E-55 October 2021

PHARMACOPOEIAL DISCUSSION GROUP CORRECTION OF SIGN-OFF COVER SHEET

CODE: E-55

NAME: GELATIN

(Correction of the sign-off cover sheet of Rev 3 signed on 2 October 2019)

Harmonized attributes

Attribute	EP	JP	USP
Definition	+	+	+
Identification (A)	+	+	+
(B)	+	+	+
(C)	+	+	+
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; - will not stipulate

Non-harmonized attributes

Characters/description

yg Km p Local requirements

EP	JP	USP
Functionality-Related Characteristics (Gel strength*)	Heavy metals, Arsenic, Containers	IR identification, Definition includes local texts, such as "(including fish and poultry)"

^{*} Gel strength is a harmonized attribute. It is also included in the Functionality-Related Characteristics section of the EP monograph.

Reagents and reference materials

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

European Pharmacopoeia

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Sig	nature

Name

Date

Petra Doerr

27/10/2021

Japanese Pharmacopoeia

Signature

Name

Yakihiro Goda 15. Nov, 2021

United States Pharmacopeia

Signature

Name

Date

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KEV.~ MORE 9-NOU-2021