

**PHARMACOPOEIAL DISCUSSION GROUP
CORRECTION OF SIGN-OFF COVER SHEET**

CODE: E-58

NAME: MANNITOL

(Correction 3 of sign-off coversheet signed on June 6, 2012)

Harmonised 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-harmonised attributes

Description/Characters, Containers/Packaging and storage

Local requirements

EP	JP	USP
Second identification (specific optical rotation, melting point, TLC).	Test for required detectability and System repeatability (Related	None

E-58

Correction sign-off cover sheet

December 2022

Absence of <i>Salmonella</i> . Functionality-Related Characteristics (Particle-size distribution, Powder flow).	substances), System repeatability (Assay)	
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Reagents and reference materials

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

Each pharmacopoeia will consider actual titrant concentration in equations according to their local rules of calculation for titration.

European Pharmacopoeia

Signature

Name

Date

DocuSigned by:

 82DD39EBFD74446...

Petra Doerr

20.12.2022

Japanese Pharmacopoeia

Signature

Name

Date

Y. Goda
 for Y. Yoshida

Yukihiko Goda

20 Jan, 2023

United States Pharmacopoeia

Signature

Name

Date

DocuSigned by:

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Kevin Moore

12/15/2022