

PHARMACOPOEIAL DISCUSSION GROUP

CODE: E-16

NAME: CROSPROVIDONE

(Correction 2 of the sign-off cover sheet signed on 3 October 2018)

Harmonised attributes

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

Legend

+ will adopt and implement ; – will not stipulate

Non-harmonised attributes

Characters/Description, Identification by IR, Labelling.

Local requirement

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

Reagents and reference materials

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

European Pharmacopoeia

Signature

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Name

Petra Doerr

Date

28/10/2021

Japanese Pharmacopoeia

Signature

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for Y. Yoshida

Name

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Date

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United States Pharmacopeia

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9 - NOV - 2021