Frequently Asked Questions
(Technical assessment and sample analysis)
2025

Code: EDREX: NP.CADC.005
Version No: 2/2025
Issue Date: 26/1/2025
Effective date: 26/1/2025

Frequently asked questions

Question	Explanation
General Questions for Inquiries and Complaints	
How can the electronic services, offered on the official EDA website, be accessed?	Use the link to EDA Shababeek , in the 'Electronic programs and application links' section, on the main page of the EDA website EDA Shababeek ➢ Click on the EDA Shababeek link ➢ Select the Central Administration of Drug Control (CADC) from the list ➢ Select the link to the required service ➢ Fill in the required data in the electronic form Kindly pay attention to the correct selection of the required link and the relevant administration: Evaluation and Approval (registration)/ Post Approval Control (local registered product/imported registered product)
How are applicants notified of any changes in the electronic submission links?	In case any link is changed, this will be announced on the EDA website, and updated in EDA Shababeek
How can a request be placed to change the applicant's official mail, via which correspondence with the Central Administration of Drug Control takes place?	Submit an official request (hard copy) to the General Administration of Technical Support, accompanied with a letter of delegation from the applicant.

Question	Explanation
How is a file for marketing authorization (registration) of a pharmaceutical product submitted?	Use the link to EDA Shababeek on the main page of the EDA website EDA Shababeek and select the link for the required service as follows First: request to make an appointment for payment of fees for submission of registration file at the central administration Second: request to submit electronic file, and upload the e-file. Third: request to submit replies to assessment/analysis requirements Fourth: if requirements are fulfilled, request to make an appointment for submission of samples and required documents
How is a file for marketing authorization (registration) of a cosmetic product/medical device submitted?	Use the link to EDA Shababeek on the main page of the EDA website EDA Shababeek and select the link for the required service First: request to make an appointment to submit file at the central administration Second: file is reviewed upon receipt, and if requirements are fulfilled, a payment permit is issued and the file is accepted. Third: if needed, request to make an appointment to receive/reply to analysis requirements
How is the file uploaded and an appointment made to submit samples and pay fees for post-approval local/imported products?	Use the link to EDA Shababeek on the main page of the EDA website EDA Shababeek and select the link for the required service
How are replies to assessment requirements or analysis requests submitted?	Use the link to EDA Shababeek on the main page of the EDA website EDA Shababeek ➢ Request to make an appointment by select the link to request to submit replies to assessment/analysis requirements ➢ Submit the requirements on the designated date

Question	Explanation
How can the applicant learn about the guidelines issued by the Central Administration Of Drug Control (regarding file assessment, reliance, cosmetics notification system etc..?	➢ Select "Laws, decrees and regulations" from the main page on the EDA website ➢ Select "guidelines" from the menu ➢ Select the link for CADC from the menu CADC Guidelines
How can a chromatography column submitted as an analysis requirement be reclaimed?	Use the link to EDA Shababeek on the main page of the EDA website EDA Shababeek and select the link for the required service
How should the applicant communicate to inquire about a product undergoing technical assessment or analysis, or in case there is an issue with fulfilment of assessment or completion of analysis?	Contact us using the email of the respective administration, which is specified in the procedure for inquires and complaints, published on EDA's website, in CADC's notice to applicant section, according to the following steps: ➢ Use the link EDA Shababeek ➢ Select CADC from the list ➢ Select the link for inquiries about products ➢ Follow the steps specified in the procedure for inquiries and complaints Kindly pay attention when selecting the respective administration: Evaluation and Approval (registration), Post-approval Control (local registered product/imported registered product) Or use the link CADC's notice to applicant directly

Question	Explanation
How can a meeting be arranged to resolve an issue pertaining to file assessment or sample analysis?	**Follow the steps in the procedure for inquiries and complaints published on EDA's website, in CADC's notice to applicant section**
How can a complaint be submitted pertaining to a product undergoing assessment or analysis?	**Follow the steps in the procedure for inquiries and complaints published on EDA's website, in CADC's notice to applicant section**
Questions Concerning File Technical Assessment and Evaluation	
What are the new services that have been introduced?	➢ **Granting Renewal Certificate for registration file renewal—Fast Track** ➢ **Pre-submission file assessment for imported products (for marketing authorization and post-approval variations)—Fast Track** ➢ **Pre-submission file assessment for locally produced products (for marketing authorization and post-approval variations)—Fast Track** ➢ **Pre-submission file assessment for registered imported products —Fast Track** ➢ **Pre-submission file assessment for registered locally produced products —Fast Track**

