

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: Nov. 6, 2013

Signatures:

European
Pharmacopoeia



Japanese
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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: Nov. 6, 2013

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