

This is a preview of "ISO 13319-1:2021". [Click here to purchase the full version from the ANSI store.](#)

First edition  
2021-03

---

---

# 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*



Reference number  
ISO 13319-1:2021(E)

© ISO 2021



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

This is a preview of "ISO 13319-1:2021". Click here to purchase the full version from the ANSI store.

## Contents

|   | Page      |
|---|-----------|
| Foreword .....  | v         |
| <b>1 Scope</b> .....  | <b>1</b>  |
| <b>2 Normative references</b> .....   | <b>1</b>  |
| <b>3 Terms and definitions</b> .....  | <b>1</b>  |
| <b>4 Symbols</b> .....  | <b>2</b>  |
| <b>5 Principle</b> .....  | <b>3</b>  |
| <b>6 General operation</b> .....  | <b>4</b>  |
| 6.1 Response .....  | 4         |
| 6.2 Size limits .....   | 5         |
| 6.3 Effect of coincident particle passage .....   | 5         |
| 6.4 Dead time .....   | 6         |
| 6.5 Analysis volume .....   | 7         |
| <b>7 Repeatability and reproducibility of counts</b> .....  | <b>7</b>  |
| 7.1 Instrument repeatability .....  | 7         |
| 7.2 Method reproducibility/intermediate precision .....   | 8         |
| <b>8 Operational procedures</b> .....   | <b>8</b>  |
| 8.1 General .....   | 8         |
| 8.2 Instrument location .....   | 8         |
| 8.3 Linearity of the aperture/amplifier system .....  | 8         |
| 8.4 Linearity of the counting system .....  | 8         |
| 8.5 Choice of electrolyte solution .....  | 8         |
| 8.5.1 General .....   | 8         |
| 8.5.2 Special considerations for small apertures ( $D < 50 \mu\text{m}$ ) .....                               | 9         |
| 8.5.3 Special considerations for large apertures ( $D > 400 \mu\text{m}$ ) .....                              | 9         |
| 8.6 Preparation of electrolyte solution .....   | 9         |
| 8.7 Recommended sampling, sample splitting, sample preparation and dispersion .....                           | 9         |
| 8.7.1 General .....   | 9         |
| 8.7.2 Method 1: Using a paste .....   | 10        |
| 8.7.3 Method 2: Alternative method applicable to low-density particles of less<br>than $50 \mu\text{m}$ ..... | 10        |
| 8.7.4 Suspensions and emulsions .....   | 11        |
| 8.7.5 Verification of the dispersion .....  | 11        |
| 8.8 Choice of aperture(s) and analysis volume(s) .....  | 11        |
| 8.9 Clearing an aperture blockage .....   | 11        |
| 8.10 Stability of dispersion .....  | 12        |
| 8.11 Calibration .....  | 12        |
| 8.11.1 General .....  | 12        |
| 8.11.2 Calibration procedure — microsphere calibration .....  | 13        |
| <b>9 Analysis</b> .....   | <b>13</b> |
| <b>10 Calculation of results</b> .....  | <b>13</b> |
| <b>11 Instrument qualification</b> .....  | <b>14</b> |
| 11.1 General .....  | 14        |
| 11.2 Report .....   | 14        |
| <b>Annex A (informative) Derivation of maximum count number to limit coincidence</b> .....                    | <b>15</b> |
| <b>Annex B (informative) Fishbone diagram for method development</b> .....                                    | <b>17</b> |
| <b>Annex C (informative) Calibration and control of frequently used apertures</b> .....                       | <b>19</b> |
| <b>Annex D (informative) Mass integration method for calibration and mass balance</b> .....                   | <b>20</b> |
| <b>Annex E (informative) Calibration for the measurement of porous and conductive particles</b> .....         | <b>26</b> |

This is a preview of "ISO 13319-1:2021". [Click here to purchase the full version from the ANSI store.](#)

|   |           |
|---|-----------|
| <b>Annex F (informative) Technique using two (or more) apertures .....</b>  | <b>29</b> |
| <b>Annex G (informative) Chi-squared test of the correctness of instrument operation or<br/>sample preparation.....</b> | <b>31</b> |
| <b>Bibliography.....</b>  | <b>33</b> |

This is a preview of "ISO 13319-1:2021". [Click here to purchase the full version from the ANSI store.](#)

## 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](http://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](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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](http://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](http://www.iso.org/members.html).