

**President of Egyptian Drug Authority's Decree No. (342) of 2022  
Regarding Accrediting the Quality Control of The Cosmetic Products**

**President of Egyptian Drug Authority:  
Having Perused:**

- Law on Pharmacy Profession Practice No. (127) of 1955, and its amendments;
- Law on Practicing the Profession of Medical Chemistry, Bacteriology and Pathology; and Organizing Medical Diagnostic Laboratories, Scientific Research Laboratories, Biopharmaceutical Laboratories No. (367) of 1954 and its amendments;
- Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019, and its executive regulation;
- Decree of the President of Egyptian Drug Authority No. (122) of 2022 on Enrolling and Circulating Cosmetics
- Decree of the President of Egyptian Drug Authority No. (123) of 2022 regarding service fees for Enrolling and circulating cosmetics products.
- Material presented by the Chairperson of the Central Administration of Drug Control; and
- Having considered the interest of work.

**Has Decided**

**(Article One)**

This decree shall apply to the accreditation of quality control laboratories for cosmetics. For the purposes of implementing its provisions, the following terms shall have the meanings set out for each term hereunder:

**Quality control laboratories of cosmetics products:** They are independent laboratories established in accordance with applicable laws and regulations, or laboratories affiliated to any of the pharmaceutical institutions licensed by Egyptian Drug Authority, which grant a certificate of accreditation for tests related to the safety and security of various groups of cosmetics.

**Cosmetics products :** They are products prepared to be applied to the external parts of human body, teeth and the mucous membrane of oral cavity for the purposes of cleaning, perfuming, protecting or keeping them in a good condition; changing and improving their appearance or any other products existed or developed and classified as cosmetics according to the international references.

**(Article Two)**

The laboratories that meet the conditions shall be granted an accreditation certificate of testing the safety and security of different groups of cosmetics. These laboratories shall be enrolled in the list of cosmetics quality control laboratories in the Central Administration of Drug Control.

**(Article Three)**

Without prejudice to the requirements of laboratory licenses in accordance with the law of establishing them, the laboratories accredited by Egyptian Drug Authority shall be considered one of the pharmaceutical facilities in accordance with the definition contained in Article (1) Paragraph (5) of the executive regulations of the law on establishing the Egyptian Drug Authority promulgated by Prime Minister's Decree No. (777) of 2020.

**(Article Four)**

The validity of the accreditation certificate is one year; where the laboratory's performance shall be evaluated annually to ensure its compliance with the requirements of the laboratories quality control. The application of renewal of the laboratory's accreditation shall be submitted at least three months before the end of the accreditation certificate validity.

**(Article Five)**

The head of the Central Administration of Drug Control shall issue a regulatory guideline of the mechanisms and procedures of implementing this decree within five working days from the date of its approval.

**(Article Six)**

Without prejudice to the applicable laws and regulations, the laboratory which violate the provisions of the decree hereto or the regulatory guideline of the mechanisms and procedures referred to, the accreditation certificate of the laboratory shall be withdrawn and it shall be removed from the list of accredited laboratories in addition to the criminal liability that may result whenever it is necessary.

**(Article Seven)**

The service fee attached hereto shall be paid for the services provided by the Central Administration of Drug Control regarding the Authority's accreditation program of the quality control laboratories of cosmetic products.

**(Article Eight)**

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

**(Article Nine)**

This decree shall come into effect from the date of its issuance, and any other provisions that may contradict this DECREE shall be null and void.

**President of  
Egyptian Drug Authority  
Prof. Tamer Mohamed Essam  
Written on: June 9th, 2021**

**The service fee of the Authority's accreditation program of laboratories of quality control for cosmetics submitted by the Central Administration of Drug Control**

SN	Provided service	Service fee in LE
1.	An application to obtain / renew the accreditation certificate.	5,000 LE
2.	An application for approving / renewing of test accreditation for a main category of cosmetic products.	20,000 LE
3.	An application to approve an additional test product for an approved group during the certificate validity period.	5,000 LE
4.	Approving of the analysis results for a single batch of a local cosmetic product.	2,000 LE
5.	Approving of the analysis results for a single batch of an imported cosmetic product.	4,000 LE

