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:			
Immediate-release dosage forms	+	+	+
Extended-release dosage forms	+	+	+
Delayed-release dosage forms	+	–	+
Procedure, apparatus 3:			
Immediate-release dosage forms	+	–	+
Extended-release dosage forms	+	–	+
Delayed-release dosage forms	+	–	+
Procedure, apparatus 4:			
Immediate-release dosage forms	+	+	+
Extended-release dosage forms	+	+	+
Delayed-release dosage forms	+	–	+
Interpretation:			
Immediate-release dosage forms	+	+	+
Extended-release dosage forms	+	+	+
Delayed-release dosage forms	+	–	+

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 l 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 I 06 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
		2/10/19

Japanese Pharmacopoeia

Signature	Name	Date
	Haruhiro Okuda for Fumi Yamamoto	Oct 2nd, 2019

United States Pharmacopeia

Signature	Name	Date
	KEVIN MOORE	02-OCT-2019