

PHARMACOPOEIAL DISCUSSION GROUP

REVISION 2

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 | IR identification, 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: 31/01/17

Signatures:



European
Pharmacopoeia



Japanese
Pharmacopoeia



United States
Pharmacopeia

PHARMACOPOEIAL DISCUSSION GROUP

REVISION 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 | + | - | +(1) |

(1) 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 |
|------------|----|---|
| Characters | | IR identification, Labelling including the method of hydrolysis |

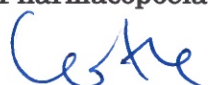
Reagents and reference materials

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

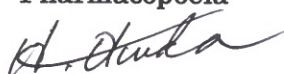
Date: 31/01/18

Signatures:


European
Pharmacopoeia



Japanese
Pharmacopoeia



United States
Pharmacopoeia


 KEVIN MARR
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