

# PHARMACOPEIAL DISCUSSION GROUP

## SIGN-OFF DOCUMENT

NAME: MICROCRYSTALLINE CELLULOSE, Rev. 1

	Harmonized attributes		
	EP	JP	USP
Definition	+	+	+
Identification			
A	+	+	+
B	+	+	+
Conductivity	+	+	+
pH	+	+	+
Loss on drying <sup>1</sup>	+	+	+
Residue on ignition	+	+	+
Bulk density <sup>2</sup>	-	+	+
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)

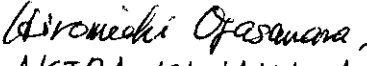
#### Reagents and reference materials

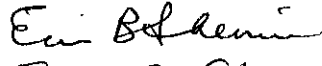
Each pharmacopoeia will adapt the text to take account of local reference materials and reagent specifications.

Date: 11-May-2005

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<sup>1</sup> USP will retain, as a specific local attribute that the value can be within a percentage range, as specified within the labeling.

<sup>2</sup> USP will retain, as a specific local attribute that the Bulk density value is within the labeled specification.