STABILITY TESTING OF APIs AND FPPs

Overview

This document provides links to two stability guidelines, outlining the core stability data required for registering Active Pharmaceutical Ingredients (APIs) and Finished Pharmaceutical Products (FPPs). **Suppliers are required to provide stability data as per either of the guidelines, with requirements laid out for climatic zone IVb.** Note that the WHO TRS cross-refers ICH stability guidelines - highlighting the same scientific principle behind the two guidelines.

1) WHO TRS 1010 - Annex 10: GUIDELINES ON STABILITY TESTING OF ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED PHARMACEUTICAL PRODUCTS

The WHO guidance on stress testing, batch selection, container-closure systems, specifications, testing frequency, storage conditions, stability commitments, evaluation, labeling, and ongoing stability studies.

The document includes three appendices:

- **Testing Parameters** – Specific parameters for stability testing.
- **Recommendations for Labeling Statements** – Guidance on appropriate stability-related labeling.
- **Interpretation of Storage Statements** – Instructions for storage statements when products approved in climatic zone II are distributed in zone IV.

2) ICH QUALITY GUIDELINES: Q1A - Q1F STABILITY

The International Council for Harmonisation (ICH) has developed a series of guidelines, designated Q1A through Q1F, to standardize stability testing for pharmaceuticals across different regions. These guidelines provide comprehensive instructions on evaluating

how the quality of drug substances and products varies over time under the influence of environmental factors such as temperature, humidity, and light. The guidelines cover:

- **Q1A(R2): Stability Testing of New Drug Substances and Products**
- **Q1B: Photostability Testing of New Drug Substances and Products**
- **Q1C: Stability Testing for New Dosage Forms**
- **Q1D: Bracketing and Matrixing Designs for Stability Testing**
- **Q1E: Evaluation of Stability Data**
- **Q1F: Stability Data Package for Registration Applications in Climatic Zones III and IV**

Link to Guidelines

TRS 1010 - ANNEX 10: WHO GUIDELINES ON STABILITY TESTING OF ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED PHARMACEUTICAL PRODUCTS

ICH OFFICIAL WEB SITE : ICH QUALITY GUIDELINES - Q1A - Q1F STABILITY