PHARMACOPOEIAL DISCUSSION GROUP **CORRECTION 2**

CODE: E-55a

NAME: Gelatin, Gelling grade

Harmonized Attributes

Attribute	EP	JP	USP
Definition	+	+*	+
Identification (A)	+	+	+
(B)	+	+	+
Tests			
(1) pH	+	+	+
(2) Conductivity	+	+	+
(3) Sulphur dioxide	+	+	+
(4) Peroxides	+	+	+
(5) Gel strength	+	+	+
(6) Iron	+	+	+
(7) Chromium	+	÷	+
(8) Zinc	+	+	+
Loss on drying	+	+	+
Microbial contamination	+	+	+
Storage	+	+	+
Labelling	+	+	+

Legend

+ will adopt and implement;

Non-harmonized attributes

* In JP, "Purified protein obtained from collagen of animals by enzymatic hydrolysis" is not included in the definition. The wording ", and/or enzymatic hydrolysis" in the definition will be bracketed by black diamonds to indicate that this part is not harmonized.

Local requirements

Functionality related characteristics (EP), Heavy metals (JP), Arsenic (JP).

Reagents and reference materials

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

Date:

Signatures: U6(6/10

European Pharmacopoeia

Japanese Pharmacopoeia

26/6/2014

June 25, 2014 **United States** Pharmacopeia

Harahiro Olavela Jon E. Clark for Takeyuki Saton

January 2014 CP :EP

Date

PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION 2

CODE: E55b

NAME: Gelatin (non-gelling grade)

(Correction of the sign-off document dated 6 November 2013)

Item to be corrected: TEST, Peroxides, Suitability test.

Suitability test. Dip a test strip for 1 s into hydrogen peroxide standard solution ($\frac{10 \text{ 2}}{2}$ ppm H₂O₂) [prepared by dilution of hydrogen peroxide solution ($\frac{30 \text{ g}}{1 \text{ H}_2\text{O}_2}$)], such that the reaction zone is properly wetted. Remove the test strip, shake off excess liquid and after 15 s compare the reaction zone with the colour scale provided. The test strips are suitable if the colour matches that of the $\frac{10 \text{ 2}}{2}$ ppm concentration.

Name

European Pharmacopoeia

Signature

Japanese Pharmacopoeia

Signature
Name
Date

7. Lawarini Toru KAWANISH May 9, 2014

For Takeyuki Sulou
United States Pharmacopeia

Signature
Name
Date

Lall A Sheeh

CATHERINE M SMEUAN

Tob 27, 2014

