The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

ICH Topic Q 1 C
Stability Testing: Requirements for New Dosage Forms

Step 4, Consensus Guideline, 5 November 1996

NOTE FOR GUIDANCE ON STABILITY TESTING: REQUIREMENTS FOR NEW DOSAGE FORMS
(CPMP/ICH/280/95)

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STABILITY TESTING: REQUIREMENTS FOR NEW DOSAGE FORMS
(CPMP/ICH/280/95)

[ICH Harmonised Tripartite Guideline]

GENERAL

The ICH harmonised Tripartite Guideline on Stability Testing of New Active Substances and Medicinal Products[*] was issued on October 27, 1993. This document is an annex to the ICH parent stability guideline and addresses the recommendations on the data which should be submitted regarding stability of new dosage forms by the owner of the original application, after the original submission for new active substances and medicinal products.

NEW DOSAGE FORMS

A new dosage form is defined as a medicinal product which is a different pharmaceutical product type, but containing the same active substance as included in an existing product approved by the pertinent regulatory authority.

Such pharmaceutical product types include products of a different route of administration (e.g., oral to parenteral), new specific functionality/delivery systems (e.g., immediate release tablet to modified release tablet) and different dosage forms of the same route of administration (e.g., capsule to tablet, solution to suspension).

Stability protocols for new dosage forms should follow the guidance in the parent stability guideline in principle. However, a reduced stability database at submission time (e.g., 6 months accelerated and 6 months long term data from ongoing studies) may be acceptable in certain justified cases.

[*] ICH Harmonised Tripartite Guideline: Stability testing of new active substances and medicinal products, ICH Topic Q1A