First edition
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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).

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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.