PHARMACOPOEIAL DISCUSSION GROUP CORRECTION OF SIGN-OFF COVER SHEET CODE: E-11

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(Correction of the sign-off cover sheet of Rev. 1 Corr. 1 signed on November 15, 2021)

Harmonised attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification	500		Ph I
A	+	+	+
В	+	+	The A CH
pH 2 A A A A A A A A A A A A A A A A A A	+-	+	+
Loss on drying	+	+ 3 1 2 1 1	+ ().
Residue on ignition	+	+	+
Water-soluble substances	+	+ ,	+ sal wite v'
Ether-soluble substances	+	+	+

Legend

+: will adopt and implement

-: will not stipulate

Non-harmonised attributes

Characters/Description, Microbial limits, Containers and storage/Packaging and storage, Labelling

Local requirements

EP	JP	USP
Solubility, Functionality- Related Characteristics (Loss on drying*, Particle size distribution and Powder flow)	Definition (after partial hydrolysis as occasion demands), Identification (2) – dispersion test	None

^{*} Loss on drying is a harmonized 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.

E-11

Correction sign-off cover sheet

December 2022

European Pharmacopoeia

Signature

Name

Date

- DocuSigned by:

Petra Doerr

Petra Doerr

20.12.2022

Japanese Pharmacopoeia

Signature

Name

Date

y. Joda

for Y. Yoshida

Yakihiro Goda

20 Jan, 2023

United States Pharmacopeia

Signature

Name

Date

-DocuSigned by:

tenin Moore

Kevin Moore

12/15/2022