

PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

CODE: E-31

NAME: POLYSORBATE 80

Revision of the sign-off cover sheet Corr. 2 signed on 13 November 2014

Attribute	Ph. Eur.	JP	USP
Definition	+	+	+
Identification (Composition of fatty acids)	+	+	+
Acid value	+	+	+
Hydroxyl value	+	+	+
Peroxyde value	+	+	+
Saponification value	+	+	+
Composition of fatty acids	+	+	+
Ethylene oxide and dioxan	+	+	+
Water	+	+	+
Total ash	+	+	+
Storage	+	+	+

Legend:

+ : will adopt and implement

- : will not stipulate

Non-harmonised attributes

Characters/description, ~~Heavy metals~~, Identification by IR

Local requirements

Second identification B, C, E (EP.), ~~Heavy metals (JP)~~

Reagents and reference materials

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

Date:

Signatures:

26 Oct 2016

Oct 26, 2016

Oct. 26, 2016



European
Pharmacopoeia

C. Viale



Japanese
Pharmacopoeia

Hamshiro Okuda
for Masanobu Yumuda



United States
Pharmacopoeia

CATHARINE SHEEHAN