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Determination of particle size distribution — Electrical sensing zone method —

Part 1: Aperture/orifice tube method

Détermination de la distribution granulométrique — Méthode de détection de zones électrosensibles —

Partie 1: Méthode d'ouverture/d'orifice du tube

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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).

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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

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

3.7
envelope volume
volume of the envelope given by the three-dimensional boundary of the particle to the surrounding medium

3.8
effective density
density of a porous particle where open pores are filled with liquid and closed pores are not (so included in the density)

4 Symbols

For the purposes of this document, the following symbols apply.

A_p	amplitude of the most frequent pulse
A_x	amplitude of the electrical pulse generated by an arbitrary particle
D	aperture diameter
d_m	certified mean diameter of the microspheres used for primary calibration
d_{micr}	mean diameter of the sieved fraction as determined using microscopy
d_{ESZ}	mean diameter of the sieved fraction as determined using the ESZ instrument
df	degrees of freedom
d_L	particle diameter at the lower boundary of a size interval or channel
d_p	modal diameter of a certified particle size reference material
d_{ref}	reference diameter of the microspheres
d_U	particle diameter at the upper boundary of a size interval or channel
f_{resp}	response factor
K_d	calibration constant of diameter
K_{da}	arbitrary calibration constant of diameter of any value to start the mass calibration procedure
m	mass of sample
M_b	mass balance, percentage of particles accounted for in a measurement in comparison to input particle mass
M_m	mass of particles measured by the instrument
n	number used to signify the maximum of an integral be it channel number [in Formula (D.1)] or number of repeat measurements [in Formulae (G.1) and (G.2)]
n_c	counted particle number
N_c	mean of a Poisson distribution, used to describe the temporal spread of counts within a size bin

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