

## Density Changes in Lactose Tablets

**Keyphrases** □ Tableting, lactose—effect of particle size and speed of compaction on density □ Compaction—effect of particle size and speed of compaction on lactose tablet density □ Density, lactose tablets—effect of particle size and speed of compaction □ Lactose, crystalline and spray dried—tablet density changes related to particle size and compaction speed

Sir:

Fell and Newton (1) considered the density changes during compaction at two different speeds of several particle-size fractions of crystalline and spray-dried lactose. They referred to earlier work in which we (2) reported that application of the Heckel (3) treatment allowed an interpretation of the mechanism of consolidation. Our work showed that while lactose consolidated by particle rearrangement, particle-size reduction, and plastic deformation, sodium chloride consolidated by particle rearrangement and plastic deformation. These findings supported earlier work showing that tablet strength was dependent upon original particle size for sodium chloride but not for lactose (4, 5).

This concept of two principle mechanisms of consolidation, *i.e.*, with or without fragmentation, was supported by the results of Hardman and Lilley (6), and it appeared that the Heckel equation could be used to distinguish between these mechanisms (7). We have subsequently repeated much of this work using equal volumes (measured at zero applied pressure) of different particle-size fractions of both lactose and sodium chloride. Under these circumstances, use of the Heckel treatment did not produce an identical trace for the different particle-size fractions of lactose. Measurements of the slope of the individual traces showed considerable variation for the mean yield pressure<sup>1</sup> of lactose varying between 85 MPa for the 250–420- $\mu\text{m}$ . fraction and 175 MPa for the fraction smaller than 125  $\mu\text{m}$ . Variation may be caused by a number of factors such as the presence of trace quantities of moisture or other contaminant materials; the method of measurement of the volume, either under pressure or after ejection from the die; the dimensions of the compact; the presence or absence of lubricant; and a particle-size effect *per se* as indicated by the work of Griffith (8).

In the current work, the materials were classified using a sonic-sifter<sup>2</sup> and stored in a desiccator after oven

drying to remove free moisture. The previously reported value for the mean yield pressure of lactose of 401 MPa (2) resulted from an omission of the value of  $e$  in calculation and should read 174 MPa, which is in close agreement with the values reported by Fell and Newton (1) and supported by the present results. For lactose, we found a tendency for the mean yield pressure to increase with a decrease in particle size, as would be expected from the Griffith theory. This theory states that as the size of crystals decreases, there is an increase in the stress necessary to cause extension of any crystal cracks.

The Heckel (3) graph for lactose showed a straight line in all cases except at low pressures. However, for sodium chloride, a linear relationship is observed even at low pressures, indicating that, while lactose deforms by fragmentation in the early stages of compaction, sodium chloride apparently deforms only by plastic deformation.

If particle rearrangement takes place, it would be expected to occur at extremely low pressures as indicated by Fell and Newton (1). However, for both lactose and sodium chloride, the volume at zero applied pressure coincides with the Heckel plot. This would indicate that in the present case such rearrangement is not an important mechanism of consolidation, possibly because the use of a large diameter die permitted optimal packing of the particles during initial filling of the die.

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<sup>1</sup> Pa = pascal, S.I. unit of pressure; 1 MPa = 1 MNm<sup>-2</sup>.

<sup>2</sup> Allen-Bradley sonic-sifter, Milwaukee, Wis.