

Particle Size Analysis of Powdered Aspirin Using the Saturn DigiSizer 5200

Particle size distribution analysis is frequently used to characterize pharmaceutical powders. Efficacy and dosage sizes are often correlated to median or mean particle diameters. Pharmaceutical production is often monitored using rapid particle size analysis typical of laser light scattering. The Saturn DigiSizer[®] can be used to quickly provide high resolution particle size distribution analyses. Commercially available powdered aspirin samples are used to illustrate how particle size analysis may be used to monitor product quality.

Samples of powdered aspirin were purchased at a number of local pharmacies over a period of weeks to obtain different lots of powder to look at the differences between production lots. Several packets within a given package were analyzed to look for differences within the lot. Two packages of a single lot of a second aspirin brand were purchased to investigate differences in particle size distribution between brands, and between packages from the same lot. Again, multiple packets were analyzed from both packages.

All samples were added dry to the Liquid Sample Handling Unit of the Saturn DigiSizer, and were dispersed in odorless mineral spirits with two minutes of ultrasonic treatment using the probe built into the DigiSizer. A small amount of Micromeritics SediSpense A-11 was used to help disperse the powder. All samples were analyzed consecutively from 3 to 8 times each. The average of the individual tests was used in the following comparisons. The SPC features of the DigiSizer software were used to generate the control charts provided.

A control chart showing the analysis results for 4 packets taken from each of three different lots of BC powdered aspirin is shown in Figures 1 through 3. The mean values and 3 sigma control limits are indicated.

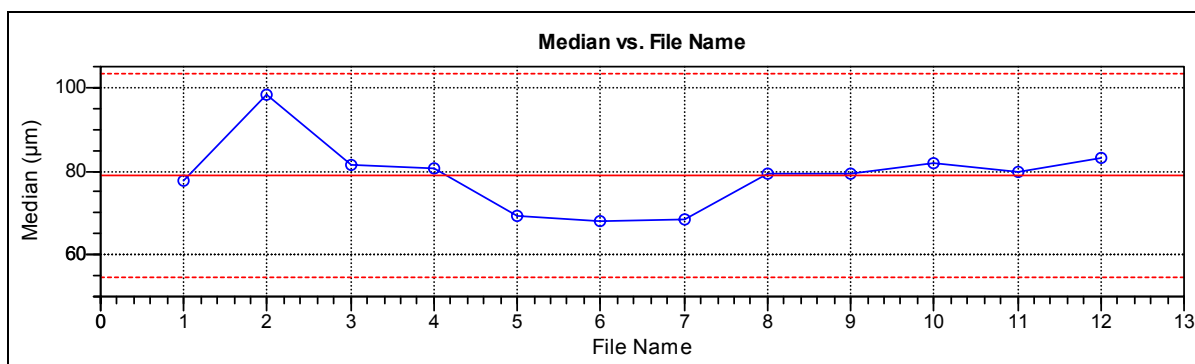


Figure 1. Median diameter for 12 analyses of BC powder, 4 packets from three different production lots.

