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

YG
KM PD

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

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

European Pharmacopoeia

Signature	Name	Date
P. Dorr	Petra Dorr	28/10/2021

Japanese Pharmacopoeia

Signature	Name	Date
Y. Goda for Y. Yoshida	Yukihiro Goda	15 Nov, 2021

United States Pharmacopeia

Signature	Name	Date
T. M	Kevin Moore	9-NOV-2021