

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

**DRAFT CONSENSUS GUIDELINE**

**EVALUATION AND RECOMMENDATION OF  
PHARMACOPOEIAL TEXTS FOR USE IN THE ICH REGIONS  
ON  
POLYACRYLAMIDE GEL ELECTROPHORESIS  
GENERAL CHAPTER**

**Q4B ANNEX 10**

Current *Step 2* version  
dated 11 June 2009

*At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Steering Committee to the regulatory authorities of the three ICH regions (the European Union, Japan and the USA) for internal and external consultation, according to national or regional procedures.*

**Q4B Annex 10  
Document History**

**Current *Step 2* version**

Code	History	Date
Q4B Annex 10	Approval by the Steering Committee under <i>Step 2</i> and release for public consultation.	11 June 2009

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**Draft ICH Consensus Guideline**

Released for Consultation on 11 June 2009, at *Step 2* of the ICH Process

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# EVALUATION AND RECOMMENDATION OF PHARMACOPOEIAL TEXTS FOR USE IN THE ICH REGIONS

## ON POLYACRYLAMIDE GEL ELECTROPHORESIS GENERAL CHAPTER

### Q4B ANNEX 10

#### 1. INTRODUCTION

This annex is the result of the Q4B process for the Polyacrylamide Gel Electrophoresis General Chapter.

The proposed texts were submitted by the Pharmacopoeial Discussion Group (PDG).

#### 2. Q4B OUTCOME

##### 2.1 Analytical Procedures

The ICH Steering Committee, based on the evaluation by the Q4B Expert Working Group (EWG), recommends that the official pharmacopoeial texts, the Section in Ph.Eur. 2.2.31. Electrophoresis entitled “Sodium Dodecyl Sulphate Polyacrylamide Gel Electrophoresis (SDS-PAGE)”, JP General Information 23. SDS-Polyacrylamide Gel Electrophoresis, and USP <1056> Biotechnology-derived Articles – Polyacrylamide Gel Electrophoresis, can be used as interchangeable in the ICH regions.

##### 2.2 Acceptance Criteria

The texts evaluated did not contain acceptance criteria.

#### 3. TIMING OF ANNEX IMPLEMENTATION

When this annex is implemented (incorporated into the regulatory process at ICH *Step 5*) in a region, it can be used in that region. Timing might differ for each region.

#### 4. CONSIDERATIONS FOR IMPLEMENTATION

##### 4.1 General Consideration

When sponsors or manufacturers change their existing methods to the implemented Q4B-evaluated pharmacopoeial texts that are referenced in Section 2.1 of this annex, any change notification, variation, and/or prior approval procedures should be handled in accordance with established regional regulatory mechanisms pertaining to compendial changes.

## **4.2 FDA Consideration**

Based on the recommendation above, and with reference to the conditions set forth in this annex, the pharmacopoeial texts referenced in Section 2.1 of this annex can be considered interchangeable. However, FDA might request that a company demonstrate that the chosen method is acceptable and suitable for a specific material or product, irrespective of the origin of the method.

The pharmacopoeial text is nonmandatory and is provided for informational purposes only.

## **4.3 EU Consideration**

For the European Union, the monographs of the Ph. Eur. have mandatory applicability. Regulatory authorities can accept the reference in a marketing authorisation application, renewal or variation application citing the use of the corresponding text from another pharmacopoeia as referenced in Section 2.1, in accordance with the conditions set out in this annex, as fulfilling the requirements for compliance with the Ph. Eur. Chapter 2.2.31. on the basis of the declaration of interchangeability made above.

## **4.4 MHLW Consideration**

The pharmacopoeial texts referenced in Section 2.1 of this annex can be used as interchangeable in accordance with the conditions set out in this annex. Details of implementation requirements will be provided in the notification by MHLW when this annex is implemented.

The pharmacopoeial text is nonmandatory and is provided for informational purposes only.

## **5. REFERENCES USED FOR THE Q4B EVALUATION**

- 5.1** The PDG Stage 5B sign-off document: *Japanese Pharmacopoeial Forum*, Volume 9, number 1 (January 2000).
- 5.2** The pharmacopoeial references for Polyacrylamide Gel Electrophoresis General Chapter for this annex are:
  - 5.2.1** *European Pharmacopoeia (Ph. Eur.)*: 6<sup>th</sup> Edition (official in January 2008), Electrophoresis (reference 01/2008:20231);
  - 5.2.2** *Japanese Pharmacopoeia (JP)*: The JP General Information 23. SDS-Polyacrylamide Gel Electrophoresis as it appears in the Japanese Pharmacopoeia Fifteenth Edition (March 31, 2006, The Ministry of Health, Labour and Welfare Ministerial Notification No. 285);
  - 5.2.3** *United States Pharmacopoeia (USP)*: <1056> Biotechnology-derived Articles – Polyacrylamide Gel Electrophoresis official in USP 32, May 1, 2009.