

PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION

CODE: ... E01

NAME: ...Ethanol (96 per cent)

(Correction of the sign-off document Rev 2 signed on 2012.11.07)

Item to be corrected : . Test for volatile impurities, calculation of the limit for Acetaldehyde and Acetal: formula


Acetaldehyde + acetal: maximum 10 ppm(V/V), expressed as acetaldehyde.

Calculate the sum of the contents of acetaldehyde and acetal in parts per million (V/V) using the following expression:

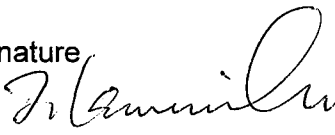
$$\frac{10 \times A_E}{A_T - A_E} + \frac{30 \times C_E \times 44.05}{(C_T - C_E) \times 118.2}$$

- $A_E$  = area of the acetaldehyde peak in the chromatogram obtained with test solution (a).
- $A_T$  = area of the acetaldehyde peak in the chromatogram obtained with reference solution (b).
- $C_E$  = area of the acetal peak in the chromatogram obtained with test solution (a).
- $C_T$  = area of the acetal peak in the chromatogram obtained with reference solution (c).
- 44.05 = molecular mass of acetaldehyde.
- 118.2 = molecular mass of acetal.

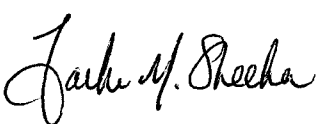
European Pharmacopoeia

Signature	Name	Date
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Japanese Pharmacopoeia

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 for Haruo Akagawa	Toru KAWANISHI	27/6/2013

United States Pharmacopeia

Signature	Name	Date
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