

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

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

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

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2 INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL  
3 REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE  
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7 **Draft Consensus Guideline**  
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12 **Q4B - Annex 2**

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

16  
17 **ON**  
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19 **Test for Extractable Volume of Parenteral Preparations General Chapter**  
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25 **Current *Step 2* Version**  
26 **Dated October 30, 2007**  
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36 *At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert*  
37 *Working Group, is transmitted by the ICH Steering Committee to the regulatory authorities of the three*  
38 *ICH regions (the European Union, Japan and the USA) for internal and external consultation, according*  
39 *to national or regional procedures.*

1 **Q4B -- Annex 2**  
2 **Evaluation and Recommendation of Pharmacopoeial Texts**  
3 **for Use in the ICH Regions**

4 ON

5 **Test for Extractable Volume of Parenteral Preparations General Chapter**  
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7 **ICH Consensus Guideline**

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

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14 This annex is the result of the Q4B process for the Test for Extractable Volume of Parenteral  
15 Preparations General Chapter. The proposed texts were submitted by the Pharmacopoeial Discussion  
16 Group (PDG).  
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18 **2. Q4B Outcome**

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20 **2.1. Analytical Procedures**

21 The ICH Steering Committee, based on the evaluation by the Q4B Expert Working Group  
22 (EWG), recommends that the official pharmacopoeial texts Ph.Eur. 20917 Test for Extractable  
23 Volume of Parenteral Preparations, JP 6.05 Test for Extractable Volume of Parenteral  
24 Preparations, and the section in USP <1> *Injections* General Chapter entitled "Volume in  
25 Containers" can be used as interchangeable in the ICH regions.  
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27 **2.2. Acceptance Criteria**

28 The acceptance criteria are the same in the three pharmacopoeias.  
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30 **3. Timing of Annex Implementation**

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32 When this annex has been implemented (incorporated into the regulatory process at ICH Step 5) in a  
33 region, it can be used in that region. Timing may differ for each region.  
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35 **4. Considerations for Implementation**

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37 4.1 General consideration: When sponsors or manufacturers change their existing methods to the  
38 implemented Q4B-evaluated pharmacopoeial texts that are referenced in Section 2.1 of this  
39 annex, any change notification, variation, and/or prior approval procedures should be handled in  
40 accordance with established regional regulatory mechanisms pertaining to compendial changes.  
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42 4.2 FDA consideration: Based on the recommendation above, and in accordance with the conditions  
43 set forth in this annex, the pharmacopoeial texts referenced in Section 2.1 of this annex can be  
44 considered interchangeable. However, FDA might request that a company demonstrate that the  
45 chosen method is acceptable and suitable for a specific material or product, irrespective of the  
46 origin of the method.  
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48 4.3 EU consideration: For the European Union, the monographs of the Ph. Eur. have mandatory  
49 applicability. Regulatory authorities can accept the reference in a marketing authorisation  
50 application, renewal or variation application citing the use of the corresponding text from  
51 another pharmacopoeia as referenced in Section 2.1, in accordance with the conditions set out in  
52 this annex, as fulfilling the requirements for compliance with the Ph. Eur. Chapter, Test for

53 Extractable Volume of Parenteral Preparations: 20917, on the basis of the declaration of  
54 interchangeability made above.

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56 4.4 MHLW consideration: The pharmacopoeial texts referenced in Section 2.1 of this annex can be  
57 used as interchangeable in accordance with the conditions set out in this annex. Details of  
58 implementation requirements will be provided in the notification by MHLW when this annex is  
59 implemented.

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## 62 5. References used for the Q4B Evaluation

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64 5.1 The PDG Stage 5B sign-off document: *Japanese Pharmacopoeial Forum*, Volume 13,  
65 Number 3 (August 2004).

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67 5.2 The pharmacopoeial references for *Test for Extractable Volume of Parenteral Preparations*:

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69 5.2.1 *European Pharmacopoeia* (Ph. Eur.): Supplement 5.3 (official on January 2006), Test  
70 for Extractable Volume of Parenteral Preparations (reference 01/2006:20917)

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72 5.2.2 *Japanese Pharmacopoeia* (JP): 6.05 Test for Extractable Volume of Parenteral  
73 Preparations as it appears in the JP Fifteenth Edition (March 31, 2006, The Ministry of  
74 Health, Labour and Welfare Ministerial Notification No. 285)

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76 5.2.3 *United States Pharmacopeia* (USP): official text published in the Revision Bulletin  
77 issued November 14, 2006, and as will appear in USP 30, 2<sup>nd</sup> Supplement. The USP  
78 official text also appeared in the Interim Revision Announcement appearing in  
79 Volume 33, number 2, of *Pharmacopoeial Forum*, official April 1, 2007. The official  
80 text is incorporated in <1> *Injections* General Test Chapter as the section entitled  
81 "Volume in Containers".  
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