

PHARMACOPOEIAL DISCUSSION GROUP

E16 - CROSPROVIDONE: STAGE 5B

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

Legend

+ will adopt and implement ; – will not stipulate

Non-harmonised attributes

Characters, Identification by IR, heavy metals, labelling.

Reagents and reference materials

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

Date: 9/11/10

Signatures:

European Pharmacopoeia

J. Kawachi
for Masatoshi Narita
Japanese Pharmacopoeia

United States Pharmacopoeia