

PHARMACOPOEIAL DISCUSSION GROUP
CORRECTION OF THE SIGN-OFF COVER SHEET
E-64 ISOMALT

(Correction of the sign-off cover sheet Corr. 2 signed on 29 November 2016)

Harmonized Attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification	+	+	+
Conductivity	+	+	+
Reducing sugars	+	+	+
Related substances	+	+	+
Nickel	-	+	+
Water	+	+	+
Assay	+	+	+
Labelling	+	+	+

Legend

+ will adopt and implement ; - will not stipulate

Non-harmonized attributes

Description (incl. test for optical rotation)/Characters, Packaging and storage

Local requirements

EP	JP	USP
Second identification (TLC, colour reaction)	Identification (colour reaction); Heavy metals	Identification by TLC; assay (RSD NMT 2.0%)

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. K. EITEL

Date

3/10/18

Japanese Pharmacopoeia

Signature



Name

H. OKUDA
for Fumi Yamamoto

Date

3. Oct 2018

United States Pharmacopoeia

Signature



Name

KEVIN MOORE

Date

3-OCT-2018