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

Annex 4B: Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-organisms 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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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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INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL
REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

Draft Consensus Guideline

Q4B - Annex 4B
Evaluation and Recommendation of Pharmacopoeial Texts
for Use in the ICH Regions

ON

Microbiological Examination of Non-Sterile Products:
Tests for Specified Micro-organisms
General Chapter

Current Step 2 Version
Dated June 5, 2008

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 4B

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ICH Consensus Guideline
Released for Consultation on June 5, 2008, at Step 2 of the ICH Process

1. Introduction
This annex is the result of the Q4B process for Microbiological Examination of Non-Sterile
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. 2.6.13. Microbiological
Examination of Non-Sterile Products: Tests for Specified Micro-organisms, JP 4.05
Microbiological Examination of Non-Sterile Products: II. Microbiological Examination of Non-
Sterile Products: Tests for Specified Micro-organisms, and USP <62> Microbiological
Examination of Non-Sterile Products: Tests for Specified Micro-organisms can be used as
interchangeable in the ICH regions.

2.2 Acceptance Criteria
The proposed texts evaluated did not contain acceptance criteria.

3. Timing of Annex Implementation
When this annex is 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, in accordance with the conditions set out in this annex, as fulfilling the requirements for compliance with the Ph. Eur. Chapter 2.6.13. on the basis of the declaration of interchangeability made above.

4.4 MHLW consideration: The pharmacopoeial texts referenced in Section 2 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


5.2 The pharmacopoeial references for Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-organisms for this annex are:

5.2.1 *European Pharmacopoeia* (Ph. Eur.):

5.2.2 *Japanese Pharmacopoeia* (JP):

5.2.3 *United States Pharmacopeia* (USP):