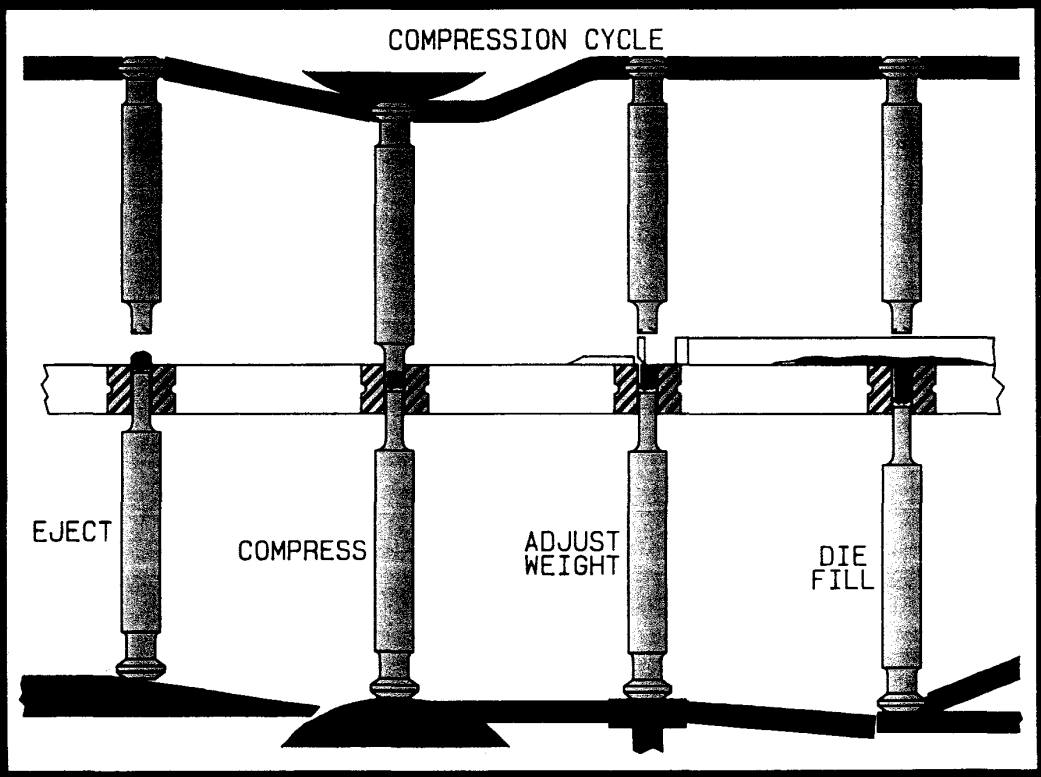
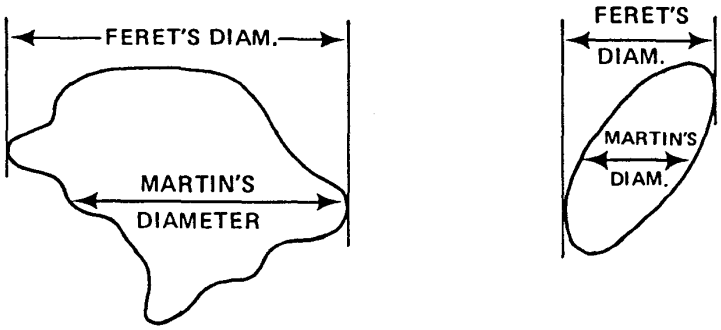
Pharmaceutical Dosage Forms: Tablets Volume 2

Second Edition, Revised and Expanded

Edited by Herbert A. Lieberman, Leon Lachman, and Joseph B. Schwartz





Martin's diameter = mean length of line paralleling the direction of measurement bisecting the particle, and terminating at the particle boundaries

Faret's diameter = mean length of line paralleling the direction of measurement and terminating at two tangents to the outer-most boundaries of the particle

Figure 50 Statistical diameters.

1. Sampling the material to be analyzed (discussed earlier in this chapter
2. Preparing the sample for analysis (see Sec. IV)
3. Generating the data
4. Treatment and presentation of the data

F. Particle Size Statistics

In generating the data, individual or groups of particles from each sample are sized and counted. The sizing and counting follow a particular pattern in order to put this data into an orderly, meaningful form which can be statistically analyzed for interpretive and comparative purposes. For example, it will be assumed that initial microscopic observation of a sample reveals a size range between 0.5 to 60 μm. To begin the statistics, this range is divided into convenient equal parts known as class intervals and the mean of each class interval is determined. For convenience of calculation, the lower limit of the first class interval is assumed to be zero. The particles are sized, counted, and tallied under their proper class interval as shown in Table 10.

