Central Administration of Pharmaceutical Products
General Administration For Stability

Requirement for post approval stability studies submission (Shelf-Life Extension /Change In-Use Study/Change in Stability Storage Conditions)

Year 2024

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• Purpose:

This guidance for submission intended to provide applicant on technical and other general data requirements to support stability studies post market approval submission in case of shelf-life extension /change In-use study /change in Stability Storage Conditions without variation approval for locally manufactured pharmaceutical product

• Scope:

Applicable to Human, herbal preparations, and veterinary products of locally manufactured Pharmaceutical products submitted for variation.

• Requirements for stability studies submission:

1-Change in the shelf-life of the FPP (as packaged for sale)

2-Change in the in-use period of the FPP (after first opening or after reconstitution or dilution)

3-Change in the labelled storage conditions of the finished pharmaceutical product (as packaged for sale), the product during the in-use period or the product after reconstitution or dilution

Description of change	Conditions to be fulfilled	Requirements
Change in the shelf-life of the FPP (as packaged for sale) involving		
Extension	1-2	1-3-6-7
Change in the in-use period of the FPP (after first opening or after reconstitution or dilution):		
Extension	Non	1-2-6-7
Change in the labelled storage conditions of the FPP (as packaged for sale), the product during the in-use period or the product after reconstitution or dilution		
Extension:	3	4-5-6-7

Conditions to be fulfilled:

1. No change to the primary packaging type in direct contact with the FPP and to the recommended conditions of storage.

2. Stability data were generated in accordance with the currently accepted stability protocol.

3. The change is not necessitated by failure to meet specifications resulting from unexpected events arising during manufacture, or because of stability concerns

Requirements:

1. Copy of the currently accepted shelf-life specifications and when applicable specification after dilution or reconstitution.

2. Proposed shelf-life, summary of long-term stability testing according to currently accepted protocol and test results for a minimum of two pilot- or production-scale batches for a period sufficient to support the proposed shelf-life.

3. Updated post-acceptance stability protocol and stability commitment and justification of change

4.Proposed in-use period, for 2 pilot batches or production (as required in EMA guidelines for in use) test results and justification of change.

5-if applicable, stability and/or compatibility test results to support the change to the storage conditions.

6- Commitment from stability testing site that method of analysis submitted for assay/ related/anti-oxidant/preservative is the same method of analysis submitted and validated in CADC (last updated guidelines for file assessment for pharmaceutical products for human use). (annex 1)

7- In case of change method, justification is required and full validation data and comparative results between previous and new method.

Notes:

For long term stability study storage condition used is 30°C / 65% RH

Egypt is categorized in climatic zone IVA,

For full requirement of Stability study dossier please refer to “EDA Guidance for File Content of Stability Study Dossier”

https://www.edaegypt.gov.eg/media/qaeji1s5/note-to-applicant-guidance-for-file-content-of-stability-study.pdf

References:

1. **WHO** guidelines on variations to a prequalified product TRS 981 annex 3-2013
2. **EDA** Guidelines for Human Pharmaceuticals Variations, Updated Version
3. **EMA** Note for Guidance on In-use Stability Testing of Human Medicinal Products 2001
4. **ICH** -Q1A(R2) Stability Testing of New Drug Substances and Products
5. **ICH**-Q1E evaluation for stability data

6. **TRS** 1010 ANNEX 10 ,2018 WHO guidelines on stability testing of active pharmaceutical ingredients and finished pharmaceutical products
7. **VICH** –GL3 Stability testing of new veterinary drug substances and medicinal products - Scientific guideline
8. **EMA** Stability testing of herbal medicinal products and traditional herbal medicinal products - Scientific guideline

Annex 1

Commitment

We, [Company Name], the owner of the product/ site of stability study

[Product Name],

Committed that method of analysis submitted for assay/ related/anti-oxidant/preservative is the same method of analysis submitted and validated in

Applicant Company Signature, Date & Stamp:

Stability performed by (signature, stamp)