

## PHARMACOPOEIAL DISCUSSION GROUP

### E16 - CROSPVIDONE: 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. KERSTEL

Date

21/01/18

#### Japanese Pharmacopoeia

Signature



Name

H. OKUDA  
for Fumii Yamamoto

Date

3. Oct 2018

**United States Pharmacopeia**

Signature

Name

Date

*gk:m*

KEVIN MOORE

3-OCT-2018