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 TABLET FRIABILITY GENERAL CHAPTER

Q4B ANNEX 9

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 9
Document History

Current *Step 2* version

Code	History	Date
Q4B Annex 9	Approval by the Steering Committee under *Step 2* and release for public consultation.	11 June 2009

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

ON

TABLET FRIABILITY GENERAL CHAPTER

Q4B ANNEX 9

Draft ICH Consensus Guideline

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

TABLE OF CONTENTS

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ON

TABLET FRIABILITY GENERAL CHAPTER

Q4B ANNEX 9

1. INTRODUCTION

This annex is the result of the Q4B process for the Tablet Friability 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 analytical procedures described in the official pharmacopoeial texts, Ph.Eur. 2.9.7. Friability of Uncoated Tablets, JP General Information 26. Tablet Friability Test, and USP <1216> Tablet Friability, can be used as interchangeable in the ICH regions.

2.2 Acceptance Criteria

For interchangeability, the loss of mass for a single determination should be not more than 1.0 percent, unless otherwise specified in the dossier. When three determinations are conducted, then the mean loss of mass for the three determinations should be not more than 1.0 percent, unless otherwise specified in the 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.

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 2.9.7. 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 14, number 1 (March 2005).

5.2 The pharmacopoeial references for Tablet Friability General Chapter for this annex are:

5.2.1 *European Pharmacopoeia (Ph. Eur.):* Supplement 6.6 (published June 2009, official January 2010), Friability of Uncoated Tablets (reference 01/2010:20907);

5.2.2 *Japanese Pharmacopoeia (JP):* The JP General Information 26. Tablet Friability Test as it appears in the JP Fifteenth Edition (March 31, 2006, The Ministry of Health, Labour and Welfare Ministerial Notification No. 285), officially updated by errata published by MHLW at:

http://www.std.pmda.go.jp/jpPUB/Data/ENG/jpdata/H201105_jp15_errata.pdf on November 5, 2008;

5.2.3 *United States Pharmacopeia (USP):* <1216> Tablet Friability, official in USP 32, May 1, 2009.