

## **1.3**

# **ICH Q1C Stability Testing Requirements for New Dosage Forms**

**January 1998**

**Comments for its application**

## General

- Data for new dosage forms by the owner of the original application**
- New Dosage forms**
  - Medicinal product which is a different pharmaceutical product type but containing the same active substance as included in an existing product.
  - Products of a different route of administration (e.g. oral to parenteral)
  - Different dosage form of the same route of administration.
- Stability Protocol**

A reduced database may be acceptable in certain justified cases

  - 6 months accelerated and long term testing