

PHARMACOPOEIAL DISCUSSION GROUP

E-10 CELLULOSE, MICROCRYSTALLINE

REVISION 3

- Harmonised Attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification			
A (IR)	+	+	+
B (wet chemistry)	+	+	+
C (degree of polymerization)	+	+	+
Conductivity	+	+	+
pH	+	+	+
Loss on drying	+	+ (1)	+ (1)
Residue on ignition	+	+	+
Bulk density	-	+	+
Water-soluble substances	+	+	+
Ether-soluble substances	+	+	+
Microbial limits	±	±	±

(1) JP and USP will retain, as local requirement, that the value can be within a percentage range, as specified within the labelling

Legend

+: will adopt and implement

–: will not stipulate

- Non-harmonised attributes

Characters/Description, Microbial limits, Labelling, Containers and storage/Packaging and storage

- Local requirements

EP	JP	USP
Solubility	Definition (reference to labelling), Identification (2) – dispersion test, Heavy metals.	Particle-size distribution estimation by analytical sieving

km
H.O
Ce

Reagents and reference materials

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

Date: 31/10/18

Signatures:



European Pharmacopoeia
Pharmacopoeia



Japanese Pharmacopoeia



United States