PHARMACOPOEIAL DISCUSSION GROUP

CODE: E-02

NAME: DEHYDRATED ETHANOL, ANHYDROUS ETHANOL

CORRECTION OF SIGN-OFF COVER SHEET (Previous Corr 2 sign-off on June 26, 2014)

Harmonised attributes

Attribute	EP	JP	USP
Identification A, B	+	+	+
Appearance	+	+	+
Acidity or alkalinity	+	+	+
Relative density	+	+	+
Absorbance	+	+	+
Volatile impurities	+	+	+
Residue on evaporation	+	+	+
Storage	+	+	+

Legend: + will adopt and implement; - will not stipulate

Definition and Relative density

Each pharmacopoeia specifies a different range for the content; the values for relative density vary accordingly and, in addition, are expressed at different temperatures.

Non-harmonised attributes

Characters/Description (EP, JP)

Local requirements:

EP	JP	USP
Second Identification (ID tests C and D), list of impurities	Shelf life, Containers	Identification test: Limit of methanol*, Clarity of solution,
		Color of solution

^{*}The identification test of limit methanol refers to the harmonized test for volatile impurities.

Reagents and reference materials

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

Each pharmacopeia will consider actual titrant concentration in equations according to their local rules of calculation for titration.

Km PD

European Pharmacopeia

Signature

P.Om

Name

Petra DOCTT

Date

27/10/2021

Japanese Pharmacopeia

Signature

Y-Goda for Y. Yoshida Name

Yakihiro Goda

Date

15 Nov, 2021

United States Pharmacopeia

JL T. M

Signature

Name

KEVIN MOONE

Date

9-1101-2021