PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT (REVISION 2)

CODE: E-02

NAME: DEHYDRATED ETHANOL, ANHYDROUS ETHANOL

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: identification tests C and D, list of impurities (EP); expiration date (JP)

Reagents and reference materials

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

Date: 1017,2012

Signatures:

European Pharmacopoeia

for Harno Akagawa
Japanese Pharmacopoeia

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Inited States Pharmacopeia