

**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

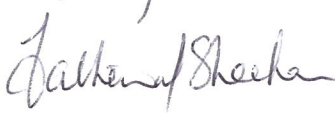
Each pharmacopoeia will adapt the text to take account of local reference materials and reagent specifications.

Date: 26 Oct 2016

Signatures:


 European
 Pharmacopoeia
 C. Vielle

Oct 26, 2016

 Hanehiko Otsuda
 for Masamitsu Yamada
 Japanese
 Pharmacopoeia

Oct 26, 2016

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