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

ERIC W. MARTIN PhC, BSc, MS, PhD,

Adjunct Professor of Biomedical Communication, Columbia University College of Pharmaceutical Sciences; Director of Medical Communication, Lederle Laboratories, Division of American Cyanamid Company. Formerly Editor, *Journal of the American Pharmaceutical Association*, Executive Editor, Pfizer's *Spectrum*, Editor-in-Chief, *Remington's Pharmaceutical Sciences;* Author of *Techniques of Medication*, *Hazards of Medication*, and some 80 other biomedical publications; licensed pharmacist in Canada and the United States; Founder and first President, Drug Information Association; President, American Medical Writers Association, 1970–1971; Fellow AAAS, American Medical Writers Association, and International Academy of Law and Science, etc.

SEVENTH EDITION

MACK PUBLISHING COMPANY

1971

Library of Congress Catalog Card Number: 70-165831
Printed in the United States of America

CHAPTER 20

Coating

Chapter preparation by
James R. McCowan, PhD
Professor of Pharmaceutics
School of Pharmacy
University of Arkansas, Medical Center
Little Rock, Arkansas 72201

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

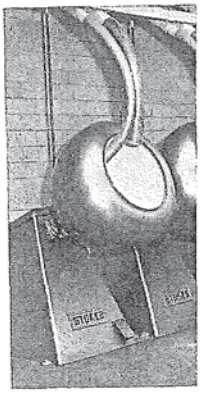


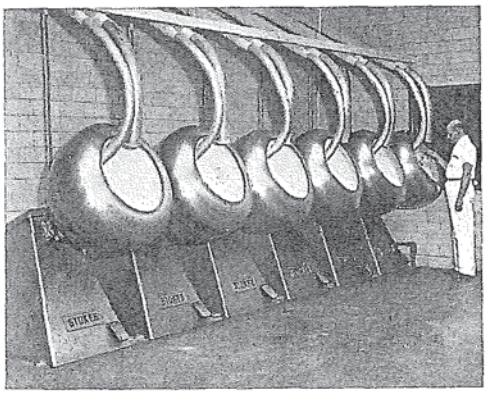
Fig 20-1—Stokes' t

Sugar Coating

Probably th
coating for ta
scale is a sugar
sive thin layer
are applied to t
and tumble in
pans are availa
shapes but are
sels, usually m
steel and are r
shaft so that th
Polishing pans
pans that have
they may be
sugar coating
by adding the
tion or suspens
equipped with
cold air throu
drying. Exhau
move moisture
See Fig 20-1 to

Tablets whi
made with co
a spherical sh
difficult to coa
should be re
placed in the

The usual s
(1) waterproo
of moisture in
ing to fill out
(3) smooth c
smooth surfac



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.

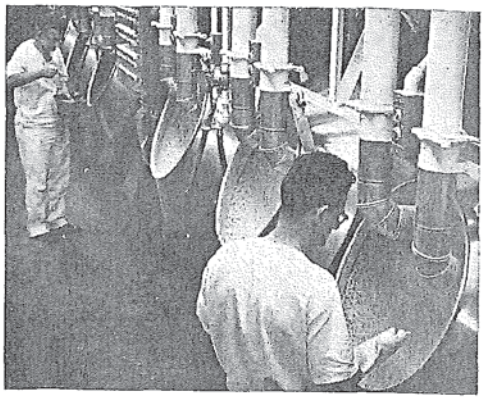
Polishing—After the coloring coats have been applied, the coated tablets are then polished by rotating them in the polishing pan with lumps of wax or with the addition of a solution of the wax in a volatile solvent. See Fig 20-4.

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 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-

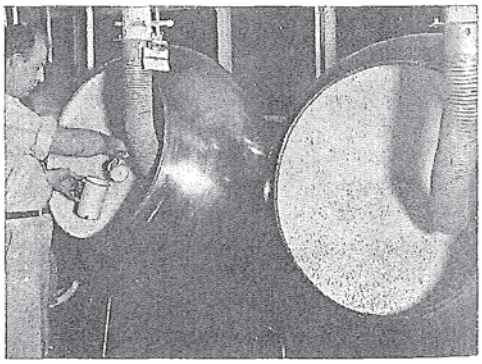
Schering Corp

Fig 20-3—Weighing operation and polishing room.



Lilly

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



F J Stokes Corp

Fig 20-5—Coating tablets at Wyeth Laboratories.

Fig 20-6—Tabl
the end of the
from the table

sonnel. Hov
been devise
cedures to i
formity, to
cycles and
ables.[2, 3]

Film Coati

A more re
a soluble fil
or films are
ing and smo
coating tim
terials may
solution in
and waterp
coating is
their origin
original siz
with solubl
the use of p
titanium di

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.