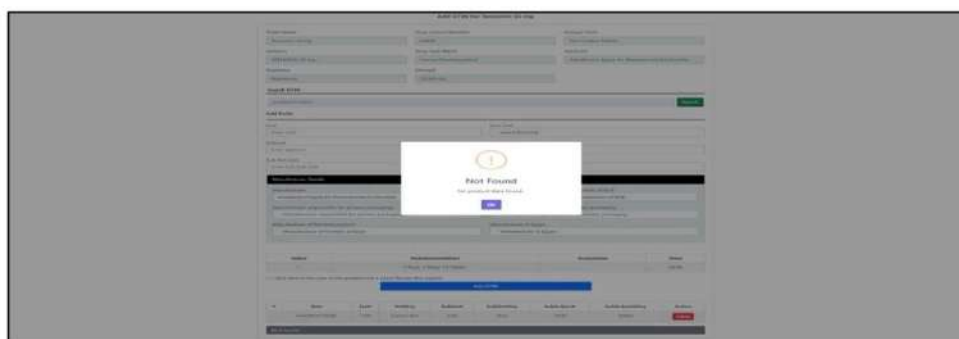
Click Here to Add

You Can Go Back

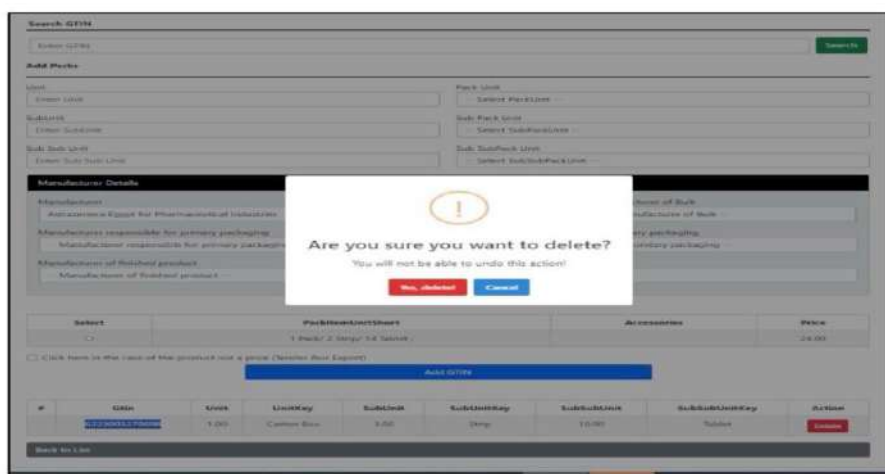


Important Notes:

1. Please ensure all data is correct before clicking on **Add GTIN**.
2. If an incorrect identification number (**GTIN**) is entered or if it has been previously submitted, a "**Not Found**" message will appear, as shown in the image below.



3. If the identification number is entered incorrectly or requires modification, you must click **Delete** to be able to enter the identification number again, as shown in the image below.



4. After adding the identification number for the packages, it will appear on the main screen next to the product, as shown in the image below.

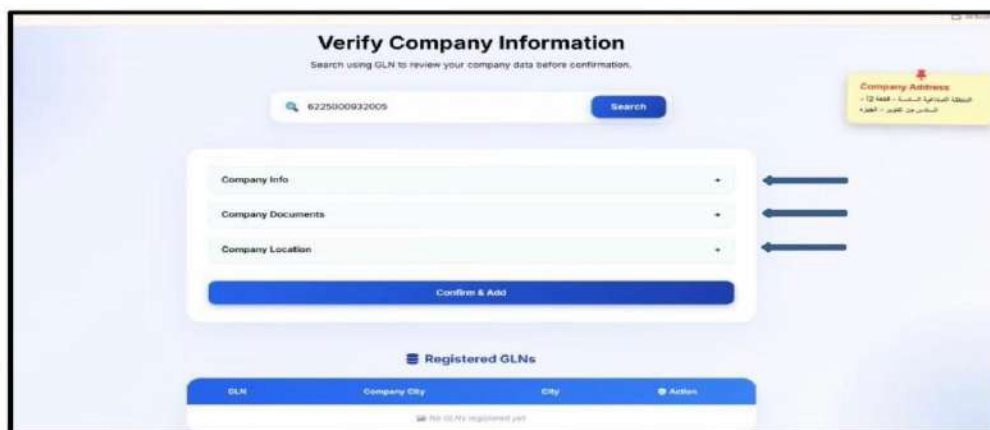
GTIN Data									
Filter and Search									
Search by Trade Name or Drug Number									
Enter trade name or drug number									
Filter by Drug Type ☒ Human Pharmaceutical ☐ Herbal Medicine ☐ Biological ☐ Complementary ☐ Dietary									
#	Trade Name	Strength Value	Strength Unit	Dosage Form	Generics	Drug Number	Registatus	GTIN	Action
1	Cetirizine Hydrochloride	10.000	mg	Film Coated Tablets	Cetirizine HCl 10 mg ;	143	Under-Registered		Add GTIN
2	Tenormin 50 mg	50.000	mg	Film Coated Tablets	ATENOLOL 50 mg ;	24468	Registered	8225003270699	Add GTIN

