

PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

CODE: E-58

NAME: MANNITOL

Harmonized Attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification by IR *	+	+	+
Appearance of solution	+	+	+
Conductivity	+	+	+
Melting point	+	+	+
Reducing sugars	+	+	+
Related substances	+	+	+
Nickel	+	+	+
Loss on drying	+	+	+
Microbial contamination	+	-	+
Bacterial endotoxins	+	-	+
Assay	+	+	+
Labelling	+	-	+

* EP and USP will use Mannitol Reference Standard; JP will use Reference Spectrum

Legend

+ will adopt and implement ; - will not stipulate

Non-harmonized attributes

Description/Characters, Heavy metals, Container/packaging and storage

Local requirements

EP	JP	USP
Identification (specific optical rotation, melting point, TLC) Absence of <i>Salmonella</i> Functionality-related characteristics		

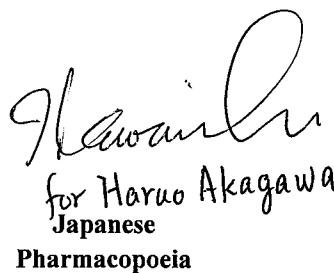
Reagents and reference materials

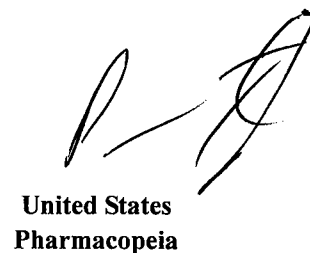
Each pharmacopoeia will adapt the text to take account of local reference materials and reagent specifications.

Date: 06/06/2012

Signatures:


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