

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

**ICH HARMONISED TRIPARTITE GUIDELINE**

**EVALUATION AND RECOMMENDATION OF PHARMACOPOEIAL  
TEXTS FOR USE IN THE ICH REGIONS ON  
DISINTEGRATION TEST GENERAL CHAPTER  
Q4B ANNEX 5**

Current *Step 4* version  
dated 10 June 2009

*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.*

**Q4B Annex 5  
Document History**

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**Current *Step 4* version**

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

**ON**

**DISINTEGRATION TEST GENERAL CHAPTER  
Q4B ANNEX 5**

**ICH Harmonised Tripartite Guideline**

Having reached *Step 4* of the ICH Process at the ICH Steering Committee meeting on 10 June 2009, this guideline is recommended for adoption to the three regulatory parties to ICH

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

ON

## DISINTEGRATION TEST GENERAL CHAPTER Q4B ANNEX 5

### 1. INTRODUCTION

This annex is the result of the Q4B process for Disintegration Test 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 for tablets and capsules, the official pharmacopoeial texts, Ph. Eur. 2.9.1. Disintegration of Tablets and Capsules, JP 6.09 Disintegration Test, and USP <701> Disintegration, can be used as interchangeable in the ICH regions subject to the conditions detailed below. Testing conditions for specific dosage forms are outside the scope of the harmonization of this chapter.

**2.1.1** For tablets and capsules larger than 18 millimeters (mm) long for which a different apparatus is used, the Disintegration Test is not considered to be interchangeable in the three regions.

**2.1.2** The Disintegration Test is not considered to be interchangeable in the three regions for dosage forms referred to in the regional compendia as *delayed-release, gastro-resistant, or enteric-coated*.

**2.1.3** Product-specific parameters such as media and the use of discs should be specified in the application dossier.

#### 2.2 Acceptance Criteria

Acceptance criteria are outside the scope of the harmonization of this chapter and should be specified in the application dossier.

### 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.

## **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 2.9.1. 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.

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

- 5.1** The PDG Stage 5B sign-off document (Rev. 1): *Japanese Pharmacopoeial Forum*, Volume 16, number 4 (December 2007).
- 5.2** The pharmacopoeial references for Disintegration Test General Chapter for this annex are:
  - 5.2.1** *European Pharmacopoeia* (Ph. Eur.): Supplement 6.3 (official January 2009) Disintegration of Tablets and Capsules (reference 01/2009: 20901);
  - 5.2.2** *Japanese Pharmacopoeia* (JP): 6.09 Disintegration Test as it appeared in the partial revision of the JP 15<sup>th</sup> edition made official March 31, 2009, by the Ministry of Health, Labour and Welfare Ministerial Notification No. 190;
  - 5.2.3** *United States Pharmacopeia* (USP): Revision Bulletin <701> Disintegration issued June 6, 2008, and official August 1, 2008.