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

ANALYTICAL SIEVING GENERAL CHAPTER

Q4B ANNEX 12

Current *Step 4* Version
dated 9 June 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 12
Document History

Code	History	Date
Q4B Annex 12	Approval by the Steering Committee under *Step 2* and release for public consultation.	29 October 2009

Current *Step 4* version

Q4B Annex 12	Approval by the Steering Committee under *Step 4* and recommendation for adoption to the three ICH regulatory bodies.	9 June 2010

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ICH Harmonised Tripartite Guideline

Having reached *Step 4* of the ICH Process at the ICH Steering Committee meeting on 9 June 2010, this guideline is recommended for adoption to the three regulatory parties to ICH

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ANALYTICAL SIEVING GENERAL CHAPTER

Q4B ANNEX 12

1. INTRODUCTION

This annex is the result of the Q4B process for the Analytical Sieving 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. 2.9.38. Particle-size Distribution Estimation by Analytical Sieving, JP 3.04 Particle Size Determination entitled Method 2. Analytical Sieving Method, and USP General Chapter <786> Particle Size Distribution Estimation by Analytical Sieving, 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.

4.3 EU Consideration

For the European Union, 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 2.9.38. 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: *Japanese Pharmacopoeial Forum*, Volume 16, number 2 (June 2007).

5.2 The pharmacopoeial references for the Analytical Sieving General Chapter for this annex are:

5.2.1 *European Pharmacopoeia* (Ph. Eur.): Supplement 6.2 (published December 11, 2007, and official July 2008), Particle-size Distribution Estimation by Analytical Sieving (reference 07/2008:20938);

5.2.2 *Japanese Pharmacopoeia* (JP): 3.04 Particle Size Determination as it appeared in Supplement II to the JP Fifteenth Edition (September 30, 2009, The Ministerial Notification No. 425). The English version of the JP text was published June 4, 2010, and is available at www.std.pmda.go.jp/jpPUB/index_e.html;

5.2.3 *United States Pharmacopeia* (USP): <786> Particle Size Distribution Estimation by Analytical Sieving, USP 32 Supplement 2 (official 12/1/09), and Errata in Interim Revision Announcement to USP 32 appearing in *Pharmacopeial Forum*, Vol. 35, no. 5, released September 1, 2009, and official October 1, 2009.