

PHARMACOPOEIAL DISCUSSION GROUP

CODE: E-64

NAME: ISOMALT

CORRECTION 1

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, ~~Heavy metals~~, Packaging and storage

Local requirements

EP	JP	USP
Identification (TLC, colour reaction)	Identification (colour reaction); <u>Heavy metals</u>	Identification by TLC; <u>assay</u> (RSD NMT 2.0%)

Reagents and reference materials

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

Date:

Nov. 29, 2016.

Signatures:

European  
Pharmacopoeia

Japanese  
Pharmacopoeia  
Haruhiko Okuda  
Jun Masamitsu Yamada

United States  
Pharmacopoeia

CATHERINE SHERIDAN