

**PHARMACOPOEIAL DISCUSSION GROUP  
CORRECTION OF SIGN-OFF COVER SHEET  
CODE: E-54**

**NAME: COPOVIDONE**

(Correction of the sign-off cover sheet of Corr. 1 signed on October 2, 2019)

**Harmonised attributes**

Attribute	EP	JP	USP
Definition	+	+	+
Labelling	+	+	+
Identification*	+	+	+
K-value	+	+	+
pH	+	+	+
Purity			
(1) Clarity and color of solution	+	+	+
(2) Aldehydes	+	+	+
(3) Peroxides	+	+	+
(4) Hydrazine	+	+	+
(5) 1-vinyl-2-pyrrolidone and vinyl acetate	+	+	+
(6) 2-Pyrrolidone	+	+	+
Loss on drying	+	+	+
Residue on ignition	+	+	+
Assay			
Vinyl acetate	+	+	+
Nitrogen	+	+	+

\* EP and USP will adopt Copovidone Reference Standard; JP will adopt Reference Spectrum

**Legend**

+ will adopt and implement; – will not stipulate

**Non-harmonised attributes**

Characters/Description, Containers and storage/Packaging and storage

**Local requirements**

EP	JP	USP
Second identification iodine test, color reaction. Functionality-Related Characteristics (Viscosity, Particle-size distribution, Bulk and tapped density)	None	Identification B (iodine test)

**Reagents and reference materials**

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

Each pharmacopoeia 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*  
82DD39EBFD74446...

Petra Doerr

20.12.2022

**Japanese Pharmacopoeia**

Signature

Name

Date

*Y. Goda*  
*for Y. Yoshida*

*Yukihiro Goda* *20 Jan, 2023*

**United States Pharmacopoeia**

Signature

Name

Date

DocuSigned by:  
*Kevin Moore*  
A7467E52FCC94E9...

Kevin Moore

12/15/2022