Third: Facility Location Code Entry (GLN)

To enter the identification number for the facility, click on **GLN**.



3. The screen below will appear, allowing you to review the master data as registered with the coding agency.



Verify Company Information
Search using GLN to review your company data before confirmation.

6225000932005 **Search**

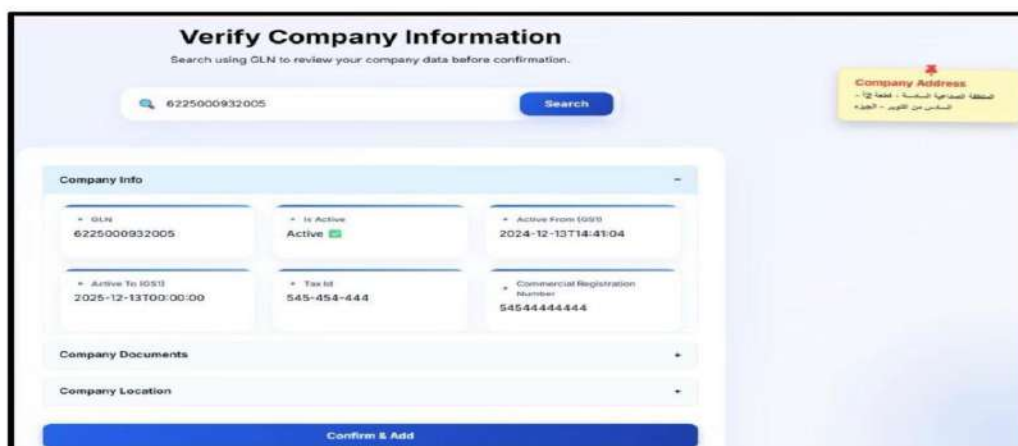
Company Address
المسقط العددي لشركة - فرع 12
السكن من القوي - الفرع

Company Info
Company Documents
Company Location

Confirm & Add

Registered GLNs

GLN	Company City	City	Action
No GLNs registered yet			



Verify Company Information
Search using GLN to review your company data before confirmation.

6225000932005 **Search**

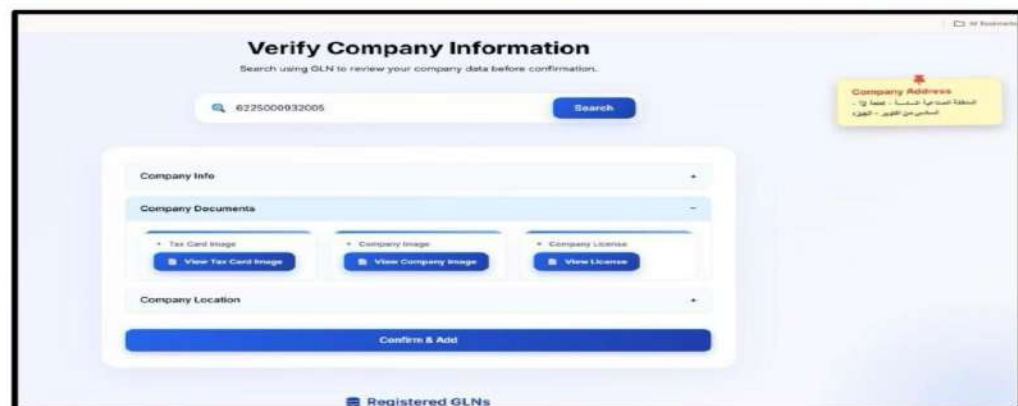
Company Address
المسقط العددي لشركة - فرع 12
السكن من القوي - الفرع

Company Info

- GLN: 6225000932005
- Is Active: Active
- Active From (GSI): 2024-12-13T14:41:04
- Active To (GSI): 2025-12-13T00:00:00
- Tax ID: 545-454-444
- Commercial Registration Number: 54544444444

Company Documents
Company Location

Confirm & Add



Verify Company Information
Search using GLN to review your company data before confirmation.

