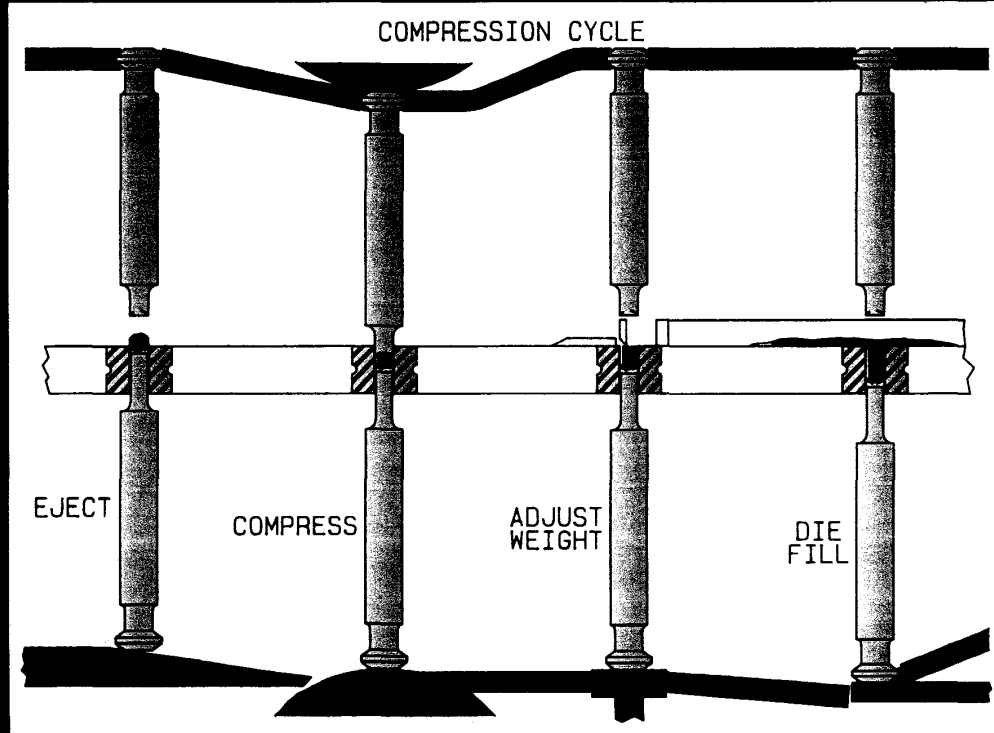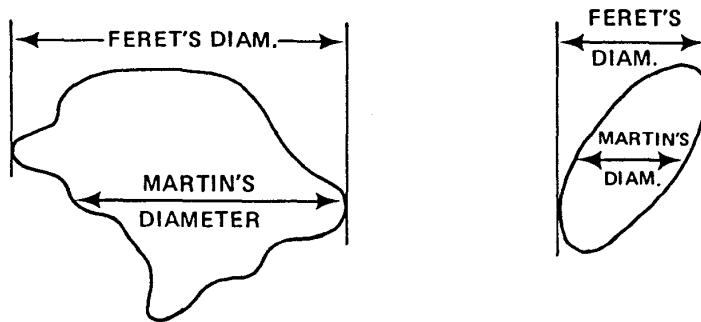# Pharmaceutical Dosage Forms: Tablets Volume 2

Second Edition, Revised and Expanded

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

COMPRESSION CYCLE

EJECT   COMPRESS   ADJUST WEIGHT   DIE FILL

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

Faret's diameter = mean length of line paralleling the direction of measure-
ment 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 ex-
ample, 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 calcula-
tion, 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 sym-
metrical. 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

