

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

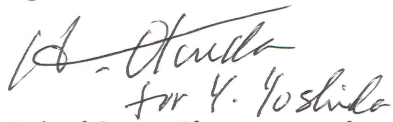
VIERCE @ Wura

Date

22-Dec-2020

Japanese Pharmacopoeia

Signature



for Y. Yoshida

Name

Harechiro Okuda

Date

16 Dec/2020

United States Pharmacopoeia

Signature



Name

KEVIN MOORE

Date

19-NOV-2020