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

**Part 3:
Light extinction liquid-borne particle
counter**

iTeh STANDARD PREVIEW

(standard) *Détermination de la distribution granulométrique — Méthodes
d'interaction lumineuse de particules uniques —*

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

[https://standards.iteh.ai/catalog/standards/sist/ca176865-f41a-4bdf-a998-
d087c0222414/iso-21501-3-2007](https://standards.iteh.ai/catalog/standards/sist/ca176865-f41a-4bdf-a998-d087c0222414/iso-21501-3-2007)



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 21501-3:2007

<https://standards.iteh.ai/catalog/standards/sist/ca176865-f41a-4bdf-a998-d087c0222414/iso-21501-3-2007>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2007

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Terms and definitions.....	2
3 Requirements	2
3.1 Size calibration.....	2
3.2 Verification of size setting	2
3.3 Counting efficiency.....	2
3.4 Size resolution	2
3.5 Maximum particle number concentration	3
3.6 Sampling flow rate.....	3
3.7 Sampling time	3
3.8 Sampling volume	3
3.9 Calibration interval	3
3.10 Test report	3
4 Test method.....	4
4.1 Size calibration.....	4
4.2 Verification of size setting.....	6
4.3 Counting efficiency.....	6
4.4 Size resolution	6
4.5 Maximum particle number concentration.....	7
4.6 Sampling flow rate.....	8
4.7 Sampling time	8
4.8 Sampling volume	8
4.9 Calibration	8
Annex A (informative) Uncertainty of particle size calibration	9
Annex B (informative) Size resolution.....	11
Bibliography	12

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 21501-3 was prepared by Technical Committee ISO/TC 24, *Sieves, sieving and other sizing methods*, Subcommittee SC 4, *Sizing by methods other than sieving*.

This first edition of ISO 21501-3, together with ISO 21501-2 and ISO 21501-4, cancels and replaces ISO 13323-1:2000, which has been technically revised.

ISO 21501 consists of the following parts, under the general title *Determination of particle size distribution — Single particle light interaction methods*:

- Part 2: *Light scattering liquid-borne particle counter*
- Part 3: *Light extinction liquid-borne particle counter*
- Part 4: *Light scattering airborne particle counter for clean spaces*

The following part is under preparation:

- Part 1: *Light scattering aerosol spectrometer*

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 part of ISO 21501 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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO 21501-3:2007](https://standards.iteh.ai/catalog/standards/sist/ca176865-f41a-4bdf-a998-d087c0222414/iso-21501-3-2007)

<https://standards.iteh.ai/catalog/standards/sist/ca176865-f41a-4bdf-a998-d087c0222414/iso-21501-3-2007>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 21501-3:2007

<https://standards.iteh.ai/catalog/standards/sist/ca176865-f41a-4bdf-a998-d087c0222414/iso-21501-3-2007>

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

Part 3: Light extinction liquid-borne particle counter

1 Scope

This part of ISO 21501 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 part of ISO 21501 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.

Instruments that conform to this part of ISO 21501 are 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 part of ISO 21501:

- size calibration; <https://standards.iteh.ai/catalog/standards/sist/ca176865-f41a-4bdf-a998-d087c0222414/iso-21501-3-2007>
- verification of size setting;
- counting efficiency;
- size resolution;
- maximum particle number concentration;
- sampling flow rate;
- sampling time;
- sampling volume;
- calibration interval;
- test report.

2 Terms and definitions

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

2.1 calibration particles
mono-disperse spherical particle with a known mean particle size, e.g. polystyrene latex (PSL) particle, that is traceable to an international standard of length, and where the standard uncertainty of the mean particle size is equal to or less than $\pm 2,5$ %

NOTE The refractive index of calibration particles is close to 1,59 at a wavelength of 589 nm (sodium D line).

2.2 counting efficiency
ratio of the measured result of a light extinction liquid-borne particle counter (LELPC) to that of a reference instrument using the same sample

2.3 particle counter
instrument that counts the number of particles and measures their size using the light scattering method or the light extinction method

**2.4 pulse height analyser
PHA**
instrument that analyses the distribution of pulse heights

2.5 size resolution
measure of the ability of an instrument to distinguish between particles of different sizes

<https://standards.iteh.ai/catalog/standards/sist/ca176865-f41a-4bdf-a998-d087c0222414/iso-21501-3-2007>

3 Requirements

3.1 Size calibration

The recommended procedure for the size calibration is described in 4.1.

