Notice to applicant

Central Administration Pharmaceutical Products
General Administration For Stability

Stability Studies Review and Evaluation Time Frame

Year 2024

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Stability Studies Review and Evaluation Time Frame

Scope:

This guidance is applied for any stability studies submitted for Reviewing and Evaluation.

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:

1- Reviewing of regulatory documents: 7 WDS
2- Timeframe for all Locally manufactured generic products submitted stability studies from complete file submission to issuing approval technical report is 60 WDS
3- Imported products in one of SRAs or WHO prequalified: 55WDS
4- Imported products approved from FDA and EMA in addition to one of SRAs or WHO prequalified: 15 WDS
5- Imported products approved from FDA or EMA in addition to one of SRAs or WHO prequalified: 30 WDS
6- Imported products marketed in one of SRAs or WHO prequalified: 40 WDS
7- Imported products from non-reference and not marketed in one of reference countries: 80 WDS
8- Imported products from non-reference and not marketed in one of reference countries: 70 WDS
9- Emergency of imported products: 3 WDS, Emergency of locally manufactured products: MWDS

N.B: Time frame settled is from complete file submission to issuing approval technical report

1.1 Abbreviations:

WDS: Working Days
SRA: Stringent regulatory authority