

**Central Administration CAPP
General Administration Stability**

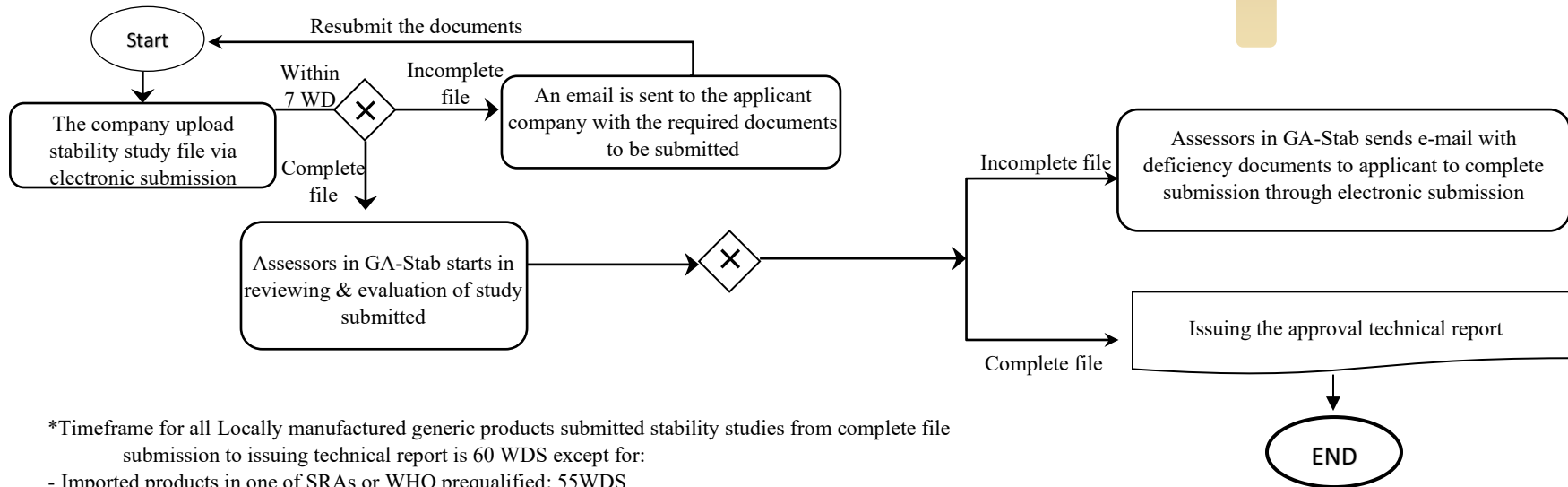
Flow chart for Stability Submission Year 2024

Code: EDREX:NP. CAPP.073

Version No:3

Issue Date:11-9-2024

Effective date (if needed):11-9-2024



*Timeframe for all Locally manufactured generic products submitted stability studies from complete file submission to issuing technical report is 60 WDS except for:

- Imported products in one of SRAs or WHO prequalified: 55WDS
- Imported products approved from FDA and EMA in addition to one of SRAs or WHO prequalified: 15 WDS
- Imported products approved from FDA or EMA in addition to one of SRAs or WHO prequalified: 30 WDS
- Imported products marketed in one of SRAs or WHO prequalified: 40 WDS
- Imported products from non-reference and not marketed in one of reference countries: 80 WDS
- Imported products from non-reference and not marketed in one of reference countries: 70 WDS