

EDA PT Catalogue Year 2026

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- **List of Abbreviations**

- **EDA-PTP:** EDA Proficiency Testing Program.
- **ILC:** Inter-laboratory Comparison
- **PT:** Proficiency Testing
- **SD:** Standard deviation

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1. Introduction

The Egyptian Drug Authority Proficiency Testing Program EDA PT program is one of the programs of the Accreditation Programs unit in the Central Administration of Drug Control established in accordance to the Minister's Decree no 591 for the year 2021

The policy for using our reports:

Understanding PT/ ILC final report: Review Your Performance, communicate results with your staff and take appropriate actions if needed

Disclaimers:

The revision of **PT/ ILC final report** the only revision to be use of any obsolete revisions of this document is forbidden.

Tampering with, editing, or falsifying any part of **PT/ ILC final report** invalidates its findings.

1.1. Purpose and Scope of proficiency testing

Proficiency testing: is a key element of laboratory quality assurance. It allows laboratories to monitor their analytical performance over time, identify potential issues, and provide independent evidence of technical competence to customers and accreditation bodies.

The program is responsible for organizing proficiency testing/ Inter-laboratory comparison schemes for testing laboratories working in pharmaceutical fields.

Our scope covers various disciplines and techniques, including physical, chemical, microbiological and biological testing

To view the EDA -PTP accredited scope and EGAC accreditation certificate please visit EGAC website > accredited Cabs or EDA Egypt website

1.2. Quality Standards

All PT schemes are conducted in strict accordance with ISO/IEC 17043 (Conformity assessment — General requirements for proficiency testing). Statistical analyses follow the guidelines of ISO 13528.

2. Scheme Organization:

2.1. Coordination and Responsibilities

EDA PT Program maintains a dedicated management team responsible for the design, execution, and reporting of each round. This includes selecting suitable test materials and managing participant data.

2.2. Advisors and Advisory Groups

Whenever needed, the program reaches technical experts and advisory groups provide specialized knowledge for specific matrices or analytes, ensuring that the schemes remain relevant to industry needs and scientifically robust.

2.3. Typical Scheme Framework

A standard PT cycle involves:

1. **Preparation:** Material sourcing and homogeneity testing.
2. **Distribution:** Shipment to participants.
3. **Analysis:** Participants test the material using their routine methods.
4. **Reporting:** Data submission and statistical evaluation.
5. **Final Report:** Issuance of performance scores after ensuring the stability of PT items

2.4. Application

Participants can apply via the official link: [Application for EDA-PT Schemes – Fill out form](#)

Or communicate by the official E-mail: dc.edapt@edaegypt.gov.eg

2.5. Participation

Frequency of participation is determined by the specific scheme cycle as announced in our Annual PT Plan (visit EDA Egypt website media)

2.6. Fees

The service fees are identified according to the minister's decrees 579 for year 2021 and 273 for year 2022 for further updates, please visit EDA Egypt website.

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2.7. Confidentiality

- EDA-PT program is responsible for all data & information created or obtained during the performance of different PT activities and is considered proprietary information and regarded as confidential.
- When EDA PT program intends to place in public domain any information or when required by law to release confidential information, it informs the concerned clients in advance with this information unless prohibited by law.
- All information submitted to EDA-PT program is kept strictly confidential and anonymous. In all reports issued by EDA- PT program, participants are referred to as “Lab XX”, where XX is a code number. Electronic communications conducted by official EDA email individually to each participant.

3. Test Materials:

3.1. Preparation

Materials are prepared closely to routine samples, in our schemes we use PT items from different sources as: CRM, formulated samples, market authorized samples.

Packaging and storage materials vary according to pt items used, preparation methodology, MSDS, long/ short storage.

All details about preparation mentioned in the PT/ILC final report

3.2. Quality Control:

Rigorous Homogeneity and Stability testing are performed to ensure that any variation in results is due to laboratory performance, not the material itself. The measurements can be performed by program staff or outsourced by competent laboratory while the study is performed by the program statistician.

PT items homogeneity may not be verified experimentally depending on their source.

