INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

분석 절차 밸리데이션

(VALIDATION OF ANALYTICAL PROCEDURES)

Q2(R2)

Final version

Adopted on 1 November 2023

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 ICH regions.

Q2(R2)

Document History

Code	History	Date
Q2	Approval by the Steering Committee under Step 2 and release for public consultation.	26 October 1993
Q2A	Approval by the Steering Committee under Step 4 and recommendation for adoption to the three ICH regulatory bodies.	27 October 1994
Q2B	Approval by the Steering Committee under Step 2 and release for public consultation.	29 November 1995
Q2B	Approval by the Steering Committee under Step 4 and recommendation for adoption to the three ICH regulatory bodies.	6 November 1996
Q2(R1)	The parent guideline is now renamed Q2(R1) as the guideline Q2B on methodology has been incorporated to the parent guideline. The new title is "Validation of Analytical Procedures: Text and Methodology".	November 2005
Q2(R2)	Complete revision of guideline to include more recent application of analytical procedures and to align content with Q14. Endorsement by the Members of the ICH Assembly under Step 2 and release for public consultation.	24 March 2022
Q2(R2)	Adoption by the Regulatory Members of the ICH Assembly under Step 4.	1 November 2023
Q2(R2)	Error Correction to Table 5: Dissolution with HPLC as product performance test for an immediate release dosage form Reportable Range Linearity formulae on page 25; Correction to Tables 6-11 on pages 26-32.	30 November 2023

ICH Harmonised Guideline

Validation of Analytical Procedures

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목차

1. 서론(INTRODUCTION)

1.1 목적(Objective)

This guideline presents elements for consideration during the validation of analytical procedures included as part of registration applications. Analytical procedure validation forms a part of the analytical procedure lifecycle, as described within ICH Q14 Analytical Procedure Development. ICH Q2(R2) provides guidance on selection and evaluation of the various validation tests for analytical procedures. This guideline includes a collection of terms and their definitions, which are meant to bridge the differences that often exist between various compendia and documents of the ICH member regulatory authorities.
등록 신청 문서에 기술하는 분석 절차의 밸리데이션 시에 고려해야 할 주요 사항을 이 문서에서 정리한다. 분석 절차 밸리데이션은 ICH Q14 "분석 절차 개발"에 기술된 분석 절차 라이프사이클의 한 부분에 해당된다. ICH Q2(R2) 문서는 분석 절차의 밸리데이션 시험 항목을 선정하고 평가하는 방법에 관한 가이드라인을 제시하기 위한 것이다. 또한 각종 용어를 정리하고 의미를 설명한다. 이 용어와 정의는 ICH 회원 규제 기관의 문서와 각종 공정서 사이에 존재하는 차이를 좁히기 위한 것이다.

The objective of validation of an analytical procedure is to demonstrate that the analytical procedure is fit for the intended purpose. Further general guidance is provided on validation studies for analytical procedures.
분석 절차 밸리데이션의 목적은 분석 절차가 예정 목적에 적합함을 증명하는 것이다. 분석 절차의 밸리데이션 시험에 관한 일반적인 가이드라인을 제시한다.

1.2 적용 범위(Scope)

This guideline applies to analytical procedures used for release and stability testing of commercial drug substances and products, hereafter referred to as 'products'. The guideline can also be applied to other analytical procedures used as part of the control strategy (ICH Q10 Pharmaceutical Quality System) following a risk-based approach. The scientific principles described in this guideline can be applied in a phase-appropriate manner to analytical procedures used during clinical development.
상업적 원료의약품과 완제의약품(이하 "제품")의 승인 시험과 안정성 시험에 사용되는 분석 절차에 이 가이드라인이 적용된다. 또한 리스크 기반 방식에 따라 관리 전략(ICH Q10 "제약 품질 시스템")의 한 부분으로 사용되는 다른 분석 절차에도 이 가이드라인이 적용될 수

있다. 이 가이드라인에 기술된 과학적 원칙을 임상 개발 시에 사용되는 분석 절차에 단계별로 적절하게 적용할 수 있다.

The guideline is directed to common uses of analytical procedures, such as assay, potency, purity, impurity (quantitative or limit test), identity or other quantitative or qualitative measurements.
정량, 역가, 순도, 불순물(정량 시험 또는 한도 시험), 확인 또는 기타 정량적/정성적 측정 방법 등 일반적인 용도의 분석 절차에 이 가이드라인이 적용된다.