INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED TRIPARTITE GUIDELINE

STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS Q1A(R2)

Current *Step 4* version

dated 6 February 2003

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.

Q1A(R2)
Document History

First Codification	History	Date	New Codification **November 2005**
Q1	Approval by the Steering Committee under *Step 2* and release for public consultation.	16 September 1992	Q1
Q1A	Approval by the Steering Committee under *Step 4* and recommendation for adoption to the three ICH regulatory bodies. Q1 was renamed Q1A.	27 October 1993	Q1A
Q1A(R)	Approval by the Steering Committee of the first revision under *Step 2* and release for public consultation.	7 October 1999	Q1A(R1)
Q1A(R)	Approval by the Steering Committee of the first revision under *Step 4* and recommendation for adoption to the three ICH regulatory bodies.	8 November 2000	Q1A(R1)

Current *Step 4* version

Q1A(R2)	Approval by the Steering Committee of the second revision directly under *Step 4* without further public consultation, to include consequences of the adoption of Q1F (Stability Data Package for Registration Applications in Climatic Zones III and IV), and recommendation for adoption to the three ICH regulatory bodies.	6 February 2003	Q1A(R2)

COVER NOTE FOR REVISION OF Q1A(R)
STABILITY TESTING OF
NEW DRUG SUBSTANCES AND PRODUCTS

The purpose of this note is to outline the changes made in Q1A(R) that result from adoption of ICH Q1F "Stability Data Package for Registration Applications in Climatic Zones III and IV". These changes are:

1. The intermediate storage condition has been changed from 30°C ± 2°C/60% RH ± 5% RH to 30°C ± 2°C/65% RH ± 5% RH in the following sections:
   - 2.1.7.1 Drug Substance - Storage Conditions - General Case
   - 2.2.7.1 Drug Product - Storage Conditions - General Case
   - 2.2.7.3 Drug products packaged in semi-permeable containers
   - 3 Glossary - "Intermediate testing"

2. 30°C ± 2°C/65% RH ± 5% RH can be a suitable alternative long-term storage condition to 25°C ± 2°C/60% RH ± 5% in the following sections:
   - 2.1.7.1 Drug Substance - Storage Conditions - General Case
   - 2.2.7.1 Drug Product - Storage Conditions - General Case

3. 30°C ± 2°C/35% RH ± 5% RH has been added as a suitable alternative long-term storage condition to 25°C ± 2°C/40% RH ± 5% and the corresponding example for the ratio of water-loss rates has been included in the following section:
   - 2.2.7.3 Drug products packaged in semi-permeable containers

Mid-stream switch of the intermediate storage condition from 30°C ± 2°C/60% RH ± 5% RH to 30°C ± 2°C/65% RH ± 5% RH can be appropriate provided that the respective storage conditions and the date of the switch are clearly documented and stated in the registration application.

It is recommended that registration applications contain data from complete studies at the intermediate storage condition 30°C ± 2°C/65% RH ± 5% RH, if applicable, by three years after the date of publication of this revised guideline in the respective ICH tripartite region.

STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS

ICH Harmonised Tripartite Guideline

First Recommended for Adoption at *Step 4* of the ICH Process on 27 October 1993.

Revised under *Step 2* of the ICH Process on 7 October 1999 and Recommended for Adoption at *Step 4* of the ICH Process on 8 November 2000.

This guideline has been Revised a second time and has reached *Step 4* of the ICH Process at the ICH Steering Committee meeting on 6 February 2003. It is recommended for adoption to the three regulatory parties to ICH

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