

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

CODE: E-64

NAME: ISOMALT

(Correction 2 of the sign-off cover sheet of Corr. 1 signed on November 29, 2016)

Harmonised 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-harmonised attributes

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

Local requirements

EP	JP	USP
Second identification (TLC, colour reaction)	Identification (colour reaction)	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.

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

E-64

Correction sign-off cover sheet

December 2022

European Pharmacopoeia

Signature

Name

Date

DocuSigned by:
Petra Doerr
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:
Kevin Moore
A7467E52FCC94E9...

Kevin Moore

12/15/2022