

Freeze Drying of Pharmaceutical Products

Original

Freeze Drying of Pharmaceutical Products / Fissore, D.; Pisano, R.; Barresi, A. A. - STAMPA. - (2019).
[10.1201/9780429022074]

Availability:

This version is available at: 11583/2786116 since: 2020-01-29T14:45:26Z

Publisher:

CRC Press

Published

DOI:10.1201/9780429022074

Terms of use:

This article is made available under terms and conditions as specified in the corresponding bibliographic description in the repository

Publisher copyright

(Article begins on next page)

Freeze Drying of Pharmaceutical Products

Edited by
Davide Fissore, Roberto Pisano, and
Antonello Barresi



CRC Press

Taylor & Francis Group

Boca Raton London New York

CRC Press is an imprint of the
Taylor & Francis Group, an **informa** business

CRC Press
Taylor & Francis Group
6000 Broken Sound Parkway NW, Suite 300
Boca Raton, FL 33487-2742

© 2020 by Taylor & Francis Group, LLC

CRC Press is an imprint of Taylor & Francis Group, an Informa business

No claim to original U.S. Government works

Printed on acid-free paper

International Standard Book Number-13 978-0-367-07680-1 (Hardback)

This book contains information obtained from authentic and highly regarded sources. Reasonable efforts have been made to publish reliable data and information, but the author and publisher cannot assume responsibility for the validity of all materials or the consequences of their use. The authors and publishers have attempted to trace the copyright holders of all material reproduced in this publication and apologize to copyright holders if permission to publish in this form has not been obtained. If any copyright material has not been acknowledged, please write and let us know so we may rectify in any future reprint.

Except as permitted under U.S. Copyright Law, no part of this book may be reprinted, reproduced, transmitted, or utilized in any form by any electronic, mechanical, or other means, now known or hereafter invented, including photocopying, microfilming, and recording, or in any information storage or retrieval system, without written permission from the publishers.

For permission to photocopy or use material electronically from this work, please access www.copyright.com (www.copyright.com/) or contact the Copyright Clearance Center, Inc. (CCC), 222 Rosewood Drive, Danvers, MA 01923, 978-750-8400. CCC is a not-for-profit organization that provides licenses and registration for a variety of users. For organizations that have been granted a photocopy license by the CCC, a separate system of payment has been arranged.

Trademark Notice: Product or corporate names may be trademarks or registered trademarks, and are used only for identification and explanation without intent to infringe.

Library of Congress Cataloging-in-Publication Data

Names: Fissore, Davide, editor. | Pisano, Roberto (Of Politecnico di Torino), editor. | Barresi, Antonello, editor.

Title: Freeze drying of pharmaceutical products / edited by Davide Fissore, Roberto Pisano, Antonello Barresi.

Other titles: Advances in drying science & technology.

Description: Boca Raton : CRC Press, [2020] | Series: Advances in drying science and technology | Includes bibliographical references and index. | Summary: "Pharmaceuticals typically rely on compounds that are unstable as aqueous solutions and therefore need to be dried for an extended shelf lifetime. While lyophilization remains the gold standard in dehydration technology, it is among the most expensive and time-consuming unit operations in pharma manufacturing. This book provides an overview of the most recent and cutting edge developments and technologies in the field, focusing on formulation developments and process monitoring and considering new technologies for process development like the micro freeze dryer. Case studies from freeze dryer manufacturer and pharmaceutical companies are discussed"—Provided by publisher.

Identifiers: LCCN 2019026901 (print) | ISBN 9780367076801 (hardback ; alk. paper) | ISBN 9780429022074 (ebook)

Subjects: MESH: Technology, Pharmaceutical | Freeze Drying—methods | Freeze Drying—trends | Pharmaceutical Preparations

Classification: LCC RM301.25 (print) | LCC RM301.25 (ebook) | NLM QV 778 | DDC 615.1/9—dc23

LC record available at <https://lccn.loc.gov/2019026901>

LC ebook record available at <https://lccn.loc.gov/2019026902>

Visit the Taylor & Francis Web site at
www.taylorandfrancis.com

and the CRC Press Web site at
www.crcpress.com

Contents

Series Preface.....	vii
Preface.....	ix
Editors.....	xv
Contributors.....	xvii
Chapter 1 The Freeze-Drying of Pharmaceutical Products: Introduction and Basic Concepts	1
<i>Davide Fissore, Roberto Pisano, and Antonello Barresi</i>	
Chapter 2 Formulation Design and Optimization Using Molecular Dynamics	11
<i>Roberto Pisano and Andrea Arsiccio</i>	
Chapter 3 Established and Novel Excipients for Freeze-Drying of Proteins.....	33
<i>Ivonne Seifert and Wolfgang Friess</i>	
Chapter 4 Infrared Imaging and Multivariate Image Analysis (MIA): A New PAT for Freeze-Drying Monitoring and Control	53
<i>Domenico Colucci, José Manuel Prats-Montalbán, Alberto Ferrer, and Davide Fissore</i>	
Chapter 5 Through-Vial Impedance Spectroscopy (TVIS): A New Method for Determining the Ice Nucleation Temperature and the Solidification End Point	77
<i>Geoff Smith and Yowwares Jeeraruangrattana</i>	
Chapter 6 Innovations in Freeze-Drying Control and In-Line Optimization	99
<i>Antonello Barresi, Roberto Pisano, and Davide Fissore</i>	
Chapter 7 Use of a Micro Freeze-Dryer for Developing a Freeze-Drying Process.....	131
<i>Taylor N. Thompson and Davide Fissore</i>	

