

ICH HARMONISED TRIPARTITE GUIDELINE

**STABILITY TESTING:
PHOTOSTABILITY TESTING OF
NEW DRUG SUBSTANCES AND PRODUCTS
Q1B**

Current *Step 4* version
dated 6 November 1996

This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA.

Q1B
Document History

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Current *Step 4* version

Q1B	Approval by the Steering Committee under <i>Step 4</i> and recommendation for adoption to the three ICH regulatory bodies.	6 November 1996	Q1B
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ICH Harmonised Tripartite Guideline

Having reached *Step 4* of the ICH Process at the ICH Steering Committee meeting
on 6 November 1996, this guideline is recommended for adoption
to the three regulatory parties to ICH

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1. GENERAL

The ICH Harmonized Tripartite Guideline covering the Stability Testing of New Drug Substances and Products (hereafter referred to as the Parent Guideline) notes that light testing should be an integral part of stress testing. This document is an annex to the Parent Guideline and addresses the recommendations for photostability testing.

A. Preamble

The intrinsic photostability characteristics of new drug substances and products should be evaluated to demonstrate that, as appropriate, light exposure does not result in unacceptable change. Normally, photostability testing is carried out on a single batch of material selected as described under Selection of Batches in the Parent Guideline. Under some circumstances these studies should be repeated if certain variations and changes are made to the product (e.g., formulation, packaging). Whether these studies should be repeated depends on the photostability characteristics determined at the time of initial filing and the type of variation and/or change made.

The guideline primarily addresses the generation of photostability information for submission in Registration Applications for new molecular entities and associated drug products. The guideline does not cover the photostability of drugs after administration (i.e. under conditions of use) and those applications not covered by the Parent Guideline. Alternative approaches may be used if they are scientifically sound and justification is provided.

A systematic approach to photostability testing is recommended covering, as appropriate, studies such as:

- i) Tests on the drug substance;
- ii) Tests on the exposed drug product outside of the immediate pack;
and if necessary ;
- iii) Tests on the drug product in the immediate pack;
and if necessary ;
- iv) Tests on the drug product in the marketing pack.

The extent of drug product testing should be established by assessing whether or not acceptable change has occurred at the end of the light exposure testing as described in the Decision Flow Chart for Photostability Testing of Drug Products. Acceptable change is change within limits justified by the applicant.

The formal labeling requirements for photolabile drug substances and drug products are established by national/regional requirements.

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