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# PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA



# YY/T 1447-2016

## Implants for surgery - In vitro evaluation for apatite-forming ability of implant materials

外科植入物 植入材料磷灰石形成能力的体外评估

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## Foreword

This standard is drafted in accordance with the rules given in GB/T 1.1-2009. This standard uses the translation method equivalent to ISO 23317..2012 "Surgical implants implanted material in apatite formation ability in vitro evaluation estimate". For ease of use, this standard has been modified as follows:

--- in accordance with the Chinese language used to modify some of the format;

--- to some of the statements applied to international standards to apply to the formulation of our standards;

--- Chapter 2 "normative reference document" has been converted into GB and the standard of the standard with the national standard and the standard instead. And the normative reference in this standard international documents are consistent with the relationship between China's documents are as follows: Technical specifications and test methods for laboratory use (ISO 3696. 1987, MOD); Generic surgical implants - General requirements (ISO 14630..2005, IDT) - YY/T 0640-2008. Please note that some of the contents of this document may involve patents. The issuer of this document does not assume responsibility for the identification of these patents. This standard is proposed by the State Food and Drug Administration. This standard by the National Surgical Implantation and Orthopedic Equipment Standardization Technical Committee Orthopedic Implants Sub-Technical Committee (SAC/TC110 / SC1). The drafting unit. the State Food and Drug Administration Tianjin Medical Device Quality Supervision and Inspection Center, Shanghai Beiao Road biological materials Limited company. The main drafters of this standard. Jiang Xi, Jing Ming, Lu Jianxi, Lu Xiao, Lin Kaoli.

Studies have shown that a variety of different materials through the apatite layer and living bone connection. In cells and proteins that are only identical to human plasma Ion concentration in the simulated body fluid (SBF), the surface of the material can form an apatite layer, and the composition of the formation of apatite and bone mineral composition And the structure is very similar. The ability of apatite formation on the implant material was evaluated in SBF solution, and the ability of bone material to be measured in vivo was evaluated before the animal test Often meaningful. When the bioactive material is implanted in the body, a thin layer of Ca and P is formed on its surface. The material thus passes

through the phospholipid There is no clear boundary between the stone layer and the living tissue. Studies have shown that when the material is soaked in SBF, the same is true on the surface of the material Can form such an apatite layer, its composition and structure and bone mineralization is very similar. As the bioactivity of the material increases, its surface is short Into the apatite also increased. The apatite layer can be detected by a thin film X-ray diffraction spectrometer and/or a scanning electron microscope. The formation of apatite in SBF can also be similar to the following forms of bone apatite.

--- calcium deficiency type apatite;

--- low calcium/phosphorus atomic ratio of apatite; - containing impurities such as Mg2, Na, Cl-, HCO3; Low crystallinity.

Note 1. Since apatite has biological activity, the formation of apatite on the surface of the material contributes to the attachment of the material to the living bone. In vitro through SBF Solution soaking, the surface of the material can also form the same as the body of apatite deposition. For example, Bioglass, CaO-SiO2 glass, Na2O-CaO-SiO

2 Glass, CeraboneAW, Ceravital type glass ceramics, hydroxyapatite ceramic and alkali heat treatment Titanium surface in the body can form calcification, This has a certain correlation with calcification in the in vitro SBF. However, the formation of apatite on the surface of the material does not mean that there is not much Good bone connection. It has been reported that some absorbable materials such as beta-tricalcium phosphate Ca3 (PO4) 2 and calcium carbonate, the surface of which does not form an apatite layer Can be connected to the living bone.

Note 2. It has been reported that, after different compositions of Na2O-CaO-SiO2 glass implanted in rabbit bone defects, the material osteogenic ability and in vitro SBF apatite Ability to have a correlation. Surgical implants for implantation of apatite In vitro evaluation of the ability to form

## 1 Scope

YY/T 1447 describes how to tell, without an animal study, whether an implant material is likely to bond to bone. It specifies the method for detecting apatite formed on the surface of a material immersed in simulated body fluid, the laboratory proxy for the bone-bonding behaviour of a bioactive surface. The test is used on bioactive glasses, calcium phosphate coatings and treated metal surfaces, where the claim of osteoconductivity has to be supported by evidence before an implant can be registered. Because it replaces an animal experiment with a bench measurement, it is the first piece of evidence a developer generates when screening candidate surfaces. The standard carries Amendment 1 of 2023. For anyone submitting a bone-contacting implant in China, this is the method a reviewer expects the apatite-forming claim to rest on.

This standard specifies the method of detecting apatite formed on the surface of a material

in simulated body fluids (SBF).

## 2 Normative reference documents

The following documents are indispensable for the application of this document. For dated references, only the dated edition applies to this article Pieces. For undated references, the latest edition (including all modifications) applies to this document.

ISO 3696. 1987 Analysis of laboratory water specifications and test methods (Waterforanalyticallaboratoryuse-Specifica- tionandtestmethods)

ISO 14630 Passive Surgical Implants General Requirements (Non-activesurgicalimplants-Generalrequirements)

## 3 Terms and definitions

ISO 14630 and the following terms and definitions apply to this standard.

3.1 Apatite apatite Calcium phosphate, including bone mineral and the main inorganic constituents that make up bones and teeth, are similar to hydroxyapatite [Ca10 (PO4) 6 (OH) 2].

Note. Bone minerals also contain ions such as CO32-, F-, Na and Mg2.

3.2 Apatite - formingability The ability of the surface of the material to form apatite.

3.3 Bioactivity In the material interface to trigger a specific biological reaction, making the organization and material to form a connection characteristics.

3.4 Induction period inductionperiod The sample was immersed in the simulated body fluid to detect the time of formation of apatite on the surface of the material.

3.5 Simulated body fluid simulatedbodyfluid (SBF) An inorganic solution having a plasma composition similar to that of the human body and containing no organic component.

3.6 Criteria for assessing the formation of apatite standard glass standardglassforevaluatingapatite-formingability In the SBF and implanted animals show the specific formation of apatite, with a specific chemical composition of the standard glass.