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(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 2(R1)
### 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 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

(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 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.

4.5 In Canada, any of the 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


5.2 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);


5.2.3 *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".