Question	Explanation
How to benefit from the Updated Procedure for File Review, for post-approval variation batches, to optimize the product's available shelf life	Use the link to EDA Shababeek on the main page of the EDA website EDA Shababeek and select the link for applying for the updated procedure, according to Updated Procedure for File Review for Products Submitted to PAC for Analysis: The product technical file will be assessed prior to production of variation batch, hence the batch certificate of analysis will not be required, and the time taken for file assessment will not affect the available time of circulation of the product in the market
How to benefit from application of the procedure for technical file assessment and sample analysis for the first 3 batches simultaneously, to optimize requirements and reduce turnaround time	For submission of the first 3 batches simultaneously, after assessment requirements for the Administration of Evaluation and Approval have been fulfilled, follow the instructions for the procedure In case the criteria in the instructions are not fulfilled, follow the Updated Procedure for File Review for Products Submitted to PAC for Analysis
What steps should be followed to ensure the fulfilment of the assessment requirements for a file submitted for registration?	Comply to the technical assessment guideline published on EDA's website, which can be reached by selecting "Laws, decrees and regulations" from the main page on the EDA website, selecting "guidelines" from the menu and selecting the link for CADC from the following menu CADC Guidelines
How is the reference determined for the test for impurities and the acceptance limits for a product?	Comply to the technical assessment guideline published on EDA's website, which can be reached by selecting "Laws, decrees and regulations" from the main page on the EDA website, selecting "guidelines" from the menu and selecting the link for CADC from the following menu CADC Guidelines

Question	Explanation
When must testing for the residual solvent be performed on a product?	Consult the decision tree in the technical assessment guideline published on EDA's website, which can be reached by selecting "Laws, decrees and regulations" from the main page on the EDA website, selecting "guidelines" from the menu and selecting the link for CADC from the following menu CADC Guidelines
How is the file for validation of an analytical method prepared?	Consult the guidance in the section for chemical analysis in the technical assessment guideline published on EDA's website, which can be reached by selecting "Laws, decrees and regulations" from the main page on the EDA website, selecting "guidelines" from the menu and selecting the link for CADC from the following menu CADC Guidelines
Will equivalent columns be accepted for the analysis of product samples?	Equivalent columns are accepted, according to the published guidelines
How can a meeting be arranged to discuss and resolve an issue pertaining to file assessment?	Follow the steps in the procedure for inquiries and complaints, published on EDA's website, in CADC's notice to applicant section
What is the procedure for updating/altering the method of analysis of a product?	For a product undergoing registration • Use the link to EDA Shababeek on the main page of the EDA website EDA Shababeek and select the link to request changing the method of analysis of a product under registration For a registered product

Question	Explanation
	• Use the link to EDA Shababeek on the main page of the EDA website EDA Shababeek and select the link to request changing the method of analysis of a registered product
What is pre-submission assessment and what benefit can be gained from it?	The applicant submits a file for technical assessment prior to submission of samples. If the technical requirements are fulfilled, the fulfilment statement is sent to the applicant, as well as the analysis requirements The analysis requirements are to be submitted with the samples collected by EDA inspectors, within the validity period of the fulfilment statement, whereby the file will not be assessed again, saving time
What is the validity period for a pre-submission fulfilment statement?	One year
How is pre-submission assessment applied for?	Use the link to EDA Shababeek on the main page of the EDA website EDA Shababeek and select the link for requesting pre-submission assessment
How are replies to requirements for pre-submission assessment submitted?	Use the link to EDA Shababeek on the main page of the EDA website EDA Shababeek and select the link for submitting replies to pre-submission assessment requirements.
What products are eligible for reliance pathway?	Products that have been granted a Certificate of Pharmaceutical Product by one or more of the NRAs listed in the Technical Committee's approved list of reference authorities.

Question	Explanation
How can one learn about the guideline for the reliance pathway, published on the EDA website?	Select “Laws, decrees and regulations” from the main page on the EDA website, selecting “guidelines” from the menu and selecting the link for CADC from the following menu CADC Guidelines
What is the benefit of applying for the reliance pathway?	The analysis requirements and the analysis time are reduced.
How can the reliance pathway be applied for?	Apply for pre-submission assessment to the administration of Evaluation and Approval (registration) or the administration of Post-approval control (imported registered product) using the relevant service link
When is registration file renewal applied for?	In the course of re-registration proceedings.
What is the procedure for applying for registration file renewal?	Use the link to EDA Shababeek on the main page of the EDA website EDA Shababeek and select the link for requesting registration file renewal.
How is the renewal certificate received?	The certificate is emailed to the applicant as soon as it is issued.

Question	Explanation
Questions Concerning Sample Receipt and Analysis	
What measures can be taken by the applicant to ensure streamlined sample receipt and fulfilment of requirements?	➢ **Follow the Checklist to ensure all requirements are fulfilled prior to submission and ensure streamlined sample receipt**
How can a verified copy of the final report or the approved product composition for a product be acquired from the General Administration of Evaluation and Control?	➢ **Submit a request to the relevant administration (Evaluation and Approval/Post-approval Control). If approved, pay the designated fees.** ➢ **Use the link EDA Shababeek and select the link for the service** ➢ **Fill in the required data in the electronic form and upload an image of the payment receipt, ensuring the correct administration is specified** ➢ **Submit the original payment receipt at the appointed time for receiving the requested document**
How can a detailed final report be acquired from the Administration of Post-approval Control?	➢ **Submit a request to the manager of the Administration of Post -approval Control (PAC), and if approved, pay the designated fees.** ➢ **Submit the original receipt to PAC, and the report will be sent by email**
How can a modification of a product specification be requested, for a product undergoing registration?	**Use the link EDA Shababeek and select the link for the request to modify product specification.**

Question	Explanation
How can amendment of an issued final report be requested?	**Submit a request via email to the respective administration in the General Administration of Evaluation and Control. A reply will be sent within 5 days to the applicant's official email , and the applicant may be directed to use the link EDA Shababeek and select the link for the request to modify product specification**