

**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:** 15/11/14

**Signatures:**

  
European  
Pharmacopoeia

  
for Kazuhiko Mori  
Japanese  
Pharmacopoeia

  
United States  
Pharmacopoeia  
Kevin Moore