PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT
CODE: Q-08
NAME: Extractable Volume of Parenterals
Update to Revision 1 for USP Local Requirements

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.

Harmonised provisions:

<table>
<thead>
<tr>
<th>Provision</th>
<th>EP</th>
<th>JP</th>
<th>USP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-dose Containers</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Multi-dose Containers</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Cartridges and prefilled syringes</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Parenteral infusions</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

Non-harmonised provisions:

Not applicable

Local requirement

<table>
<thead>
<tr>
<th>EP</th>
<th>JP</th>
<th>USP</th>
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</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>Added as national text to the Volume in Container section in USP &lt;1&gt; Injections that would give guidance for sterile solid formulations. Previously, the section only discussed how to determine volume in container for liquid products, and industry was seeking clarity/guidance on volume determination for sterile solid formulations. Text printed in Second Supplement to USP 33-NF 28 Reissue in June 2010, Official February 1, 2011.</td>
</tr>
</tbody>
</table>

European Pharmacopoeia

[Signature]

WERTHE

Date

Nov. 9, 2010

Japanese Pharmacopoeia

[Signature]

Tori KAWANISHI

Date

Nov. 9, 2010

United States Pharmacopoeia

[Signature]

Susan S. deMars

Date

9 November 2010