Guidance on Egyptian Drug Authority Proficiency Testing Program For 2023

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1. Introduction

In the context of the Egyptian Drug Authority's keenness to support the pharmaceutical industry and continuously update the regulatory mechanisms in line with the latest international quality standards.

The Egyptian Drug Authority Proficiency Testing Program "EDA-PT program" aims to provide proficiency testing rounds covering various techniques used in quality control laboratories operating in the field of l quality control of pharmaceutical products as a means of monitoring the performance of these laboratories and identifying opportunities for improvement to enhance performance efficiency that will be reflected on the quality of test results, ultimately leading to the availability of safe and effective medication for Egyptian patients.

2. Scope

- Egyptian Drug Authority laboratories
- Quality control laboratories in Pharmaceutical companies
- EDA accredited QC laboratories by "EDA- Pharma Lab Program"
- Testing laboratories in the field of quality control of pharmaceutical products.

3. Abbreviations:

- **EDA**: Egyptian Drug Authority
- **PT**: Proficiency Testing

4. Definitions:

- **Proficiency Testing:** Evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons
- **Scheme:** Proficiency testing designed and operated in one or more proficiency testing rounds for a specified area of measurement, testing, calibration, examination, sampling, or inspection
- **Round:** Single complete sequence of proficiency testing, including the evaluation and reporting of the performance of participants

5. Main subject

5.1.Program Privileges

The participant laboratory in proficiency testing rounds organized by the Egyptian Drug Authority receives a detailed report explaining the technical performance accompanied by a certificate (if requested by the participant), which helps the participant laboratory to:

- Ensure compliance with the ISO/IEC 17025:2017 international standard requirements for the accreditation of testing and calibration laboratories.
- Evaluate the performance of participants by comparing the participants' results, as well as helping in identifying training needs.
- Conduct improvement and raise laboratory technical performance by investigating their test results.

Moreover, the implementation of these measures contributes to enhancing the quality of laboratory analysis results and ensuring their credibility in the market.

5.2.Schemes covered by the program

- **Planned Rounds:**

  These rounds are announced in advance on the official website of the Egyptian Drug Authority

- **Un-planned Rounds:**

  These are rounds organized upon the request of the customer to provide proficiency testing programs for special purposes

5.3.Sets of measurements and tests included in the program

The Egyptian Drug Authority aims to provide proficiency testing rounds using the following sets of measurements and tests, which are announced on the official website of the Egyptian Drug Authority:

Group 1

Chemical tests include:

a) **Quantitative analysis as:**
   - Assay HPLC/ UV
   - Dissolution rate by HPLC/ UV

b) **Qualitative analysis as:**
   - IR identification

Group 2

Includes the Physical tests as:

- PH determination

Group 3

Includes the microbiological tests

5.4.Executive Mechanism

Planned Rounds

Responsible body	Action
Central Administration of Drug Control	Announcement of the annual PT plan
Applicant	Apply electronically (at least 3 days before distribution)
Central Administration of Drug Control	Send instructions to participants according to electronic application
Applicant	Confirmation via the payment registration link (within 5 before distribution)
Central Administration of Drug Control	Deliver samples to participants as per announced distribution date
Applicant	Perform test and send results at the specified time according to the instructions of the participants on the relevant form.
Central Administration for Drug Control	Preparing and sending PT final report to the participants (10 days)

Un-planned Rounds

Responsible	Action
Applicant	Apply electronically & submission of requirement as in **Annex 1** after EDA PT -program acceptance
Central Administration for Drug Control	Study and respond to customer Determine the analysis requirements, if any, and the quantities of materials required **Annex 1**
Applicant	Pay service fees in case of acceptance Delivering all requirements & documents as in **Annex** 2&3 (5 days)
Applicant	Confirm the participation via the payment registration link (within 5 before distribution)
Central Administration for Drug Control	Prepare scheme, deliver samples and instructions to participants (10 days)
Applicant	Perform the test and send results at the specified time according to the instructions of the participants on the relevant form.
Central Administration for Drug Control	Preparing and sending PT final report to participants (10 days)

5.5.Service fees

Service	Fees (L.E)
Application for participation in the PT program	5000

5.6.General Terms and Conditions:

- The applicant must adhere to the regulatory rules and technical controls issued by the Egyptian Drug Authority.
- If the applicant does not adhere to the specified time frames, the application is considered to be canceled.
- If the applicant does not confirm participation in any of the rounds organized by the Egyptian Drug Authority, the application is considered to be canceled.
- The applicant has the right to submit an appeal in case of Non-satisfactory evaluation or to get additional time for the test.

5.7.Official E-mails

- For application and inquiries
  dc.edapt@edaegypt.gov.eg
- For complaints
  complaint@edaegypt.gov.eg

5.8.Electronic links

- Application Form:
  https://forms.office.com/r/1Xk1eQyAYj
- Documents (Annex 1) submission:
  https://forms.office.com/r/2Gkqct4Vhg
- Technical inquiries:

https://forms.office.com/r/d0VdUTuXqN

- Customer feedback:
  https://forms.office.com/r/sAv83nfdY9
- Registration& fees:
  https://forms.office.com/r/tNAzVDBUVG

5.9.Confidentiality deployment

All data and information regarding the EDA-PT program schemes are strictly confidential and anonymous. This includes but is not limited to, the identity of customers/participants and their results.

6. References

- ISO/IEC 17043:2023
- ISO 13528:2022
- Official Method of Analysis of AOAC INTERNATIONAL 22nd, Edition (22)
- The Fitness for Purpose of Analytical Methods
- ICH Topic Q2 (R1) Validation of Analytical Procedures: Text and Methodology

7. Annexes/ Attachments

7.1.Attachments: None

7.2.Annexes:

- **Annex 1**: Document and analysis requirement
- **Annex2**: Labeling& Packaging requirement
- **Annex3**: Requested documents to be delivered as hard copies

Annex 1: Document and analysis requirement

Materials	APIs
	Placebo
	Reference material RM
Documents	Certificate of analysis
	Safety datasheet
	Method of Analysis/ Reference
	Method Validation/ Verification

Annex 2: Labeling& Packaging

- **Vials:**

Name of the manufacturer.	Name.
Expiry/Retest date	Identification code i.e., Batch no., Lot no.
Water content	Potency (if applicable)
Weight	Storage condition
	Safety instructions

- **Sealing:**

Suitable tightly sealed containers according to their storage conditions.

Annex 3: Documents to be delivered as hard copies

- An original application form signed by the authorized person.
- Delegation letter to who receives and delivers the PT items and PT round relevant documents.

  Original copy of the receipt for payment of the service fees