3.2 Verification of size setting

The reported particle size range setting error of LELPC shall be equal to or less than ± 10 % when the test is carried out by the method described in 4.2.

3.3 Counting efficiency

The counting efficiency shall be (100 ± 20) % when the test is carried out by the method described in 4.3.

3.4 Size resolution

The size resolution shall be equal to or less than 10 % when the test is carried out by the method described in 4.4.

3.5 Maximum particle number concentration

The maximum measurable particle number concentration shall be specified by the manufacturer. The coincidence loss at the maximum particle number concentration of an LELPC shall be equal to or less than 10 %.

NOTE When the particle number concentration is higher than the maximum particle number concentration, the number of uncounted particles increases because of an enhanced probability of multiple particles existing in the sensing volume (coincidence error) and/or saturation of the electronic system.

3.6 Sampling flow rate

The manufacturer shall specify the standard uncertainty of the sampling flow rate. It shall be checked by the user prior to the measurement so that the sampling flow rate is within the range specified by the manufacturer.

The standard uncertainty of sampling flow rate shall be within the manufacturer's specification.

If the LELPC does not have a flow rate control system this subclause does not apply, however the manufacturer shall specify the allowable flow rate range of the LELPC.

3.7 Sampling time

The standard uncertainty in the duration of sampling time shall be equal to or less than ± 1 % of the preset value.

This subclause does not apply when the LELPC is not equipped with a sampling system.

This subclause does not apply when the LELPC is equipped with a volumetric sampling system.

3.8 Sampling volume

The standard uncertainty of sampling volume shall be equal to or less than ± 5 % of the preset value.

This subclause does not apply when the LELPC is not equipped with a volumetric sampling system.

3.9 Calibration interval

It is recommended that the calibration interval of an LELPC be one year or less.

3.10 Test report

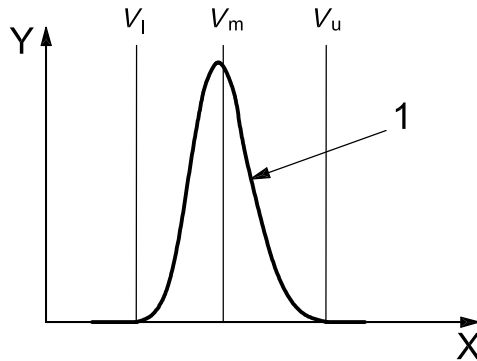
The following minimum information shall be recorded:

- a) date of calibration;
- b) calibration particle sizes;
- c) verification of size setting;
- d) flow rate;
- e) size resolution (with the particle size used);
- f) counting efficiency;
- g) voltage limit or channel of an internal pulse height analyser (PHA).

4 Test method

4.1 Size calibration

When calibrating an LELPC with calibration particles of known size, the median voltage (or internal PHA channel), corresponds to the particle size (see Figure 1). The median voltage (or internal PHA channel) should be determined by using a particle counter with variable voltage limit (or internal PHA channel) settings. The median voltage (or internal PHA channel) is the voltage (or internal PHA channel) that equally divides the total number of pulses counted. When a particle counter with variable voltage limit settings is not available, a PHA can be used in place of the counter.



Key

X pulse height voltage (or channel)

