ICS 11.040.30
CCS C30

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1910-2023

Medical-grade beta-tricalcium phosphate powder for additive manufacturing

用于增材制造的医用beta-磷酸三钙粉末

Issued on: September 5, 2023 **Implemented on: September 15, 2024**

Issued by: National Medical Products Administration

Table of Contents

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. Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the China Institute for Food and Drug Control. This document was drafted by: Dianyun Biotechnology (Hangzhou) Co., Ltd., China Institute of Food and Drug Control, Maihai New Material Technology (Gu'an) Co., Ltd., Northwestern Polytechnical University, Zhejiang University of Science and Technology, South China University of Technology Medical Device Research and Inspection Center, Sichuan Medical Device Biomaterials and Products Inspection Center Co., Ltd., Tianjin Medical Device Quality Supervision and Inspection Center, National Human Tissue Function Reconstruction Engineering Technology Research Center Center, Zhejiang Institute of Medical Device Inspection, Shanghai Biolu Biomaterials Co., Ltd., Zhejiang Epuri Nano New Materials Co., Ltd., Suzhou Ding'an Technology Co., Ltd. The main drafters of this document. Zeng Qingfeng, Wei Jing, Han Qianqian, Mao Xin, Liu Zhenqi, Yu Shuyin, Liu Yongsheng, Kong Xiangdong, Liu Jia, Deng Xiang, Ma Chunbao, Ren Li, Xu Pinghua, Lu Xiao, Ni Chenghui, Li Yadong.

Medical beta-tricalcium phosphate powder is suitable for a variety of additive manufacturing processes, such as stereolithography, binder injection, powder bed fusion and extrusion. Craftsmanship. Due to different additive manufacturing processes, the particle size and distribution, powder morphology, specific surface area, bulk density, and vibration of medical beta-tricalcium phosphate powder are affected. The requirements for solid density and fluidity are different, so it needs to be controlled based on the specific process type and product quality requirements. Medical beta-tricalcium phosphate powder for additive manufacturing

1 Scope

YY/T 1910 is the material standard for medical-grade beta-tricalcium phosphate powder used as feedstock in additive manufacturing. Beta-TCP is the resorbable calcium phosphate used for bone graft substitutes, and printing it lets a scaffold be made with a pore architecture matched to the defect it fills. Powder for printing has to satisfy more than chemistry: particle size distribution, morphology and flowability determine whether a layer spreads evenly and whether the printed part has the density it was designed for. This document specifies the composition, the phase purity and the physical characteristics such a powder must have, and the methods that verify them. For a manufacturer of printed bone scaffolds in China, this is the specification the incoming material is certified against.

This document specifies the performance requirements, test methods, labeling, packaging, transportation and Storage. This document applies to medical beta-tricalcium phosphate powder produced by light-curing, extrusion and powder-laying additive manufacturing processes.

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 19077 Particle size distribution laser diffraction method

GB/T 19587 Determination of specific surface area of solid materials by gas adsorption BET method

GB 23101.3 Hydroxyapatite for surgical implants Part

3 Terms and definitions

The terms and definitions defined in GB/T 35021 and GB/T 35351 apply to this document.

4 Performance requirements

4.1 Appearance It should be white powder with no visible colored matter.

4.2 X-ray diffraction It should be consistent with the characteristic peaks in the X-ray diffraction spectrum of beta-tricalcium phosphate in Appendix A [diffraction angles (2theta) are approximately 27.8°, 31.0°, and 34.4° respectively] consistent.