Central Administration of Pharmaceuticals Products
General Administration of Stability

Notice for the service recipient

Mechanism for Submitting Stability Studies for All Types of Locally Manufactured Products and Imported Products

Year 2023

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Notice for the service recipient

1. Introduction

This is a guideline clarifying the regulating rules for the companies to submit stability studies for the locally manufactured product and imported products submitted for revision and evaluation by the General Administration of Stability affiliating to the Central Administration of Pharmaceutical Products.

2. Scope of Implementation

This mechanism shall apply to stability studies of various pharmaceutical products, biocides, locally manufactured or imported from reference and non-reference countries.

- Under registration
- Submitted for re-registration
- Submitted to fulfill variation requirements of the registered pharmaceutical products.
- Submitted to fulfill the requirements of the registration notification

Part One: Booking an Appointment to Submit Stability Studies

1. Submitting an application to obtain an appointment to submit stability studies:

The company shall send an email on the specified days to the following e-mail and in the following times to submit stability studies of locally manufactured and imported products:

stability.appointment@edaegypt.gov.eg

- Stability studies for local products of all types on Tuesday and Wednesday of each week.
- Stability studies for all types of imported products on Thursday of every week.

2.Submission limits

The company shall adhere to the monthly permitted submission limits indicated in the following table:

According to the product type	Maximum limit (for applicant company)
Locally manufactured products (except for biocides)	6 files monthly for one company
Locally manufactured biocides products	4 files monthly for one company
Imported pharmaceutical products	6 files monthly for one company

3. Rules and Steps for Sending the E-mail

The company must adhere to the following steps when sending the e-mail:

- E-mail for booking appointments and required documents shall be sent to the following e-mail:
  stability.appointment@edaegypt.gov.eg
- The size of the sent e-letter shall not exceed 7 MB.
- The companies must adhere to the official working days and hours.
- The sent PDF file shall bear the name of the product. Which e-mail shall include the documents of each type of study as shown in the table. The e-mail shall not include any unrequired documents.
- The stability study shall be completed before setting a date.
- Any e-mail sent to another e-mail address other than the specified one or outside the official working days or hours shall not be taken into account.

4. Documents required for setting an appointment

The purpose of submitting the study shall be explained in the e-mail sent and the required documents shall be attached according to the following:

Required documents in the e-mail	The purpose of submitting a stability study for the different products (locally manufactured or imported from reference or non-reference countries)
1. Under registration submitted products	- Approval to proceeding with the product registration procedures. - Approval of choosing the trade name. - A letter stating the dates in which the stability study started and ended, the numbers of batches on which the study was conducted and the place in which it was conducted. - In the event that a stability study is submitted on a pilot or production batch, a report shall be submitted by the Central Administration of Operations stating the number batch and type. - In case of exceeding the deadline specified for approval to proceed with registration procedures for human pharmaceutical products, any of the following shall be submitted: an application for extending the deadline, pharmacovigilance approval or pricing notification for the product.
2. Products submitted for re-registration	- An approval to proceed with the procedures for re-registering the product or transfer letter by the competent department. - A letter stating the dates in which the stability study started and ended, the numbers of batches on which the study was conducted and the place in which it was conducted. - Product registration notification.
3. Products submitted to meet variation requirements for the registered pharmaceutical products.	- Approval of the competent department to make the change for which a stability study is required. The changing storage conditions or extending the shelf life of the product, shall be excluded. - A letter stating the dates in which the stability study started and ended, the numbers of batches on which the study was conducted and the place in which it was conducted. - In the event that a stability study is submitted on a trial or production batch, a report shall be submitted from the Central Administration of Operations stating the batch number, type and order.
4. Products submitted to fulfill the requirements of the registration license	- A valid product registration license. - A letter stating the dates in which the stability study started and ended, the numbers of batches on which the study was conducted and the place in which it was conducted. - A report from the Central Administration of Operations stating the batch number, type and order, shall be submitted.

Part Two: Submitting the required Documents of Stability Studies

The company shall send a file of completing the stability studies, along with the checklist of the product, on Sunday and Wednesday during the official working hours on the following link:

https://forms.gle/yMXf4MinhwWLMzPF8

Part Three: Upon receiving of the stability study file

Upon receiving of the complete stability study file, it shall be listed on the waiting list to be technically evaluated, provided that the stability studies status shall be followed up on the following link:

https://docs.google.com/spreadsheets/d/1Rs7xkApTLgi7ZnHt2xMbp4qW1D6L_Wjo8XZ51sF78k/edit#gid=0