Chapter 8	Continuous Manufacturing in Lyophilization of Pharmaceuticals: Drawbacks of Batch Processing, Current Status, and Perspectives	145
	<i>Roberto Pisano, Luigi C. Capozzi, and Jos A.W.M. Corver</i>	
Chapter 9	Use of CFD for the Design and Optimization of Freeze-Dryers	165
	<i>Antonello Barresi</i>	
Index	189

Editors

Davide Fissore is Professor of Chemical Engineering at Politecnico di Torino (Italy). His research activity is mainly focused on process modelling and optimisation, and on the design and validation of model-based tools for process monitoring and control. One of the topics of his research activity is the freeze-drying of pharmaceutical products and foodstuffs. He developed various devices to monitor and optimise the in-line (using a control system) or off-line (using the design space of the product) freeze-drying process for a given product. He acted as a consultant for several pharmaceutical companies, focusing on process development and scale up. Davide Fissore is author or co-author of 90 papers appeared in international peer-reviewed journals and 15 book chapters, and he currently holds 9 patents, issued or pending.

Roberto Pisano is a Professor of Chemical Engineering at Politecnico di Torino (Italy), where he earned a PhD in 2009. Professor Pisano's research focuses on the application of both computational and experimental methods to engineering chemical products and processes, with particular emphasis on pharmaceutical processing and formulation of both small molecules and biologics. He was a visitor researcher at Centre de Ressources Technologiques—Institut Technique Agro-Industriel (Strasbourg, France) in 2008 and at the Department of Chemical Engineering of Massachusetts Institute of Technology (Cambridge, USA) in 2016. He has worked with many pharmaceutical companies in research or consulting. He has published more than 75 papers and 7 book chapters and currently has 4 patents issued or pending.

Antonello Barresi is currently full Professor of Transport Phenomena at Politecnico di Torino (Italy), in charge of the course on Process Development and Design. Currently he serves as Italian national delegate to the Working Party on Drying for the European Federation of Chemical Engineers. His main research interests in drying include drying and freeze-drying of pharmaceuticals and enzymes, modelling and optimization of freeze-drying processes, and control of industrial freeze-dryers. Most recent research is focused on process transfer, scale-up and cycle development, and new approaches for process development and quality control in freeze-drying of pharmaceutical and food products. He is the author of more than 250 papers (of which about 160 are published in international journals or books) and more than 100 conference presentations.



Taylor & Francis

Taylor & Francis Group

<http://taylorandfrancis.com>

Contributors

Andrea Arsiccio

Dipartimento di Scienza Applicata e
Tecnologia
Politecnico di Torino
Torino, Italy

Antonello Barresi

Dipartimento di Scienza Applicata e
Tecnologia
Politecnico di Torino
Torino, Italy

Luigi C. Capozzi

Dipartimento di Scienza Applicata e
Tecnologia
Politecnico di Torino
Torino, Italy

Domenico Colucci

Dipartimento di Scienza Applicata e
Tecnologia
Politecnico di Torino
Torino, Italy

Jos A. W. M. Corver

RheaVita
Ghent, Belgium

Alberto Ferrer

Department of Applied Statistics
and Operational Research and
Quality
Universitat Politècnica de València
Valencia, Spain

Davide Fissore

Dipartimento di Scienza Applicata e
Tecnologia
Politecnico di Torino
Torino, Italy

Wolfgang Friess

Department of Pharmacy,
Pharmaceutical Technology and
Biopharmaceutics
Ludwig-Maximilians-Universität
Munich, Germany

Yowwares Jeeraruangrattana

Health and Life Sciences Faculty
Leicester School of Pharmacy
De Montfort University
Leicester, United Kingdom

Roberto Pisano

Dipartimento di Scienza Applicata e
Tecnologia
Politecnico di Torino
Torino, Italy

José Manuel Prats-Montalbán

Department of Applied Statistics and
Operational Research and Quality
Universitat Politècnica de València
Valencia, Spain

Ivonne Seifert

Department of Pharmacy
Pharmaceutical Technology and
Biopharmaceutics
Ludwig-Maximilians-Universität
Munich, Germany

Geoff Smith

Health and Life Sciences Faculty
Leicester School of Pharmacy
De Montfort University
Leicester, United Kingdom

Taylor N. Thompson

Millrock Technology, Inc.
Kingston, New York



Taylor & Francis

Taylor & Francis Group

<http://taylorandfrancis.com>