

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 (± 2 ppm H₂O₂) [prepared by dilution of hydrogen peroxide solution (30 g/l H₂O₂)], 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 ± 2 ppm concentration.

European Pharmacopoeia

Signature



Name

K. ESTEL

Date

26/6/14

Japanese Pharmacopoeia

Signature



for Takeyuki Satou

Name

Toru KAWANISHI

Date

May 9, 2014

United States Pharmacopoeia

Signature



Name

CATHERINE M. SHEEHAN

Date

Feb. 27, 2014

PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION 2

CODE: E-55b

NAME: Gelatin, Non-gelling grade

Harmonized Attributes

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

Legend

+ will adopt and implement ;

-: JP will sign the draft for E-55b (gelatin, non-gelling grade) but will not implement it as this grade is hardly ever used in Japan.

Non-harmonized attributes

Local requirements

Functionality-related characteristics (EP).

Reagents and reference materials

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

Date:

Signatures:

European
Pharmacopoeia

Japanese
Pharmacopoeia

United States
Pharmacopoeia