Gelatin

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Expert Committee: Monographs—Excipients

A harmonized standard for Gelatin has been approved by the Pharmacopeial Discussion Group (PDG) as described in its PDG Sign-Off Cover Page. Having reached Stage 6 of the PDG process, the Gelatin monograph has been formally approved by the USP Monographs—Excipients Expert Committee in accordance with the Rules and Procedures of the 2010–2015 Council of Experts. Stage 4 monographs for Gelatin, Gelling Grade and Gelatin, Non-Gelling Grade were published in PF 37(1) and will be combined to one Gelatin monograph at Stage 6.

Changes from the existing *USP–NF* monograph include the introduction to the following new tests:

- pH
- Conductivity
- Peroxides
- Gel Strength (Bloom Value) for Gelling Grades
- Iron (30 PPM limit)
- Chromium (10 PPM limit)
- Zinc (30 PPM limit)
- Loss on Drying
- Labeling to indicate Gel Strength, or indicate that it is non-gelling.

Changes from the existing *USP–NF* monographs include revisions to the existing tests.

- Visual Identification tests A and B (with C for Non-Gelling Grades)
- Sulfur Dioxide updated for consistency with other PDG monographs

Please note that while Stage 6 harmonization postings typically are not implemented via Revision Bulletin, this revision is being accelerated due to recent public health concerns regarding chromium content in Gelatin capsules. The current USP monograph does not include a test for Chromium. The Gelatin monograph will be incorporated into and become official with *USP 36–NF 31*.

Should you have any questions about the Gelatin monograph, please contact Kevin Moore (301-816-8369 or ktm@usp.org). For any questions about the PDG and its processes, please see the Pharmacopeial Harmonization Web page or contact Mario Sindaco (301-816-8246 or mys@usp.org).

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