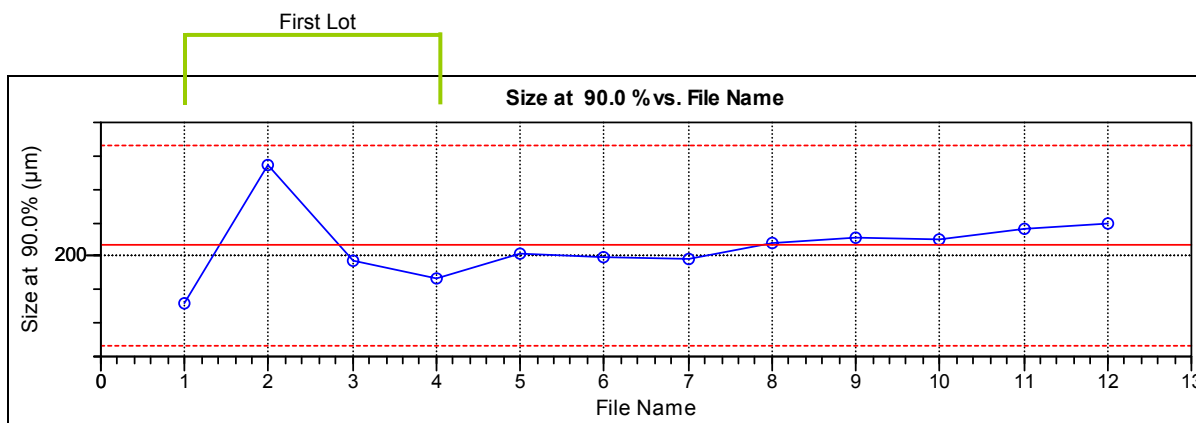


Figure 2. 90th percentile for 12 analyses of BC powder, 4 packets from three different production lots.

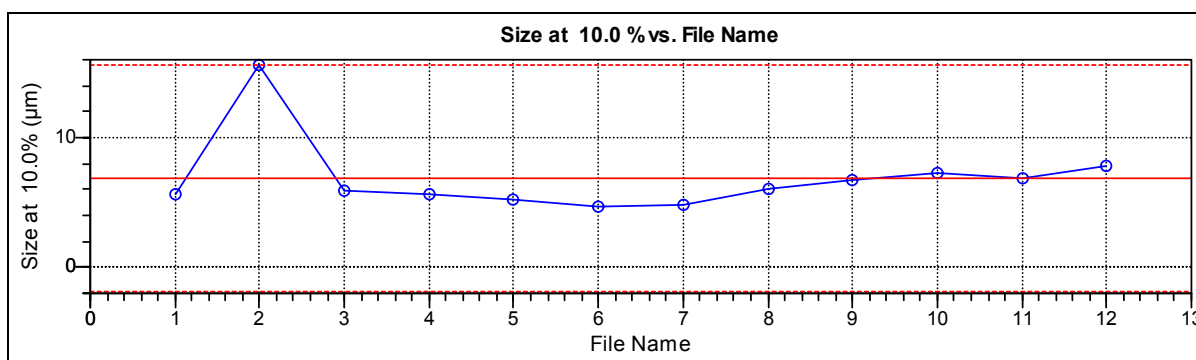


Figure 3. 10th percentile for 12 analyses of BC powder, 4 packets from three different production lots.

Notice that the results for the first lot (first 4 files) show more variation between packets than seen for the other two lots, particularly due to the second packet analyzed from the first lot.

Repeatability of analyses can be shown by comparing results from replicated analyses of a single sample. Figure 4 shows an overlay of 8 individual tests of one packet of BC powder, along with the average of the 8 tests.

