PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION OF SIGN-OFF COVER SHEET CODE: E-16

NAME: CROSPOVIDONE

(Correction 3 of the sign-off cover sheet signed on 9 November 2010)

Harmonised attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification A	+	+	+
Identification B	+	- U +	+
Identification C	+	+	+
Peroxides	+	+	+
Water-soluble substances	+	+	+
Impurity A (1-vinylpyrrolidin -2-one)	0 (tot)	takinin	
Loss on drying	+	+	+
Residue on ignition/ Sulfated ash	+	+	+
Assay	+	+	+,
Storage	+	+	+

Legend

Non-harmonised attributes

Characters/Description, Identification by IR, Labelling

Local requirement

EP	JP	USP
Functionality-Related	None	None
Characteristics (Hydration		
capacity, Particle-size		
distribution, Powder flow,		
Settling volume)		

⁺ will adopt and implement; - will not stipulate

E-16

Correction sign-off cover sheet

December 2022

Reagents and reference materials

Each pharmacopoeia 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

DocuSigned by:

Petra Doerr

20.12.2022

-82DD39EBFD74446... Japanese Pharmacopoeia

Name

Date

Signature

y-goda

Yukihiro Goda

20 Jan, 2023

United States Pharmacopeia

Signature

Name

Date

DocuSigned by:

Lewin Moore A7467E52FCC94E9...

Kevin Moore

12/15/2022