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THE ROLE OF AUTOMATION IN SUGAR COATING TABLETS

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The development of the sugar coating process into a fully automated operation is reviewed. Progress has been slow with many underlying problems, not the least of which is the lack of reporting of individual progress by the pharmaceutical industry. Three fully automated systems are reported to point out the important role of automation in studying variables involved in sugar coating.

Thirty years ago, Chilson[1] stressed that the process of sugar coating tablets should be performed more scientifically, that is, with greater precision; in effect, apply less art and more science.

Sugar coating is no less important in pharmaceuticals today, yet still it seems to represent an art more than a science. Certainly the application of automated methods to this process has evolved slowly. Some relevant applications are reviewed here.

Sutaria[2], in reviewing the process of tablet coating in 1968 discussed the important variables: the tablet core, pan, coating materials and their mode of application, and drying. He pointed to a need to standardize each of the interdependent variables of the sugar coating process, so that constant conditions could be prescribed and closely controlled at all stages. To do this, it has been necessary to mechanize each component of the operation to achieve total automation.

The coating pan was one of the first components to be mechanized or adapted for automation. Spalding[3] automated the jogging cycle of the finishing stage. Pans were especially designed for uniform drying before polishing. Batteries of four Colton fluid-drive coating stands were designed for automatic control panels. The length of time the pans rotated, the frequency of rotation, and the total cycle time could then be selected for each battery of four machines by an operator setting dials on the master panel.

Baffling the coating pan was found critical to the automated process. Sutaria[2] evaluated sixteen variants of three basic baffle designs. Lachman and Cooper[4] also found the need to use baffles in designing an automated process. These authors found that two areas in the pan show minimal movement of the tablets after the liquid is applied so that manual mixing becomes necessary. Baffles automatically keep the tablet mass mixing uniformly throughout the coating process, thus helping to minimize variation in tablet weight and size.

More recently, attempts have been made to automate the tablet coating process completely. However, the methods have been highly specialized so that in some cases the apparatus is restricted to a single film coating formulation. Wurster[5-9] was one of the first to automate the tablet coating process using a fluidized bed technique; the first attempt to carry out continuous coating. The apparatus consists of a vertical column which is constricted at the base and expanded at the top. Air is forced in through the base of the column at a sufficient velocity to support tablets placed in the column. A blower operating at a constant speed delivers air preheated by a thermostatically controlled gas burner. An atomizer positioned below the working region delivers the coating solutions to the tumbling tablets. This coating process is controlled by adjusting either the air temperature, the atomization rate, or both.

Many modifications of the original Wurster process are found in the literature[10-14]. However as mentioned, most of them describe rapid methods for applying a film rather than a classical sugar coat.

Lachman and Cooper[15] and Mody, Scott and Lieberman[16] also designed automated tablet coating processes. The first group used a punched tape transmitter to control the relays required to activate elements of the coating equipment; the second group used a series of interconnected timers to control the processing cycles.

Steps Toward Total Automation - Despite the importance of sugar-coated tablets to the pharmaceutical industry, few studies report attempts to devise an automated sugar-coating procedure. To date, from the published literature it appears that only three systems are totally automated. Lantz et. al.[17], described a method for measuring temperature changes that are encountered during application of volatile solutions to pellets in a rotating pan. These authors suggested that the change in temperature of the tablet bed in the pan should be useful in automating the coating process. Courtin and Briner[18] later used this approach to monitor the temperature of a bed of tablets in a coating pan between applications of sugar solutions. The drying time between the syrup applications was controlled by the rate and degree of temperature change in the tablet mass. An automated system controlled by temperature may well be a useful method for sugar coating. However, two major disadvantages can be cited for this type of system: The temperature is not sensitive enough to correct the drying time (a) when there is a significant change in the amount of coating liquid applied, or, (b) when there is a significant change in the relative humidity of the coating pan environment. Heyd[19] in designing an automated coating system controlled by a temperature-monitoring apparatus, found that although a reproducible drying cycle resulted under rigidly controlled conditions, the apparatus was relatively insensitive to changes in volume of syrup applied and totally insensitive to a dramatic change in relative humidity. The drying cycle time was found to be a function of the change in tablet mass temperature as well as the rate and degree of moisture loss, two inseparable variables of a temperature monitoring device.

Rose[20] recently described a fully automated tablet coating system developed through the joint effort of a team of tablet-making experts and design engineers. The system is completely self-adjusting, that is, the volume dosage of the spray solution or suspension is automatically and progressively increased to match the gradually increasing surface area of the tablets. The state of dryness of the tablet mass is continuously monitored by a lithium chloride moisture-sensing probe. The manufacturers of this automated equipment suggest that it can be used to coat any tablet shape with any formulations. However, practical utility of this apparatus has not been reported. It would be a service to the industry if such information were available.

Taking a totally new approach to automation, Heyd and Kanig[21] described a self-programming automated tablet-coating system. The usefulness of a monitoring system based upon moisture sensing was established as a means of automating the process. A radio frequency absorption system was employed to measure continuously the state of dryness of the tablet mass and to indicate when the tablets had reached a predetermined end-point. The moisture-sensing apparatus was able to monitor the drying rate accurately after the tablets had been sprayed. Analyzer readings were related directly to the relative humidity of the environment surrounding the coating pan. The instrument was extremely sensitive and permitted a constant readout of the drying rate and the moisture content by means of a specially constructed probe placed within the tablet mass.

Heyd[22] studied the operational characteristics of the automated airless spray-coating system, emphasizing two major variables: the volume of fluid delivery, and the characteristics of the spray pattern. It was found 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 used effectively to formulate and select the proper conditions for spray application of the tablet-coating liquid.

Weiss[23], using the automated tablet coating system designed by Heyd, successfully color-coated conventional subcoated tablets and capsule-shaped tablets using standard opaque color-coating suspensions. He found that 15 to 25 applications were sufficient to coat tablets uniformly. After polishing, they exhibited finished appearance comparable to commercially available sugar-coated tablets. Weiss noted that the system automatically adjusted to changes in environmental relative humidity during the coating procedures. The total processing time ranged from 80 minutes at 40% relative humidity to 95 minutes at a

55% relative humidity. Weiss also coated conventional and capsule-shaped tablet cores with opaque, sugar-film coating suspensions and found that a suitable coat resembling a film-coat could be applied in approximately 4.5 hours. He did find, however, that extremely hydrophilic tablet cores had to be coated with a protective barrier prior to coating to reduce the absorption of moisture.

The examples cited point to the type of research needed to document the variables associated with any system of tablet coating.

The brevity of this review underscores the underlying problem: a lack of published information on the automation of the sugar coating process. Our colleagues in this field do not appear to be communicating such information frequently, although it is possible that research is underway. However, the general impetus toward developing film coating may also account for the slow development of automated sugar coating. In the author's own experience, a fully automated system allows one to document the critical variables involved in sugar coating more objectively. As such variables are studied in greater depth, sugar coating can evolve into a more precise science.

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