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3.3. Non-conforming Products

Any batch failing quality control is quarantined. Participants are notified immediately if a distributed sample is found to be non-conforming.

4. Reporting of Results:

4.1. Timescales

Participants are provided with a clear window typically 10 days for most of schemes, it may be shorter due to material stability cautions or longer, depending on the test nature or in case of providing samples for participants outside the Arab Republic of Egypt for analysis and submission. Late results are generally not accepted for statistical inclusion.

4.2. Choice of Methodology

The program mostly depends on pharmacopeia methods but it's permitted sometimes to encourage to use their routine methods.

4.3. Reporting of Results

Results must be reported in specified units and formats to ensure comparability.

4.4. Permitted Results

Only one result per laboratory code is permitted unless the scheme specifically requests replicates.

4.5. Evaluation of Performance

The program depends mainly on the z and z' - scores for quantitative analysis, but other scores may be used in case of ILC schemes or to encourage laboratories to evaluate uncertainty we may use zeta-score (ζ).

4.6. Collusion and Falsification

The PT program monitors for suspicious data patterns. Collusion undermines the purpose of PT and may lead to exclusion from the scheme, the following action will be taken if such case happens:

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- The program halts the issuance of the final report to participants and communicates with the participants to send all raw data and calculation sheets and all relevant documents to ensure the traceability of the submitted results.
- The program initiates an investigation and reviews all results to ensure their validity and whether the results are proved to be falsified /colluded or not
- In case falsification or collusion is confirmed the results will be discarded and the program will evaluate if the selected statistical design used for the evaluation of the performance of the participants is still valid.
- The report will be issued if there's no impact of exclusion of falsified results on the statistical design otherwise the scheme will be cancelled and participants will be informed.

5. Data Analysis and Performance Assessment:

5.1. Approaches

- PT program use Robust Statistics to minimize the influence of outliers.
- Depending on number of participants program use Median, Algorithm or Mode.
- If number of participants is more than 30, arithmetic mean may be used.

5.2. Qualitative

Assessment based on "Pass/Fail", mostly participants receive from 3-5 different samples to show percent matching with real results and the decision for satisfactory test taken for 100% matching otherwise the result considered non- satisfactory.

5.3. Quantitative

Performance based on numerical deviation from the assigned value using one of the methods mentioned in clause 4.5 "Evaluation of performance"

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5.4. Assigned Values and Uncertainty

The assigned value is typically determined by the consensus of participants and The **Standard Uncertainty** of this value is calculated based on GUM bottom- up approach general

$$\text{expression: } U(x_{pt}) = \sqrt{u_{char}^2 + u_{hom}^2 + u_{stab}^2 + u_{trans}^2}$$

For the assigned value evaluated as reference value or from theoretical calculations of formulated PT items, The **Standard Uncertainty** of this value is calculated based on general expression.

$$U(x_{pt}) = \frac{1.25 \times S^*}{\sqrt{P}}$$

where S* is robust SD and P is no. of participants.

5.5. Standard Deviation for Proficiency Assessment (SDPA)

The SDPA defines the "fit-for-purpose" criteria and can be derived from a perception of fitness for purpose, a general model (the Horwitz equation), or from the PT round itself.

5.6. Interpreting Results

For z, z' and ζ scores

- $|\text{score}| < 2.0$: Satisfactory performance.
- $2.0 < |\text{score}| < 3.0$: Questionable (Warning signal).
- $|\text{score}| > 3.0$: Non-satisfactory (Action signal).

