AS ISO 13319.1:2026
ISO 13319-1:2021

Determination of particle size distribution — Electrical sensing zone method

Part 1: Aperture/orifice tube method



AS ISO 13319.1:2026

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How to read this Standard

This page explains the meaning of the language and structure of this Standard.

Refer to Standards Australia's Standardisation Guide 006 for more details about drafting rules.

Australian and Australian/New Zealand Standards are voluntary unless they are referenced in legislation or called up in contracts.

Requirements

To conform to a Standard, all requirements in the Standard need to be met.

A requirement is any statement in the Standard which uses the word "shall".

Recommendations, permissions and possibilities

The following words are commonly used in Standards, but statements using them do not have to be followed to conform to the Standard:

(a) "should" means that something is recommended.

(b) "may" means that something is permitted.

(c) "can" means that something is possible.

Structure of Standards

A Standard always has the following parts:

(i) The Preface states who developed the Standard, what the Standard is aiming to do, and how it relates to other documents.

(ii) The Scope states what the Standard is about, what it covers and what it does not cover.

(iii) The Normative references clause lists other documents that are referenced in the Standard as part of requirements.

(iv) The Terms and definitions clause defines important terms to help with understanding the Standard.

A Standard may also include other parts, such as the following:

(1) A normative appendix sets additional requirements that need to be conformed to.

(2) An informative appendix provides additional information or guidance. They usually do not contain requirements. If an informative appendix does contain requirements, the Standard will explain when those requirements apply.

(3) A Bibliography lists documents referenced in the Standard but not as part of requirements.

Many Standards include notes. Notes provide recommendations and/or guidance only. They never contain requirements.

Preface

This Standard was prepared by the Standards Australia Committee NT-001, Nanotechnologies.

The objective of this document is to specify the measurement of the size distribution of particles dispersed in an electrolyte solution using the electrical sensing zone method. This can include biologics such as cells, but also industrial particles such as carbon, cement, ceramic powders, metal powders, pigments and polymer powders. The method measures pulse heights and their relationship to particle volumes or diameters, and is applicable over the range (implementation dependant) from approximately 0,5 µm to above 1 mm.

This document is identical to, and has been reproduced from, ISO 13319-1:2021, *Determination of particle size distribution — Electrical sensing zone method — Part 1: Aperture/orifice tube method*.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 24, *Particle characterization including sieving*, Subcommittee SC 4, *Particle characterization.*

This first edition of ISO 13319-1 cancels and replaces ISO 13319:2007, which has been technically revised. The main changes compared to the previous edition are as follows:

— a general update to reflect the needs of modern quality assurance;

— the section on repeatability and inter system variation has been expanded;

— many instruments of this type are under strict controls within the pharmaceutical and related industries, therefore a new annex has been prepared with details of the factors which should be considered when developing a validated method in this arena;

— Clause 10 now gives details of the exact parameters which should be reported, in order to present the method and the key parameters of the result.

A list of all parts in the ISO 13319 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Determination of particle size distribution — Electrical sensing zone method

Part 1: Aperture/orifice tube method

1 Scope

This document specifies the measurement of the size distribution of particles dispersed in an electrolyte solution using the electrical sensing zone method. This can include biologics such as cells, but also industrial particles such as carbon, cement, ceramic powders, metal powders, pigments and polymer powders. The method measures pulse heights and their relationship to particle volumes or diameters, and is applicable over the range (implementation dependant) from approximately 0,5 µm to above 1 mm. This document does not address the specific requirements of the measurement of specific materials.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
dead time
time during which the electronics are not able to detect particles due to the signal processing of a previous pulse

3.2
aperture
small diameter hole through which suspension is drawn

3.3
sensing zone
volume of electrolyte solution within, and around, the aperture in which a particle is detected

3.4
analysis volume
volume of suspension that is analysed

3.5
size bin
size interval to distinguish particle size for size distribution measurement

3.6
envelope size
external size of a particle as seen in a microscope

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