PHARMACOPOEIAL DISCUSSION GROUP

Q01

DISSOLUTION REV. 2

It is understood that sign-off covers the technical content of the draft and each party will adapt it as necessary to conform to the usual presentation of the pharmacopoeia in question; such adaptation includes stipulation of the particular pharmacopoeia's reference materials and general chapters.

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

USP	EP	JP
Immediate-Release DF	Immediate-Release DF	Not Described
Modified-Release DF	Modified-Release DF	Not Described
-Extended-Release DF	Prolonged-Release DF	Not Described
-Delayed-Release DF	Gastro-Resistant DF	Enteric-Coated Preparations

Residual Differences:

1) In the USP, where dissolution failure occurs for dosage forms employing gelatine, 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.
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 of the harmonized text. USP local text for larger vessels states the following: "for a nominal capacity of 2 L, the height is 280 mm to 300 mm and its inside diameter is 98 mm to 106 mm; and for a nominal capacity of 4 L, the height is 280 mm to 300 mm and its inside diameter is 145 mm to 155 mm."

European Pharmacopoeia

Signature	Name	Date
	KEITEL	12/11/08

Japanese Pharmacopoeia

Signature	Name	Date
	for Toshiro Nakagaki	Nov. 12. 2008

United States Pharmacopeia

Signature	Name	Date
	DARRELL R. ABERNETHY	12 Nov, 2008