

**PHARMACOPOEIAL DISCUSSION GROUP
SIGN-OFF DOCUMENT**

CODE: E-58

NAME: MANNITOL

Correction of sign-off coversheet (Previously signed on 3 October 2018)

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 (Particle-size distribution, Powder flow)	Heavy metals, Test for required detectability and System repeatability (Related substances), System repeatability (Assay)	None

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

P. Doerr

Petra Doerr

28/10/2021

Japanese Pharmacopoeia

Signature

Name

Date

Y. Goda
for Y. Yoshida

Yukihiko Goda

15 Nov, 2021

United States Pharmacopoeia

Signature

Name

Date

K.T.M

Kevin Moore

9-NOV-2021