Variables Involved in an Automated Tablet-Coating System

ALLEN HEYD

Abstract ☐ Operational characteristics of an automatic airless spray tablet-coating system were evaluated. The major variables considered were volume of fluid delivery and spray pattern characteristics. The study showed that: (*a*) a linear relationship existed between the pressure employed and the volume of fluid delivered, (*b*) viscosity had a small effect on the volume of fluid delivered, (*c*) spray tip orifice size was directly related to fluid delivery volume, and (*d*) spray patterns can be effectively used in formulating and selecting the proper conditions for spray application of a tablet-coating liquid with an automatic coating system.

Keyphrases ☐ Tablet-coating system, automatic, airless—evaluation of volume of fluid delivery and spray pattern characteristics, relationships ☐ Coating of tablets, automatic, airless—evaluation of volume of fluid delivery and spray pattern characteristics, relationships

The art of tablet coating has become, in recent years, a scientific process in which an exact and reproducible amount of coating material can be delivered in a uniform manner onto a tablet mass. The evolution of this scientific process began with the design of an air suspension technique by Wurster (1), which was later refined for special automatic techniques. The impetus for developing better tablet-coating techniques was continued by Lachman and Cooper (2) and Mody *et al.* (3), who developed automatic film coating. More recently, Heyd and Kanig (4) described an improved automated tablet-coating system.

Once these automated systems were developed, the need for a better coating procedure became evident. The conventional method of completely wetting down the tablets and then allowing them to dry with the aid of forced hot air could no longer be used. Instead, some variation of short intermittent wetting and drying cycles was introduced to apply the tablet coat more uniformly. In addition, a complete reformulation of the coating solution was sometimes necessary when converting from the conventional tablet-coating technique to an automated process. Accordingly, the spray apparatus selected in an automated system must be evaluated with respect to the variables involved in the use of diverse coating solutions as well as for the mechanical aspects of the process.

The purpose of this study was to evaluate the influence of the automated coating system *per se* and the nature of the coating liquid on the volume of coating fluid delivery and its spray pattern.

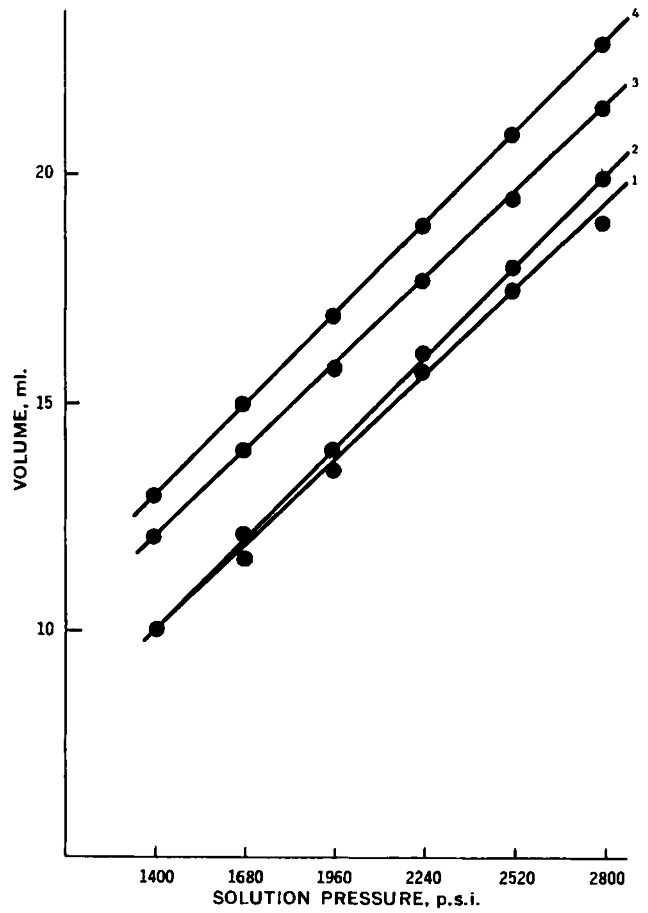

Figure 1—*Pressure-volume curves, 3-sec. delivery. Key: 1, calcium carbonate, 5%; 2, syrup USP; 3, water; and 4, alcohol USP.*

