

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

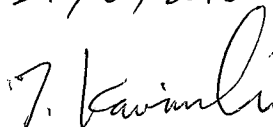
27/6/2013

June 27, 2013

Signatures:



**European
Pharmacopoeia**



for Haruo Akogawa
Japanese

Pharmacopoeia



**United States
Pharmacopoeia**