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Biological evaluation of medical devices - Measurement of shed and released nanoparticles - Particle tracking analysis

医疗器械生物学评价 纳米颗粒脱落和释放测量 颗粒跟踪分析法

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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.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

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Biological evaluation of medical devices Nanoparticle shedding and release measurement Particle tracking analysis

1 Scope

This document describes the sample preparation method for particle detachment and release in medical devices, the particle size of nanoparticles in the detachment and release medium, and particle size distribution.

Methods for particle tracking analysis of distribution and concentration.

This document applies to the characterization of particle size distribution and number concentration of detached and released nanoparticles in medical devices (including nanomaterial medical devices).

Analysis of the detachment or release of particles of other sizes in medical devices can also refer to this document.

2 Normative references

GB/T 6682

GB/T 30544.1

GB/T 30544.4

GB/T 30544.6

GB/T 42348

3 Terms and Definitions

The terms and definitions defined in GB/T 30544.1, GB/T 30544.4, GB/T 30544.6 and GB/T 42348, as well as the following terms and definitions, apply. This document.

3.1 particles

Tiny substances with clearly defined physical boundaries.

Note 1.Also known as a particle.

Note 2.Physical boundaries can also be described as interfaces.

Note 3.The particles can move as a whole.

Note 4.This general particle definition applies to nano-objects.

[Source. GB/T 30544.6-2016, 2.9]

3.2 nanoparticles

For nano-objects with all three external dimensions at the nanoscale, there is no significant difference in the length of their longest and shortest axes.

Note. When the difference between the longest and shortest axes of a nanoparticle is significant (greater than 3), the terms nanofiber or nanosheet are used to refer to nanoparticles.

[Source. GB/T 30544.4-2019, 2.4]

3.3 particle size

The linear size of particles determined by a specific measurement method under specified measurement conditions.

Note. Different particle size analysis methods are based on measurements of different physical properties. Regardless of the actual physical property measured, the results given are linear representations of the particles.

Size. For example, the equivalent diameter of a sphere.

[Source. GB/T 30544.6-2016, 3.1.1]

3.4 [Source. GB/T 30544.6-2016, 3.1.2]

The functional relationship between particle distribution and particle size.

Note. Particle size distribution is expressed as cumulative distribution or distribution density (the distribution of material within a certain size range divided by the width of that size range).

3.5 hydrodynamic diameter

The equivalent diameter of a particle that has the same diffusion coefficient as a real particle in the fluid.

[Source. GB/T 30544.6-2016, 3.2.6]

3.6 [Source. GB/T 42348-2023, 3.12]

A method that uses laser light to irradiate particles undergoing Brownian motion in a suspension and measures particle size by utilizing the positional changes of individual particles.

Note 1.The translational diffusion coefficient was obtained by analyzing the change of particle position over time, and then calculated using the Stokes-Einstein equation.

Fluid dynamics diameter is used as particle size.

Note 2.Nanoparticle tracking analysis (NTA) is often referred to as PTA. NTA is a part of PTA because PTA covers a wide range of particle sizes, not just nanoparticles. Meter scale range.

3.7 Viscosity

A measure of the resistance to the flow or deformation of a liquid.

[Source. GB/T 42348-2023, 3.15]

4 Principles

Particle tracking analysis (PTA) technology uses a laser light source to illuminate a particle suspension, and then observes and collects the scattering of particles using an optical microscope.

The optical signal is used to track and record the Brownian motion of each particle, utilizing the one-dimensional, two-dimensional, and three-dimensional data of the particles per unit time.

The average spatial displacement yields the diffusion coefficient of particles in the sample solution; according to the Stokes-Einstein equation, the diffusion coefficient can be obtained.

The hydrodynamic diameter is obtained, and thus the particle size information of the particles in the sample system is obtained. The particle size is then estimated from the number of tracked particles and the known sampling volume. The concentration.

5.1 Instruments and Equipment

The main testing instruments are.

a) Particle tracking analyzer. equipped with a single or multiple laser light sources and an imaging camera; equipped with a temperature control unit, the operating temperature can be measured and...

Temperature measurement error is better than ±3°C;

b) Dissolution apparatus. equipped with dissolution cups, drive unit, constant temperature water bath or other heating devices, etc.