Central Administration Pharmaceutical Products General Administration For Stability

Stability Studies Review and Evaluation Time Frame Year 2025

Code: EDREX:NP. CAPP.068

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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 in GA-Stab.

Objective:

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

Process Time Frame:

	Process of the Stability General Administration	Local, Imported (Reference or Non- Reference Country) Pharmaceutical Products
1	Screening of regulatory documents	7 WDs
Normal Track		
2	Evaluation of new submission	20 WDs
3	Evaluation of company response	15 WDs
Fast Track		
2	Evaluation of new submission	10 WDs
3	Evaluation of company response	10 WDs

Abbreviations:

WDS: Working Days

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