# 2.4.49. Powder Fineness

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

**Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.**

DRAFT FOR COMMENTS

## Document History and Schedule for the Adoption Process

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| Further follow-up action as required. | |

## 2.4.49. Powder Fineness

*This General Chapter has been harmonized with corresponding texts of the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopeia.*

*Particle Size Distribution Estimation (2.5.7)* is estimated by analytical sieving or by application of other suitable methods where appropriate. A simple descriptive classification of powder fineness is provided in this chapter. For practical reasons, sieves are commonly used to measure powder fineness. Sieving is most suitable where a majority of the particles are larger than about 75 µm, although it can be used for some powders having smaller particle sizes where the method can be validated. Light diffraction is also a widely used technique for measuring the size of a wide range of particles.

Where the cumulative distribution has been determined by analytical sieving or by application of other methods, particle size may be characterised in the following manner:

$x_{90}$ = particle size corresponding to 90 per cent of the cumulative undersize distribution;
$x_{50}$ = median particle size (i.e. 50 per cent of the particles are smaller and 50 per cent of the particles are larger);
$x_{10}$ = particle size corresponding to 10 per cent of the cumulative undersize distribution.

It is recognised that the symbol *d* is also widely used to designate these values. Therefore, the symbols $d_{90}$, $d_{50}$, $d_{10}$ may be used.

The following parameters may be defined based on the cumulative distribution.

$Q_r(x)$ = cumulative distribution of particles with a dimension less than or equal to x where the subscript *r* reflects the distribution type.

| ***r*** | **Distribution type** |
|---|---|
| 0 | Number |
| 1 | Length |
| 2 | Area |
| 3 | Volume |

Therefore, by definition:

$Q_r(x) = 0.90$ when $x = x_{90}$
$Q_r(x) = 0.50$ when $x = x_{50}$
$Q_r(x) = 0.10$ when $x = x_{10}$

An alternative but less informative method of classifying powder fineness is by use of the descriptive terms in Table -1.

Table - 1

| **Classification of powders by fineness** | | |
|---|---|---|
| **Descriptive term** | **$x_{50}$ (µm)** | **Cumulative distribution by volume basis, Q3(x)** |
| Coarse | > 355 | $Q_3(355) < 0.50$ |
| Moderately fine | 180 – 355 | $Q_3(180) < 0.50$ and $Q_3(355) \geq 0.50$ |
| Fine | 125 – 180 | $Q_3(125) < 0.50$ and $Q_3(180) \geq 0.50$ |
| Very fine | ≤ 125 | $Q_3(125) \geq 0.50$ |

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