Notice to Service Recipient

Mechanism for Submitting Stability Files of Pharmaceutical Products Used to Treat the Coronavirus

Year 2021

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The company shall upload the link of the stability study file each **Tuesday** from 9 a.m. to 12 p.m. to the following e-mail allocated for receiving stability files of exceptional products:

stability.emergency@edaegypt.gov.eg

1. **Products submitted for obtaining an initial exceptional approval:**

The company shall send the following documents in the aforementioned e-mail:

a) Box Approval.
b) Naming Approval.
c) An inspection report stating that this batch is the first production batch of the product.
d) Analysis certificate of the product from the Central Administration of Laboratories.
e) References product declares pack, storage conditions, shelf life, and inactive ingredient(s).
f) Cover letter on applicant paper illustrating shelf life and storage condition of the product.

2. **In case of sending stability files to follow up on the results of stability studies for exceptional products at time points (three months and six months), the following documents shall be sent by e-mail:**

Folder One: Registration Documents

- Summary Sheet (PDF and Word File).
- Composition.
- Certificate of responsibility (signed and stamped).
- The initial exceptional stability approvals of the product.
- Exceptional registration license.
- Raw material factory undertaking.
- Finished product specifications.
- References Product Insert declares pack, storage conditions, shelf life, and inactive ingredient.
- Cover letter include shelf life & storage conditions (temperature or any other side storage statement), & pack in details.

Folder Two:

- Certificate of Analysis.
- Stability study tables.
- Method of Analysis.
- Stability contract (if any).

Folder Three:

- Validation Report and its charts.
- Assay Charts.
- Dissolution Charts.