

PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

CODE: E32

NAME: Povidone Rev.1 Corr. 1

- Harmonised Attributes

Attribute	EP	JP	USP
Definition	+	+	+
Labeling	+	+	+
Identification			
(1)	+	+	+
(2)	+	+	+
pH	+	+	+
Aldehydes	+	+	+
1-Vinyl-2-pyrrolidone	+	+	+
Peroxides	+	+	+
Hydrazine	+	+	+
Formic acid	+	+	+
2-Pyrrolidone	+	+	+
Water	+	+	+
Residue on ignition	+	+	+
K-value	+	+	+
Assay	+	+	+

Legend

+: will adopt and implement

–: will not stipulate

- Non-harmonised attributes

Characters/Description, Appearance of solution, Packaging and Storage

- Local requirements

EP	JP	USP
Definition (chemical formula and chemical structure), Second identification (B,C,D), K-value (size no. 1 viscometer, minimum flow time 100 s) 1-vinylpyrrolidin-2-one (retention time for vinyl acetate and relative	Heavy metals	Identification B (dichromate test), Identification C (thiocyanate test), Identification D (iodine test), Lead

retention for 1-vinylpyrrolidin-2-one; washing of pre-column by mobile phase back flow) 2-pyrrolidone (washing of pre-column by mobile phase back flow)		
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Reagents and reference materials

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

Date:

Signatures:

Nov. 4th, 2015

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European Pharmacopoeia

Japanese Pharmacopoeia

United States Pharmacopeia