

PHARMACOPEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

NAME: MICROCRYSTALLINE CELLULOSE

	Harmonized attributes		
	EP	JP	USP
Definition	+	+	+
Labeling	-	+	+
Identification			
A	+	+	+
B	+	+	+
Conductivity	+	+	+
pH	+	+	+
Loss on drying ¹	+	+	+
Residue on ignition	+	+	+
Bulk density ²	-	+	+
Water-soluble substances	+	+	+
Ether-soluble substances	+	+	+

Legend

+ will adopt and implement; - will not stipulate

Non-harmonized attributes

Characters, Heavy metals, Microbial limits, Labeling, Packaging and storage

Specific local attributes

Identification C—Dispersion test (JP), Organic volatile impurities (USP), Particle size distribution estimation by analytical sieving (USP)

Reagents and reference materials

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

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Signatures:

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¹ USP will retain, as a specific local attribute that the value can be within a percentage range, as specified within the labeling.
² USP will retain, as a specific local attribute that the Bulk density value is within the labeled specification.