Updated Procedure for File Review for Products Submitted to PAC for Analysis 2023

Code: EDEREX: NP.CADC.008
Version No: 1/2023
Issue Date: 4/2023
Effective date: 1/4/2023

The Central Administration of Drug Control **(CADC)** announces the **updated procedure** for the review of documents for **locally produced** products submitted to the administration of Post-approval Control (PAC) for quality testing, in the interest of assuring the streamlining of procedures and availability of products to the public.

This pathway applies in the condition that the required documents are submitted electronically, via the specified link, no longer than 6 months prior to submission of samples for analysis, whereby the documents shall be reviewed and the applicant shall be notified of the technical and/or analysis requirements prior to sample submission.

The procedure applies to the following categories:

- **Batches for variation, as soon as the variation approval is issued, for normal and fast track**.
- **First three production batches, normal and fast track**
- **Batches collected in the context of the random sampling plan, for fast track,**

The applicant may apply for this pathway for batches collected through random sampling, normal track, and shortage products batches, if documents can be submitted no longer than 6 months prior to sample collection and submission for analysis

Steps to be followed regarding the updated procedure:

- Hand in the "submission of samples to the administration of post approval control" form to the Receipt Unit, indicating the sample collection category and number of batches, along with a copy of the product composition and the final report issued by CADC for registration (marketing authorization).
- The receipt unit specialist specifies the analysis fees accordingly
- Upload the required documents and the payment receipt (indicating the product name and number of batches) via the following link https://docs.google.com/forms/d/e/1FAIpQLScL3WhNixZSxI50kuuBCp_33QGKrkCwjtmNTeyPCcVHgNCdYg/viewform
- Once the samples have been collected and secured to be submitted to CADC for analysis, upload the certificates of analysis for the batches to be submitted using the specified link for request for file submission and making appointment for sample submission
- Upon sample submission to CADC, hand in the following to the Receipt Unit:

The analysis requirements and a copy of the e-mail specifying those requirements
A copy of the payment receipt
Sample collection form and analysis request from the Central Administration of Operations
The previously uploaded "submission of samples to the administration of post approval control" form
-A fulfilment statement will thereby be sent by email, to the applicant, within 5 working days from the date of sample submission
In case of variation batches, the applicant must compile a file consisting of the final documents, approved for fulfilment of technical requirements, and upload the file using the link for "request for file submission and making appointment for sample submission". The file must include the following:
Product composition, final product specifications, product method of analysis and final certificate of analysis.

- This procedure shall be implemented and shall be the mandatory pathway for files of variation batches (normal and fast track), effective 1/10/2023
- Submitted samples shall be rejected if the sample attachments are incomplete or the requirements are not fulfilled
- If there are any previous correspondences with the General Administration of Technical Support, upload them with the sample documents.
- CADC reserves the right to request more samples or analysis requirements, if and when needed, after the initiation of the analysis process, which will be communicated via requests sent from the Administration of Post-approval Control.

Required Documents

Variation Batches Files

1- Product specifications
2- Certificate of analysis for the batch to be submitted, if issued.
3- Certificate of analysis of the drug substance, specifying the name of the supplier, the batch number, as well as the supplier's certificate of analysis.
4- Reference material certificate (reference standard or certified reference material CRM)
5- The latest registration license, or re-registration approval.
6- The product composition, approved or stamped by the EDA inspector for registered products according to the relevant ministerial decree.
7- The latest Final Report issued for the registration of the product by the Administration of Evaluation and Approval
8- Payment receipt indicating the product name and number of batches
9- Variation Committee approvals for products for which there are post authorization variations.
10- Methods of analysis and their validations
11- A declaration, by the applicant, of the category of sample collection and the number of batches sampled
12- A disclaimer for reclamation of columns submitted with analysis requirements no longer than 1 month after the issuance of the final report.

Random Sampling Files

1- Product specifications
2- Certificate of analysis for the batch to be submitted, if issued.
3- A declaration that the applicant has not changed the method of analysis approved for registration, and if the method has been changed, the applicant must submit a request to modify an MOA and submit the payment receipt along with the updated method and its validation.
4- Reference material certificate of analysis (use the EDA template)
5- Payment receipt, in case of a previously submitted modified method of analysis.
6- The latest registration license, or re-registration approval.

7- The approved product composition according to which the product has been manufactured.
8- The most recent Final Report, issued for the registration of the product by the Administration of Evaluation and Approval, or the Detailed Final Report, issued by the Administration of Post-approval Control, in case of a previously approved variation (changing raw material supplier or manufacturing site)
   If the final report is irretrievable, submit a declaration to that effect (valid for 2 years), with a copy of the product specifications from the approved stability studies.
   If the stability study specifications are not available, submit the manufacturer's product specifications accompanied with the manufacturer's declaration that they are the specifications previously approved for registration.
9- Payment receipt indicating the product name and number of batches.
10- Variation Committee approvals for products for which there are post authorization variations.
11- A disclaimer for reclamation of columns submitted with analysis requirements no longer than 1 month after the issuance of the final report

First Production Batches Files

1- Product specifications
2- Certificate of analysis for the batch to be submitted, if issued.
3- A declaration that the applicant has not changed the method of analysis approved for registration, and if the method has been changed, the applicant must submit a request to modify an MOA and submit the payment receipt along with the updated method and its validation.
4- Reference material certificate of analysis (use the EDA template)
5- The latest registration license, or re-registration approval.
6- The approved product composition according to which the product has been manufactured.
7- Variation Committee approvals for products for which there are post authorization variations.
8- The Final Report, issued for the registration of the product by the Administration of Evaluation and Approval. In case the report has not yet been issued, submit a declaration that the batch submitted for registration is still undergoing analysis.
9- Payment receipt indicating the product name and number of batches
10- "Attachments receipt form" specific to submission to the Administration of Evaluation and Approval, if available

11- Cover letter with CADC registration number
12- A disclaimer for reclamation of columns submitted with analysis requirements no longer than 1 month after the issuance of the final report

- If the applicant does not opt for the above pathway, for locally produced and imported product batches, from which samples haves been collected through **random sampling** or for analysis of the **first production batches**, the procedure previously announced on 15/5/2023 will apply, and the fulfilment statement will be sent to the applicant within 5 working days from the date of sample submission, in the condition that all requirements, specified in the latest requirements email, are submitted (whereby the latest fulfilment email dates back to no earlier than 1/2022 , for random sampling batches, and 5/2022 for first production batches)

- CADC reserves the right to request the submission of methods of analysis in the files for random sampling batches and first production batches if they are not available in CADC's archive.

Submission of Samples to the Administration of Post Approval Control Form	
Trade name	
License holder	
Applicant	
manufacturer	
Dosage form	
Number of batches submitted	
Batch number of finished product (if applicable)	
Manufacturing date	
Expiration date	
Package	
Raw material supplier	
Raw material batch number	
Type of submission	☐ **variation** ☐ **Random sampling** ☐ **1st three batches** ☐ **shortage**
Kind of submission	☐ **fast** ☐ **normal**
Contact person	
Contact information	**Telephone** **Mail** **fax**
Date	
signature	