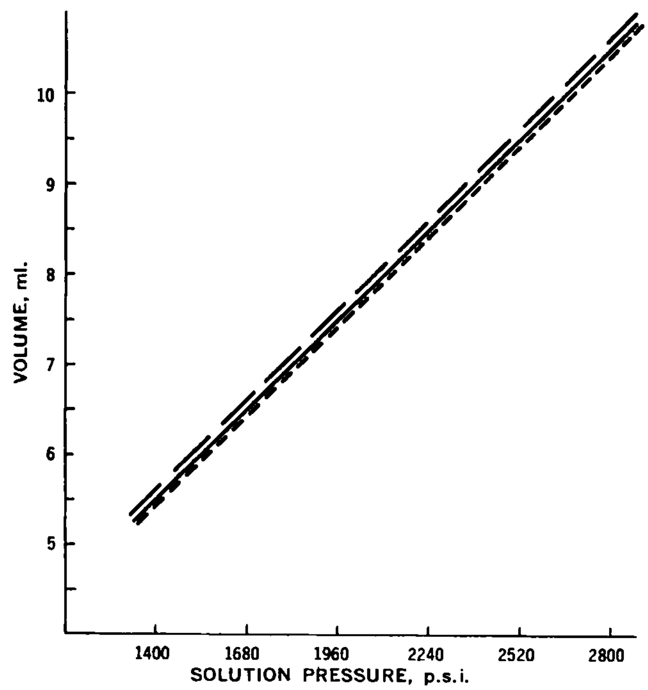

Figure 2—*Pressure-volume curves, calcium carbonate suspensions. Key: — —, 5%; ——, 15%; and ---, 35%.*

Table I—Delivery Volume as a Function of Pressure

Liquid	Rate, ml./p.s.i. (10^3)	Total Volume Delivered, ml. 1400 p.s.i.	2100 p.s.i.	2800 p.s.i.
Calcium carbonate, 5%	6.7	10	14.7	19
Syrup USP	7.1	10	15	20
Water	6.8	12	16.8	21.5
Alcohol USP	7.1	13	18	23

EXPERIMENTAL

Materials and Equipment—The liquids used in this study were: distilled water; syrup USP; shellac, 2.7 kg. (6 lb.) cut; 5, 15, and 35% (w/v) aqueous suspensions of calcium carbonate; and a 2% (w/v) solution of methylcellulose[1], 500 cps.

The equipment utilized to evaluate the factors involved in an automated tablet-coating system was a self-programming automated tablet-coating system with two automatic spray guns[2] as previously described (4).

Fluid Delivery Studies—Fluid delivery experiments were conducted to ascertain the influence of pressure, spray tip orifice size, and type of liquid on the volume of spray delivered.

The volume of fluid delivery in milliliters was determined from 1400 to 2800 p.s.i. nozzle pressure in 140 p.s.i. pressure increments. The tip orifice sizes varied from 0.023 cm. (0.009 in.) to 0.053 cm. (0.021 in.) in diameter. All experiments were conducted in an air conditioned room at approximately 25° and 30–40% relative humidity.

Three-second fluid spray delivery cycles were used, and five replicate samples of each liquid under study were collected, at each pressure and nozzle tip size, in a 100-ml. graduated cylinder; the resulting volumes were recorded.

Spray Pattern Characteristics—Spray patterns were determined for the liquids studied, each containing 1% (w/v) FD&C Red No. 2 dye for contrast. The spray from the activated gun of the automated tablet-coating system was directed at a specially designed target which consisted of a 61-cm. square pane of glass with five concentric circles painted 10 cm. apart. The tip of the spray gun was positioned 30 cm. from the glass surface and at the center point of the target. The spray cycle was set for a 0.25-sec. solution delivery. The patterns were subsequently observed at 1400-, 1960-, and 2800-p.s.i. nozzle pressure (the lower, middle, and upper pressure range, respectively) for all tip sizes ranging from 0.023 cm. (0.009 in.) to 0.053 cm. (0.021 in.) in orifice diameter. After each spray, the pattern dimensions were taken and pattern uniformity was noted.

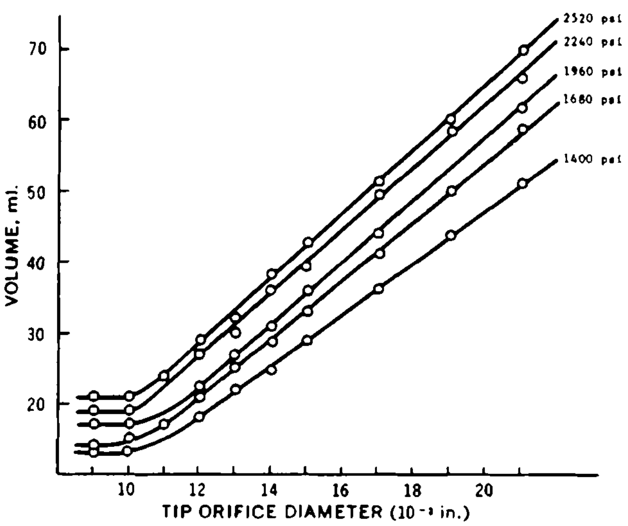

Figure 3—*Change in delivery with respect to change in tip orifice size using water.*

[1] Methocel MC, Dow Chemical Co., Midland, Mich.
[2] Graco Hydro-Spray Unit, Gray Co., Minneapolis, Minn.