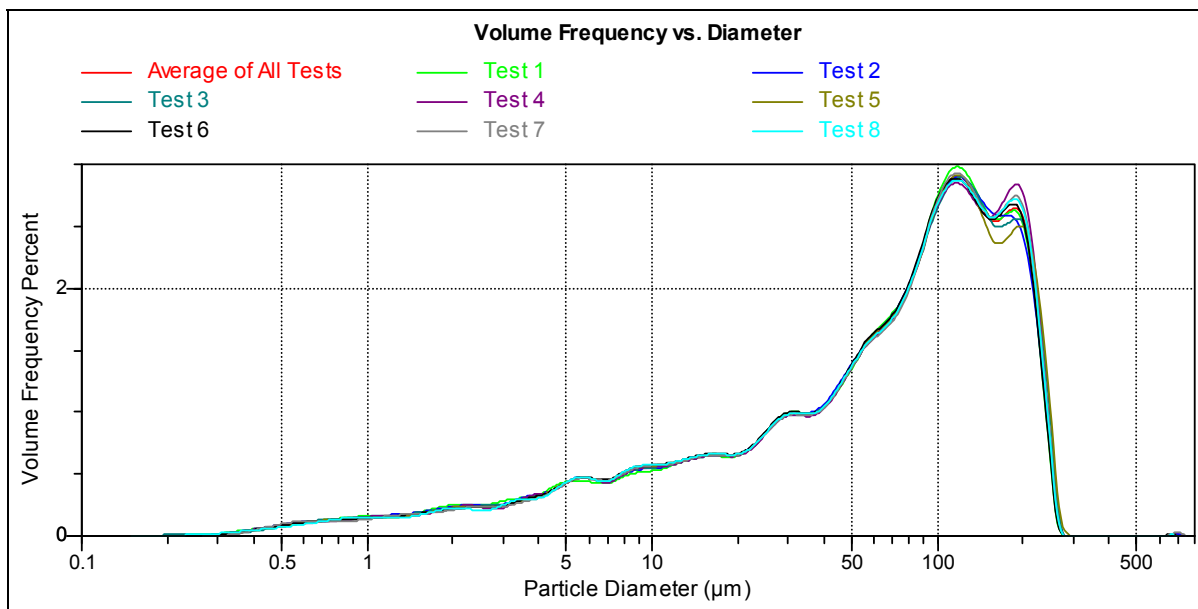


Figure 4. Overlay of 8 individual tests of one packet of BC powder, along with the average result of the 8 tests.

Six packets from each of 2 boxes of the *same* lot of Goody’s powdered aspirin were analyzed in a similar method as that of the BC powder. Control charts for the same statistics are shown in Figures 5 through 7.

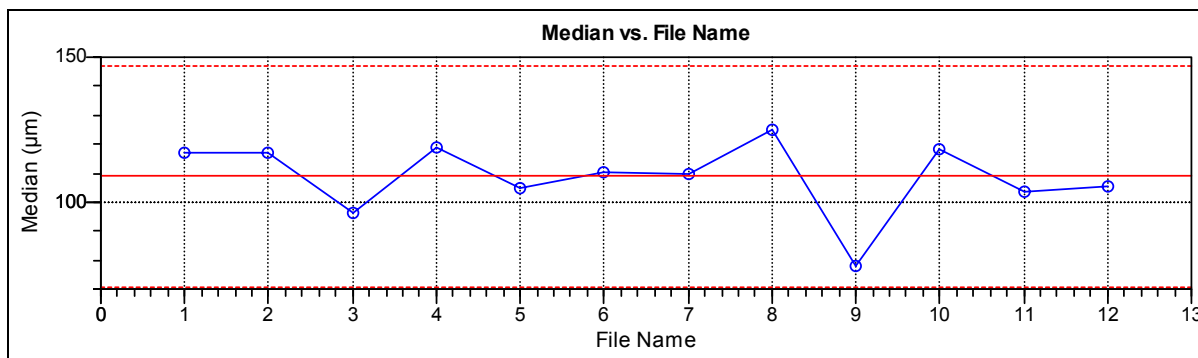


Figure 5. Median diameter for 12 analyses of Goody’s aspirin, 6 packets from each of 2 packages of the same lot.

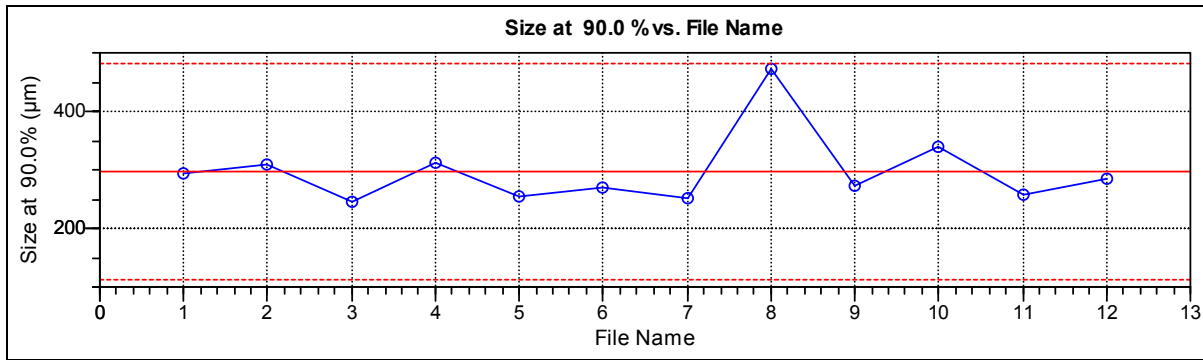


Figure 6. 90th percentile for 12 analyses of Goody's aspirin, 6 packets from each of 2 packages of the same lot.

