

# PHARMACOPOEIAL DISCUSSION GROUP

## SIGN-OFF DOCUMENT

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.

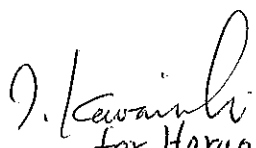
### Reagents and reference materials

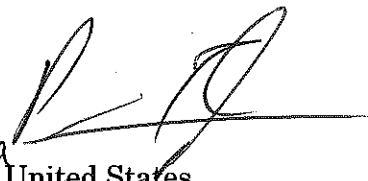
Each pharmacopoeia will adapt the text to take account of local reference materials and reagent specifications.

Date: 6/6/2012

Signatures:

  
European  
Pharmacopoeia

  
Japanese  
Pharmacopoeia

  
United States  
Pharmacopoeia

**PHARMACOPOEIAL DISCUSSION GROUP  
SIGN-OFF DOCUMENT**

**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**

**Reagents and reference materials**

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

Date: 6/6/2012

Signatures:

European  
Pharmacopoeia

T. Kawamichi  
Toru KAWANISHI  
Japanese  
Pharmacopoeia  
for Haruo Akagawa

United States  
Pharmacopoeia