E-13 October 2021

PHARMACOPEIAL DISCUSSION GROUP CORRECTION OF SIGN-OFF COVER SHEET CODE: E-13

NAME: CELLACEFATE (CELLULOSE ACETATE PHTHALATE) (Correction of the sign-off cover sheet of Rev 1 Corr 1 signed on 6 June 2012)

Harmonised attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification	+	+	+
Viscosity	+	+	+
Water	+	+	+
Residue on ignition	+	+	+
Limit of free acid	+	+	+
Phthalyi 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"

Local requirements

EP	JP	USP
Functionality-Related Characteristics (Viscosity*, Solubility of a film, Phthaloyl groups*, Acetyl groups*)	Heavy metals	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.

Km PD

^{*}In JP, this is referred to as "Description"

European Pharmacopoeia

Signature

Name

Date

P. Dm

Petra Doerr

Yukihiro Goda

28/10/2021

15 Nov, 2021

Japanese Pharmacopoeia

Signature

Name

Date

y Goda for Y. Yoshida

United States Pharmacopeia

Signature

Name

Date

The Time

Kern moore

9-NOU-2021