

PHARMACOPOEIAL DISCUSSION GROUP

REVISION OF SIGN-OFF COVER SHEET

CODE: E44

NAME: Stearic Acid

(Revision of the sign-off cover sheet of Revision 1 Correction 1 signed on Nov. 13, 2014)

Item to be revised: Local requirement for JP

Harmonised attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification A	+	+	+
Identification B	+	+	+
Identification C	+	+	+
Acidity	+	+	+
Iodine value	+	+	+
Freezing point	+	+ ¹	+
Assay	+	+	+
Labelling (type of stearic acid)	+	+	+

Legend

+ will adopt and implement ; – will not stipulate

Non-harmonised attributes

Characters/description, Nickel, Labelling (source of stearic acid).

Local requirements

JP: Heavy metals, Residue on ignition, Container and Storage, ¹ Freezing point (Alternative apparatus)

USP: Microbial limits

EP: Appearance

Reagents and reference materials

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

European Pharmacopoeia

Signature

C. Steu

Name

W. ESTEL

Date

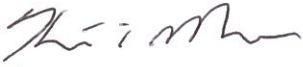
11/11/15

*K. M.
H. O.*

Japanese Pharmacopoeia

Signature	Name	Date
 for Kazuhiko Mori	Haruhiko Okuda	July 1st 2015

United States Pharmacopeia

Signature	Name	Date
	KEVIN MOORE	01-JUL-2015