

E-13

Correction sign-off cover sheet

December 2022

**PHARMACOPEIAL DISCUSSION GROUP
CORRECTION OF SIGN-OFF COVER SHEET**

CODE: E-13

**NAME: CELLACEFATE (CELLULOSE ACETATE PHTHALATE)
(Correction 2 of the sign-off cover sheet of Rev. 1 signed on 9 November 2010)**

Harmonised attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification	+	+	+
Viscosity	+	+	+
Water	+	+	+
Residue on ignition	+	+	+
Limit of free acid	+	+	+
Phthalyl content	+	+	+
Content of acetyl	+	+	+

Legend

+ will adopt and implement; – will not stipulate

Non-harmonised attributes

Characters*, Packaging and storage

*In USP, this is referred to as “Description and Solubility”

*In JP, this is referred to as “Description”

Local requirements

EP	JP	USP
Functionality-Related Characteristics (Viscosity*, Solubility of a film, Phthaloyl groups*, Acetyl groups*)	None	None

* Viscosity, Phthaloyl groups and Acetyl groups are harmonised attributes. They are also included in the Functionality-Related Characteristics section of the EP monograph.

Reagents and reference materials

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

Each pharmacopeia will consider actual titrant concentration in equations according to their local rules of calculation for titration.

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European Pharmacopoeia

Signature

Name

Date

DocuSigned by:
Petra Doerr
82DD39EBFD74446...

Petra Doerr

20.12.2022

Japanese Pharmacopoeia

Signature

Name

Date

Y. Goda
for Y. Yoshida

Yukihiko Goda

20 Jan, 2023

United States Pharmacopeia

Signature

Name

Date

DocuSigned by:
Kevin Moore
A7467E52FCC94E9...

Kevin Moore

12/15/2022