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

Annex 4C: Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use 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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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.

For questions regarding this draft document contact (CDER) Robert King 301-796-1242, or (CBER) Christopher Joneckis 301-827-0373.
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.
Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions

ON Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use

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 Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use.

For each regulatory region the pharmacopoeial text is non-mandatory and is provided for informational purposes only.

The proposed texts were submitted by the Pharmacopoeial Discussion Group (PDG).

2. Q4B Outcome

The ICH Steering Committee, based on the evaluation by the Q4B Expert Working Group (EWG), recommends that the official pharmacopoeial texts, Ph.Eur. 5.1.4. Microbiological Quality of Non-Sterile Pharmaceutical Preparations and Substances for Pharmaceutical Use, JP General Information 12. Microbial Attributes of Nonsterile Pharmaceutical Products, and USP <1111> Microbiological Attributes of Non-sterile Pharmaceutical Products can be used as interchangeable in the ICH regions.

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 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 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
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: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use are:

5.2.1 *European Pharmacopoeia* (Ph. Eur.): 6.3 Edition (official on January 2009)
Microbiological Quality of Non-Sterile Pharmaceutical Preparations and Substances for Pharmaceutical Use (reference 01/2009: 50104)

The English version was published on January 9, 2008.

5.2.3 United States Pharmacopeia (USP):