PHARMACOPEIAL DISCUSSION GROUP CORRECTION OF SIGN-OFF COVER SHEET

CODE: E-39

NAME: SODIUM STARCH GLYCOLATE

(Correction 2 of the sign-off cover sheet of Rev. 3 signed on 27 June 2013)

Harmonised attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification		1 (40 %)	The state of the s
A	+	+	+
В	+	+	+
pН	+	+	+
Loss on drying	+	+	+
Limit of iron	+	+	+
Limit of sodium chloride	+	+	+
Limit of sodium glycolate	+	+	+
Assay	+	+	+
Microbial Contamination	+	+	+\\\

Legend

Non-harmonised attributes

Characters, Packaging and storage, Identification (IR), Labelling

Local requirements

EP	JP	USP	777
Appearance of solution, Identification (complies with pH test), Identification (formation of a suspension), Functionality-Related Characteristics (Settling volume, Degree of substitution, Particle-size distribution)	None	Identification (sodium flame test)	

⁺ will adopt and implement; - will not stipulate

E-39

Correction sign-off cover sheet

December 2022

Reagents and reference materials

Each pharmacopeia will adapt 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.

European Pharmacopoeia

Signature

Name

Date

DocuSigned by:

Petra Doerr

20.12.2022

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Japanese Pharmacopoeia

Signature

Name

Date

Yakihiro Goda 20 Jan, 2023

y. goda for Y. Yoshida

United States Pharmacopeia

Signature

Name

Date

-DocuSigned by:

teun Moon

Kevin Moore

12/15/2022