

PHARMACOPEIAL DISCUSSION GROUP

CORRECTION OF SIGN-OFF COVER SHEET

Q-01 DISSOLUTION

(Correction of the Sign off cover sheet Rev 3, signed 10 June 2010)

Harmonised provisions

Provision	Ph. Eur.	JP	USP
Apparatus 1 (Basket apparatus)	+	+	+
Apparatus 2 (Paddle apparatus)	+	+	+
Apparatus 3 (Reciprocating cylinder)	+	–	+
Apparatus 4 (Flow-through cell)	+	+	+
Procedure, apparatus 1 or 2:			
<i>Immediate-release dosage forms</i>	+	+	+
<i>Extended-release dosage forms</i>	+	+	+
<i>Delayed-release dosage forms</i>	+	–	+
Procedure, apparatus 3:			
<i>Immediate-release dosage forms</i>	+	–	+
<i>Extended-release dosage forms</i>	+	–	+
<i>Delayed-release dosage forms</i>	+	–	+
Procedure, apparatus 4:			
<i>Immediate-release dosage forms</i>	+	+	+
<i>Extended-release dosage forms</i>	+	+	+
<i>Delayed-release dosage forms</i>	+	–	+
Interpretation:			
<i>Immediate-release dosage forms</i>	+	+	+
<i>Extended-release dosage forms</i>	+	+	+
<i>Delayed-release dosage forms</i>	+	–	+

LEGEND

+: will adopt and implement

–: will not stipulate

Table of terminology of release characteristic of dosage forms:


Some of the terminology used to describe the release characteristic of dosage forms has not been harmonised. The following terminology equivalency table is given to aid understanding of the sign-off text.

USP	JP	Ph. Eur.
Immediate-release dosage forms		Conventional-release dosage forms
Extended-release dosage forms		Prolonged-release dosage forms


Residual Differences:

- 1) *In the USP, where dissolution failure occurs because of evidence of cross-linking in dosage forms containing gelatin, the test may be repeated with the addition of enzymes.*
- 2) *USP specifies the use of USP calibrators for the calibration of dissolution apparatus.*
- 3) *As indicated in the text, JP will not include Apparatus 3, nor sections related to delayed-release dosage forms. As for delayed-release dosage forms, JP stipulates a different local procedure and interpretation.*
- 4) *Procedure, Apparatus 1 or 2, EP will allow performance of the test without removal of the thermometer if validation has been carried out in this way.*
- 5) *The USP will specify the procedure and acceptance criteria for pooled dissolution.*
- 6) *The use of larger vessels in Apparatus 1 and 2 is accepted as a local USP requirement and is therefore currently outside the harmonized text. USP local text for larger vessels states the following, "for a nominal volume of 2L, the height is 280 mm to 300 mm and its inside diameter is 98 mm to 106 mm; and for a nominal capacity of 4L, the height is 280 mm to 300 mm and its inside diameter is 145 mm to 155 mm."*

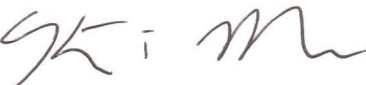
European Pharmacopoeia

Signature	Name	Date
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Japanese Pharmacopoeia

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United States Pharmacopoeia

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