

ASTM F1185 – 23: Changes at a Glance

A revised version of **ASTM’s Standard Specification for Composition of Medical-Grade Hydroxylapatite for Surgical Implants** was published in April 2023. This document provides a summary of the relevant changes¹ compared to the previous version F1185 – 03 (Reapproved 2014).

Section	Summary of Change
Title	The term Medical-Grade was added to the title to specify the scope of the standard.
1.7	A statement of compliance with WTO guidelines for the development of international standards was added.
4.1	The calcium to phosphorus ratio can now be determined as an alternative to calcium and phosphorus concentrations. X-ray fluorescence and X-ray diffraction were added as alternatives to ion chromatography.
4.3	Elemental impurities must now be determined according to USP <232> and <233> and ICH Q3D. Detailed information on the methodology and assessment of impurity levels was added.
4.3.1	The number of impurity elements of interest were increased from 4 to 24.
4.3.2	Each raw material lot must be tested for elemental impurities. If the manufacturer can demonstrate adequate process control, sampling frequency may be reduced.
4.3.5	Limits for elemental impurities must be determined in a risk assessment.
5.	The biological response to new devices can now be characterized according to ANSI/ISO 10993-1 in addition to the previously referenced Practices F748 and F981.
7.	The section was replaced with a more elaborate section on Guidance for Manufacturing Control and Quality Assurance , which provides references and explanations to the frameworks 21 CFR 820, ANSI/ISO/ASQ 9000, ANSI/ISO/ASQ 9001, and ANSI/ISO/ASQ 13485.
8.	A new section specifying the content of certificates of analysis was added.
X2.	The appendix now provides additional information on the selection of impurity limits according to USP <232> and the choice and terminology of impurity elements of interest according to ICH Q3D.

Analysis of Hydroxylapatite raw materials and end products performed at **RMS Foundation** complies with the updated requirements of ASTM F1185 – 23 and is offered as a service accredited according to ISO 17025.

Contact us for more information.

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¹ This list of revisions is not exhaustive. For a comprehensive comparison, readers are referred to the original documents.