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ICH guideline Q4B annex 11 to note for evaluation and recommendation of pharmacopoeial texts for use in the ICH regions on capillary electrophoresis – general chapter Step 5

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Q4B annex 11 to note for evaluation and recommendation of pharmacopoeial texts for use in the ICH regions on capillary electrophoresis – general chapter

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1. Introduction

This annex is the result of the Q4B process for the Capillary Electrophoresis 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 analytical procedures described in the official pharmacopoeial texts, Ph.Eur. 2.2.47. Capillary Electrophoresis, JP General Information 4. Capillary Electrophoresis, and USP General Information Chapter <1053> Biotechnology-derived Articles – Capillary Electrophoresis,¹ can be used as interchangeable in the ICH regions.

2.2. Acceptance criteria

The 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, regulatory authorities can accept the reference in a marketing authorisation application, renewal or variation application citing the use of the corresponding text from another

¹ The harmonized text under review has been incorporated into USP informational chapter <1053> Biotechnology-derived Articles – Capillary Electrophoresis, which is official (as of the July 1, 2009, USP Revision Bulletin). The USP proposed in Pharmacopoeial Forum (Vol. 36, number 1) to drop the existing (mandatory) General Chapter <727> Capillary Electrophoresis (also now official), and rename the (nonmandatory) chapter <1053> to Capillary Electrophoresis. The official date for this change will be May 1, 2011 (USP 34-NF29).

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 2.2.47. 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. Health Canada consideration

In Canada any of the pharmacopoeial 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 11, number 4 (October 2002).

5.2 The pharmacopoeial references for Capillary Electrophoresis General Chapter for this annex are:

5.2.1 European Pharmacopoeia (Ph. Eur.):

Supplement 6.6 (published June 2009, and official January 1, 2010), Capillary Electrophoresis (reference 01/2008:20247).

5.2.2 Japanese Pharmacopoeia (JP):

General Information 4. as it appears in the JP Fifteenth Edition (March 31, 2006, The Ministry of Health, Labour and Welfare Ministerial Notification No. 285). The English text was officially updated by errata published by MHLW at http://www.std.pmda.go.jp/jpPUB/Data/ENG/jpdata/H201105_jp15_errata.pdf on May 28, 2010.

5.2.3 United States Pharmacopoeia (USP):²

<1053> Biotechnology-derived Articles – Capillary Electrophoresis, *USP Revision Bulletin* posted May 29, 2009, official July 1, 2009.

² See footnote 1