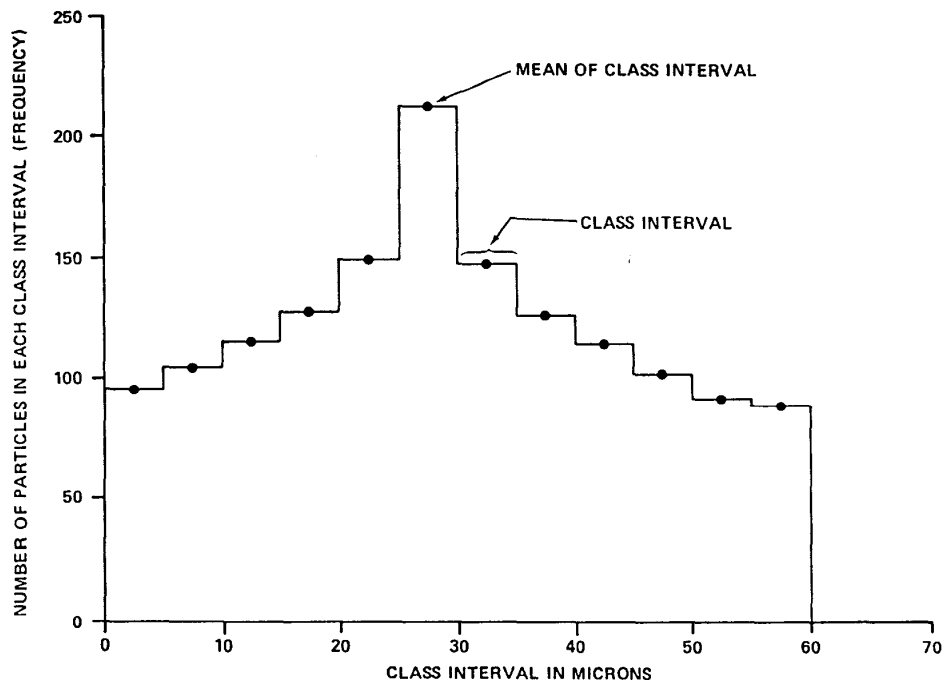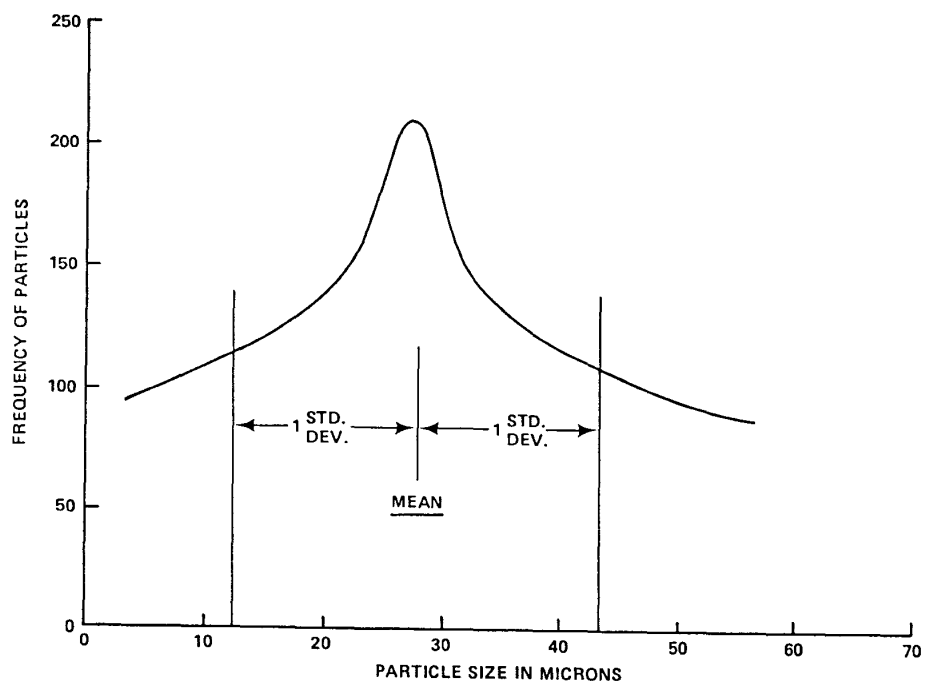| Class interval (μm)	Mean of the class interval (μm)	Number of particles counted in each class interval
0 – 5	2.5	96
5 – 10	7.5	105
10 – 15	12.5	116
15 – 20	17.5	129
20 – 25	22.5	150
25 – 30	27.5	212
30 – 35	32.5	148
35 – 40	37.5	127
40 – 45	42.5	114
45 – 50	47.5	101
50 – 55	52.5	93
55 – 60	57.5	88

Figure 51 Histogram.

Figure 52   Frequency curve.

