

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:

Provision	EP	JP	USP
Single-dose Containers	+	+	+
Multi-dose Containers	+	+	+
Cartridges and prefilled syringes	+	+	+
Parenteral infusions	+	+	+

Non-harmonised provisions:

Not applicable

Local requirement

EP	JP	USP
NA	NA	Added as national text to the Volume in Container section in USP <1> <i>Injections</i> 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 <i>Second Supplement to USP 33-NF 28 Reissue</i> in June 2010, Official February 1, 2011.

European Pharmacopoeia



Signature

L. ESTE

Name

9/11/10

Date

Japanese Pharmacopoeia



for Masatoshi Narita

Signature

Toru KAWANISHI

Name

Nov. 9, 2010

Date

United States Pharmacopoeia



Signature

Susan S. de Mars

Name

9 November 2010

Date