

**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. Doerr*

*Petra Doerr*

*28/10/2021*

**Japanese Pharmacopoeia**

Signature

Name

Date

*Y. Goda*  
*for Y. Yoshida*

*Yukihiko Goda*

*15 Nov, 2021*

**United States Pharmacopeia**

Signature

Name

Date

*Kevin Moore*

*KEVIN MOORE*

*9-NOV-2021*