

PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION 1

E-54 Copovidone
(Correction of the sign-off document signed on 3rd 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

LESITEL

Date

21/10/19

Japanese Pharmacopoeia

Signature

Name

Hiromichi Okada
for Fumi Yamamoto

Date

Oct 2nd, 2019

United States Pharmacopoeia

Signature

Name

KEVIN MURPHY

Date

02-OCT-2019