

E-25

Correction sign-off cover sheet

December 2022

**PHARMACOPEIAL DISCUSSION GROUP
CORRECTION OF SIGN-OFF COVER SHEET**

CODE: E-25

NAME: MAGNESIUM STEARATE

(Correction 2 of the sign-off cover sheet signed on June 3, 2008)

Harmonised attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification			
A	+	+	+
B	+	+	+
Acidity or alkalinity	+	+	+
Loss on Drying	+	+	+
Limit of chloride	+	+	+
Limit of sulfate	+	+	+
Limit of cadmium	+	-	+
Limit of nickel	+	-	+
Limit of lead	+	-	+
Stearic acid and palmitic acid	+	+	+
Assay	+	+	+

Legend

+ will adopt and implement; - will not stipulate

Non-harmonised attributes

Characters, Labeling, Microbial limits, Specific surface area, Packaging and Storage

Local requirements

EP	JP	USP
Second identification (identification A, Freezing point, Acid Value) Functionality-Related Characteristics (Particle-size distribution, Specific Surface Area, Thermogravimetry)	Relative Content of Stearic Acid and Palmitic Acid, <i>System Suitability</i> – Test for required detectability, and Time span of measurement	None

Reagents and reference materials

Each pharmacopeia will adopt the text to take account of local reference materials and reagent specifications.

Each pharmacopeia will consider actual titrant concentration in equations according to their local rules of calculation for titration.

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European Pharmacopoeia

Signature

Name

Date

DocuSigned by:
Petra Doerr
82DD39EBFD74446...

Petra Doerr

20.12.2022

Japanese Pharmacopoeia

Signature

Name

Date

Y. Goda
for Y. Yoshida

Yukihiko Goda

20 Jan, 2023

United States Pharmacopoeia

Signature

Name

Date

DocuSigned by:
Kevin Moore
A7467E52FCC94E9...

Kevin Moore

12/15/2022