

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:

Signatures: 26 Oct 2016

Oct 26, 2016

Oct. 26, 2016



European
Pharmacopoeia

C. Viale



Japanese
Pharmacopoeia

Hambiro Amda
for Masanobu Yimuda



United States
Pharmacopoeia

CATHERINE SHEEHAN