## PHARMACOPOEIAL DISCUSSION GROUP

## SIGN-OFF DOCUMENT, Rev. 1

## **NAME: DISSOLUTION**

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.

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	<b>Enteric-Coated Preparations</b>

## 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) EP and JP will allow both pulsated and non-pulsated flow for Apparatus 4.
- 4) As indicated in the text, JP will not include Apparatus 3, nor sections related to delayed-release dosage forms.
- 5) 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.
- 6) The USP will specify the procedure and acceptance criteria for pooled dissolution.

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Japanese Pharmacopeia	Date
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