

DISPENSING OF MEDICATION

Formerly Husa's Pharmaceutical Dispensing

A Manual on the Formulation of Pharmaceutical Products,
the Dispensing of Prescriptions, and
The Professional Practice of Pharmacy

EDITOR

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CHAPTER 20

Coating



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The coating of pills has been performed since antiquity, and with the advent of tablets and capsules, methods have been devised for coating these dosage forms also.

Tablets and capsules may be coated for various reasons: to protect the ingredients from light or air to insure stability of the medicinal, to mask an objectionable taste or odor, or to improve the appearance of the dosage form. Such coatings readily disintegrate or dissolve in the stomach and are not intended to affect the activity of the medicinal following administration. Coatings used to mask taste and odor or to improve appearance are primarily used to gain patient acceptance of the dosage form.

A special type of coating, referred to as an *enteric* coating, may be applied to tablets and capsules. Coatings of this type do not disintegrate in the stomach but will disintegrate or dissolve in the intestinal fluids. Enteric coating may be utilized to control the site of drug release, to protect the activity of the medicinal from the gastric pH or to

prevent nausea or gastric irritation caused by the uncoated medicinal.

Various techniques and coating materials may be employed to allow the medicinal to be released from the tablet in such a manner as to give a delayed action, a repeat action, or a sustained action. Compression coating, or dry coating, may be utilized to prevent incompatibilities by putting one drug in a tablet core and compressing a dry coating containing another drug around the tablet core. Products of this type are frequently referred to as a "tablet within a tablet." Repeat action or sustained action may also be obtained with compression coating.

1

Butisol Sodium R.A. (McNeil) 30 mg
D.T.D. No. 21
Sig: One three times a day

2

Pabirin Buffered tablets (Dorsey) No. 100
Sig: Two tablets every four hours

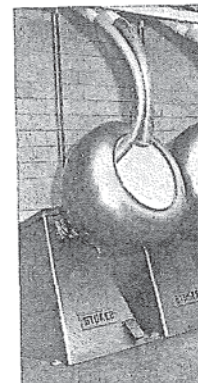


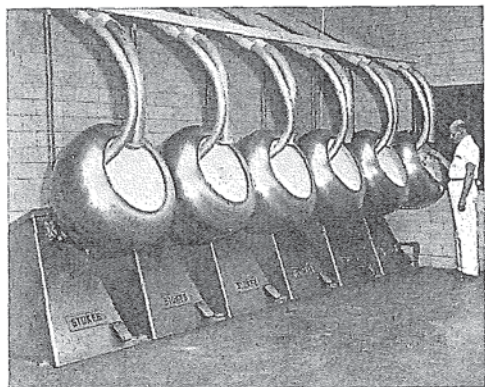
Fig 20-1—Stokes' t

Sugar Coating

Probably the coating for tablet scale is a sugar coating. Thin layers of sugar are applied to the tablet and tumble in the pans. The pans are available in various shapes but are usually made of steel and are rotated on a shaft so that the tablets are polished. Polishing pans are used for pans that have the sugar coating. The sugar coating is applied by adding the sugar solution or suspension to the tablets equipped with a cold air through the drying. Exhaust fans move moisture out of the pan. See Fig 20-1 to

Tablets which are made with compression coating a spherical coating is difficult to coat. The coating should be replaced in the coating pan.

The usual steps in sugar coating are (1) waterproofing the tablet to prevent moisture from entering to fill out the pores, (2) rough coating, and (3) smooth coating. The smooth coating is applied to the smooth surface of the tablet.



Ciba

Fig 20-1—Stokes' tablet coating pans.

Sugar Coating

Probably the most commonly used coating for tablets on a commercial scale is a sugar coating in which successive thin layers of the coating material are applied to the tablets as they rotate and tumble in the coating pan. Coating pans are available in various sizes and shapes but are essentially spherical vessels, usually made of copper or stainless steel and are mounted on the end of a shaft so that they may be made to rotate. Polishing pans frequently are coating pans that have been lined with canvas, or they may be canvas drums. Since the sugar coating of tablets is accomplished by adding the coating material in solution or suspension form, coating pans are equipped with air blowers to force hot or cold air through the pans to facilitate drying. Exhaust ducts are used to remove moisture and dust from the pans. See Fig 20-1 to 20-6.

Tablets which are to be coated are made with convex surfaces approaching a spherical shape since flat tablets are difficult to coat. Dust and broken tablets should be removed before tablets are placed in the coating pan.

The usual stages of coating consist of (1) waterproofing to prevent penetration of moisture into the tablet, (2) subcoating to fill out and build up the tablets, (3) smooth coating to produce a hard smooth surface, (4) coloring and finishing

to obtain the desired color, and (5) polishing to give the finished product a high gloss.

