

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

CODE: E-31

NAME: POLYSORBATE 80

(Correction 3 of the sign-off cover sheet of Corr. 2 signed on November 13, 2014)

Harmonised attributes

Attribute	EP	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

EP	JP	USP
Second identification (hydroxyl value, Saponification value, composition of fatty acids, color reaction), Functionality-Related Characteristics (Hydroxyl value, Composition of fatty acids)	None	Specific Gravity Viscosity

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Correction sign-off cover sheet

December 2022

Reagents and reference materials

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

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

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

Yukihiro Goda

20 Jan, 2023

United States Pharmacopoeia

Signature

Name

Date

DocuSigned by:
Kevin Moore
A7467E52FCC94E9...

Kevin Moore

12/15/2022