PHARMACOPOEIAL DISCUSSION GROUP
SIGN-OFF DOCUMENT
NAME: DISSOLUTION, REV. 3

Rev. 3:
Change to wire diameter specification in Figure 1 to "0.22-0.31 mm" and replacement of Figure 2a with a figure showing 7 coils.

Rev. 2:
The terminology used to describe modified-release dosage form 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 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.
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	Date 10/06/2010
Japanese Pharmacopeia for Masatoshi Narita	Date June 10, 2010
United States Pharmacopeia	Date 10-Jun-2010