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 TEST FOR EXTRACTABLE VOLUME OF PARENTERAL PREPARATIONS GENERAL CHAPTER Q4B ANNEX 2

Current *Step 4* version
dated 5 June 2008

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 2
Document History

Code	History	Date
Q4B Annex 2	Approval by the Steering Committee under *Step 2* and release for public consultation.	1 November 2007

Current *Step 4* version

Q4B Annex 2	Approval by the Steering Committee under *Step 4* and recommendation for adoption to the three ICH regulatory bodies.	5 June 2008

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

ON

TEST FOR EXTRACTABLE VOLUME OF PARENTERAL PREPARATIONS GENERAL CHAPTER

ICH Harmonised Tripartite Guideline

Having reached *Step 4* of the ICH Process at the ICH Steering Committee meeting on 5 June 2008, 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

TEST FOR EXTRACTABLE VOLUME OF PARENTERAL PREPARATIONS GENERAL CHAPTER

1. INTRODUCTION

This annex is the result of the Q4B process for the Test for Extractable Volume of Parenteral Preparations 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, Ph.Eur. 2.9.17. Test for Extractable Volume of Parenteral Preparations, JP 6.05 Test for Extractable Volume of Parenteral Preparations, and the section in USP <1> *Injections* General Chapter entitled "Volume in Containers" can be used as interchangeable in the ICH regions.

2.2 Acceptance Criteria

The acceptance criteria are the same in the three pharmacopoeias.

3. TIMING OF ANNEX IMPLEMENTATION

When this annex has been 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, Test for Extractable Volume of Parenteral Preparations: 2.9.17., 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: *Japanese Pharmacopoeial Forum*, Volume 13, Number 3 (August 2004).

5.2 The pharmacopoeial references for Test for Extractable Volume of Parenteral Preparations:

5.2.1 *European Pharmacopoeia* (Ph. Eur.): Supplement 5.3 (official on January 2006), Test for Extractable Volume of Parenteral Preparations (reference 01/2006:20917);

5.2.2 *Japanese Pharmacopoeia* (JP): 6.05 Test for Extractable Volume of Parenteral Preparations as it appears in the JP Fifteenth Edition (March 31, 2006, The Ministry of Health, Labour and Welfare Ministerial Notification No. 285);

5.2.3 *United States Pharmacopeia* (USP): official text published in the Revision Bulletin issued November 14, 2006, and as appeared in USP 30, 2nd Supplement, official December 1, 2007. The official text is incorporated in <1> *Injections* General Chapter as the section entitled "Volume in Containers".