E-19

Correction sign-off cover sheet

December 2022

PHARMACOPEIAL DISCUSSION GROUP CORRECTION OF SIGN-OFF COVER SHEET CODE: E-19 NAME: HYDROXYPROPYLCELLULOSE (Correction 3 of the sign-off cover sheet signed on June 27, 2013)

Harmonised attributes

Attribute	EP	ЛР	USP
Definition	+	+	+
Identification A (thin film)	+	+	1. Stock
Identification B (IR)	+	+	+
pH	+	+	1
Loss on Drying	+	+	+
Residue on ignition	+	+	+
Silica	+	+	+
Assay for hydroxypropoxy groups	+	+	e +

Legend

+ will adopt and implement; - will not stipulate

Non-harmonised attributes

Characters/Description, Packaging and storage, Viscosity, Labeling

Local requirements

EP	JP	USP
Identification (Cloud Point),	None	Lead
Functionality-Related		
Characteristics (Viscosity,		-
Degree of substitution (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.

DocuSign Envelope ID: 5DE3CF9A-5512-49A5-B467-220BA2797BA1

E-19 Correction sign-off cover sheet December 2022

European Pharmacopoeia

Signature

Name

Petra Doerr

20.12.2022

Date

Petra Doerr 82DD39EBFD74446...

DocuSigned by:

Japanese Pharmacopoeia

Signature

y. goda for Y. Yoshida

United States Pharmacopeia

Signature

-DocuSigned by:

A7467E52FCC94E9...

Name

Yakihiro Goda

Date

20 Jan, 2023

Kevin Moore

Name

Date 12/15/2022

2/2