

PHARMACOPOEIAL DISCUSSION GROUP

E16 - CROSPROVIDONE: STAGE 3B (Former Stage 5B)

Correction of the sign-off cover sheet signed on Nov. 9, 2010

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
	Heavy metals	

Reagents and reference materials

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

European Pharmacopoeia

Signature



Name

S. KUBITEL

Date

31 Oct 2018

Japanese Pharmacopoeia

Signature



Name

H. OKUDA
for Tsunemi Yamamoto

Date

3. Oct 2018

United States Pharmacopeia

Signature

Name

Date



KEVIN MOORE

3-OCT-2008