Notice to applicant

Central Administration Pharmaceutical Products
General Administration For Stability

Stability Studies Review and Evaluation Time Frame

Year 2024

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1 Stability Studies Review and Evaluation Time Frame

Scope:

This guidance applies for any stability studies submitted for Reviewing and Evaluation according to the pharmaceutical product country of origin.

Objective:

This guidance aims to provide applicants with the time frames required for Reviewing and Evaluation of the stability studies for pharmaceutical products submitted.

- Process Time Frame:

	Process of the Stability General Administration	Locally Manufactured Pharmaceutical Products and Imported (Reference or Non-Reference Country) Pharmaceutical Products
1	Appointment Request	7MWD
2	Reviewing	5 MWD

3- Concerning timeframe from fulfilled stability study submission to issuing approval technical report:
For all submitted stability studies 60 MWDS except for:
-Case II (Track A) :10 MWDS, Case II (Track B):20 MWDS & Case II (Track C) imported from ref.countries: 40 MWDS
-Emergency of imported products: 3 MWDS, Emergency of locally manufactured products: 5 MWDS.

1.1 Note:

- For stability studies of pharmaceutical products represented to the Stability General Administration according to fast-track requesting speeding up the process so that it's finished within 10 working days from the date of receiving of the fulfilled Fast Track stability study dossier according to the announcement published on EDA Website.

1.2 Abbreviations:

MWD: Maximum Working Days.