

PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

CODE: E-64

NAME: ISOMALT

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)	Identification by TLC

Reagents and reference materials

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

Date: 27/6/13

27/6/2013

June 27, 2013

Signatures:

European
Pharmacopoeia

for Haruo Akagawa
Japanese
Pharmacopoeia

United States
Pharmacopoeia