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**Light extinction liquid-borne particle
counter**

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal for establishment of Japan Air Cleaning Association (JACA)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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Light extinction liquid-borne particle counter

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of **ISO 21501-3** published in 2007, while modifying some of its technical contents so as to make them easier to understand, as well as to enhance the usability of this Standard.

The portions with continuous sidelines or dotted underlines are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with the explanations is given in Annex JB.

1 Scope

This Standard describes a calibration and verification method for a light extinction liquid-borne particle counter (hereafter referred to as the “particle counter”), which is used to measure the size and number or particle number concentration of particles suspended in the liquid. The typical size range of particles measured by the particle counter in the method specified in this Standard is between 1 μm and 100 μm in particle size.

This particle counter is not used for measurements of hydraulic oils used for hydraulic power units.

NOTE 1 The instruments that conform to this Standard are used for the evaluation of the cleanliness of pharmaceutical products (e.g. injections, water for injections, infusions), as well as the measurement of size and number or particle number concentration of particles in various liquids.

NOTE 2 The particle size measured by the particle counter is not the actual particle size—it is the light extinction equivalent diameter of the calibration particles suspended in pure water.

The particle size is a diameter of particle and is also called the particle diameter.

NOTE 3 The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 21501-3:2007 *Determination of particle size distribution—Single particle light interaction methods—Part 3: Light extinction liquid-borne particle counter* (MOD)

The symbols which denote the degree of correspondence in the contents in the corresponding International Standard and **JIS** are IDT (identical), MOD (modified) and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standard (including amendments) indicated below shall be applied.

JIS B 9925 *Light scattering liquid-borne particle counter*
JIS Z 8103 *Glossary of terms used in measurement*
JIS Z 8122 *Contamination control—Terminology*

3 Terms and definitions

For the purpose of this Standard, the terms and definitions given in **JIS B 9925**, **JIS Z 8103** and **JIS Z 8122** and the following apply.

3.1 counting reference standard solution

a solution in which the calibration particles of known particle size are suspended in pure water, of which, therefore, the particle number concentration is verified

NOTE : Pure water as referred to herein means the water in which foreign matter is removed up to the degree not influencing the test.

4 Measurement principle

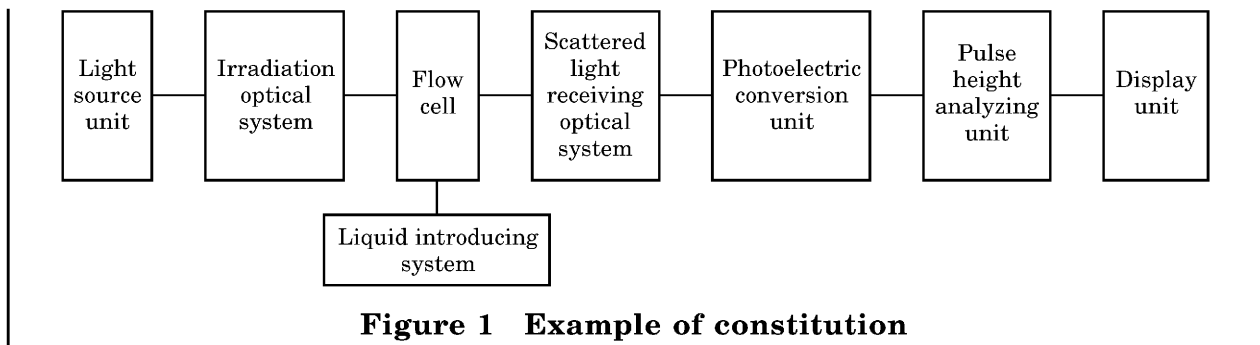
When light is irradiated to particles, since particles scatter the light by which they are hit, the size of particles can be measured from the amount of light that is lost due to this scattering (light extinction quantity), and the number of particles can be counted from the number of pulses of light extinction generated when particles pass through the luminous flux. More concretely, the sample liquid is introduced into flow cell through the sample introduction opening of a particle counter at a certain rate and is made to pass through irradiation region of light. The quantity of light decreased by the scattering of individual particles is converted to pulse-shaped electric signals by photo electric sensing element and the number of particles is obtained by counting these signals. Since there is a definite relation between the pulse height value of pulse-shaped signal and particle size, the number of passing particles larger than the specific particle size can be obtained by analyzing the pulse height value of particle size of each division.

5 Basic constitution

The particle counter consists of a light source unit, an irradiation optical system, a liquid introduction system, a flow cell, an optical system for receiving light, a photoelectric conversion unit, a pulse height analyzing unit, a display unit, etc. as shown in figure 1. In some particle counters, a liquid introducing system and/or a display unit are/is not included in the particle counter.

Further, it shall be possible to take out the information with which peak height distribution of calibration particle can be created.

NOTE : The types of liquid introducing systems include the compression type using air pressure or the like, the suction type which draws liquids by means of a syringe or the like, and the self-flowing type which introduces liquids from the distribution pipe by utilizing the pressure in the pipe.



6 Performance

6.1 Size calibration

Size calibration should be performed in accordance with 7.1.

6.2 Verification of size setting

The reported particle size range setting error of the particle counter shall be equal to or less than $\pm 10\%$ when the test is carried out by the method described in 7.2.

6.3 Counting efficiency

The counting efficiency, when tested in accordance with 7.3, shall be $(100 \pm 20)\%$.

6.4 Size resolution

The size resolution, when tested in accordance with 7.4, shall not be greater than 10 %.

6.5 Maximum particle number concentration

The coincidence loss for the maximum particle number concentration shall be calculated by equation (4) given in 7.5, and shall be not greater 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 and/or saturation of the electronic system.

6.6 Sampling flow rate

The user shall check prior to the measurement that the sampling flow rate is within the range of standard uncertainty stated in the specifications, etc.

The sampling flow rate shall be tested in accordance with 7.6, and its deviation from the specified flow rate shall not exceed the range given in the specifications.

6.7 Sampling time

The standard uncertainty in the duration of sampling time, when it is tested in accordance with 7.7, shall be equal to or less than $\pm 1\%$ of the preset value.

Subclause 6.8 shall be applied instead of this subclause if the particle counter is equipped with a volumetric sampling system.