

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:

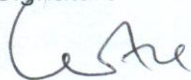
"Alternatively, products that do not meet the 25 mg/25% threshold limit may be tested for uniformity of dosage units by Mass Variation instead of the Content Uniformity test if the concentration relative standard deviation (RSD) of the drug substance in the final dosage units is not more than 2%, based 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

W. F. STEL

Date

10.06.2014



Japanese Pharmacopoeia

Signature

T. Kawanishi
for Masatoshi Narita

Name

Toru KAWANISHI

Date

16/6/2011

United States Pharmacopeia

Signature

SS de M

Name

Susan S. de M

Date

June 15, 2011