

**PHARMACOPOEIAL DISCUSSION GROUP
CORRECTION OF SIGN-OFF COVER SHEET
CODE: E-10
NAME: CELLULOSE, MICROCRYSTALLINE**

(Correction of the sign-off cover sheet of Rev 3 signed on 3 October 2018)

Harmonised attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification			
A (IR)	+	+	+
B (wet chemistry)	+	+	+
C (degree of polymerization)	+	+(1)	+
Conductivity	+	+	+
pH	+	+	+
Loss on drying	+	+(2)	+(2)
Residue on ignition	+	+	+
Bulk density	-	+	+
Water-soluble substances	+	+	+
Ether-soluble substances	+	+	+
Microbial limits	+	+	+

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

(2) 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, Labelling, Packaging and storage

Local requirements

EP	JP	USP
Solubility, Functionality-Related Characteristics (Loss on drying*, Particle-size distribution, Powder flow)	Definition (reference to labelling), Heavy metals.	Particle-size distribution estimation by analytical sieving

* Loss on drying is a harmonised attribute. It is also included in the Functionality-Related Characteristics section of the EP monograph.

Reagents and reference materials

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

European Pharmacopoeia

Signature



Name

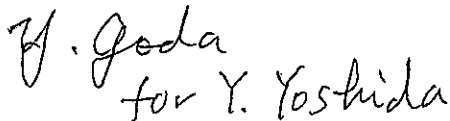
Petra Dourr

Date

28/10/2021

Japanese Pharmacopoeia

Signature



Name

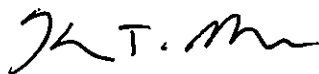
Yukihiro Goda

Date

15 Nov, 2021

United States Pharmacopoeia

Signature



Name

KEVIN MOORE

Date

9-NOV-2021