

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

**CODE: E-25**

**NAME: MAGNESIUM STEARATE**

Correction of the sign-off cover sheet (previous sign-off on 27 June 2013)

	Harmonized attributes		
	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-harmonized attributes**

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

**Local requirements**

EP	JP	USP
Second identification (Freezing point, Acid Value) FRC (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 Heavy metals	none

**Reagents and reference materials**

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

**European Pharmacopoeia**

Signature



Name

VIERLE G. MUE

Date

22-Dec-20

**Japanese Pharmacopoeia**

Signature

H. Otsuda  
for Y. Yoshida

Name

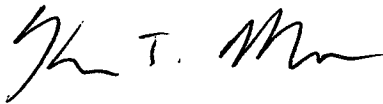
Hanahiko Otsuda

Date

16 Dec/2020

**United States Pharmacopoeia**

Signature



Name

KEVIN MOORE

Date

19-NOV-2020