

## PHARMACOPOEIAL DISCUSSION GROUP

## CORRECTION 1

E-54 Copovidone  
(Correction of the sign-off document signed on 3<sup>rd</sup> October 2018)

Item to be corrected:

**K-value**

“Weigh exactly an amount of Copovidone, equivalent to 1.000 g, calculated on the dried basis,” to be corrected to “Weigh accurately an amount of Copovidone, equivalent to 1.00 g, calculated on the dried basis,”.

**- Harmonized 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-harmonized attributes**

Characters/Description, Containers and storage/Packaging and storage

**Local requirements**

EP	JP	USP
Second identification (identifications B, C)	Heavy Metals	Identification B (iodine test)

**Reagents and reference materials**

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

**European Pharmacopoeia**

Signature



Name

LEITEL

Date

21/10/19

**Japanese Pharmacopoeia**

Signature



Name

Itanahiro Okada  
for Fumi Yamamoto

Date

Oct 2<sup>nd</sup>, 2019

**United States Pharmacopoeia**

Signature



Name

Kevin Moore

Date

02-OCT-2019