

PHARMACOPOEIAL DISCUSSION GROUP
CORRECTION OF SIGN-OFF COVER SHEET

E-58: MANNITOL

Correction of sign-off coversheet signed on 26 June 2014

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, Containers/Packaging and storage

Local requirements

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

Reagents and reference materials

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

European Pharmacopoeia

Signature



Name

S. KISTEL

Date

31/01/14

Japanese Pharmacopoeia

Signature

H. Okuda

Name

H. OKUDA
for Fumi Yamamoto

Date

3. OCT 2018

United States Pharmacopeia

Signature

Kevin Moore

Name

KEVIN MOORE

Date

3-OCT-2018