PHARMACOPOEIAL DISCUSSION GROUP

CODE: Q-003/04
NAME: Uniformity of Dosage Units
Revision 1

Harmonized provisions:

Provision	EP	JP	USP
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:

N/A

Local Attributes:

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

European Pharmacopoeia

Signature	Name	Date
	WERTEL	9/11/10

Japanese Pharmacopoeia

Signature	Name	Date
T. Kawanishi for Masatoshi Narita	Toru KAWANISHI	Nov. 9 2010

United States Pharmacopeia

Signature	Name	Date
	Susan S. deMars	9 November 2010