Notice to Applicant

Central Administration of Drug Control
Accreditation Programs Unit

The most frequently asked questions for the Egyptian Drug Authority Certification of Reference Materials Program

For 2025

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FAQs

Question	Answer
First : General questions	
1. What's the aim of the program?	• The Egyptian Drug Authority Certification of reference materials program aims to provide a mechanism for certifying and the continuous provision of the required reference materials by the general administration of quality control laboratories, and accordingly ensuring the rapid fulfillment of analysis requirements and the arrival of safe and effective drugs to the Egyptian patient.
2. What are the privileges of the program?	• Granting an accreditation certificate for the qualified reference materials, valid for three years. • Logging the qualified reference materials into the list of approved reference materials. • Continuous verification for the reference materials received by the General Administration of Quality Control Laboratories in the Central Administration of Drug Control.
3. Who can apply for reference material certification?	• Reference material suppliers or their agents. • Local and international pharmaceutical companies. • Public and private service laboratories.
4. What are the communication channels for the program?	• **The official email of the Egyptian Drug Authority Certification of Reference Materials Program** dc.crmlabaccredit@edaegypt.gov.eg • **Electronic links of the program** • **Link** to submit annex I documents: https://forms.office.com/r/VSkb5CLpqS • Direct communication with EDA CRM team at AGOUZA branch. • **Link to the EDA White List** https://edaegyptmy.sharepoint.com/:w:/g/personal/dc_crmlabaccredit_edaegypt_gov_eg/Eet0pLfjVbNdWPESjukjCgBzKEZ6RMCf0CH2OEMlDmDMw?rtime=RmBZ8z0920g

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5. What are the reference material groups according to EDA CRM Accreditation Program?	• **Group 1**: this group includes official references, standards from the national institutes of measurement, and internationally recognized bodies and organizations. The reference materials of this group are not subjected to any evaluation or verification procedure. • **Group 2A**: Reference materials supplied by a body that is accredited according to ISO 17034, this group is evaluated by reviewing the attached documents and conducting verification if necessary • **Group 2B**: Reference material is supplied by a party that meets the requirements of ISO 17034, this group is evaluated by reviewing the attached documents and conducting verification • **Group 3**: Reference materials from other sources (working standards/ secondary reference materials). – Tests for certification and verification are carried out for this group.
6. What is the Egyptian Drug Authority's White List of approved standard substances?	• It is a list of reference materials from groups 2A and 2B from suppliers that have been evaluated and approved by EDA CRM program and announced on the Authority's official website. These materials can be submitted to the general administration for approval and control to fulfill the analysis requirement.
7. Does the Egyptian Drug Authority provide reference materials for pharmaceutical companies?	• The Egyptian Drug Authority does not provide reference materials to pharmaceutical companies. But it can use the available reference materials in case those companies, wishing to certify their reference materials, have difficulties in providing these necessary materials in order not to obstacle the certification process and fulfill the needs of these companies.
8. Does the program include the certification of reference materials required for analysis of pesticides, disinfectants, and cosmetics?	• The program includes the certification of the reference materials required for the analysis of medicinal pharmaceutical products. The Egyptian Drug Authority's CRM program does not yet include the certification of reference materials required for the analysis of pesticides, disinfectants, or cosmetics. The program only includes the certification of reference materials for the analysis of human, veterinary, and herbal products (Pure markers).

Question	Answer
Second: Questions related to the implementation process	
9. What are the pre-accreditation procedures?	1. The applicant (supplier/company) sends an email requesting accreditation. 2. The Accreditation Program Unit, through the CRM program, sends the application form and the required documents to be submitted. 3. The applicant pays the application fee, submits the payment receipt through E Payment system, and fills out the application form. 4. The applicant submits the documents required to be uploaded electronically (Annex I) along with an application form signed by the company's authorized representative and a copy of the payment receipt, via the relevant link. 5. The Standard Materials Program Officer in the Accreditation Programs Unit will respond to the company with acceptance or rejection after reviewing the documents via the official email, specifying any analysis requirements and the number of samples required. 6. If the requirements are met, the applicant shall book an appointment to pay the analysis fees and submit a maximum of 12 vials (Annex 2) and the documents required to be submitted in paper form (Annex 3) and any analysis requirements to the Accreditation Programs Unit within 5 working days. 7. If the analysis results conform, the Accreditation Programs Unit reviews the results and issues a final report and COA for each reference material. 8. In the event that the standard material(s) are compliant with a standard material supplier or their agent, the standard material(s) and the name of the supplier/agent will be listed in the EDA Certified Reference Materials white list on the official website of the Egyptian Drug Authority.

