BS ISO 21501-3:2019

BSI Standards Publication

Determination of particle size distribution — Single particle light interaction methods

Part 3: Light extinction liquid-borne particle counter

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National foreword

This British Standard is the UK implementation of ISO 21501-3:2019. It supersedes BS ISO 21501-3:2007, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee LBI/37, Particle characterization including sieving.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Determination of particle size distribution — Single particle light interaction methods —

Part 3: Light extinction liquid-borne particle counter

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Partie 3: Compteur de particules en suspension dans un liquide par extinction de la lumière

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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 second edition cancels and replaces the first edition (ISO 21501-3:2007), which has been technically revised. The main changes from the previous edition are as follows:

— Clause 4 for “Principle” and Clause 5 for “Basic configuration” have been added;

— “size calibration” and “verification of size setting” have been combined as “size setting error” in the requirements (Clause 6);

— “Test report” (3.10 in the previous edition) has been changed to 6.9 on “Reporting of test and calibration results”;

— information about uncertainties has been enriched and is now the subject of Annex B.

A list of all parts in the ISO 21501 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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Introduction

Monitoring particle contamination levels is required in various fields, e.g. in the electronic industry, in the pharmaceutical industry, in the manufacturing of precision machines and in medical operations. Particle counters are useful instruments for monitoring particle contamination in liquid. The purpose of this document is to provide a calibration procedure and verification method for particle counters, so as to minimize the inaccuracy in the measurement result by a counter, as well as the differences in the results measured by different instruments.

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Determination of particle size distribution — Single particle light interaction methods —

Part 3: Light extinction liquid-borne particle counter

1 Scope

This document describes a calibration and verification method for a light extinction liquid-borne particle counter (LELPC), which is used to measure the size and particle number concentration of particles suspended in liquid. The light extinction method described in this document is based on single particle measurements. The typical size range of particles measured by this method is between 1 µm and 100 µm in particle size.

The method is applicable to instruments used for the evaluation of the cleanliness of pharmaceutical products (e.g. injections, water for injections, infusions), as well as the measurement of number and size distribution of particles in various liquids.

The following are within the scope of this document:

— size setting error;

— counting efficiency;

— size resolution;

— maximum particle number concentration;

— sampling flow rate error;

— sampling time error;

— sampling volume error;

— calibration interval;

— reporting results from test and calibration.

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:

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

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

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