PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

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.

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) EP 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 text without removal of the thermometer if validation has been carried out in this way.

European Pharmacopoeia — Date

Agnès ARTIGES — 10 June 04

Japanese Pharmacopeia — Date

for S. Kishida — 22 June '04

United States Pharmacopeia — Date

Eric B Sherman — 10-June-04