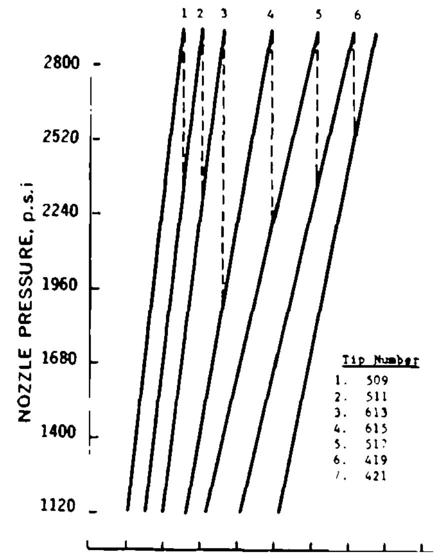

Figure 4—*Fluid delivery curves, 3-sec. cycle.*

RESULTS AND DISCUSSION

Fluid Delivery—The pressure–volume curves in Fig. 1, constructed from fluid delivery data obtained with a 0.023-cm. (0.009-in.) spray tip and a 3-sec. delivery, show that the change in fluid volume delivered as a function of pressure was constant. The curves are representative of some of the liquids studied, and each shows excellent linearity. The rate of change of delivery (Table I) for the liquids represented in Fig. 1 was essentially the same.

A 3–4-ml. difference in total volume delivered at each pressure increment was found between the four liquids studied. These small volume differences do not appear to be significant, but the data show a trend toward a decrease in volume delivered with an increase in fluid viscosity and solids content when comparing syrup and calcium carbonate with water and alcohol. A significant difference would be expected at a much lower or at atmospheric pressure. The data, therefore, indicate that fluid volume delivery is essentially independent of the physical properties of the fluid at very high pressures.

Fluid delivery curves for the three calcium carbonate suspensions, which varied from a "watery" to an "ointment-like" consistency (Fig. 2)[3], are in essence identical and confirm that the elevated pressures used in the study obliterated the effects of the physical properties of the fluids delivered.

In Fig. 3, the volume of water delivered in 3 sec. *versus* tip orifice diameter shows a good linear relationship within the range of 0.030 cm. (0.012 in.)–0.053 cm. (0.021 in.). This finding is unusual because one would expect an orifice–volume relationship based on

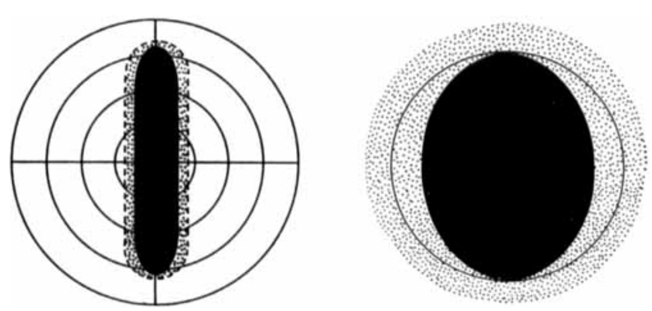

Figure 5—*Spray patterns with water. Left: 0.023-cm. (0.009-in.) tip size and 30 × 9-cm. pattern size. Right: 0.053-cm. (0.021-in.) tip size and 40 × 30-cm. pattern size.*

[3] Data points for Fig. 2 were omitted for the purpose of clarity.

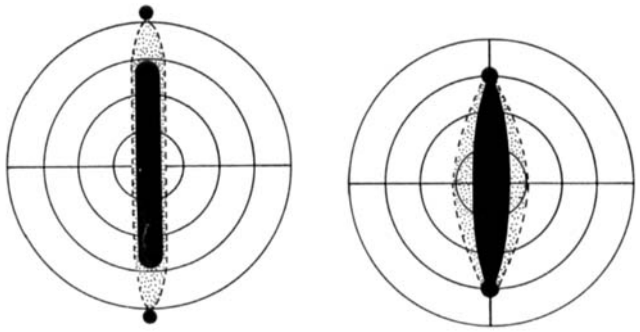

Figure 6—*Spray patterns with syrup USP. Left: 0.023-cm. (0.009-in.) tip size and 29 × 8-cm. pattern size. Right: 0.053-cm. (0.021-in.) tip size and 32 × 12-cm. pattern size.*

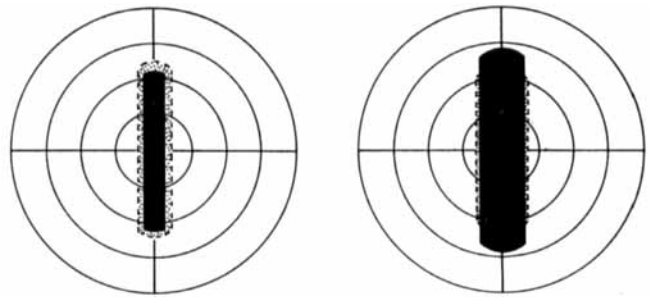

Figure 8—*Spray patterns with shellac, 2.7 kg. (6 lb.) cut. Left: 0.023-cm. (0.009-in.) tip size and 24 × 5.5-cm. pattern size. Right: 0.053-cm. (0.021-in.) tip size and 29 × 12-cm. pattern size.*

the square of the orifice diameter. All fluids studied showed similar results.

