STABILITY TESTING OF ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED PHARMACEUTICAL PRODUCTS: ANNEX 10 (TRS 1010)

Document Location: Stability and Shelf Life- Other testing requirements

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Overview

This document outlines the core stability data package required for registration of active pharmaceutical ingredients (APIs) and finished pharmaceutical products (FPPs). These guidelines are required for new and existing APIs.

This guidance provides general guidance, information on stress testing, selection of batches, information on appropriate container-closure systems, specification guidance. It also provides information on testing frequency, storage conditions, stability commitments, evaluation, statements and labelling and any ongoing stability studies that may be required.

This document also contains three Appendices- one on testing parameters, one on recommendations for labelling statements, and the final one on Interpretation of storage statements for products approved in climatic zone II when the products are to be distributed in zone IV.

Overall, manufacturers should follow this document to ensure that their products remain safe and stable.

Link to Document

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