Central Administration of drug control
Accreditation Programs Unit

FAQs for EDA Pharm Lab Accreditation Program

For 2023

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FAQs

Question	Answers
First: General questions	
1. What is the purpose of the program?	The program aims to upgrade the level of the pharmaceutical industry and the regulatory performance in the quality control laboratories of pharmaceutical companies by granting the Egyptian Drug Authority an accreditation certificate for the quality control laboratories in the factories of pharmaceutical companies for some pharmaceutical products in accordance with the standards set by the Egyptian Drug Authority.
2. What is the Program privileges?	- File assessment is done once upon applying for product accreditation. And there is no other assessment when the product batch is randomly withdrawn. - The analysis results of pharmaceutical companies' laboratories are approved without the analysis in the laboratories of the Central Administration of Drug Control for the product listed in the accreditation scope attached to the company certificate. - The company is granted an accreditation certificate (valid for one year and to be renewed) for the accredited products. - Granting additional privileges, in case of accreditation of more than five products, according to the number of products applied to be accredited. - Fulfilling a quality requirement of the Ministerial decree No. 273 for 2022 by participating/ passing proficiency test as one of the evaluation tools for accredited laboratories, without any additional fees.
3. What types of batches which included in the program?	- The batches of random withdrawn samples. - Second and third production batches. - Batches that obtained approval for variation such as supplier addition, supplier change, or change of manufacturing site.
4. What is the duration for obtaining the certificate?	- The accreditation process may take from 40 to 70 days in case of commitment to the predetermined announced time frames.

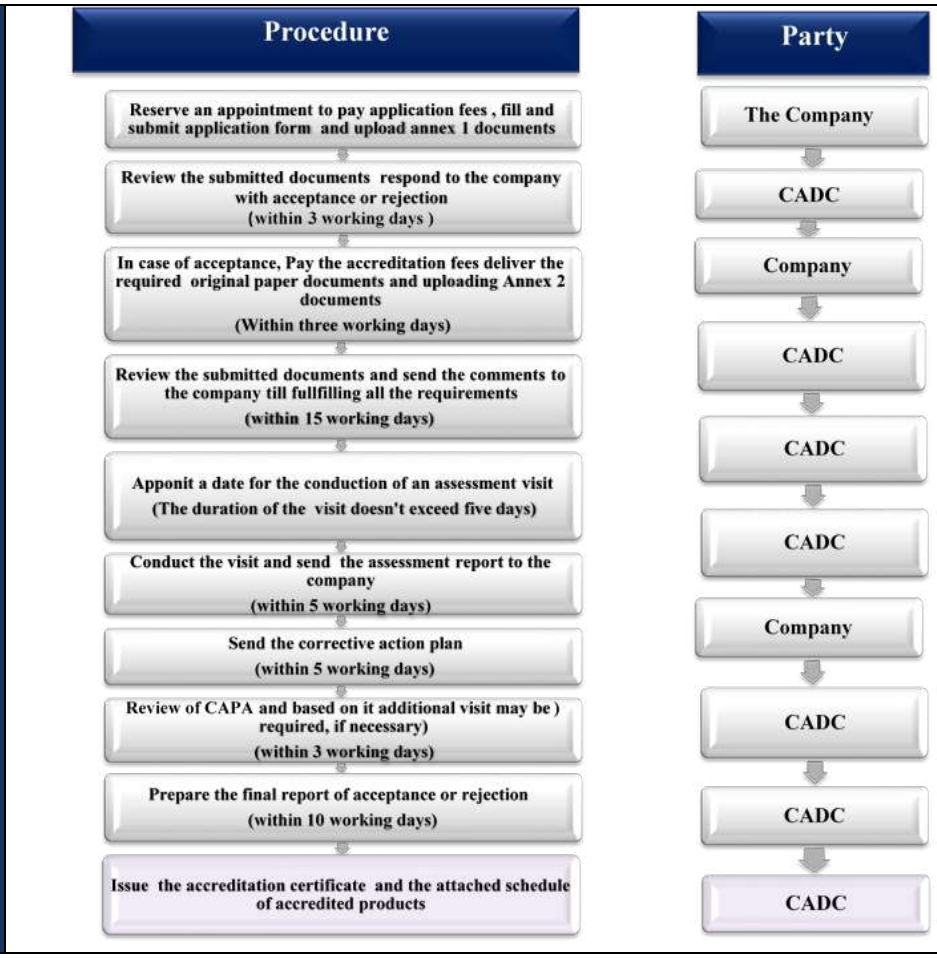
5. What is the minimum allowed number of products to grant the accreditation certificate?	The company shall apply for the accreditation of at least five registered products (random withdrawn samples).
6. Does the company grant more privileges in case of the increasing number of accredited products?	The Company grants additional privileges according to:

