R. Withington, A.C. Peters, Roche Products Limited, P O Box 8, Welwyn Garden City, Herts AL7 7AY

One of the advantages of particle size analysis by microscopy over other methods is that it requires direct observation of the particles and enables their morphology to be considered in assessing the analysis results. However, the method described in British Standard 3406:part 4, although statistically well based, relies on an inherently inaccurate subjective assessment of particle projected area. Further disadvantages are the method's lack of speed and the operator fatigue that it induces. Attempts to alleviate these problems have led to the development of several semiautomatic and fully automatic image analysis systems. Most of these systems rely on computer analysis of a television image of the particles that are to be sized.

We demonstrate here a semi-automatic image analysis system based on a microprocessor controlled digitizer. A microscope image of the particles is projected onto a digitizing platen and the outlines of individual particles traced with a stylus that is connected to the microprocessor control unit. During each measurement the position of the stylus on the digitizing platen is continuously determined so that the area enclosed by the outline (particle projected area) can be calculated and displayed by the microprocessor. This data is automatically transferred to a desk-top computer with which the microprocessor is interfaced. After applying the magnification factor between object and projected image, data is classified by projected area into classes corresponding to the size classes of the British Standard Method. Although the measuring strategy that is adopted is designed for calculation of particle distributions by weight, distributions by number can also be calculated. Data output includes percentage and cumulative percentage undersize tabulations and histograms and the 90, 84, 50, 16 and 10% size percentiles.

Using a combination of three microscope objectives particle sizes down to 2.34 microns equivalent diameter can be measured quickly and accurately. A size analysis, including data output can be completed in about 45 minutes.

An estimate of reproducibility has been obtained by determining the size distribution of 5 individual samples from a single batch of spray dried lactose. The average median size by weight of the 5 samples was 72 microns with a standard deviation of 3 microns (4%).