

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

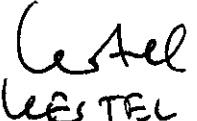
Heavy metals


Reagents and reference materials

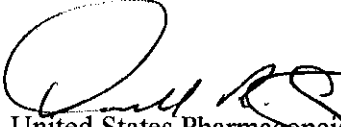
Each pharmacopoeia will adapt the text to take account of local reference substances and spectra and reagent specifications.

Date: 03 June 2008

Signatures:


 UESTEL
 European Pharmacopoeia


 Japanese Pharmacopoeia


 United States Pharmacopoeia

for Toshio Nakagaki DARRELL R. FIEBERWEITZ