⟨811⟩ POWDER FINENESS

Change to read:

▲The particle size distribution should be estimated by *Particle Size Distribution Estimation by Analytical Sieving* ⟨786⟩ or by application of other methods where practical. 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.▲*USP35*

Delete the following:

▲**Sieves for Pharmacopeial Testing**—Sieves for Pharmacopeial testing are described under *Particle Size Distribution Estimation by Analytical Sieving* ⟨786⟩.▲*USP35*

Delete the following:

▲**Powdered Vegetable and Animal Drugs**—In determining the powder fineness of a vegetable or animal drug, no portion of the drug may be rejected during milling or sifting unless specifically permitted in the individual monograph.▲*USP35*

Delete the following:

▲**Air Permeation Method for Determining Fineness of Sub-sieve Size Particles**—The average particle size measured is in the range of 0.2 to 50 µm. The test specimen is loaded into a precision bore tube and is compacted between two paper disks and porous plugs by a rack-and-pinion packing plunger. The determination of the particle size of the specimen in the uniformly packed column is based on its resistance to the flow of a closely regulated current of dried air. The liquid level of a flowmeter–manometer corresponds directly to particle size. Special handling instructions and procedures are provided in the individual monographs.▲*USP35*

Change to read:

Classification of Powder Fineness—▲Where the cumulative distribution has been determined by analytical sieving or by application of other methods, powder fineness may be classified in the following manner:

x_{90} = particle dimension corresponding to 90% of the cumulative undersize distribution
x_{50} = median particle dimension (i.e., 50% of the particles are smaller and 50% of the particles are larger)
x_{10} = particle dimension corresponding to 10% of the cumulative undersize distribution

It is recognized that the symbol d is also widely used to designate these values. Therefore, the symbols d_{90}, d_{50}, and 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:

1. $Q_R(x) = 0.90$ when $x = x_{90}$
2. $Q_R(x) = 0.50$ when $x = x_{50}$
3. $Q_R(x) = 0.10$ when $x = x_{10}$▲*USP35*

An alternative but less informative method of classifying powder fineness is by use of the terms in the following table.

▲Classification of Powders by Fineness

Descriptive Term	X_{50} (µm)	Cumulative Distribution by Volume Basis, $Q_3(x)$
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	$Q_3(125) \geq 0.50$

▲*USP35*