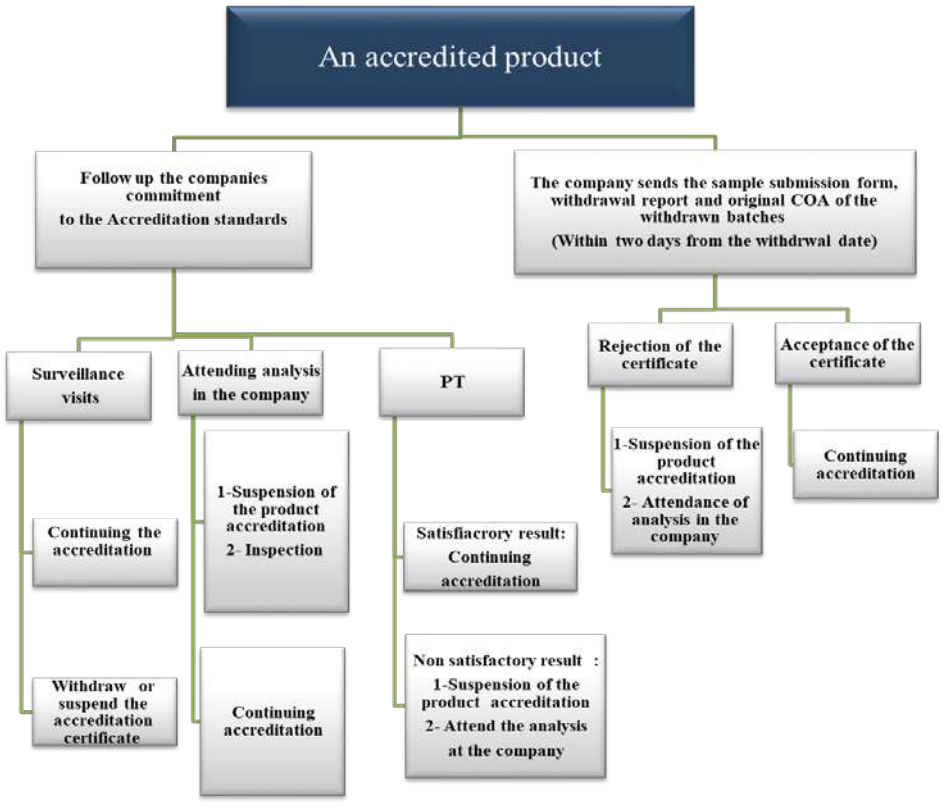
	Type of service	Additional privileges
1	Accreditation request for "5 to 9 " registered products (random withdrawn samples).	None
2	Accreditation request for “10 to 14” registered products (random withdrawal samples), with permission to submit accreditation requests for the same products that obtained approval for supplier addition or change.	Request to accredit additional two products, “Second and third production batches, a batch that has obtained an approval for supplier addition or change or change in manufacturing site.”
3	Accreditation request for “15 to 19” registered products (random withdrawal samples), with permission to submit accreditation requests for the same products that obtained an approval for supplier addition or change.	Request to accredit additional four products, “Second and third production batches, a batch that has obtained an approval for supplier addition or change or change in manufacturing site.”
4	Accreditation request for more than “20” registered products. (Random withdrawal samples), with permission to submit accreditation requests for the same products that obtained approval for supplier addition or change.	Request to accredit additional six products, “Second and third production batches, a batch that has obtained an approval for supplier addition or change or change in manufacturing site.”

