PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION OF SIGN-OFF COVER SHEET

CODE: E-31

NAME: POLYSORBATE 80

(Correction 2 of the sign-off cover sheet signed on July2016)

Item to be corrected:

- Composition of fatty acids: addition of a note about the elution order.
- Acid value: addition of a note about the different solvent.
- Residue on ignition: addition of a note about the difference of heating condition.

Attribute	Ph. Eur.	JP	USP
Definition	+	+	+
Identification (Composition of fatty acids)	+	+	+
Acid value*	+	+	+
Hydroxyl value	+	+	+
Peroxide value	+	+	+
Saponification value	+	+	+
Composition of fatty acids**	+	+	+
Ethylene oxide and dioxan	+	+	+
Water	+	+	+
Total ash/ Residue on ignition ***	+	+	+
Storage	+	+	+

* *Acid value:* EP and USP use ethanol (96 per cent); JP will use ethanol (95).

** *Composition of fatty acids:* JP includes elution order of the fatty acid methyl esters.

*** *Total ash/ Residue on ignition:* JP includes additional heating conditions: "and gradually heat with as lower temperature as possible to carbonize completely".

Legend:

+ : will adopt and implement

– : will not stipulate

Non-harmonised attributes

Identification by IR, Characters/description

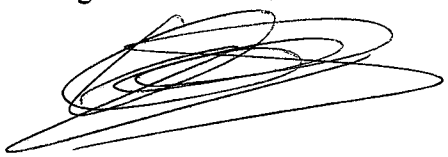
Local requirements

Ph. Eur.	JP	USP
Second identification B, C, E	Heavy metals	none

CU H.O. KTm

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

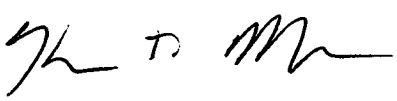
European Pharmacopoeia

Signature	Name	Date
	VIERCE Ohno	22-Dec-20

Japanese Pharmacopoeia

Signature	Name	Date
H. Okuda for Y. Yoshida	Harukiro Okuda	16 Dec 2020

United States Pharmacopeia

Signature	Name	Date
	KEVIN MOORE	19-NOV-2020