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(R1)

Current *Step 4* version

dated 27 September 2010

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(R1)
Document History

Code	History	Date
Q4B Annex 5	Approval by the Steering Committee under *Step 2* and release for public consultation.	5 June 2008
Q4B Annex 5	Approval by the Steering Committee under *Step 4* and recommendation for adoption to the three ICH regulatory bodies.	10 June 2009

Current *Step 4* version

Q4B Annex 5(R1)	Integration of the Health Canada Interchangeability Statement under Section 4.5 after approval by the Steering Committee.	27 September 2010

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

ON

DISINTEGRATION TEST GENERAL CHAPTER

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

(This annex was revised -R1- to include the Interchangeability Statement from Health Canada on September 27, 2010)

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

ON

DISINTEGRATION TEST GENERAL CHAPTER
Q4B ANNEX 5(R1)

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.

4.5 Health Canada Consideration

In Canada, any of the pharmacopoeial texts cited in section 2.1 of this annex and used in accordance with the conditions set out in this annex can be considered interchangeable.

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 15th 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.