

**PHARMACOPOEIAL DISCUSSION GROUP
SIGN-OFF DOCUMENT
CODE: E-54
NAME: COPOVIDONE**

- 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.

Date: 21/10/17

Signatures:



European Pharmacopoeia



Japanese Pharmacopoeia



United States Pharmacopoeia