6225000932005 **Search**

Company Address
المسقط العددي لشركة - فرع 12
السكن من القوي - الفرع

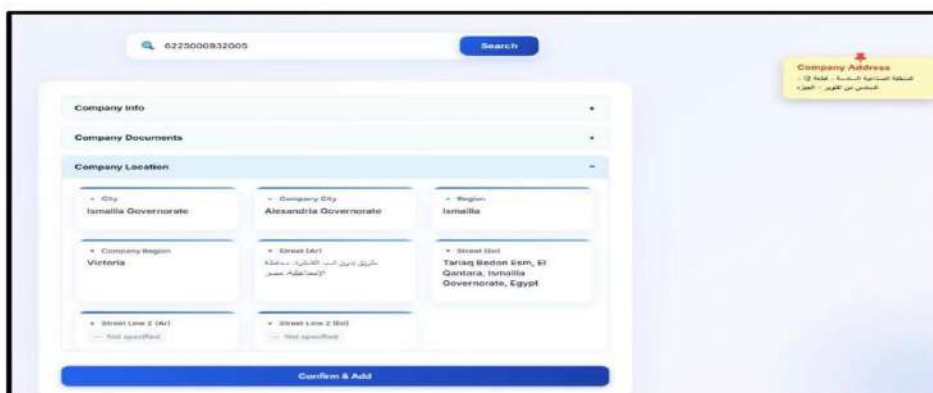
Company Info
Company Documents
Company Location

Company Documents

- Tax Card Image: **View Tax Card Image**
- Company Image: **View Company Image**
- Company License: **View License**

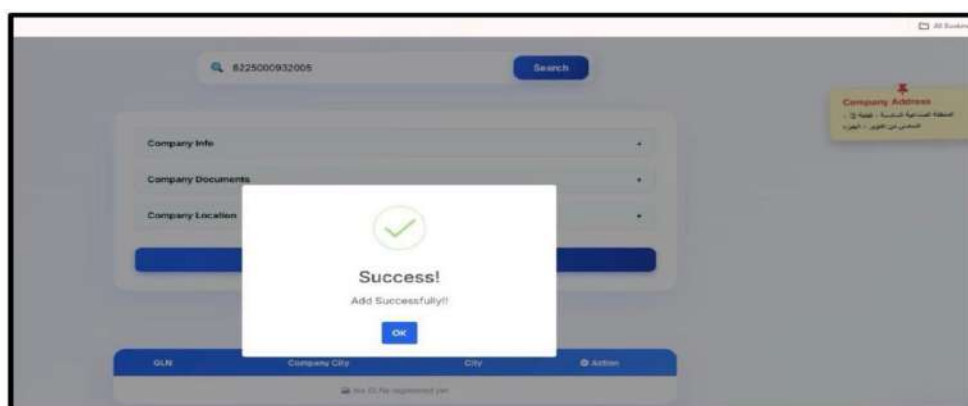
Confirm & Add

Registered GLNs



The screenshot shows a web form for adding a company. At the top, there is a search bar with the ID '6325000932005' and a 'Search' button. Below this, the form is divided into sections: 'Company Info', 'Company Documents', and 'Company Location'. The 'Company Location' section is expanded, showing fields for 'City' (Ismailia Governorate), 'Company City' (Alexandria Governorate), 'Region' (Ismailia), 'Street (Ar)' (Tariq Medon Elm, El Gharbia, Ismailia Governorate, Egypt), and 'Street Line 2 (Ar)' (Not specified). A 'Confirm & Add' button is at the bottom of the form. A yellow tooltip for 'Company Address' is visible on the right side.

4. After reviewing the data, you can click on **Confirm & Add**.



The screenshot shows the same form as before, but with a 'Success!' modal dialog box in the center. The dialog box contains a green checkmark icon, the text 'Success!', and 'Add Successfully!'. There is an 'OK' button at the bottom of the dialog. The background form is dimmed.

5. The location code (GLN) will appear at the bottom of the page, and you can also add another location code (if available).

Verify Company Information

Search using GLN to review your company data before confirmation.

