

VICH GL4 (STABILITY 2)
May 1999
For implementation at Step 7

STABILITY TESTING FOR NEW VETERINARY DOSAGE FORMS

Recommended for Implementation
at Step 7 of the VICH Process
on 20 May 1999
by the VICH Steering Committee

THIS GUIDELINE HAS BEEN DEVELOPED BY THE APPROPRIATE VICH EXPERT WORKING GROUP ON THE BASIS OF THE ICH GUIDELINES ON THE SAME SUBJECT AND HAS BEEN SUBJECT TO CONSULTATION BY THE PARTIES, IN ACCORDANCE WITH THE VICH PROCESS. AT STEP 7 OF THE PROCESS THE FINAL DRAFT IS RECOMMENDED FOR ADOPTION TO THE REGULATORY BODIES OF THE EUROPEAN UNION, JAPAN AND USA.

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GENERAL

This document is an annex to the VICH parent stability guideline, Stability Testing of New Drug Substances and Products in the Veterinary Field (VICH GL3) and addresses the recommendations on what should be submitted regarding stability of new dosage forms by the owner of the original application, after the original submission for new drug substances and products.

NEW DOSAGE FORMS

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

Such pharmaceutical product types include products of different administration route (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 administration route (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 may be acceptable in certain justified cases.