

**PHARMACOPOEIAL DISCUSSION GROUP**

**CORRECTION 3**

**CODE: E-55a**

**NAME: Gelatin, Gelling grade**

**Harmonized Attributes**

Attribute	EP	JP	USP
Definition	+	+ (1)	+
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	+	+	+ (2)

(1) See Non-harmonized attributes

(2) See Local requirements

**Legend**

+ will adopt and implement

**Non-harmonized attributes**

Definition: the following statement "and/or by enzymatic hydrolysis" is not included in JP monograph.

Characters/description

**Local requirements**

EP	JP	USP
	Heavy metals, Arsenic, Containers	Labelling including the method of hydrolysis

**Reagents and reference materials**

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

Date: 26 Oct 2016

Signatures:

European  
Pharmacopoeia  
R.O.  
C. Vialla

Oct 26, 2016

Chitanda  
Japanese  
Pharmacopoeia  
Hiroki Ochiai  
son  
Masanobu Yamada

Oct. 26, 2016  
Balkum Sheekh  
United States  
Pharmacopeia

CATHERINE SUREAN

**PHARMACOPOEIAL DISCUSSION GROUP**

**CORRECTION 3**

**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	+	-	+ <sup>(1)</sup>

<sup>(1)</sup> See Local requirements

**Legend**

+ will adopt and implement;

∴ JP has signed 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**

EP	JP	USP
		Labelling including the method of hydrolysis

**Reagents and reference materials**

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

Date: 20 Oct 2016

Oct 20, 2016

Oct. 26, 2016  
Gelatin of Sheek  
United States  
Pharmacopeia  
CATHERINE SUEEWAH

Signatures:

Q. S. European  
Pharmacopoeia  
[Type text]  
C. U. Schelle

Japanese  
Pharmacopoeia  
*A. Okada*  
Hachiro Okada  
for  
Masanobu Yamada

0.11  
CB

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## PHARMACOPOEIAL DISCUSSION GROUP

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## CORRECTION 3

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CODE: E55b

4

NAME: GELATIN, NON-GELLING GRADE

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(Correction to the sign-off cover sheet signed on June 2014)

6

7 Item to be corrected:

8 Identification C, to replace "A red color develops" by "A red to violet color develops".

9

10

11

12 European Pharmacopoeia

13 Signature



Name

Date

26 Oct 2016

14

15

16 Japanese Pharmacopoeia

17 Signature



Name

Date

Haruhiko Obada  
for Masamichi Yamada

Oct. 26, 2016

18

19

20 United States Pharmacopeia

21 Signature



Name

Date

CATHERINE SWEENEY

Oct. 26, 2016

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