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 2023

Code: EDREX: NP. CADC.007
Version No:1/2023
Issue Date: 27/4/2023
Effective date (if needed): 27/4/2023

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. 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 • **Links for inquiries about the availability of a primary reference material** https: //docs.google.com/forms/d/e/1FAIpQLSd-n7hCLza0QIggR2l-Wl9iVVheA8zr4UYp81gBMnGN1GjoDQ/viewform https://docs.google.com/spreadsheets/d/1c2Bp97z08k9tXpzwFmc--g1n0n-E3VtaE6vqNxx6Xcs/edit#gid=1441246793 • **Link to the EDA White List** https://edaegyptmy.sharepoint.com/:w:/g/personal/dc_crmlabaccredit_edaegypt_gov_eg/Eet0pLfjVbNdWPESjukjCgBzKEZ6RMCf0CH2OEMlDmDMw?rtime=RmBZ8z0920g

4. 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.
5. What is EDA white list?	• 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.
6. 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.
7. What are the program's services fees?	

SN	Service	Fees
1	Request to grant/renew the certification of one reference material	5000 LE
2	Issuance of COA of verification tests of an EDA-certified reference material	1000 LE
3	Qualification and analysis of a reference material of an active pharmaceutical ingredient	5000 LE
4	Qualification and analysis of reference material of reference material of an impurity.	10,000 LE
5	Conduction of verification tests for reference material	2000 LE

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).

Second: Questions related to the implementation process

9. What are the pre-accreditation procedures?	1. The applicant (supplier/company) sends an email requesting certification 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, 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-authorized person. 5. The Accreditation Programs Unit responds to the company after studying the documents via the official email, requests any file assessment or analysis requirements, and informs the applicant of the number of vials required to be sent for analysis if required. 6. If the requirements are met, the applicant shall deliver the vials, with a maximum of 10 vials (Annex II), the documents required to be delivered in paper (Annex III), 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 analysis report and COA for each reference material. 8. 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 procedures?	- The company wants to verify a reference material(s) and sends an email to request verification of the reference material(s) - The applicant delivers samples of the candidate reference material, with a maximum of 10 vials. - The verification test is performed in the Reference laboratory in EDA within 5 working days.

11. What are the documents required to certify Group 2A reference materials?	- A copy of a valid ISO 17034:2016 certificate is attached with the accreditation scope. - Evidence of legal representation in case of dealing with official agents of international companies or suppliers of reference materials. - COAs or reports including the data required per ISO guide 31, indicating the accreditation logo of the accreditation body.
12. 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.
13. 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**.
14. What are the documents required to certify a reference material from Group 2B?	- Certificate of Analysis. - Material safety data sheet. - Evidence of characterization of submitted standards (e.g. IR, UV spectra, LC/MS, etc. …).

15. What are the documents required to certify a reference material from Group 3?	- Certificate of Analysis. - Material Safety data sheet. In case of In-house reference material also send: - Testing Monograph - Validation studies for methods described in the relevant testing monographs. - Evidence of characterization of submitted standards (e.g. IR, UV spectra, LC/MS, etc…).
16. What is the number of vials required for analysis in group 3?	- Maximum 10 vials. Two vials are used for analysis, and the remaining vials are delivered to the company after conformity, identified using EDA's labeling.
17. 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.
18. 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

19. 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 relevant link. 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.
20. What's the method for inquiring about the availability of primary reference material?	- The availability of any material can be inquired using these links: https://docs.google.com/forms/d/e/1FAIpQLSd-n7hCLza0QIggR2l-Wl9iVVheA8zr4UYp81gBMnGN1GjoDQ/viewform https://docs.google.com/forms/d/e/1FAIpQLSd-n7hCLza0QIggR2l-Wl9iVVheA8zr4UYp81gBMnGN1GjoDQ/viewform
21. 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.

22. 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.
23. 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.
24. 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 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.