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

ICH HARMONISED TRIPARTITE GUIDELINE

새로운 제형의 안정성 시험

(Stability Testing for New Dosage Forms)

Annex to the ICH Harmonised Tripartite Guideline on Stability Testing for New Drugs and Products

Q1C

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.

Q1C

Document History

First Codification	History	Date	New Codification November 2005
Q1C	Approval by the Steering Committee under *Step 2* and release for public consultation.	29 November 1995	Q1C

Current Step 4 version

Q1C	Approval by the Steering Committee under *Step 4* and recommendation for adoption to the three ICH regulatory bodies.	6 November 1996	Q1C

STABILITY TESTING FOR NEW DOSAGE FORMS

Annex to the ICH Harmonised Tripartite Guideline on Stability Testing for New Drugs and Products

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.

1. 공통(GENERAL)

The ICH harmonised Tripartite Guideline on Stability Testing of New Drug Substances and Products was issued on October 27, 1993. This document is an annex to the ICH parent stability guideline 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.

새로운 원료의약품과 완제의약품의 안정성 시험에 관한 ICH 가이드라인이 1993년 10월 27일 발행되었다. 이 문서는 ICH의 안정성 시험에 관한 모 가이드라인에 부속되는 것으로, 새로운 원료의약품과 완제의약품의 최초 등록 문서 제출 이후 새로운 제형의 안정성과 관련하여 신청업체가 제출해야 할 정보에 대한 권고 사항을 제시한다.

2. 새로운 제형(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.

새로운 제형이라 함은 관련 규제 기관의 승인을 받은 기존 완제의약품과 동일한 활성 성분을 함유하지만, 다른 제품 유형으로 제조되는 완제의약품을 의미한다.

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).

이와 같은 다른 제품 유형으로는 새로운 투여 경로(예, 경구 → 주사), 새로운 기능/전달 시스템(예, 즉시 방출 정제 → 변형 방출 정제), 투여 경로는 동일하지만 제형이 다른 경우(예, 캡슐제 → 정제, 액제 → 현탁제)가 있다.

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.

새로운 제형의 안정성 프로토콜은 원칙적으로 모 가이드라인을 따라야 한다. 하지만 타당성이 있는 경우에는 제출 시점에 안정성 데이터를 일부만 제출할 수도 있다(예, 6개월 가속 데이터와 계속 진행 중인 장기 안정성 시험 가운데 6개월 데이터).