



# Frequently Asked Questions

## (Technical assessment and sample analysis)

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Question	Explanation
<b>First: General Questions</b>	
<p>How can the electronic services, offered on the official EDA website, be accessed?</p>	<p>Use the link to EDA Shababeek on the main page of the EDA website <a href="#">EDA Shababeek</a></p> <ul style="list-style-type: none"> <li>➤ Click on the EDA Shababeek link</li> <li>➤ Select the Central Administration of Drug Control (CADC) from the list</li> <li>➤ Select the link to the required service</li> <li>➤ Fill in the required data in the electronic form</li> </ul> <p>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)</p>
<p>How is a file for marketing authorization (registration) of a pharmaceutical product submitted?</p>	<p>Use the link to EDA Shababeek on the main page of the EDA website <a href="#">EDA Shababeek</a> and select the link for the required service as follows</p> <p>First: request to make an appointment for payment of fees for submission of registration file at the central administration</p> <p>Second: request to submit electronic file, and upload the e-file .</p> <p>Third: reply to assessment requirements</p> <p>Fourth: if requirements are fulfilled, request to make an appointment for submission of samples and required documents</p>
<p>How is a file for marketing authorization (registration) of a cosmetic product/medical device submitted?</p>	<p>Use the link to EDA Shababeek on the main page of the EDA website <a href="#">EDA Shababeek</a> and select the link for the required service</p>



	<p><b>First: request to make an appointment to submit file at the central administration</b></p> <p><b>Second: file is reviewed upon receipt, and if requirements are fulfilled, a payment permit is issued and the file is accepted.</b></p> <p><b>Third: if needed, request to make an appointment to receive/reply to analysis requirements</b></p>
<p><b>How is the file uploaded and an appointment made to submit samples and pay fees for post-approval local/imported products?</b></p>	<p>Use the link to EDA Shababeek on the main page of the EDA website <a href="#">EDA Shababeek</a> and select the link for the required service</p>
<p><b>How are replies to assessment requirements or analysis requests submitted?</b></p>	<p>Use the link to EDA Shababeek on the main page of the EDA website <a href="#">EDA Shababeek</a> and select the link to request to submit replies to assessment/analysis requirements</p>
<p><b>How can the applicant learn about the guidelines issued by the Central Administration Of Drug Control (regarding file assessment, reliance, cosmetics notification system etc..?)</b></p>	<ul style="list-style-type: none"> <li>➤ Select “Laws, decrees and regulations” from the main page on the EDA website</li> <li>➤ Select “guidelines” from the menu</li> <li>➤ Select the link for CADC from the menu <a href="#">CADC Guidelines</a></li> </ul>
<p><b>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?</b></p>	<p>Submit an official request (Hard cover letter) to the General Administration of Technical Support, accompanied with a letter of delegation from the applicant.</p>
<p><b>How can a column submitted as an analysis requirement be reclaimed?</b></p>	<p>Use the link to EDA Shababeek on the main page of the EDA website <a href="#">EDA Shababeek</a> and select the link for the required service</p>



<b>Second: Questions concerning file assessment</b>	
<b>What steps should be followed to ensure the fulfilment of the assessment requirements for a file submitted for registration?</b>	<p>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</p> <p><a href="#">CADC Guidelines</a></p>
<b>How is the reference determined for the test for impurities and the acceptance limits for a product?</b>	<p>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</p> <p><a href="#">CADC Guidelines</a></p>
<b>When must testing for the residual solvent be performed on a product?</b>	<p>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</p> <p><a href="#">CADC Guidelines</a></p>
<b>How is the file for validation of an analytical method prepared?</b>	<p>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</p> <p><a href="#">CADC Guidelines</a></p>



<p><b>Will equivalent columns be accepted for the analysis of product samples?</b></p>	<p>Equivalent columns are accepted, according to the published guidelines</p>
<p><b>How can a meeting be arranged to discuss and resolve an issue pertaining to file assessment?</b></p>	<p>Follow the steps in the procedure for inquiries and complaints, published on EDA's website <a href="#">inquiries and complaints</a></p>
<p><b>What is the procedure for updating/altering the method of analysis of a product?</b></p>	<p><b>For a product undergoing registration</b></p> <ul style="list-style-type: none"> <li>• Use the link to EDA Shababeek on the main page of the EDA website <a href="#">EDA Shababeek</a> and select the link to request changing the method of analysis of a product under registration</li> </ul> <p><b>For a registered product</b></p> <ul style="list-style-type: none"> <li>• Use the link to EDA Shababeek on the main page of the EDA website <a href="#">EDA Shababeek</a> and select the link to request changing the method of analysis of a registered product</li> </ul>
<p><b>What is pre-submission assessment and what benefit can be gained from it?</b></p>	<p>The applicant submits a file for technical assessment prior to submission of samples.</p> <p>If the technical requirements are fulfilled, the fulfilment statement is sent to the applicant, as well as the analysis requirements</p> <p>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</p>
<p><b>What is the validity period for a pre-submission fulfilment statement?</b></p>	<p>One year</p>



