

PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

CODE: E-13

NAME: Cellacefate (Cellulose Acetate Phthalate), Revision 1

- Harmonised Attributes

	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\*, Heavy metals, Packaging and storage

\*In USP, this is referred to as "Description and Solubility"

\*In JP, this is referred to as "Description"

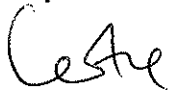
- Local requirements

EP	JP	USP
A test "solubility of a film" is included in the non-mandatory section FRC in the Ph. Eur. monograph.	N/A	N/A

Reagents and reference materials

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

European Pharmacopoeia



Signature

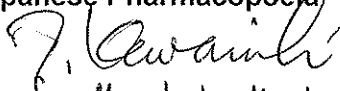
WESTEL

Name

9/11/10

Date

Japanese Pharmacopoeia



Signature

for Masatoshi Narita

Toru KAWANISHI

Name

Nov 9, 2010

Date

United States Pharmacopoeia



Signature

Susan S. de Mas

Name

9 November 2010

Date

