

Conformity assessment of CaP bone substitutes according to ISO 13175-3

Calcium phosphate ceramics (CaP) such as β tricalcium phosphate (β -TCP) and hydroxyapatite (HA) are among the best-known synthetic materials used surgically for filling of large bone defects. In order to ensure patient safety and provide optimum support for bone healing, the products must meet high requirements in terms of chemical purity, phase composition, microstructure and mechanical properties. Synthetic CaP bone graft substitutes are therefore tested for conformity with ISO 13175-3 to get market approval in Europe.

As a research and service laboratory with many years of experience in the development and product registration of medical devices, we offer our customers all analyses required by ISO 13175-3 as an attractive bundle.

In particular, we offer the following ISO 17025 accredited services:

Heavy metals and impurities: ICP-MS is a state-of-the-art analysis providing maximum sensitivity for a wide range of elements.

Crystalline phase composition: Determination by X-ray diffraction (XRD) and evaluation using the Rietveld method is also state-of-the-art and allows precise determination of phase fractions.

Shape and size: Depending on the type of product, the external dimensions are determined with a calibrated caliper,

or the particle size distribution is determined by laser diffraction or sieve analysis.

Total porosity: The total porosity is determined by comparing the apparent density, calculated from the weight and volume of the sample, with the theoretical density calculated from the phase composition.

Micropores and macropores: The size distribution of micropores and macropores is determined using electron microscopy images and a calibrated image analysis system. The applied procedures «Method A» from ISO 13175-3 and «Method A2» from EN ISO 13383-1 correspond to the current state of the standards.

Solubility and pH change: The dissolution rate in aqueous solution at pH 7.3 is measured over a period of 72 hours. The concentration of released Ca ions in the solution is determined by means of ICP-MS. The change in pH is recorded over the same period.



Mechanical strength: Several calibrated mechanical testing machines are available for compressive strength and sphere indentation tests in wet and dry conditions.

The test results are either documented in the form of test certificates or additionally statistically evaluated and interpreted in the form of a test report. Our reports are based on Good Laboratory Practice (GLP). RMS Foundation's customers benefit from the many years of experience and expertise in the field of bone graft substitutes.

Newsletter 30

In addition to the tests according to ISO 13175-3, we offer conformity tests according to the following standards:

- ASTM F 1088
- ASTM F 1185
- ASTM F 1581
- ISO 13779-2 to -6
- customer-specific requirements

We are also happy to organize further tests at external laboratories for you.

Discuss your questions with us! We are happy to advise you.

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More information as well as our service catalogue can be found on our website.

RMS Foundation has been certified according to ISO 9001 and is an ISO/IEC 17025 (type C) accredited laboratory.

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