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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 23101.6-2022

Implants for surgery - Hydroxyapatite - Part 6: Powders

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foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1.Structure and Drafting Rules of Standardization Documents"

drafted.

This document is part 6 of GB (GB/T) 23101 "Hydroxyapatite for Surgical Implants". GB (GB/T)23101 has been released

the following parts.

--- 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 uses the redrafted method modified to adopt ISO 13779-6.2015 "Hydroxyapatite for surgical implants - Part 6.Powder".

The technical differences between this document and ISO 13779-6.2015 and their reasons are as follows.

--- Regarding normative reference documents, this document has made adjustments with technical differences to adapt to the technical conditions of our country and the circumstances of the adjustment.

The situation is reflected in Chapter 2 "Normative References", and the specific adjustments are as follows.

* Replace ISO 13779-3 with GB/T 23101.3 which is equivalent to adopting international standards;

* Replaced ISO 24235 with JC/T 2176 which was revised to adopt international standards;

* Replacing ISO 14971 with YY/T 0316 which is equivalent to adopting international standards;

* Removed the European Pharmacopoeia.

--- In "trace elements" (4.3), the test method for heavy metal content was changed from the method in the European Pharmacopoeia to the method commonly used in my country,

In order to adapt to the technical conditions of our country and improve the operability.

Please note that some content of this document may be patented. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

As a bone repair material, hydroxyapatite is widely used in surgical implants.

GB (GB/T) 23101 "Hydroxyapatite for Surgical Implants" is converted from the ISO 13779 series of standards, providing hydroxyapatite

Performance requirements and related test methods for ceramics, hydroxyapatite coatings, and hydroxyapatite powders.

GB (GB/T) 23101 is temporarily composed of 5 parts, including.

--- Part 1.Hydroxyapatite ceramics. Specifies requirements for hydroxyapatite ceramics used as surgical implants.

--- Part 2.Hydroxyapatite coating. Specifies hydroxyapatite ceramic coatings for application to metallic and non-metallic surgical implants

requirements.

--- Part 3.Chemical analysis and characterization of crystallinity and phase purity. Specifies hydroxyapatite-based materials, including coatings and sintered products

Methods for the determination of chemical analysis, crystallinity and phase composition analysis of substances.

--- Part 4.Determination of coating bond strength. Specifies a method for measuring the bond strength of hydroxyapatite coatings.

--- Part 6.Powder. That is, this document specifies the requirements for the raw material of hydroxyapatite powder.

Part 5 is temporarily vacant due to ISO 13779-5 vacancies.

Surgical Implant Hydroxyapatite

Part 6.Powder

1 Scope

This document specifies the requirements for the raw material of hydroxyapatite powder.

This document applies to the production of hydroxyapatite powder raw materials for the production of surgical implants or for the production of surgical implant coatings.

This document does not apply to hydroxyapatite coatings, hydroxyapatite ceramics, glass ceramics, alpha- and beta-tricalcium phosphate or other forms of phosphorus

calcium acid.

2 Normative references

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, dated citations

documents, only the version corresponding to that date applies to this document; for undated references, the latest edition (including all amendments) applies to

this document.

GB/T 23101.3 Surgical Implant Hydroxyapatite Part 3.Chemical Analysis and Characterization of Crystallinity and Phase Purity

(GB/T 23101.3-2010, ISO 13779-3.2008, IDT)

JC/T 2176 Test method for particle size distribution of fine ceramic powder Laser diffraction method (JC/T 2176-2013, ISO 24235.2007,

MOD)

YY/T 0316 Application of Medical Device Risk Management to Medical Devices (YY/T 0316-2016, ISO 14971.2007 Correction

version, IDT)

ISO 2591-1 Screening tests - Part 1.Test methods for screening of woven wire mesh and perforated metal plates (Testsie-

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1

atomisation

The process of producing agglomerates of nearly spherical powder particles (atomized

powder) by rapidly drying suspended particles.

3.2

alpha-Tricalcium phosphate alphatricalciumphosphate; alpha-TCP

Compounds with crystal structures characterized by ICDDPDF09-0348.

Note 1.The chemical formula is Ca3(PO4)2.

Note 2.International Diffraction Data Center Powder Diffraction Card (ICDDPDF).

3.3

beta-tricalcium phosphate; beta-TCP

Compounds with crystal structures characterized by ICDDPDF09-0169.

Note 1.The chemical formula is Ca3(PO4)2.

Note 2.International Diffraction Data Center Powder Diffraction Card (ICDDPDF).