

E-09

Correction sign-off cover sheet

December 2022

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

**CODE: E-09**

**NAME: CROSCARMELOSE SODIUM**

**(Correction of the sign-off cover sheet of Rev. 1 signed on December 22, 2020)**

**Harmonised attributes**

Attribute	EP	JP	USP
Definition	+	+	+
Identification			
A (IR test)	+	+	+
B	+	+	+
C (wet chemistry)	+	+	+
pH	+	+	+
Loss on drying	+	+	+
Residue on ignition	+	+	+
Degree of substitution	+	+	+
Settling volume	+	+	+

**Legend**

+ will adopt and implement; – will not stipulate

**Non-harmonised attributes**

Characters/Description, Microbial limits, Sodium chloride and sodium glycolate, Water-soluble substances, Packaging and storage/Containers and storage

**Local requirements**

EP	JP	USP
Functionality-Related Characteristics (Particle size distribution and Hausner ratio)	None	None

**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.

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**European Pharmacopoeia**

Signature

Name

Date

DocuSigned by:  
*Petra Doerr*  
82DD39EBFD74446...

Petra Doerr

20.12.2022

**Japanese Pharmacopoeia**

Signature

Name

Date

*Y. Goda*  
*for Y. Yoshida*

*Yukihiko Goda*

*20 Jan, 2023*

**United States Pharmacopoeia**

Signature

Name

Date

DocuSigned by:  
*Kevin Moore*  
A7467E52FCC94E9...

Kevin Moore

12/15/2022