For the statistical calculation all the particles counted in each class interval are assumed to be equal to the mean of their respective class interval. This data can now be put into bar graph or histogram form as shown in Figure 51. If the means of each class interval are connected by a smooth line, a distribution curve results as shown in Figure 52. This frequency curve is bell-shaped and is known as a Gaussian curve if symmetrical. The sample represented by the curve is said to have a Gaussian distribution. To normalize the data, the percentage of particles can be calculated in each class interval (Table 11), added cumulatively, and plotted to give the number distribution curve seen in Figure 53.

Table 10 Microscopic Count Data

Class interval (μm)	Mean of the class interval (μm)	Number of particles counted in each class interval
0 – 5	2.5	96
5 – 10	7.5	105
10 – 15	12.5	116
15 – 20	17.5	129
20 – 25	22.5	150
25 – 30	27.5	212
30 – 35	32.5	148
35 – 40	37.5	127
40 – 45	42.5	114
45 – 50	47.5	101
50 – 55	52.5	93
55 – 60	57.5	88

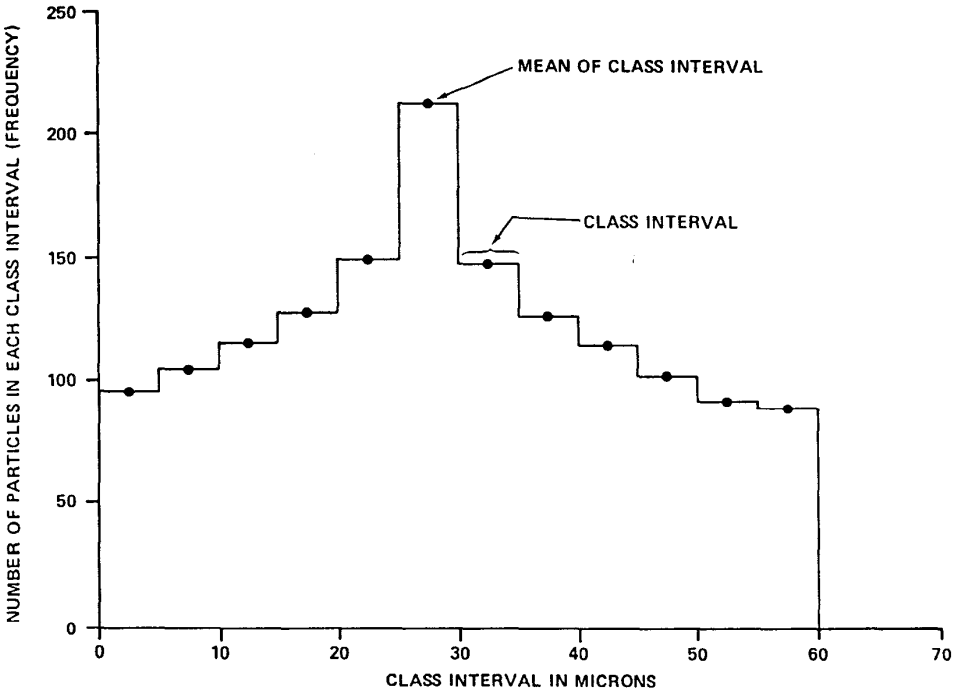


Figure 51 Histogram.

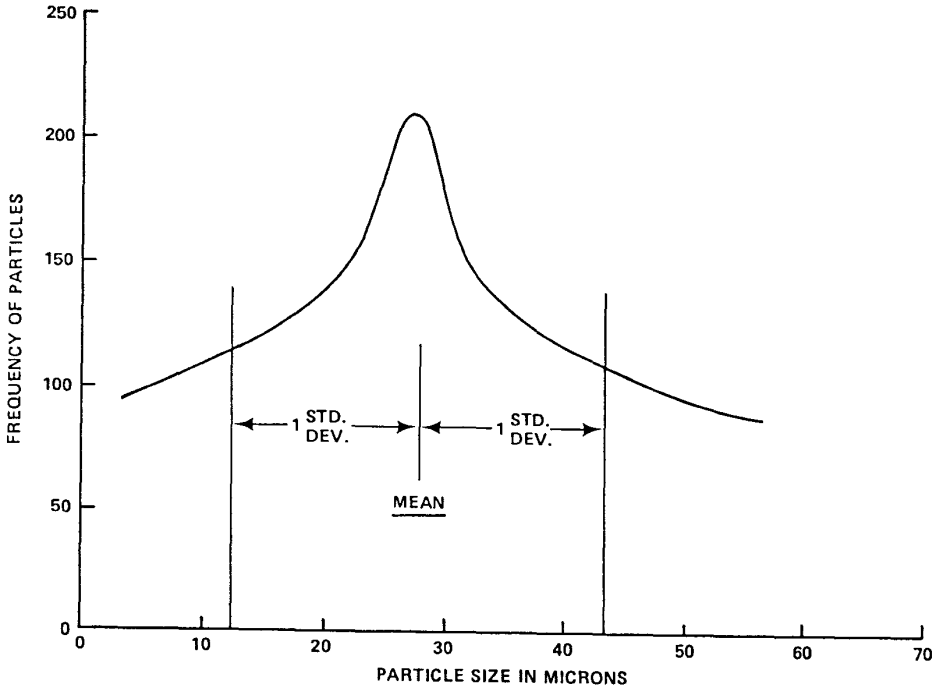


Figure 52 Frequency curve.