Since a pressure–volume relationship was found for the liquids studied, it can be postulated that pressure–volume graphs for specified spray time cycles and tip orifice sizes can be prepared for all coating liquids used in tablet-coating systems utilizing an automatic spray system. From these graphs, delivery volume at various pressures and tip orifice sizes can be estimated. Figure 4 is a theoretical example of such a graph constructed for water as the vehicle. For a specific delivery volume, a different pressure level at a constant tip size or a different tip orifice size at a constant pressure can be chosen from these constructed graphs. The vertical broken lines on the curves show the points where the tip orifice size and pressure parameters overlap so that either combination may be used.

Spray Pattern Characteristics—In general, the solutions studied formed rather individual spray patterns (Figs. 5–8). All patterns consisted of an unbroken, uniform film, usually with sharp edges and surrounded by a "corona" effect. Each solution possessed an individual spray pattern which changed in fan length and width with an increase in tip orifice size. Water produced an elongated oval when using a 0.023-cm. (0.009-in.) tip orifice size and more of a circular oval when using a 0.053-cm. (0.021-in.) tip orifice size (Fig. 5). The 85% syrup solution (Fig. 6) formed a peculiar long, slender, round-edged pattern with two dots equidistant from the ends of the long axis which were joined to the main body of the pattern by a corona. This pattern slowly changed to a dumbell shape as the tip size increased to 0.053 cm. (0.021 in.). Methylcellulose and shellac solutions as examples of polymeric substances, showed distinct rectangular forms with small coronas, which increased in width from the 0.023-cm. (0.009-in.) to the 0.053-cm. (0.021-in.) tip orifice size. The methylcellulose showed a decrease in pattern length and the shellac showed an increase in length with increased tip orifice size (Figs. 7 and 8, respectively).

Spray pattern studies serve to illustrate the type, the uniformity, and the area of surface coverage that can be achieved on a mass of moving tablets with coating solutions. They are especially useful in the development of new tablet-coating formulations and in choosing the proper tip orifice size, spray pressure, and spraying distance from the moving tablet mass. Spray patterns relate directly to the moving surface of the tablet mass, because each pattern is illustrative of the pattern that will appear on the surface of the mass at any given moment in time.

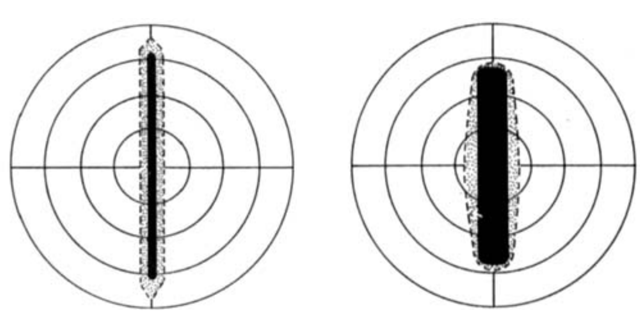

Figure 7—*Spray patterns with methylcellulose, 500 cps. Left: 0.023-cm. (0.009-in.) tip size and 34 × 3-cm. pattern size. Right: 0.053-cm. (0.021-in.) tip size and 27.5 × 7.5-cm. pattern size.*

SUMMARY

The operational characteristics of an automatic airless spray system were evaluated and the variables affecting the delivery of various liquid systems were studied. The major variables studied produced data that permitted the development of several relationships:

1. A linear relationship between the pressure employed and the volume delivered existed for all solutions studied, regardless of the nature of the solvent.
2. When compared to water, increases in viscosity or in insoluble solids content caused a very small decrease in volume of solution delivered. The volume delivered for any suspension was not materially changed with an increase in solids concentration at a given pressure.
3. Spray tip orifice size was directly related to delivery volume at a constant pressure. Normally, as previously mentioned, the orifice–volume relationship would be expected to follow a curve based on the square of the orifice diameter.
4. Spray patterns obtained under the experimental conditions were potentially useful in estimating area, shape, uniformity, and dimensions produced by a coating solution striking a mass of tablets. Estimates of this nature are valuable in selecting the proper conditions of spraying and other features such as orifice size, spray pressure, and spraying distance.
5. Pressure–volume plots were developed as prototypes of related plots which should be developed for other coating solutions. These data are useful as guides in properly coordinating spray tip, pressure, volume, and type of solution to produce optimum effects.

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