

**PHARMACOPOEIAL DISCUSSION GROUP
CORRECTION OF SIGN-OFF COVER SHEET
CODE: E-10**

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(Correction 2 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)	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.

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December 2022

Reagents and reference materials

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


European Pharmacopoeia

Signature	Name	Date
<p>DocuSigned by:  82DD39EBFD74446...</p>	<p>Petra Doerr</p>	<p>20.12.2022</p>

Japanese Pharmacopoeia

Signature	Name	Date
<p> for Y. Yoshida</p>	<p>Yukihiko Goda</p>	<p>20 Jan, 2023</p>

United States Pharmacopoeia

Signature	Name	Date
<p>DocuSigned by:  A7467E52FCC94E9...</p>	<p>Kevin Moore</p>	<p>12/15/2022</p>