The Theory and Practice of Industrial Pharmacy

LEON LACHMAN, Ph.D.
Lachman Consultant Services, Inc.
Garden City, New York

HERBERT A. LIEBERMAN, Ph.D.
H. H. Lieberman Associates, Inc.
Consultant Services
Livingston, New Jersey

JOSEPH L. KANIG, Ph.D.
Kanig Consulting and Research Associates, Inc.
Ridgefield, Connecticut

THIRD EDITION

LEA & FEBIGER • 1986 • PHILADELPHIA

Lea & Febiger
600 Washington Square
Philadelphia, PA 19106-4198
U.S.A.
(215) 922-1330

Library of Congress Cataloging in Publication Data
Main entry under title:

The Theory and practice of industrial pharmacy.

Includes bibliographies and index.
1. Pharmacy. 2. Drug trade. I. Lachman, Leon, 1929– . II. Lieberman, Herbert A., 1920– III. Kanig, Joseph L., 1921– [DNLM: 1. Drug Industry.
QV 704 T396]
RS192.L33 1985 615'.19 84-27806
ISBN 0-8121-0977-5

First Edition, 1970
Second Edition, 1976

PRINTED IN THE UNITED STATES OF AMERICA

Print No. 4 3 2 1

Contents

*Deceased.

3

Drying

ALBERT S. RANKELL, HERBERT A. LIEBERMAN,
and ROBERT F. SCHIFFMANN

There is hardly a pharmaceutical plant engaged in the manufacture of tablets or capsules that does not contain dryers. Unfortunately, the operation of drying is so taken for granted that efforts for achieving increased efficiency in the production of tablets do not include a study of drying. This chapter introduces the industrial pharmacist to the theory and fundamental concepts of drying.

Definition. For the purpose of this discussion, drying is defined as the removal of a liquid from a material by the application of heat, and is accomplished by the transfer of a liquid from a surface into an unsaturated vapor phase. This definition applies to the removal of a small amount of water from moisture-bearing table salt as well as to the recovery of salt from the sea by evaporation. Drying and evaporation are distinguishable merely by the relative quantities of liquid removed from the solid.

There are, however, many nonthermal methods of drying, for example, the *expression* of a solid to remove liquid (the squeezing of a wetted sponge), the *extraction* of liquid from a solid by use of a solvent, the *adsorption* of water from a solvent by the use of desiccants (such as anhydrous calcium chloride), the *absorption* of moisture from gases by passage through a sulfuric acid column, and the *desiccation* of moisture from a solid by placing it in a sealed container with a moisture-removing material (silica gel in a bottle).

Purpose. Drying is most commonly used in pharmaceutical manufacturing as a unit process in the preparation of granules, which can be dispensed in bulk or converted into tablets or capsules. Another application is found in the processing of materials, e.g., the preparation of dried aluminum hydroxide, the spray drying of lactose, and the preparation of powdered extracts. Drying also can be used to reduce bulk and weight, thereby lowering the cost of transportation and storage. Other uses include aiding in the preservation of animal and vegetable drugs by minimizing mold and bacterial growth in moisture-laden material and facilitating comminution by making the dried substance far more friable than the original, water-containing drug.

Dried products often are more stable than moist ones, as is the case in such diverse substances as effervescent salts, aspirin, hygroscopic powders, ascorbic acid, and penicillin. The drying reduces the chemical reactivity of the remaining water, which is expressed as a reduction in the water activity of the product. Various processes for the removal of moisture are used in the production of these materials. After the moisture is removed, the product is maintained at low water levels by the use of desiccants and/or low moisture transmission packaging materials. The proper application of drying techniques and moisture-protective packaging requires a knowledge of the theory of drying, with particular reference to the concept of equilibrium moisture content.

Psychrometry

A critical factor in drying operations is the vapor-carrying capacity of the air, nitrogen, or other gas stream passing over the drying material. This carrying capacity determines not only the rate of drying but also the extent of drying, i.e., the lowest moisture content to which a given material can be dried. The determination of the vapor concentration and carrying capacity of the gas is termed *psychrometry*. The air–water vapor system is the system most commonly employed in pharmaceutical drying operations and is therefore included in this discussion.

The concentration of water vapor in a gas is

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.