PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION

CODE: Q-03/04
NAME: UNIFORMITY OF CONTENT/MASS
(Correction of the sign-off document Rev. 2 signed on 4 November 2015)

Lines 27-33: Addition to the following to the global text: [FOLLOWING

PARAGRAPH NOT ACCEPTED BY THE UNITED STATES PHARMACOPEIA]

Alternatively, products listed in item (4) above that do not meet the 25 mg/25% threshold limit may be tested for uniformity of dosage units by *Mass Variation* instead of the *Content Uniformity* test if the concentration relative standard deviation (RSD) of the drug substance in the final dosage units is not more than 2%, based on process validation data and development data, and if there has been regulatory approval of such a change. The concentration RSD is the RSD of the concentration per dosage unit (w/w or w/v), where concentration per dosage unit equals the assay result per dosage unit divided by the individual dosage unit weight. See the RSD formula in Table 2.

In addition, other editorial corrections were made to ensure consistency with revision 1 signed off on 9 November 2010.

For previous changes related to local and non-harmonized attributes, also see revision 1 signed off 9 November 2010 and the revised cover pages signed off 15 June 2011 and 6 November 2013.

Date: 26 Oct 2016

Signatures: Oct. 26, 2016

European Pharmacopoeia — C. Violle

Japanese Pharmacopoeia — Oct 26. 2016 — Hanahiro Okuda for Masanobu Tamada

United States Pharmacopeia — CATHERINE SHEEHAN

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