

PHARMACOPOEIAL DISCUSSION GROUP

REVISION OF SIGN-OFF COVER SHEET E-11 CELLULOSE, POWDERED

(Revision of the sign-off cover sheet Rev. 1 signed on 11 May 2005)

Item to be revised: non-harmonised attributes, local requirement (EP, JP, USP)

Harmonised Attributes

Attribute	EP	JP	USP
Definition	+	+	+
Labelling	-	+	+
Identification			
A	+	+	+
B	+	+	+
pH	+	+	+
Loss on drying	+	+	+
Residue on ignition	+	+	+
Water-soluble substances	+	+	+
Ether-soluble substances	+	+	+

Legend

+ : will adopt and implement

- : will not stipulate

Non-harmonised attributes

Characters/~~Description~~, ~~Heavy metals~~, Microbial limits, ~~Containers and storage~~/Packaging and storage, ~~Labelling~~

Local requirements

EP	JP	USP
Solubility	Definition (after partial hydrolysis as occasion demands). Identification (2)C – dispersion test, Heavy metals	Organic volatile impurities

Reagents and reference materials

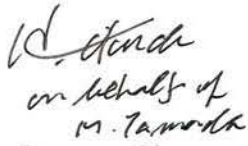
Each pharmacopoeia will adapt the text to take account of local reference materials and reagent specifications.

Date: 26/5/16

Signatures:



European Pharmacopoeia
Pharmacopoeia



Japanese Pharmacopoeia



United States