Table 11   Calculations of Cumulative Percent

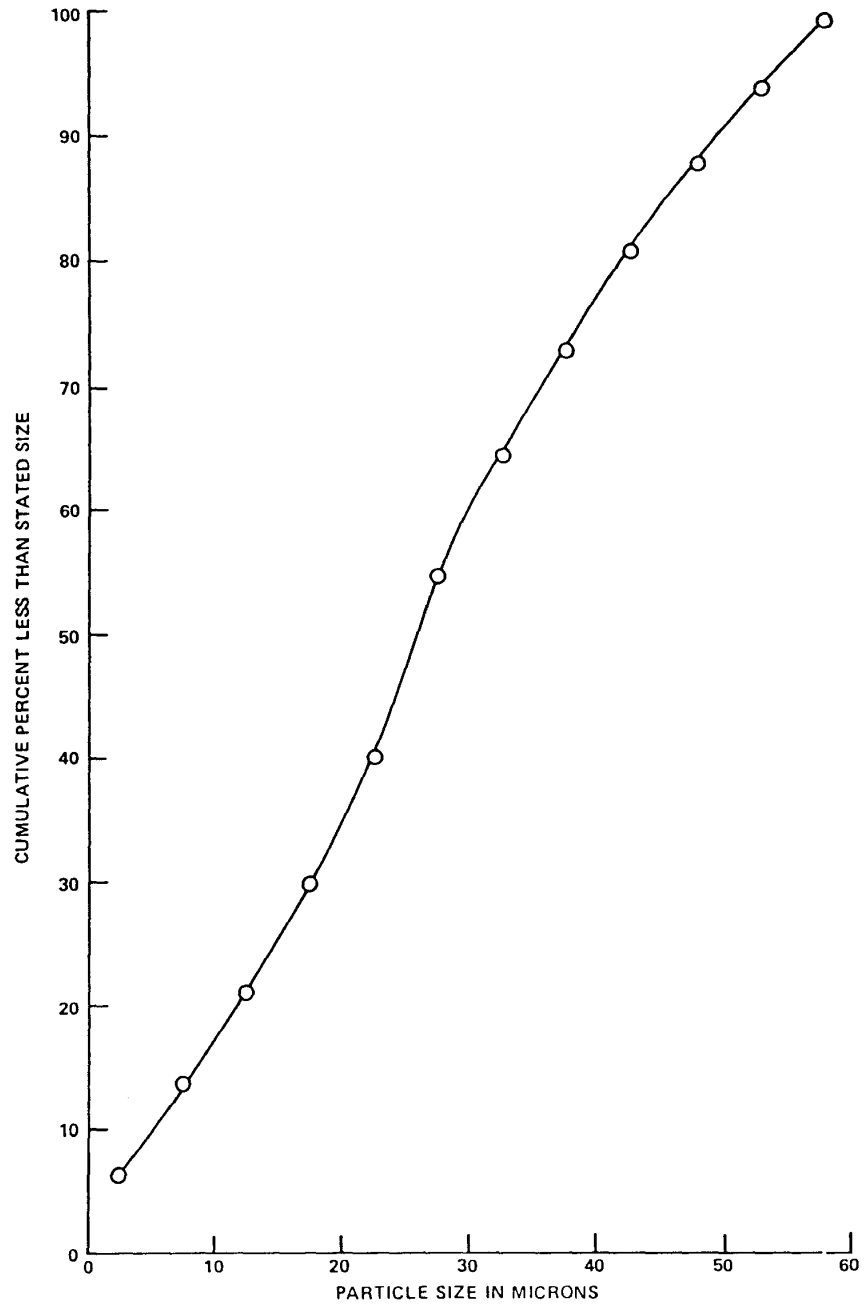| Class interval (μm)	Means (μm)	No. of particles	% of particles	Cumulative %
0−5	2.5	96	6.5	6.5
5−10	7.5	105	7.1	13.6
10−15	12.5	116	7.8	21.4
15−20	17.5	129	8.7	30.1
20−25	22.5	150	10.1	40.2
25−30	27.5	212	14.3	54.5
30−35	32.5	148	10.0	64.5
35−40	37.5	127	8.6	73.1
40−45	42.5	114	7.7	80.8
45−50	47.5	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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