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	9. The authorized representative of the company shall receive the verified standard materials and their analysis certificates and shall sign a declaration of his full responsibility for the preservation, storage and safety of the standard materials and for maintaining the Egyptian Drug Authority label on the vials, as well as for receiving the original certificates. 10. In case the analysis results don't conform, the applicant will be informed of the rejection of the reference material and other samples can be sent for re-analysis.
10. What are the post-accreditation (verification) procedures?	1. The company sends an email requesting verification of the standard material(s). 2. The applicant pays the fees within 5 days and retains the payment receipt. 3. The applicant submits the standard material sample vials, up to a maximum of 12 vials, any required analysis requirements, and the original receipt for payment of the verification test 4. In case of changing the supplier of the reference material, the new documents will be reviewed and the full analysis fees will be paid.
11. When does a company apply for a verification test for a standardized material, Group 3?	• Verification of standard materials is conducted once a year or when the company needs additional vials beyond the number approved, whichever comes first. The program also has the right to request a verification test for any of the reference materials approved by EDA if necessary.
12. What are the documents required to certify Group 2A reference materials?	1. A copy of a valid ISO 17034:2016 certificate is attached with the accreditation scope. 2. Evidence of legal representation in case of dealing with official agents of international companies or suppliers of reference materials.

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	3. Analysis certificates or reports including the data required in accordance with ISO 33401:2024, indicating the accreditation mark of the accreditation body or evidence that the analyses included therein have been subject to accreditation.
13. Are samples required to be submitted to certify Group 2A reference materials?	• No samples are required to be submitted, only documents are reviewed and samples are provided only when requested.
14. How to deal with reference material from a supplier accredited according to ISO 17034, but not listed in his accreditation scope?	• In this case, the material is evaluated as a reference material from Group 2B. The verification tests are performed without the need to submit primary reference material. In case of conformity, the reference material will be listed in the **EDA White list**.
15. What are the documents required to certify a reference material from Group 2B?	1. Certificate of Analysis. 2. Material safety data sheet. 3. Evidence of characterization of submitted standards (e.g. IR, UV spectra, LC/MS, etc. …).
16. What are the documents required to certify a reference material from Group 3?	1. Certificate of Analysis. 2. Material Safety data sheet. • **In case of In-house reference material also send:** 1. Testing Monograph 2. Validation studies for methods described in the relevant testing monographs. 3. Evidence of characterization of submitted standards (e.g. IR, UV spectra, LC/MS, etc…).

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17. What is the number of vials required for analysis in group 3?	• Maximum 12 vials. 10 vials from the submitted vials are delivered to the company after conformity, identified using EDA's labeling.
18. What are the storage conditions and closure requirements for the reference material containers?	• Reference material shall be submitted in suitable packages according to the storage conditions of the material mostly in an amber glass, tightly closed and sealed with a lid that suits the specifications of each material.
19. What is the content of the vial's label?	• Standard name. • Name of manufacturer. • Identification code i.e. Batch no., Lot no. • Expiry/Retest date • Potency (if applicable) • Water content • Storage condition • Weight • Safety instructions
20. In the case of difficulty in the provision of a primary reference material for certification, what is the procedure required to approve this material?	• Availability of primary reference materials can be inquired through the program's official mail. If it exists, the company will provide the sample vials required for certification without the need to submit the primary reference material. • In case the primary reference material is not available, the company submits an appeal to the head of Central Administration of Drug Control for an exemption from providing the primary reference material, attached with documents that declare the difficulty of providing it. The request and documents are reviewed by the Accreditation Program team in the Accreditation Programs Unit with a recommendation to take appropriate decisions.

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21. What's the method for inquiring about the availability of primary reference material?	• The availability of any material can be inquired through the official email of the Standard Materials Accreditation Program dc.crmlabaccredit@edaegypt.gov.eg
22. Does the pharmaceutical company have the right to use EDA RM for another company?	• EDA-certified reference material can only be used by its applicant company.
23. In case of toll manufacturing, can the manufacturer company apply to the program for certifying a RM used in analysis of the owner company product?	• Either companies, the manufacturer or the owner of the pharmaceutical product, can apply to the program, per the general terms and conditions.
24. Is it possible to certify a reference material from group 2B after dividing its content into new vials?	• In this case, it will be treated as a reference material from group 3, and the procedures for certifying reference material of this group will be applied to certify the new vials.
25. Is it possible to divide the primary reference material among several companies?	• It is not allowed to open the vials of the primary reference material and divide it among several companies, but a maximum of 5 companies can submit applications for the certification of the same substance at the same time and participate in the provision of the primary reference material

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	vial, necessary for analysis, with the commitment of these companies to provide the vials for the reference material samples required to be certified on the same day.
26. Are impurities accepted in the Standard Materials Certification Program?	• Yes, it has been approved using the same procedures for approving reference materials for active ingredients for all groups of standard materials in the program.
27. Can pharmaceutical primary reference standards (ex: USP, EDQM) be used to standardize Group 3 standard materials without the presence of an assigned value?	• These materials are used according to the uses mentioned in the monographs of these relevant constitutions. If the reference material is used for purposes other than those stated in the monograph, it is necessary to ensure that the material is suitable for this purpose (assigned value). Example: In the case of quantitative tests, a standard material with a specific value must be used. This is not required in the case of qualitative tests.
28. Why suppliers are not added to EDA CRM white list instead of the standard materials?	• In accordance with the international requirements for good laboratory practices, each standard material is technically evaluated before use to verify its suitability and suitability for the purpose for which it is used. If the supplier produces the same standard material with different specifications, an evaluation must be conducted to ensure that the type of material is suitable for the analysis requirements of the regulatory laboratories to obtain reliable results.