Y density

1 pulse height distribution with PSL particles

V_l lower voltage limit

V_m median voltage

V_u upper voltage limit

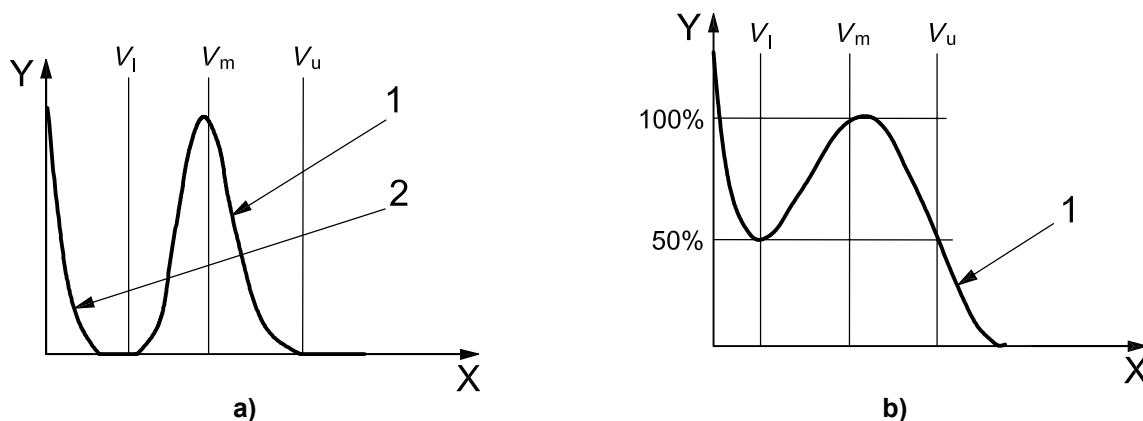
iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO 21501-3:2007](https://standards.iteh.ai/catalog/standards/sist/ca176865-f41a-4bdf-a998-d087c0222414/iso-21501-3-2007)

<https://standards.iteh.ai/catalog/standards/sist/ca176865-f41a-4bdf-a998-d087c0222414/iso-21501-3-2007>

Figure 1 — Pulse height distribution of PSL particle signals

When noise signals appear as if there are many small particles in the sample, the median voltage (or internal PHA channel) shall be determined by discarding the pulses due to “false particles” [see Figure 2 a)]. The discarding should only be done when the density at the peak due to real particles is more than twice the density at the valley that separates it from the pulses due to “false particles” [see Figure 2 b)]. In this case, V_u is the voltage greater than the median voltage, V_m , where the density is the same as V_l . The median is calculated using only the population between the voltage limits V_l and V_u .

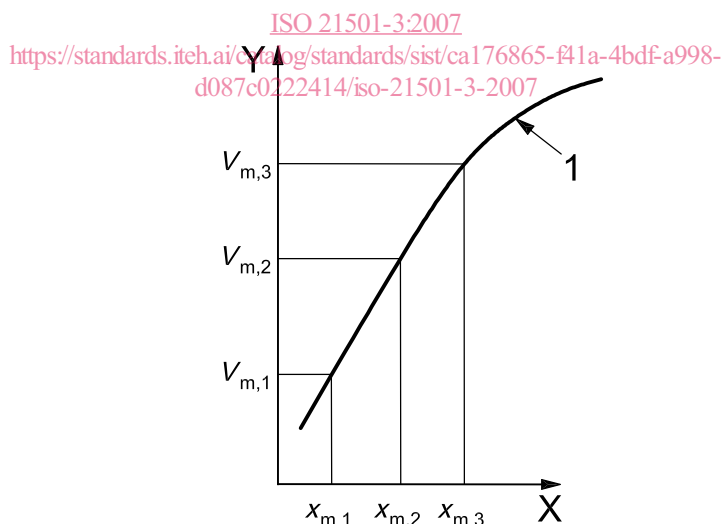


Key

- X pulse height voltage (or channel)
- Y density
- 1 pulse height distribution with PSL particles
- 2 noise (false particles, small particles and/or optical, electrical noise)
- V_l lower voltage limit
- V_m median voltage
- V_u upper voltage limit

Figure 2 — Pulse height distribution of PSL particle signals with noise

The voltages of channels corresponding to particle size should be determined in accordance with the calibration curve provided by the manufacturer (see Figure 3).



Key

- X particle size
- Y median value of calibration particles
- 1 calibration curve
- $V_{m,1}$ median voltage corresponding to particle size $x_{m,1}$
- $V_{m,2}$ median voltage corresponding to particle size $x_{m,2}$
- $V_{m,3}$ median voltage corresponding to particle size $x_{m,3}$

Figure 3 — Calibration curve

NOTE When the median voltage is determined by using an external PHA, the uncertainty in the voltage of PHA and the voltage uncertainty of the LELPC are included in setting the voltage limits of the LELPC (see Annex A).