

PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

CODE: Q-09

NAME: Particulate Contamination

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
Introduction	+	+	+
Method 1	+	+	+
Method 2	+	+	+

Non-harmonised provisions:

- The requirements for preparations supplied in containers with a nominal value of 100 mL
- JP and USP will include a detailed section on calibration of the apparatus

Local requirement

EP	JP	USP
NA	NA	<p>Added as national text in Particulate Matter in Injection <788> and currently appears in the <i>First Supplement to the USP 33-NF 28 Reissue</i> in April 2010 with an official date of October 1, 2010.</p> <ul style="list-style-type: none"> • Exemption of radiopharmaceutical preparations from the requirements of USP General Chapter <788>: <ol style="list-style-type: none"> 1. Radiopharmaceuticals preparations for parenteral use must be shipped to user center immediately after compounding and filling, due to the short half-life duration of the isotope imparting radioactivity, thus there is very minimal time for testing. Testing radiopharmaceuticals requires containment of radioactivity and it is impractical to equip a laboratory and protect analysts in such an environment. Exemption is currently in the EP. • Solution for injections administered by intramuscular or subcutaneous route must meet the requirements of <788> (Delayed Implementation: Official August 1, 2011). <ol style="list-style-type: none"> 1. It was requested that language exempting <788> testing for IM and SC preparation, be placed back into the Compendia, which was deleted during harmonization. After review of the revision file and discussion, no scientifically sound rationale for why there should be an exemption for SC and IM preparations. Some IM and SC product are not amenable to <788> testing due to their physical state. However, most IM and SC products are solutions and are amenable to testing. Committee felt an exemption should be based on the physical state of the product, not on the route of administration. Committee decided to add text that explicitly states that IM and SC products are not exempt from <788> testing.

7.K.

SR CW

	<ul style="list-style-type: none"> Parenterals packaged and labeled exclusively for use as irrigating solutions are exempt from the requirements of <788>. <ol style="list-style-type: none"> To maintain consistency between <1> and <788>, the irrigating solution exemption, which currently appears in <1>, is being added. Parenteral products for which the labeling specifies use of a final filter prior to administration are exempt from the requirements of <788> provided the scientific data are available to justify this exemption. <ol style="list-style-type: none"> It was requested that language exempting <788> testing for products passed through a final filter before administration, be placed back into the Compendia, which was deleted during the harmonization <788>. Committee did not want a final filter exemption to be used as a way to cover up poor manufacturing or product development. Committee decided to add text that would exempt products that use final filters from <788> testing, provided there were scientific data to justify such an exemption. Exemption is currently in the EP.
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European Pharmacopoeia



Signature

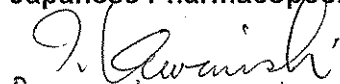
LESTER

Name

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for Masatoshi Narita
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Date