CRC Press
Taylor & Francis Group

Micro- and Nanotechnologies-Based Product Development

EDITED BY
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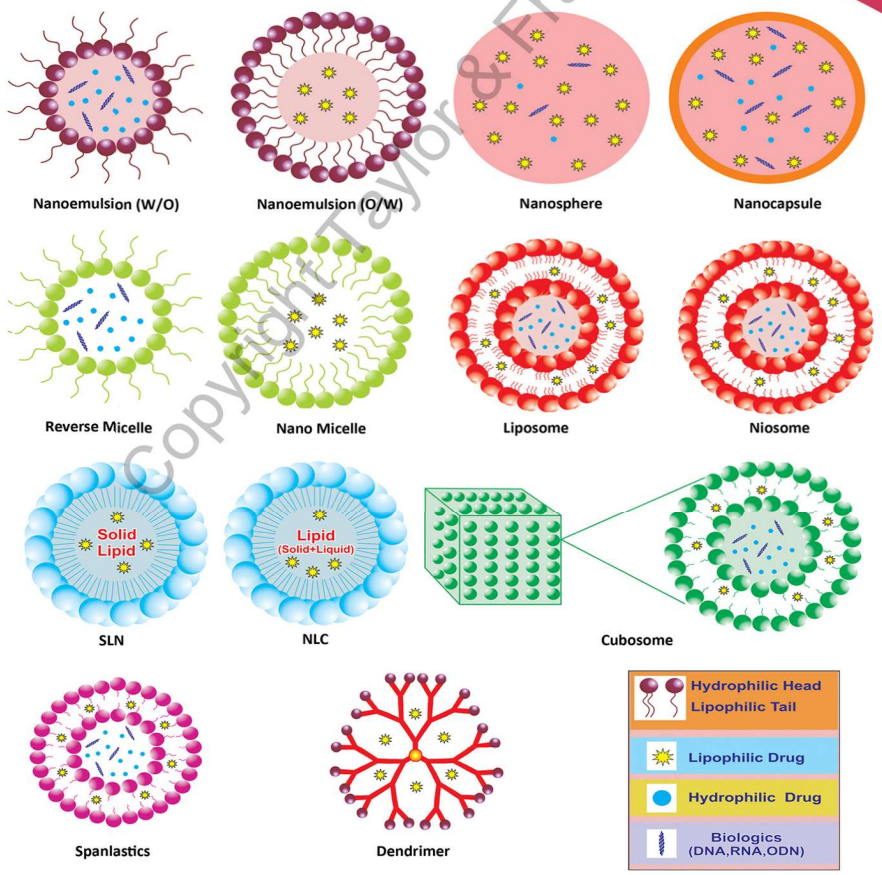

First edition published 2022
by CRC Press
6000 Broken Sound Parkway NW, Suite 300, Boca Raton, FL 33487-2742

and by CRC Press
2 Park Square, Milton Park, Abingdon, Oxon, OX14 4RN

CRC Press is an imprint of Taylor & Francis Group, LLC

Library of Congress Cataloging-in-Publication Data
Names: Mehra, Neelesh Kumar, editor. | Gulbake, Arvind, editor.
Title: Micro and nanotechnologies based product development / edited by Neelesh Kumar Mehra and Arvind Gulbake.
Description: First edition. | Boca Raton : CRC Press, 2022. | Includes bibliographical references and index.
Identifiers: LCCN 2021011182 | ISBN 9780367488451 (hardback) | ISBN 9781032050720 (paperback) | ISBN 9781003043164 (ebook)
Subjects: MESH: Nanostructures | Drug Delivery Systems | Drug Development | Nanotechnology | Microtechnology
Classification: LCC RM301.25 | NLM QT 36.5 | DDC 615.1/9—dc23
LC record available at https://lccn.loc.gov/2021011182

ISBN: 9780367488451 (hbk)
ISBN: 9781032050720 (pbk)
ISBN: 9781003043164 (ebk)

DOI: 10.1201/9781003043164

Typeset in Times
by codeMantra

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ABBREVIATIONS

AAS: Atomic absorption spectroscopy
ANDA: Abbreviated new drug application
API: Active pharmaceutical ingredient
FTIR: Fourier transform infrared spectroscopy
GPC: Gel permeation chromatography
HPLC: High-performance liquid chromatography
NMR: Nuclear magnetic resonance spectroscopy
Q1: Qualitative
Q2: Quantitative
RLD: Reference listed drug
TEM/SEM: Transmission electron microscopy/scanning electron microscopy
TGA: Thermogravimetric analysis

15.1 INTRODUCTION

Reverse engineering process or also called deformulation is quite common when one has to investigate the composition of an unknown product or a competitive product. In the pharmaceutical industry, it is helpful in the examination of various steps of product development and unit operations of scale-up and in the identification of unknown or hidden properties of excipients used like impurities or functional groups, stability and degradation product and other related substances (Bansal and Koradia 2005, Bhatti, Syed, and John 2018). Reverse pharmaceutical engineering further helps in understanding the features of polymers like molecular weight distributions, degree of substitution, monomer ratio and substituent distribution (Bhatti, Syed, and John 2018).

To develop a generic product, the pharmaceutical deformulation process starts even before the expiry of the patent. The reverse engineering process involves an exhaustive analysis to identify, quantify and characterise active pharmaceutical ingredient (API) and excipients of the original product (Oliveira et al. 2015). Since it is a time-consuming process, formulation scientist or reverse engineer has to start long before the patent expiry so that generic product development company is ready for submitting the details of their abbreviated new drug application (ANDA) product to the United States Food and Drug Administration (USFDA) as quickly as possible (Prašnikar and Škerlj 2006). As experienced by many formulators, reverse engineering is a

DOI: 10.1201/9781003043164-15