

**PHARMACOPOEIAL DISCUSSION GROUP
SIGN-OFF DOCUMENT**

CODE: E-44

NAME: STEARIC ACID

(Correction of the sign-off cover sheet of Rev. 2 signed on November 15, 2021)

Harmonised attributes

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

* USP stipulates the note [Note—Stearic Acid labeled solely for external use is exempt from the requirement that it be prepared from edible sources.]

Legend

+ will adopt and implement ; – will not stipulate

Non-harmonised attributes

Characters/description, Residue on ignition (JP/USP), Containers and storage/Packaging and storage (JP/USP).

Local requirements

EP	JP	USP
Appearance, Functionality-Related Characteristics (Particle-size distribution, Specific surface area)	None	Color of Solution, Labeling (If it is for external use only, the labeling so indicates.)

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-44

Correction sign-off cover sheet

December 2022

European Pharmacopoeia

Signature

Name

Date

DocuSigned by:
Petra Doerr
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Petra Doerr

20.12.2022

Japanese Pharmacopoeia

Signature

Name

Date

Y. Goda
for Y. Yoshida

Yukihiro Goda

20 Jan, 2023

United States Pharmacopeia

Signature

Name

Date

DocuSigned by:
Kevin Moore
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Kevin Moore

12/15/2022