Notice to applicant

Central Administration of Pharmaceutical Products
General Administration For Stability

Mechanism for receiving post approval timepoints for stability studies previously submitted to General Stability Administration
Year 2024

Code: EDREX:NP. CAPP.097
Version No:1
Issue Date: 25/12/2024
Effective date (if needed): 25/12/2024

Objectives:
To outline the mechanism for receiving data of new timepoints for stability studies previously submitted to general stability administration in order to quickly issue approval for stability study dossier.

Scope:
Applicable on:
1- Stability studies dossier of pharmaceutical products submitted for variations (submitting a 6-month analysis point after prior submission of the accelerated 3-month stability study).
2- Stability studies dossier submitted with the unified registration system (CTD) (submission of analysis points at 9&12 months after prior submission for the accelerated and long-term stability studies for a period of 6 months)
3- Stability studies dossier of imported pharmaceutical products of required timepoints data stipulated in previously issued stability approvals (completing the stability study on 3 production batches - submitting a stability study on production batch prior to pilot batch)

Procedure:
The application mechanism shall proceed as follows:

A-In case of having accelerated 3-month stability study for pharmaceutical products submitted for variations or approval for a 6-month accelerated and long-term stability study for CTD -format stability study dossier

1- Apply on submission link to submit stability study files on Tuesday and Wednesday every week and fill out the application form. CLICK HERE
2- The submission link is updated with completing the analysis points for the stability studies already submitted to general administration of stability
3- Choose the following from the box according to the type of completion of analysis points:

- Analysis point at 6 months after the issuance of the approval of the accelerated 3-month stability study submitted for the variation
- Analysis point at 9&12 months after approval of the 6-month accelerated and long-term stability study in CTD format.
- Stability studies of imported pharmaceutical products of required timepoints data stipulated in previously issued stability approvals

4- Upload the following in the application link:
- Stability approval issued for the previous analysis points
- Updated analysis point data (updates stability results tables, charts,..etc) for locally manufactured product

Or the stability study of imported pharmaceutical products that were conditional on the previously issued stability approval

- CADC Approval &/or Quality Module File Approval (if applicable)

- Commitment of absence of change in the analysis points that is previously approved
- Fulfilling the conditions of the previously issued stability approval for the previous analysis points - if they exist and the completion period has expired
- Evidence of the product's validity to receive the stability study

5- If the data for the analysis points provided are complete and the analysis results are within the acceptable limits, a stability approval will be issued within 30 working days.

B- In case of presence of the 3-month accelerated stability study stability study for pharmaceutical products submitted for variations and/or issuance of approval for a 6-month accelerated and long-term stability study for CTD -format stability study dossier is under evaluation by the general administration of Stability and the stability study has not been approved/issued.

- Regarding the stability study under evaluation, to which evaluation comments have been sent and awaiting response from the applicant representatives:
- The data for the updated analysis points (updates stability results tables, charts,) is sent with the rest of the required completions by the applicant, and a letter is attached explaining that the results of the analysis points have been completed and attached to the required completion.
- A stability approval will be issued including the analysis points that have been submitted