

## PHARMACOPOEIAL DISCUSSION GROUP

## STAGE 5B DOCUMENT

## NAME: E31 – POLYSORBATE 80

Attribute	EP	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**

Identification by IR


Heavy metals

Reagents and reference materials

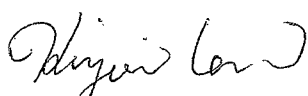
Each pharmacopoeia will adapt the text to take account of local reference substances and spectra and reagent specifications.

Date: 03 Jun, 2008


Signatures:

  
European Pharmacopoeia

LEIFERT

  
Japanese Pharmacopoeia

for Toshio Nakagaki

  
United States Pharmacopoeia

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