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

Code: EDEREX: NP.CADC.004
Version No: 1/2023
Issue Date: 4/2023
Effective date: 27/4/2023

The Central Administration of Drug Control **(CADC)** announces the **launch of a new procedure for the review of documents for locally produced products submitted to the administration of Post-approval Control (PAC) for quality testing**, (second and third production batches and random sampling batches).

This procedure features swifter issue of fulfilment statements for the reviewed files, whereby submission of methods of analysis for review is waived, and sample analysis will be performed according to the reviewed methods in the product registration file, in CADC's electronic archive, effective 15/5/2023, for random sampling batches.

If the applicant wishes, at the time of sample submission, to submit the product's analysis requirements, according to the last sent email of requirements, the fulfilment statement will be issued for the submitted batch, provided there are no other requirements for analysis or technical review of analytical methods (for 2nd and 3rd production batches), whereby a copy of the last sent email of requirements and the statement of fulfilment email, and the analysis requirements, must be submitted with the samples.

If the applicant wishes, at the time of sample submission, to submit the analysis requirements specified in "attachments receipt form" which was submitted with the registration batch and signed by the responsible person in the administration of Evaluation and Approval , the fulfilment statement will be issued for the submitted batch, provided there are no other requirements pertaining to analysis or analytical methods, whereby a copy of the "attachments receipt form" and the analysis requirements must be submitted with the samples.

Required Documents

- The applicant is required to upload PDF images of the following documents using the designated link:

1- Sample collection form
2- Sample analysis request (from Central Administration of Operations)
3- Certificate of analysis of the submitted batch/es
4- Reference material certificate using EDA template, including the traceability statement
5- Payment receipt for MOA modification, in case a previous request for method modification has been submitted
6- The latest registration license or re-registration approval
7- The approved product composition
8- The final report issued by the administration of Evaluation and Approval for product registration, or the detailed final report issued by the administration of Post-approval Control for variation batches.
9- Variation Committee approvals for products for which there are post authorization variations.

*If the applicant has not previously submitted the updated methods for the tests that required updating according to the assessment guideline published in 4/2021 (**Dissolution rate, Particulate matter, Pyrogen test)**, the applicant is required to update those methods and submit a request to modify an analytical method, and upload the method, using the designated link.

*If the applicant wishes to modify an analytical method for a registered product, use the designated link to submit a request to modify an analytical method, and upload the method along with its **validation (for in-house methods)/verification (for compendial methods).**