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*> *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.

European Pharmacopoeia

Signature | Name | Date

Japanese Pharmacopoeia

for Masatoshi Narita — Toru KAWANISHI — Nov. 9. 2010

Signature | Name | Date

United States Pharmacopeia

Susan S. deMars — 9 November 2010

Signature | Name | Date