Central Administration of Pharmaceutical Products
Pharmaceutical Product Technical Office Unit

Implementation Mechanism for the Joint EDA–USP Collaboration to Support Reference Standards for Pharmaceutical Companies in Egypt for Conducting Technical Studies Required by the Egyptian Drug Authority

Year 2025

Code: EDREX:NP. CAPP.106
Version No: 1
Issue Date: 30-4-2025
Effective date (if needed): 1-5-2025

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Introduction:

In light of the joint collaboration between the Egyptian Drug Authority (EDA) and the United States Pharmacopeia (USP), this implementation mechanism has been developed to outline how pharmaceutical companies operating in Egypt can benefit from the USP support program for reference standards used in conducting the technical studies required by the Central Administration of Pharmaceutical Products of the Egyptian Drug Authority.

Procedures:

- **The applicant company** shall submit its request through **Google Form** using the following link:
https://forms.gle/2YLbE83dgaNv2h457

The request shall include details of the USP Reference Standards, the technical studies in which those reference standards were used, and the corresponding pharmaceutical products, with each product and study identified separately. The applicant company shall bear full responsibility for the accuracy and completeness of all information submitted.

- **The General Administration of Human Pharmaceutical Registration** and **the General Administration of Stability**, under the **Central Administration of Pharmaceutical Products**, shall review the information submitted by the company through the associated **Google Sheet**. Each administration shall verify, within its respective scope of responsibility, whether the technical study specified in the request has been submitted to the Egyptian Drug Authority (EDA), by selecting **"Yes"** or **"No"** in the designated field.
- **The United States Pharmacopeia (USP) representative** shall review the information provided by the company through the **Google Sheet** and provide the necessary feedback to the relevant departments within the Egyptian Drug Authority.
- **The USP Reference Standards Support Mechanism** shall then be implemented by the United States Pharmacopeia (USP) in accordance with the established collaboration framework.