7. What are the fees for the different program's services?

The service	The service fees
Request to grant /renew an accreditation certificate	Five thousand Egyptian pounds (5000 LE)
Request for accreditation of a registered product (random withdrawal)	Ten thousand Egyptian pounds (10,000 LE)
Request for accreditation of second and third production batches of a product.	Twenty thousand Egyptian pounds (20,000 LE)
Request for accreditation of a product that obtained approval for change in manufacturing site.	Thirty thousand Egyptian pounds (30,000 LE)
Request for accreditation for a product that obtained approval for supplier addition or change.	Thirty thousand Egyptian pounds (30,000 LE)
Approval of the analysis results of each batch.	Two thousand Egyptian pounds (2000 LE)
Request for annual renewal of accreditation of an accredited product.	Ten thousand Egyptian pounds (10,000 LE)

8. What are the program communication channels?	Email: dc.labaccredit@edaegypt.gov.eg
Second: Questions related to the implementation process	
9. What are the Pre-accreditation procedures?	


Procedure
Party
Reserve an appointment to pay application fees , fill and submit application form and upload annex 1 documents
The Company
Review the submitted documents respond to the company with acceptance or rejection (within 3 working days)
CADC
In case of acceptance, Pay the accreditation fees deliver the required original paper documents and uploading Annex 2 documents (Within three working days)
Company
Review the submitted documents and send the comments to the company till fullfilling all the requirements (within 15 working days)
CADC
Apponit a date for the conduction of an assessment visit (The duration of the visit doesn't exceed five days)
CADC
Conduct the visit and send the assessment report to the company (within 5 working days)
CADC
Send the corrective action plan (within 5 working days)
Company
Review of CAPA and based on it additional visit may be required, if necessary) (within 3 working days)
CADC
Prepare the final report of acceptance or rejection (within 10 working days)
CADC
Issue the accreditation certificate and the attached schedule of accredited products
CADC

10. What are the Post-accreditation procedures?	
11. How many surveillance visits is conducted during the year?	- More than one visit is conducted during the year, starting with the initial assessment visit and then follow-up visits, not exceeding three visits and if necessary, in addition to planned periodic surveillance visits with a minimum of one visit can be conducted during the accreditation cycle. The number of visits can be increased according to the company's performance and the extent of its compliance with the program terms and conditions during the year.
12. What is the minimum grade that the company's laboratory must obtain to grant the accreditation certificate?	**The company's laboratory must obtain at least 80% to grant accreditation. When the company obtains a score of 95% or more according to the evaluation standards**: - The company is granted an accreditation certificate valid for three years and the company pays the annual fees for renewing the certificate according to the list of products submitted for renewal. - The company has the right to request approval of another product (second and third batches and batches that obtained approval for supplier addition or change or

	change in manufacturing site) in addition to what is listed t in the accreditation scope. **When the company achieves (90% - > 95%) according to the evaluation standards:** - The company has the right to request accreditation of an additional product (second and third batches and batches that obtained approval for supplier addition or change or change in manufacturing site) in addition to what is listed in the accreditation scope.
13. What is the duration of certificate validity? **When the company can request for renewal?**	- The duration of the certificate is one year and the renewal is requested at least three months before the certificate expiry.
14. What are the criteria for evaluating the performance of an accredited laboratory when renewing accreditation?	- Commitment of the company to the predetermined timeframes for all accreditation steps. - The extent to which company representatives cooperate with the assessment and witness team from CADC during the assessment visits - The score of the company according to the required standards during total assessment visits when granting accreditation or during the validity of the accreditation certificate - There is no suspension of one product or more during the accreditation period. - There is no withdrawal of the accreditation of one product or more during the accreditation cycle. - Proficiency test results (e.g. z score).
15. Does the quality control laboratory of the accredited company have the right to use the accreditation certificate of others?	- No, the accreditation certificate granted by EDA is owned only by the accredited company's quality control laboratories and the company can't use this accreditation to analyze or issue test reports to others.
16. Is the proficiency testing conducted for all the accredited products?	- The frequency of participation in proficiency tests is determined according to the number of accredited products and according to what is necessary.
17. If any change occurs during the accreditation certificate validity period, does this	- Yes, the Program must be notified in case of any changes to the accredited products. Actions are taken after evaluating the weight of the change and its impact.

require informing the program?	
18. In the case of manufacturing for others, who applies to participate in the accreditation program?	- The manufacturer whose quality control laboratories perform the analysis has the right to apply because the program approves the product analysis results issued by the accredited quality control laboratories that analyze these products.
19. Is the accreditation with ISO/IEC 17025 international standard taken into consideration in company evaluation?	- Yes, ISO/IEC 17025 accredited laboratories obtain 5 additional points during evaluation.