

PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

CODE: E-31

NAME: POLYSORBATE 80, Correction 2

Item to be corrected:

Characters section described as non-harmonised attribute and deleted from the global text. Local requirements section added.

Attribute	Ph. Eur.	JP	USP
Definition	+	+	+
Characters	+	+	+
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.)

Reagents and reference materials

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


Date: 12/11/15

Signatures:

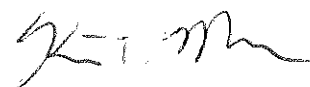
European
Pharmacopoeia



Japanese
Pharmacopoeia


for Kazuhiko Mori

United States
Pharmacopoeia


KEVIN MOORE