<p><b>How is pre-submission assessment applied for?</b></p>	<p>Use the link to EDA Shababeek on the main page of the EDA website <a href="#">EDA Shababeek</a> and select the link for requesting pre-submission assessment</p>
<p><b>How are replies to requirements for pre-submission assessment submitted?</b></p>	<p>Use the link to EDA Shababeek on the main page of the EDA website <a href="#">EDA Shababeek</a> and select the link for submitting replies to pre-submission assessment requirements.</p>
<p><b>What products are eligible for reliance pathway?</b></p>	<p>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.</p>
<p><b>How can one learn about the guideline for the reliance pathway, published on the EDA website?</b></p>	<p>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 <a href="#">CADC Guidelines</a></p>
<p><b>What is the benefit of applying for the reliance pathway?</b></p>	<p>The analysis requirements and the analysis time are reduced.</p>
<p><b>How can the reliance pathway be applied for?</b></p>	<p>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</p>
<p><b>When is registration file renewal applied for?</b></p>	<p>In the course of re-registration proceedings.</p>
<p><b>What is the procedure for applying for registration file renewal?</b></p>	<p>Use the link to EDA Shababeek on the main page of the EDA website <a href="#">EDA Shababeek</a> and select the link for requesting registration file renewal.</p>



<p><b>How is the renewal certificate received?</b></p>	<p>The certificate is emailed to the applicant as soon as it is issued.</p>
<p><b>Third: Questions concerning sample analysis</b></p>	
<p><b>What measures can be taken by the applicant to ensure streamlined product analysis?</b></p>	<ul style="list-style-type: none"> <li>➤ The applicant should commit to prompt fulfilment of requirements as specified</li> <li>➤ The applicant should adhere to the submitted method of analysis, or the MOA approved for marketing authorization, and clarify all steps and precautions that may affect the outcome of the test.</li> <li>➤ In case a method of analysis needs to be modified, the applicant should submit the request to modify an MOA promptly, so the updated method can be archived and used in analysis as soon as possible.</li> <li>➤ The applicant should submit any variation approvals with the submitted documents to save time wasted in sending inquiries and awaiting replies during analysis.</li> <li>➤ The applicant should commit to prompt replies to inquiries, and ensure accuracy of sent data.</li> </ul>
<p><b>How can a copy of the final report or the approved product composition for a product be acquired from the General Administration of Evaluation and Control?</b></p>	<ul style="list-style-type: none"> <li>➤ Submit a request to the relevant administration (Evaluation and Approval/Post-approval Control). If approved, pay the designated fees.</li> <li>➤ Use the link <a href="#">EDA Shababeek</a> and select the link for the service</li> <li>➤ Fill in the required data in the electronic form and upload an image of the payment receipt, ensuring the correct administration is specified</li> <li>➤ Submit the original payment receipt at the appointed time for receiving the requested document</li> </ul>



<p><b>How can a detailed final report be acquired from the Administration of Post-approval Control?</b></p>	<ul style="list-style-type: none"> <li>➤ Submit a request to the manager of the Administration of Post -approval Control (PAC), and if approved, pay the designated fees.</li> <li>➤ Submit the original receipt to PAC, and the report will be sent by email</li> </ul>
<p><b>How can a modification of a product specification be requested, for a product undergoing registration?</b></p>	<p>Use the link <a href="#">EDA Shababeek</a> and select the link for the request to modify product specification.</p>
<p><b>How can amendment of an issued final be requested?</b></p>	<p>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 <a href="#">EDA Shababeek</a> and select the link for the request to modify product specification</p>
<p><b>Fourth: Inquiries &amp; Complaints</b></p>	
<p><b>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?</b></p>	<p>Contact us using the email of the respective administration, which is specified in the procedure for inquires and complaints, published on EDA's website, according to the following steps:</p> <ul style="list-style-type: none"> <li>➤ Use the link <a href="#">EDA Shababeek</a></li> <li>➤ Select CADC from the list</li> <li>➤ Select the link for inquiries about products</li> <li>➤ Follow the steps specified in the procedure for inquiries and complaints</li> </ul> <p>Kindly pay attention when selecting the respective administration: Evaluation and Approval (registration), Post-approval Control (local registered product/imported registered product)</p>





	Or use the link <a href="#">inquiries and complaints</a> directly
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 <a href="#">inquiries and complaints</a>
How can a complaint be submitted pertaining to a product oundergoing assessment or analysis?	Follow the steps in the procedure for inquiries and complaints published on EDA's website <a href="#">inquiries and complaints</a>