

PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION

CODE: E-31

NAME: POLYSORBATE 80

(Correction 3 of the sign-off document signed on 3 June 2008)

Item to be corrected:

Composition of fatty acids: add 'split ratio: 1:50'.

Dioxan: read 'Calculate the content (in ppm) of dioxan using the following expression:

$$\frac{2 \times 1.03 \times CD \times Aa' \times 1000}{Ab' - Aa'}$$

Ethylene oxide: read 'Calculate the content of ethylene oxide (in ppm) using the following expression...'

European Pharmacopoeia

Signature



Name

W. ESTERL

Date

7/6/16

Japanese Pharmacopoeia

Signature



Name

H. OKUDA
on behalf of
M. Yamada

Date

June 23, 2016

United States Pharmacopoeia

Signature



Name

KEVIN
MOSE

Date

July 1, 2016