Table 11 Calculations of Cumulative Percent

Class interval (μm)	Means (μm)	No. of particles	% of particles	Cumulative %
0–5	2.5	96	6.5	6.5
5–10	7.5	105	7.1	13.6
10–15	12.5	116	7.8	21.4
15–20	17.5	129	8.7	30.1
20–25	22.5	150	10.1	40.2
25–30	27.5	212	14.3	54.5
30–35	32.5	148	10.0	64.5
35–40	37.5	127	8.6	73.1
40–45	42.5	114	7.7	80.8
45–50	47.5	101	6.8	87.6
50–55	52.5	92	6.2	93.8
55–60	57.5	88	5.6	99.4
		Total = N = 1478		

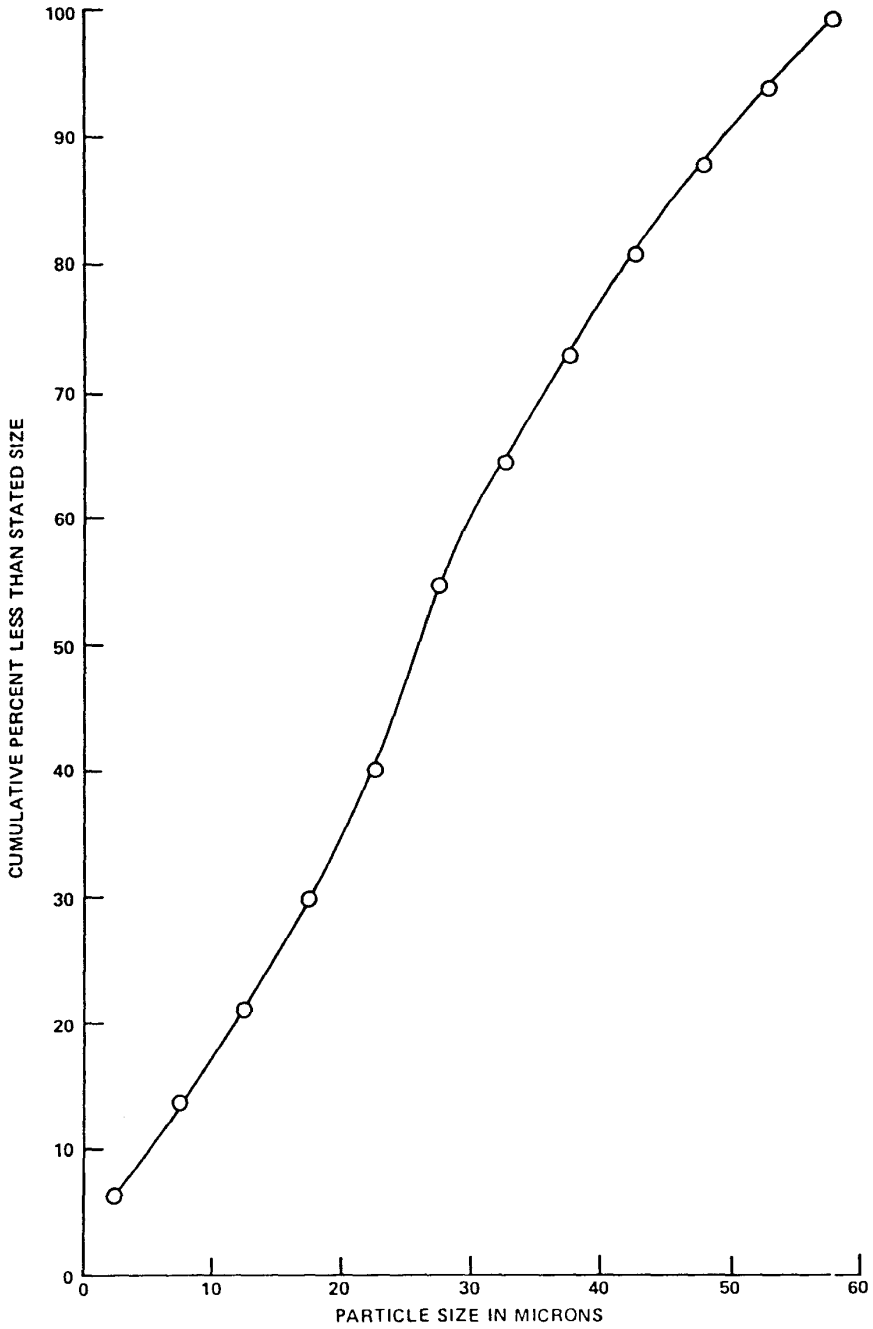


Figure 53 Cumulative distribution curve.

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