6. Final Report and Feedback:

6.1. Reports

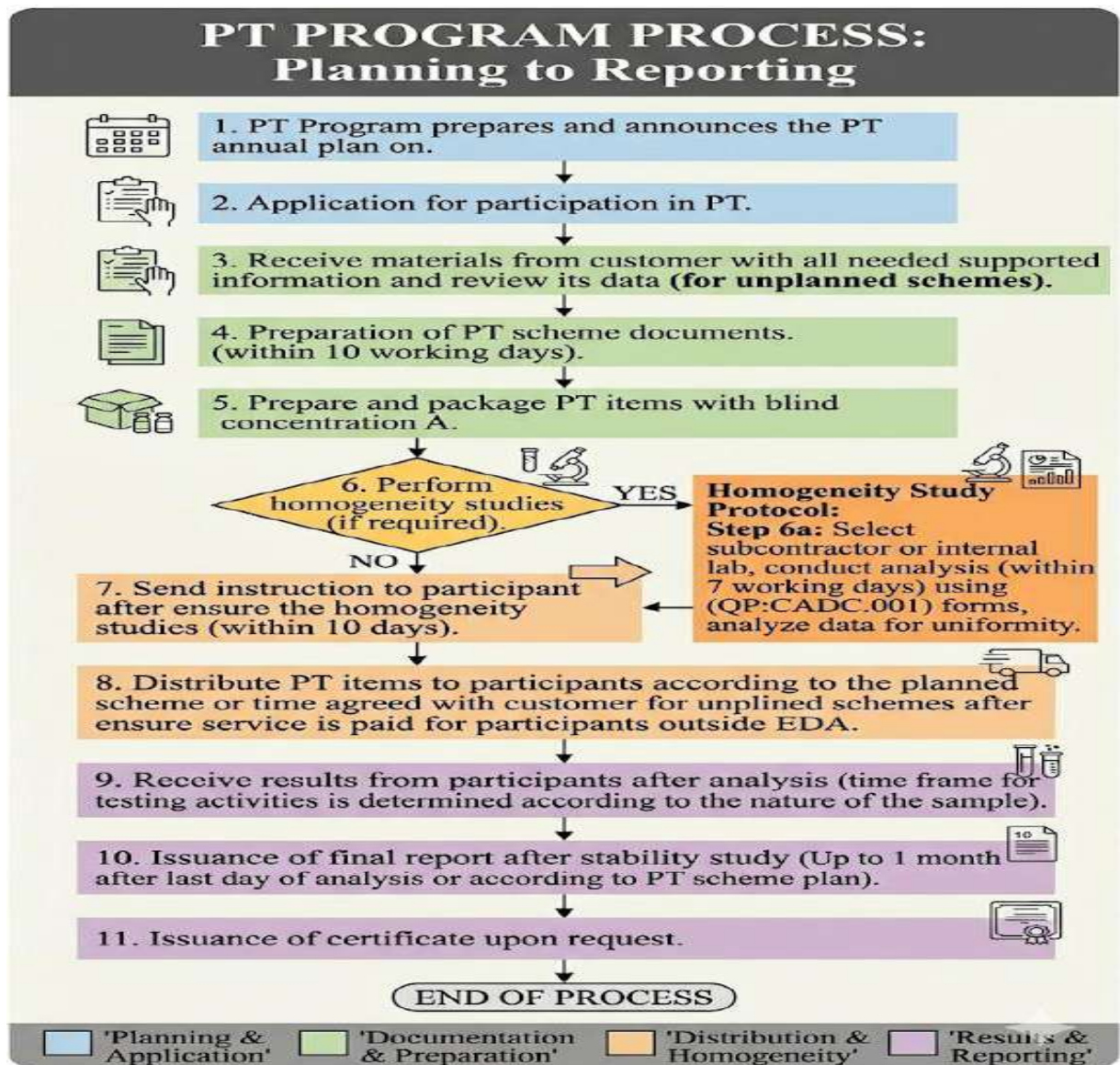
Program release an approved PT/ ILC Final reports include full details about preparation, outsourced activities, summary statistics and performance charts which is sent electronically to each participant attached with its lab code.