Waterproofing—Since the vehicle for sugar coating is water, most tablets require an initial sealing coat to prevent moisture from penetrating the tablet and destroying the ingredients of the tablet. This is accomplished by applying one or two coats of arsenic-free shellac, cellulose derivatives such as ethylcellulose, or silicones. Waterproofing materials must be applied sparingly since excess material may retard disintegration time of the coating and even result in an unwanted enteric coating.

Subcoating—As the tablets rotate in the coating pan, a heavy syrup usually containing acacia and sugar in water is added. The tablets should tumble freely in the pan until they become sticky. A dusting powder consisting of starch and powdered sugar is then applied and rotation of the pan is continued until the tablets have dried. Precipitated chalk, powdered acacia or talc may also be added to the subcoating powder. The process of adding the solution and powder is repeated until the edges of the tablets are sufficiently covered and rounded.

Smoothing—Following subcoating, a heavy sugar syrup is added to the tablets rotating in the pan. The smoothing syrup is added slowly to moisten the tablets and warm air is used to hasten drying. A dusting powder may or may



Abbott

Fig 20-2—Tablet coating pans.

not be used in conjunction with the syrup. A sufficient number of coats are applied to give a smooth surface and to build the tablets to a specific size.

Coloring—To avoid a mottled appearance, color is built up gradually by the use of diluted colored syrups. Colored syrups are made by dissolving certified water-soluble dyes in syrup and then several different dilutions of color are made by adding plain syrup to the colored syrup. Several coats of the lightest colored syrups are applied, then several coats of the next dilution are applied. The other dilutions are added in order, with the undiluted colored syrups being applied last. Drying is necessary between each coat and it is customary to dry the last coat very slowly by manually turning the pan every few minutes to prevent the tablets from sticking together and to promote the slow drying.

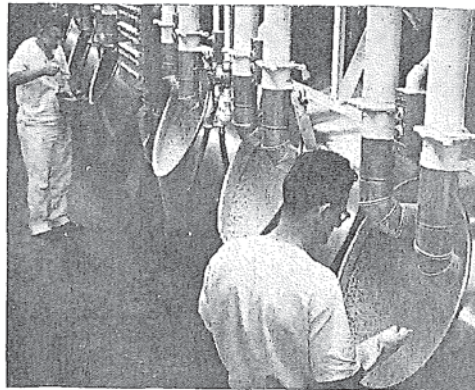
Polishing—After the coloring coats have been applied, the coated tablets are then polished by rotating them in the polishing pan with lumps of wax or with the addition of a solution of the wax in a volatile solvent. See Fig 20-4.

Since in the standard sugar coating procedure much time is spent in sealing, rounding and smoothing the tablet and overcoming the white background during the coloring phase, a revised procedure has been advanced.¹ An undercoating adhesive suspension consisting essentially



Schering Corp

Fig 20-3—Weighing operation and polishing room.

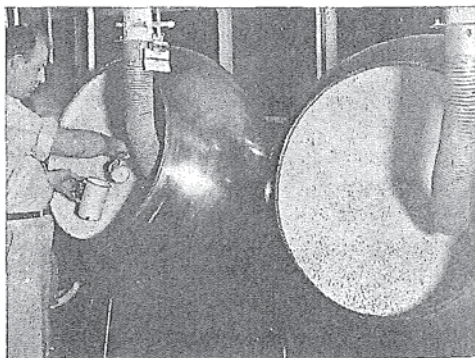


Lilly

Fig 20-4—Tablet coating pans. Polishing pans are similar but are lined with canvas.

of acacia, gelatin, sucrose and water is mixed with a stock coating formulation of dioctyl sodium sulfosuccinate, insoluble coloring material, titanium dioxide, and syrup. This undercoating suspension is applied to the rotating tablets and followed by dusting of the tablets with powdered acacia. The procedure is repeated once. The tablets are then sealed with one coat of a material such as shellac and are then finished by the application of approximately 25 coats of the stock coating formulation diluted with coating syrup. The tablets are then polished in the usual fashion. With this procedure, colored coatings can be applied to the subcoating and the application of smoothing coats is eliminated.

The process of tablet coating has long been recognized as an art dependent upon the experience and skill of the per-



F J Stokes Corp

Fig 20-5—Coating tablets at Wyeth Laboratories.

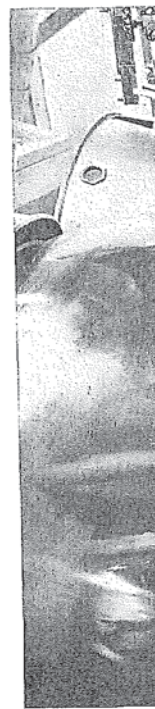


Fig 20-6—Tablet coating at the end of the run from the table.

sonnel. However, several procedures have been devised to improve uniformity, to reduce cycles and to produce more uniform tablets.^{2, 3}

Film Coating

A more recent method of coating a soluble film or films are used. In this procedure, the coating materials may be dissolved in a solvent and water. The coating is then applied to the original size of the tablet with the use of a spray of titanium di-

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