Registered GLNs

GLN	Company City	City	Action
6221032000002	Al-Sharqia Governorate	Al-Qalyubia Governorate	Delete
6221032000057	Al-Sharqia Governorate	Al-Sharqia Governorate	Delete

Verify Company Information

Search using GLN to review your company data before confirmation.

Company Info

Company Documents

Company Location

Confirm & Add

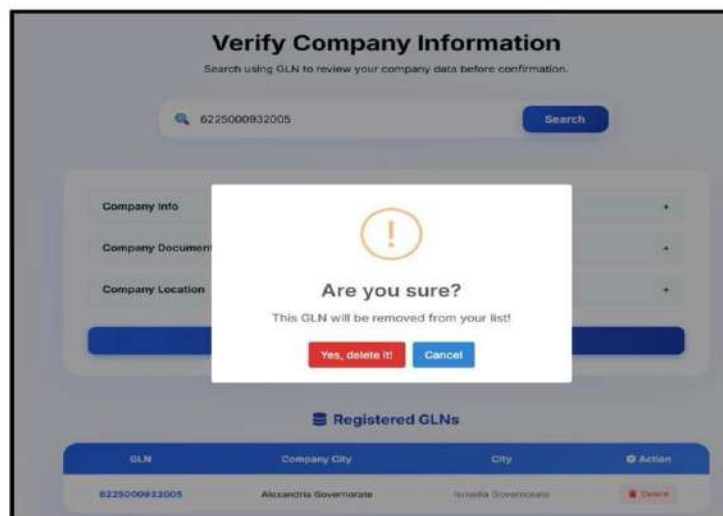
Company Address

المنطقة الصناعية الجديدة - قنطرة -
المنصورة - الدقهلية - مصر

Registered GLNs

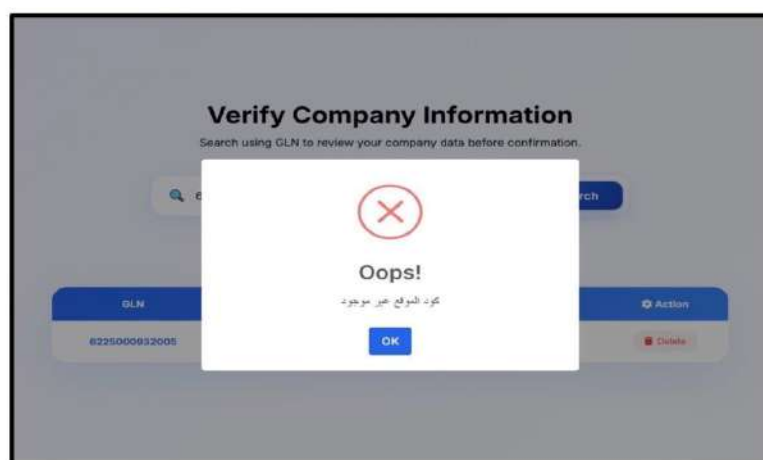
GLN	Company City	City	Action
6225000932005	Alexandria Governorate	Ismailia Governorate	Delete

Delete Option
Available

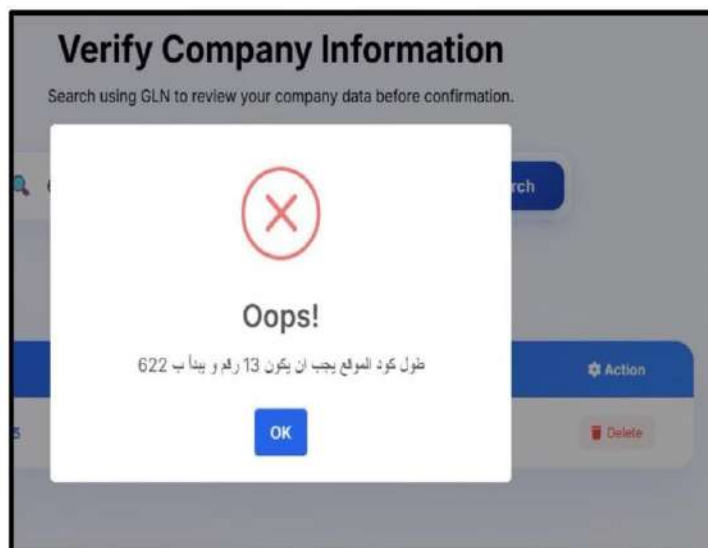


Error Messages That May Appear:

1. In case the code does not belong to the facility's ownership.



2. In case the code is entered incorrectly.



History Table

Version Number	Issue Date	Summary of Changes
1	30/06/2026	