6.2. Advice

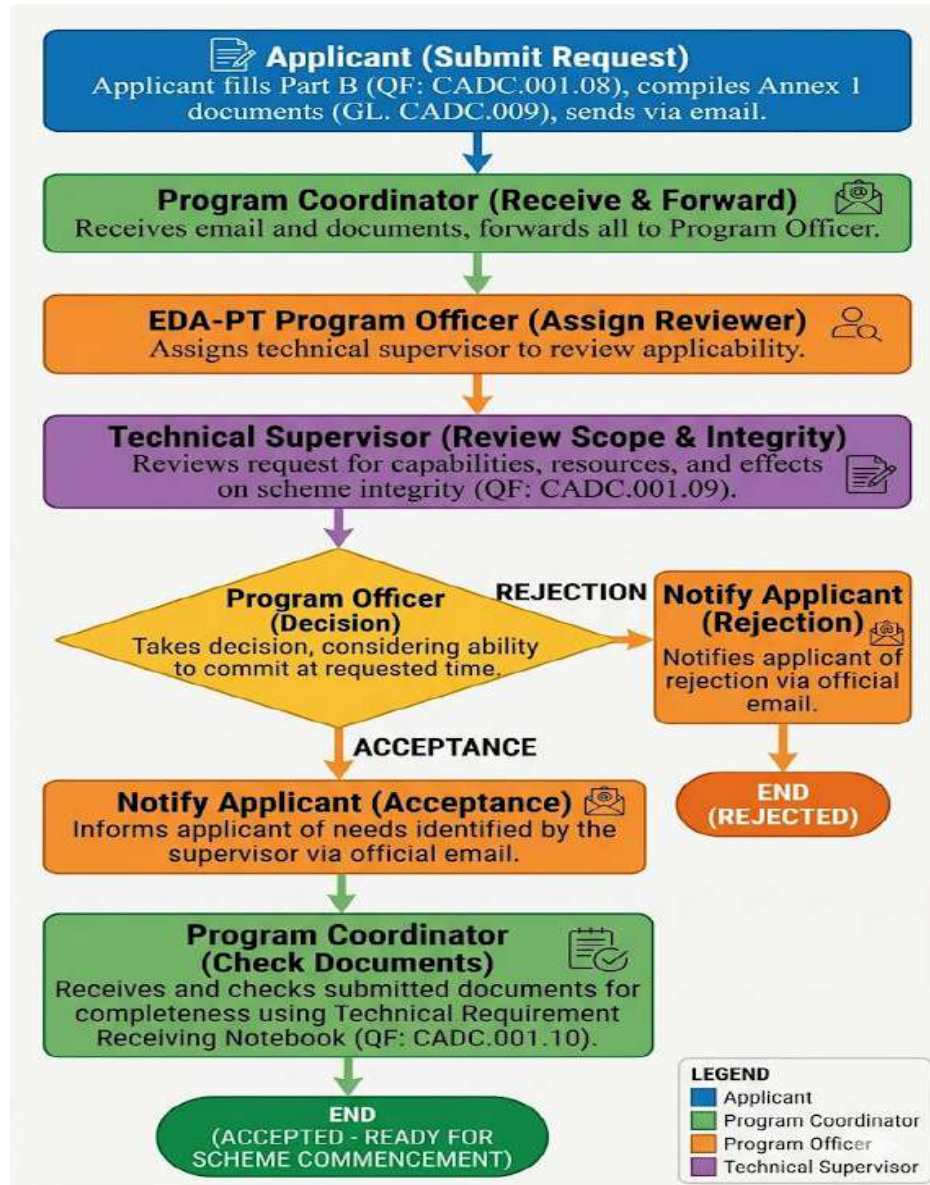
The advice and program recommendations are also covered in the PT/ILC report, If a scheme shows a general trend of poor performance, the PT program may offer technical commentary to assist in troubleshooting

7. Annexes:

7.1. Annex I: Process flow chart



7.2. **Annex II:** Documentation for non-planned/bespoke PT requests.



8. Contact information:

- 8.1. **Contact person:** Dr/ Eman Abdel Sayed Abdel Ghaffar
Mobile number: 01013651038
- 8.2. **Official Email:** dc.edapt@edaegypt.gov.eg
- 8.3. **Application link:** <https://forms.office.com/r/1Xk1eQyAYi>
- 8.4. **Technical Inquiries link:** <https://forms.office.com/r/d0VdUTuXqN>

9. References:

- 9.1. ISO/IEC 17043:2023.
- 9.2. ISO 13528:2022; Annex C “Robust Analysis”
- 9.3. ISO 13528:2022; Annex B “Homogeneity and stability of proficiency test items”

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History Table

Version No.	Issue date	Summary of Changes
01/2026	7/4/2026	Initial issue