PHARMAPOEIA 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.

<table>
<thead>
<tr>
<th>USP</th>
<th>EP</th>
<th>JP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate-Release DF</td>
<td>Immediate-Release DF</td>
<td>Not Described</td>
</tr>
<tr>
<td>Modified-Release DF</td>
<td>Modified-Release DF</td>
<td>Not Described</td>
</tr>
<tr>
<td>-Extended-Release DF</td>
<td>Prolonged-Release DF</td>
<td>Not Described</td>
</tr>
<tr>
<td>-Delayed-Release DF</td>
<td>Gastro-Resistant DF</td>
<td>Enteric-Coated Preparations</td>
</tr>
</tbody>
</table>

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 pulsed 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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