

**PHARMACOPOEIAL DISCUSSION GROUP**

CODE: Q-003/04

NAME: Uniformity of Dosage Units  
Revision 1

**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:**

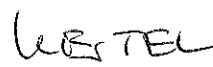
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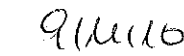
**Local Attributes:**

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

**European Pharmacopoeia**

  
Signature


  
Name

  
Date


**Japanese Pharmacopoeia**

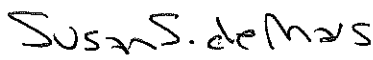
  
for Masatoshi Narita  
Signature

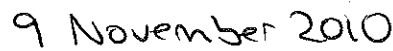
  
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Date

**United States Pharmacopoeia**

  
Signature

  
Name

  
Date