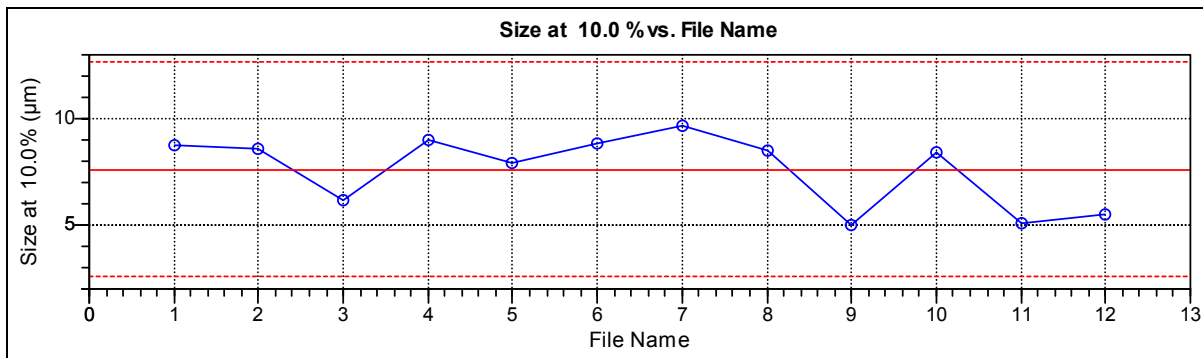


Figure 7. 10th percentile for 12 analyses of Goody's aspirin, 6 packets from each of 2 packages of the same lot.

A direct comparison of the particle size distributions for the BC and Goody's aspirin powders are shown in the overlay given in Figure 8.

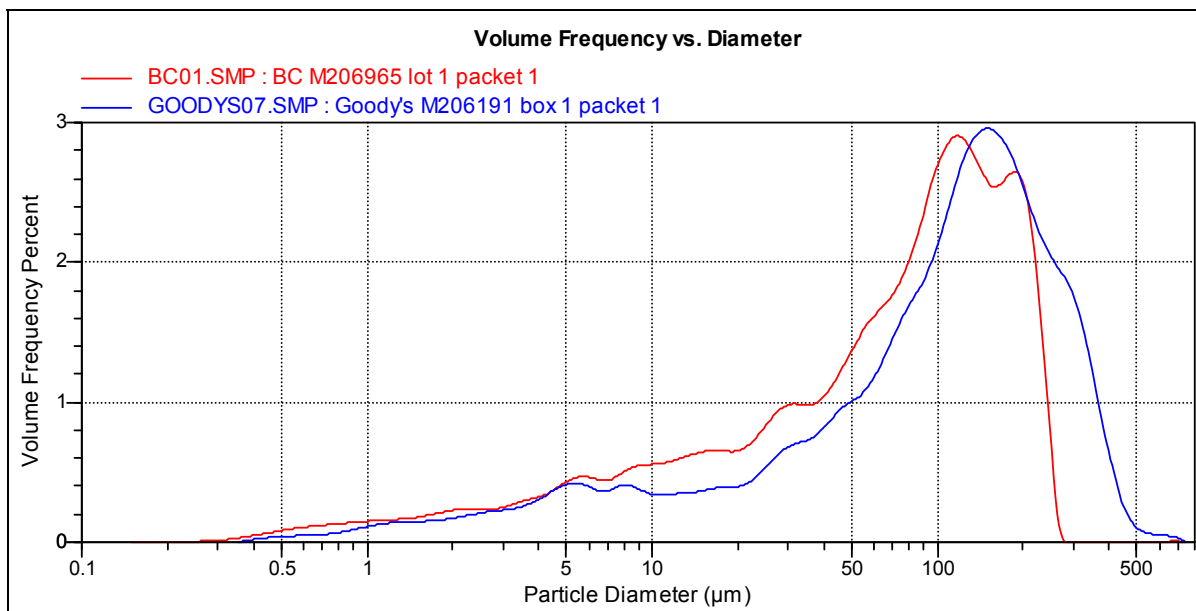


Figure 8. Overlay of analyses of BC and Goody's powdered aspirin.

No statement of comparative product quality is to be taken from these data. They are given just to show the capabilities of the use of laser scattering particle size analysis to characterize these powders, and to control and monitor their production.