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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 23101.3-2023

Replacing GB/T 23101.3-2010

**Implants for surgery - Hydroxyapatite - Part 3: Chemical
analysis and characterization of crystallinity ratio and phase
purity**

外科植入物 羟基磷灰石 第3部分：结晶度和相纯度的化学分析和表征
(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents" Drafting:

This document is Part 3 of GB/T 23101 "Hydroxyapatite for Surgical Implants": GB/T 23101 has released the following part:

---Part 1: Hydroxyapatite ceramics;

---Part 2: Hydroxyapatite coating;

---Part 3: Chemical analysis and characterization of crystallinity and phase purity;

---Part 4: Determination of coating bond strength;

---Part 6: Powder:

This document replaces GB/T 23101.3-2010 "Hydroxyapatite for surgical implants - Part 3:

Chemistry of crystallinity and phase purity" Analysis and Characterization", compared with GB/T 23101.3-2010, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

---The scope of application of the document has been changed, hydroxyapatite powder has been included in the scope of this document, and the scope of application of the document has been further clarified Domain (see Chapter 1, Chapter 1 of the:2010 edition);

---Added terms and definitions: limit of quantitation (see 3.3), alpha-tricalcium phosphate (see 3.8), beta-tricalcium phosphate (see 3.9), hydroxyapatite (see 3.10), tetracalcium phosphate (see 3.11), calcium oxide (see 3.12), uncertainty (see 3.13), crystallinity (see 3.14), background (see 3.15), noise (see 3.16), impurity phase (crystalline state) (see 3.17);

---The requirements for chemical analysis instruments and reagents have been changed (see 4.3, 4:4, 5:1, 4:4 of the:2010 edition), and the grade of analytical reagents has been clarified:

classification, and the sample solution preparation and result presentation parts have been refined (see 4.5, 4:6, 9:1 and 9:2 of the:2010 version);

---Added the detection limit (DL) and quantitation limit (QL) of impurity phases and their uncertainty requirements (see 5.6:3, 5:6:4);

---Changed the calculation method of calcium to phosphorus atomic ratio (Ca:P) (see 5.8:2, Chapter 10 of the:2010 edition), and increased the measurement uncertainty Calibration requirements (see 5.8:3);

---Changed the crystallinity test method (see 5.9:2, 5:9:3, 5:9:4, Chapter 12 of the:2010 edition), and increased the measurement uncertainty degree requirements (see 5.9:5):

This document is modified using ISO 13779-3:2018 "Hydroxyapatite for surgical implants Part 3: Chemistry of crystallinity and phase purity Analysis and Characterization":

Compared with ISO 13779-3:2018, this document has made the following structural adjustments:

---A) and b) in 4:3 correspond to 4:3:1 and 4:3:2 in ISO 13779-3:2018 respectively;

---A)~c) in 4:4 respectively correspond to 4:4:1~4:4:3 in ISO 13779-3:2018;

---A)~f) in 5:2 respectively correspond to 5:2:1~5:2:6 in ISO 13779-3:2018;

---Appendix B corresponds to ISO 13779-3:2018 Appendix G;

---Appendix C corresponds to ISO 13779-3:2018 Appendix E;

---Appendix D corresponds to ISO 13779-3:2018 Appendix B;

---Appendix E corresponds to ISO 13779-3:2018 Appendix C;

---Appendix G corresponds to ISO 13779-3:2018 Appendix H;

---Appendix H corresponds to ISO 13779-3:2018 Appendix D:

The technical differences between this document and ISO 13779-3:2018 and their reasons are as follows:

---Replaced ISO 3310-1 with normatively cited GB/T 6003.1 to adapt to my country's national conditions;

---Replaced ISO 3696 with normatively quoted GB/T 6682 to adapt to my country's national conditions;

---5.5.2 In the identification of crystalline phases, for the construction of calibration curves, determination of impurity phase content and Ca:P ratio, the optional peak-Hydroxyapatite has added the 2:1:1 peak to adapt to the existing technical conditions and correspond to the content in Appendix D:

The following editorial changes have been made to this document:

---Incorporated the amendments to ISO 13779-3:2018/AMD1:2021 (see 5.8:4), and the related terms are in the outer margins Positions are marked with vertical double lines (||):

Please note that some content in this document may be subject to patents: The publisher of this document assumes no responsibility for identifying patents:

Introduction

Hydroxyapatite, as a bone repair material, is widely used in surgical implants:

GB/T 23101 "Hydroxyapatite for Surgical Implants" was transformed from the ISO 13779 series of standards and provides hydroxyapatite ceramics Performance requirements and related test methods for porcelain, hydroxyapatite coatings and hydroxyapatite powders:

GB/T 23101 has been published in 5 parts, including:

---Part 1: Hydroxyapatite Ceramics, intended to standardize the requirements for hydroxyapatite ceramics used as surgical implants;

---Part 2: Hydroxyapatite coatings, intended to standardize hydroxyapatite ceramic coatings applied to metallic and non-metallic surgical implants requirements;

---Part 3: Chemical analysis and characterization of crystallinity and phase purity, intended to provide hydroxyapatite materials, including powders, coatings or ceramics Determination methods for chemical analysis, crystallinity and phase composition evaluation of porcelain;

---Part 4: Determination of bond strength of coatings, intended to provide a method for measuring the bond strength of hydroxyapatite coatings;

---Part 6: Powder, intended to standardize the requirements for raw materials of

hydroxyapatite powder:

No known surgical implant material has ever been shown to cause absolutely no adverse effects in humans: However, hydroxyapatite materials have long Phase 1 clinical application experience shows that if the material is properly applied, the expected biological response level can be achieved:

The biocompatibility and absorption rate of hydroxyapatite materials for surgical implants may depend on the presence of trace elements, impurities in the crystalline phase and crystallinity: Amorphous calcium phosphate, tetracalcium phosphate, alpha-tricalcium phosphate and beta-tricalcium phosphate have been shown to have higher solubility and are comparable to hydroxyl Apatite is absorbed faster in the body: Zirconia and heavy metals may compromise the biocompatibility of the material: Therefore, the group that evaluates the material Ingredients are very important:

In this area, evaluation of different crystalline and amorphous phase compositions is ongoing (including equipment and software): mentioned in this document A new method for measuring the crystallinity of hydroxyapatite was developed, and the Rietveld method was proposed as an alternative method for measuring impurity phase content:

Surgical Implants Hydroxyapatite Part 3: Crystallinity and Phase Purity Chemical Analysis and Characterization

1 Scope

This document describes the chemical analysis, crystallinity and phase composition evaluation of hydroxyapatite materials, including powders, coatings or ceramics:

method:

NOTE: These tests are intended to characterize materials and communicate them between organizations: The tests are not intended to replace a company's internal operations and assessment tests:

This document applies to the evaluation of hydroxyapatite crystallinity, phase composition, impurity elements, and calcium to phosphorus atomic ratio:

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text: Among them, the dated quotations for undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document:

GB/T 6003.1 Technical requirements and inspection of test sieves Part 1: Wire braided