

PHARMACOPEIAL DISCUSSION GROUP
CORRECTION OF SIGN-OFF COVER SHEET
CODE: E-39

NAME: SODIUM STARCH GLYCOLATE
(Correction of the sign-off cover sheet of Rev 3 signed on 27 June 2013)

Harmonized attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification			
A	+	+	+
B	+	+	+
pH	+	+	+
Loss on drying	+	+	+
Limit of iron	+	+	+
Limit of sodium chloride	+	+	+
Limit of sodium glycolate	+	+	+
Assay	+	+	+
Microbial Contamination	+	+	+

Legend

+ will adopt and implement; – will not stipulate

Non-harmonized attributes

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

Local requirements

EP	JP	USP
Appearance of solution, Identification (complies with pH test), Identification (formation of a suspension), Functionality-Related Characteristics (Settling volume, Degree of substitution, Particle-size distribution)	Heavy metals	Identification (sodium flame test)

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

P. Durr

Petra Durr

28/10/2021

Japanese Pharmacopoeia

Signature

Name

Date

Y. Goda
for Y. Yoshida

Yukihiko Goda

15 Nov, 2021

United States Pharmacopeia

Signature

Name

Date

J. T. Moore

KEVIN MOORE

9-NOV-2021