

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(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**

Code	History	Date
Q4B Annex 2	Approval by the Steering Committee under <i>Step 2</i> and release for public consultation.	1 November 2007
Q4B Annex 2	Approval by the Steering Committee under <i>Step 4</i> and recommendation for adoption to the three ICH regulatory bodies.	5 June 2008

### **Current *Step 4* version**

Q4B Annex 2(R1)	Integration of the Health Canada Interchangeability Statement under Section 4 after approval by the Steering Committee.	27 September 2010
-----------------	---	-------------------

**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)*

**TABLE OF CONTENTS**

<b>1.</b>	<b>INTRODUCTION .....</b>	<b>1</b>
<b>2.</b>	<b>Q4B OUTCOME.....</b>	<b>1</b>
2.1	Analytical Procedures.....	1
2.2	Acceptance Criteria .....	1
<b>3.</b>	<b>TIMING OF ANNEX IMPLEMENTATION .....</b>	<b>1</b>
<b>4.</b>	<b>CONSIDERATIONS FOR IMPLEMENTATION .....</b>	<b>1</b>
<b>5.</b>	<b>REFERENCES USED FOR THE Q4B EVALUATION .....</b>	<b>2</b>



**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**

- 5.1 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, 2<sup>nd</sup> Supplement, official December 1, 2007. The official text is incorporated in <1> *Injections* General Chapter as the section entitled "Volume in Containers".