Central Administration of Pharmaceutical Products
General Administration For Stability

Mechanism for Applying to Attend a Practical Injection

Year 2022

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In view of the great efforts carried out by the General Administration of Stability and in view of its continuous keenness to keep pace with the development of the pharmaceutical industry, increase the investments targeting the pharmaceutical industry field and enhance the production inside and outside the country and for the public sack and accelerating the work, the following decision was decided:

The Decision

The procedures of practical analysis of the point of analysis of all types of stability studies in which the approval of the stability studies is a condition for release, shall be attended, provided that the product shall be evaluated while attending the injection inside the place where it is conducted, and the Pharmaceutical Inspection of the Central Administration of Operations shall be notified of the release of the batch on the day following the attendance of the injection in case of satisfying results.

For benefitting from the mechanism, the company shall follow the following procedures:

1. The company shall upload the stability study file required to attend the practical analysis procedures each Thursday. The file shall be uploaded to the following link:

https://forms.gle/vNugrRGDduNmx9U69

The file shall include the following:

A. A letter stating the product name, dates in which the study start and end, as well as the analysis date of the point for which the release is required that the company requests to attend to apply the mechanism to it.

B. The company shall upload the entire stability study file to the aforementioned link within a maximum of one month before the date of the practical analysis that the company requests to attend to apply the mechanism to it.

C. The company shall submit the payment receipt in the reception hall on the ground floor from 10 a.m. to 12 p.m. on the Monday following the file uploading. The company shall be notified of the extent of fulfilling of the stability study file on the same day at which the payment receipt is delivered.

D. The company shall fulfill the stability study file within a week of receiving the payment receipt by sending the required documents on the following e-mail:

stability.followup@edaegypt.gov.eg

Note:

1. The maximum number of products permitted to be submitted each week is five products, with a maximum of two products per month for each company.
2. The practical analysis procedures shall not be attended until after fulfilling all the technical points of the stability study submitted by the company before the attendance date of the practical injection.
3. In the case of products enrolled in shortfall lists, the study shall be approved for a period of one month for the purpose of partial release the entire file shall be uploaded to the aforementioned link immediately upon completing the analysis of the point of zero-time interval.
4. The practical analysis of the required analysis point shall be attended as a condition of releasing in accordance with the status indicated in the decision, according to the date specified by the company and mentioned in the letter submitted by the company.
5. The General Administration of Operations (General Administration of Pharmaceutical Inspection) as well as the company shall be notified of the product status on the day following the attendance of the injection by posting an official e-mail for them.