E-19 October 2021

PHARMACOPEIAL DISCUSSION GROUP CORRECTION OF SIGN-OFF COVER SHEET

CODE: E-19

NAME: HYDROXYPROPYLCELLULOSE

(Correction of the sign-off cover sheet signed on 13 September 2017)

Harmonized attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification A (thin film)	. +	+	+
Identification B (IR)	+	+	+
pH	+	+	+
Loss on Drying	+	+	+
Residue on ignition	+	+	+
Silica	+	+	+
Assay for hydroxypropoxy	+	+	+
groups			

Legend

+ will adopt and implement; - will not stipulate

Non-harmonized attributes

Characters/Description, Packaging and storage, Viscosity, Labeling

Local requirements

EP	JP	USP	
Identification (Cloud Point),	Heavy Metals	Lead	
Functionality-Related Characteristics (Viscosity,			
Degree of substitution			
(Assay for hydroxypropoxy			
(Assay for hydroxypropoxy groups)*, Particle-size distribution, Powder flow)			

^{*} Degree of substitution (Assay for hydroxypropoxy groups) is a harmonised attribute. It is also included in the Functionality-Related Characteristics section of the EP monograph.

Reagents and reference materials

Each pharmacopeia will adapt the text to take account of local reference materials and reagent specifications.

Km PI

European Pharmacopoeia

Signature

Name

Date

Petra Doerr

28/10/2021

Japanese Pharmacopoeia

Signature

Name

Date

Y. Goda for Y. Yos.

Yakihiro Goda 15 Nov, 202/

United States Pharmacopeia

Signature

Name

Date

7LT.M

KEVIN MOINE

9-NOU-2021