

**President of Egyptian Drug Authority's Decree No. (273) of 2022
Regarding the Enrolling of Proficiency Testing within the Mechanisms of
Evaluating Good Laboratory Practices in the Quality Control laboratories
the Factories of Pharmaceutical Companies**

President of Egyptian Drug Authority:

Having Perused:

- Law on Pharmacy Profession Practice No. (127) of 1955, and its amend-ments;
- Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019, and its executive regulation;
- Minutes of the Authority's Board of Directors' meeting held in its session on 20/7/2020;
- Material presented by the Chairperson of the Central Administration of Drug Control; and
- Having considered the interest of work.

Has Decided

(Article One)

The proficiency testing shall be enrolled as one of the items for the periodic evaluation of good laboratory practices for the quality control laboratories in the factories of pharmaceutical companies.

(Article Two)

Without prejudice to the applied procedures and rules regarding inspection of factories of pharmaceutical companies, the result of the proficiency testing shall represent (50 percent) of the total points of the good laboratory practice scoring related to the quality control laboratories periodical evaluation visits in the aforementioned factories.

(Article Three)

The head of the Central Administration of Drug Control shall issue the time schedule of the phased implementation of the program, provided that the schedule shall include the production lines for which withdrawal decisions have been issued by the Supreme Inspection Committee according to the number of withdrawal times, the number of conducting the proficiency testing rounds for each case and the number of tests that must be conducted monthly or annually, depending on conditions, in order to passing the test. The regulatory guideline of the program's executive mechanism shall be issued within five days from the approving date hereto.

(Article Four)

The service fee attached hereto for the proficiency testing program services provided by the Accreditation Programs Unit affiliated to the Central Administration of Drug Control shall be collected.

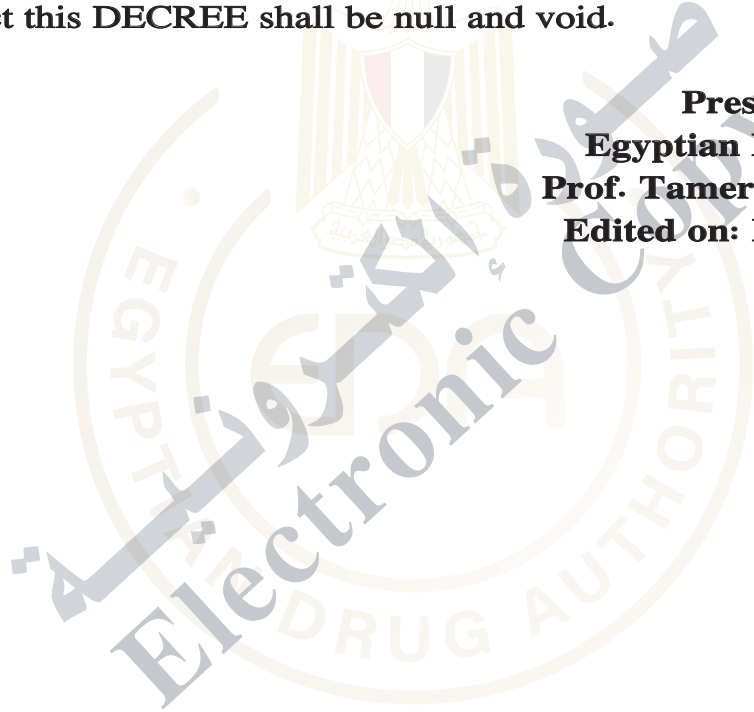
(Article Five)

The stipulated fees of the services shall be deposited into the account of Egyptian Drug Authority unit of account.

(Article Six)

This decree shall come into effect from the day following the issuance date of the time schedule and its regulatory guideline and any other provisions that may contradict this DECREE shall be null and void.

**President of
Egyptian Drug Authority
Prof. Tamer Mohamed Essam
Edited on: May 12th, 2022**



The Service Fee of the Proficiency Test Program Provided by the Accreditation Programs Unit Affiliated to the Central Administration of Drug Control

SN	Provided service	Service fee in LE
1.	Sending the sample of the proficiency testing program of evaluating the good laboratory practice.	2,500 LE
2.	Examining the analysis results submitted by the company for evaluating the good laboratory practice.	2,500 LE
3.	Issuing a certificate of passing the proficiency test of evaluating the good laboratory performance- accredited by EGAC	1,000 LE

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