

ASTM F1088 – 23: Changes at a Glance

A revised version of **ASTM’s Standard Specification for Medical-Grade Beta-Tricalcium Phosphate Raw Material for Implantable Medical Devices** was published in April 2023. This document provides a summary of the relevant changes¹ compared to the previous version F1088 – 18.

| Section | Summary of Change |
|---------|--|
| Title | The new title explicitly refers to beta-TCP raw materials used for implantable medical devices. The previous version was unspecific about its applicability to raw materials or end products. |
| 1.1 | The applicability of the standard to beta-TCP raw materials was added. |
| 1.2 | A disclaimer highlighting the user’s responsibility to establish safety, health, and environmental practices prior to using the standard was added. |
| 3.3.1 | Limits of elemental impurities shall be agreed upon between the purchaser and supplier of the raw material. |
| 3.3.2 | Elemental impurities must be determined for each raw material lot . |
| 3.3.3.1 | The concentration of each element must be reported. Previously only reporting of the concentration of uncontrolled elements was requested. |
| 4. | A new section providing Guidance for Manufacturing Control and Quality Assurance was added. It provides references and explanations to the frameworks 21 CFR 820, ANSI/ISO/ASQ 9000, ANSI/ISO/ASQ 9001, and ANSI/ISO/ASQ 13485. |
| 5. | A new section specifying the content of certificates of analysis was added. |

Raw material analysis of beta-TCP performed at **RMS Foundation** complies with the updated requirements of ASTM F1088 – 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.