

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.

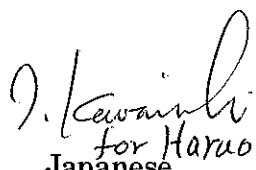
Reagents and reference materials

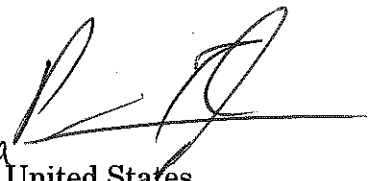
Each pharmacopoeia will adapt the text to take account of local reference materials and reagent specifications.

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