

PHARMACOPOEIAL DISCUSSION GROUP

CODE: Q-003/04

NAME: Uniformity of Dosage Units
Revision 1 – revised sign-off cover page

Harmonized provisions:

<u>Provision</u>	<u>EP</u>	<u>JP</u>	<u>USP</u>
Introduction	+	+	+*
Content Uniformity	+	+	+
Mass Variation	+	+	+
Criteria	+	+	+

*The following statement is not accepted and will not be included 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."

Non-harmonized Attributes:

The following statement will be listed as a non-harmonized attribute for EP at the end of the introductory section:

"Alternatively, products 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."

Local Attributes:

EP	JP	USP
N/A	N/A	N/A

European Pharmacopoeia

Signature



Name

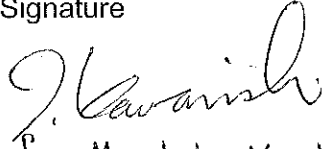
WESTEL

Date

15.06.2014

Japanese Pharmacopoeia

Signature



Name

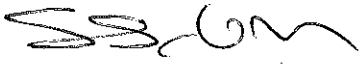
Toru KAWANISHI

Date

16/6/2011

For Masatoshi Narita
United States Pharmacopoeia

Signature



Name

Susan S. deMars

Date

June 15, 2011