Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions

Annex 2: Test for Extractable Volume of Parenteral Preparations General Chapter

For questions regarding this draft document contact (CDER) Robert King 301-796-1242, or (CBER) Christopher Joneckis 301-435-5681.

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

Draft Consensus Guideline

Q4B - Annex 2

Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions

ON

Test for Extractable Volume of Parenteral Preparations General Chapter

Current *Step 2* Version
Dated October 30, 2007

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 2

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Test for Extractable Volume of Parenteral Preparations General Chapter

ICH Consensus Guideline

Released for Consultation on November 1, 2007, at *Step 2* of the ICH Process

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. 20917 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 may 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 in accordance with 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: 20917, 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 will appear in USP 30, 2nd Supplement. The USP official text also appeared in the Interim Revision Announcement appearing in Volume 33, number 2, of *Pharmacopeial Forum*, official April 1, 2007. The official text is incorporated in <1> *Injections* General Test Chapter as the section entitled "Volume in Containers".