

**PHARMACOPOEIAL DISCUSSION GROUP**

**E-10 CELLULOSE, MICROCRYSTALLINE**

REVISION 2

**- Harmonised Attributes**

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

(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; <u>Sulfated ash (on 2.0 g).</u>	Particle-size distribution estimation by analytical sieving

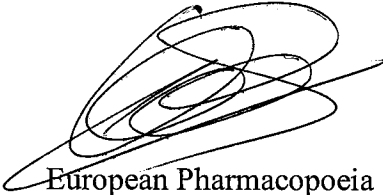
**Reagents and reference materials**

KCM  
CW  
4.0

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

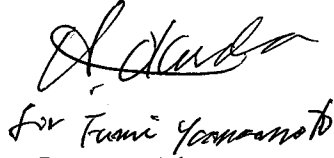
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Signatures:



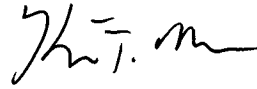
European Pharmacopoeia  
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