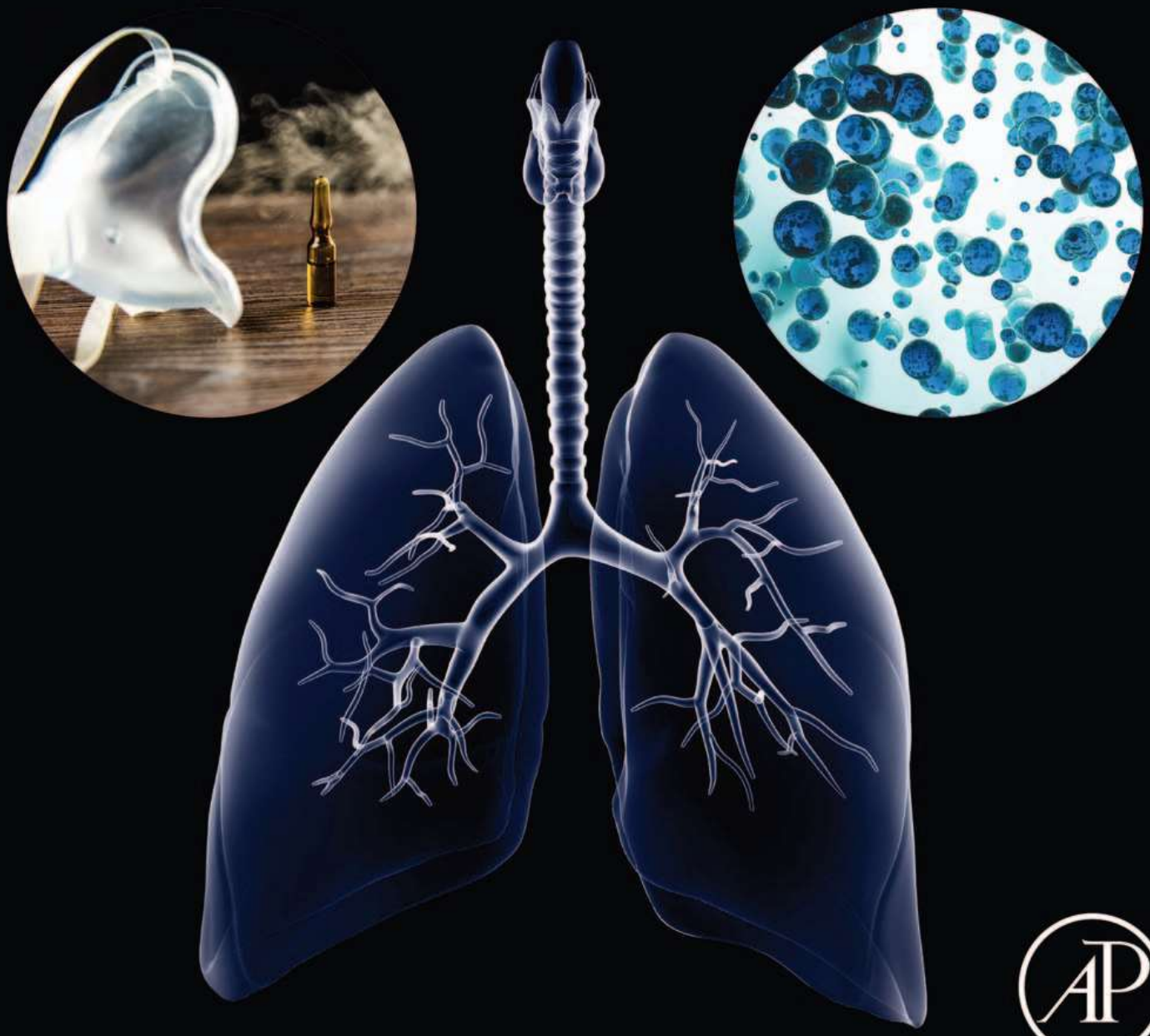
Edited by
Md Faiyazuddin, Hasan Ali, Md Akbar
and Babar Iqbal

LIPIDS IN PULMONARY DRUG DELIVERY



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Dedication

This book is dedicated to my beloved grandfather, the late Md. Shamshuddin Saheb, who departed from this world far too soon. To me, he was the whole world—a beacon of love, humility, compassion, and understanding. His family-oriented nature made him the heart of our family, and his absence leaves a profound void in my life. I will miss you deeply, Grandpa. I pray to Allah (SWT) to bless your soul and grant you Jannatul-Firdous (the highest level of heaven).

"O Allah, forgive and have mercy upon him, excuse him and pardon him, and make honorable his reception. Expand his entry, cleanse him with water, snow, and ice, and purify him of sin as a white robe is purified of filth. Exchange his home for a better home. Admit him into the Garden; protect him from the punishment of the grave and the torment of the Fire."

—*Professor (Dr.) Md. Faiyazuddin*

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CHAPTER

21

Pulmonary drug delivery of lipid-based formulations via nebulizers

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1. Introduction

Medical devices are any goods or equipment that are used to identify an illness or other conditions, to treat, cure, or prevent disease, according to the Food and Drug Administration (FDA) [1]. The Center for Medical Devices and Radiological Health (CDRH) of the FDA is responsible for categorizing, upholding, regulating, and authorizing these devices for use in humans. These gadgets are categorized according to their specialty or intended usage. Such devices are of considerable use in monitoring health, providing care, mitigating mobility, helping in surgical procedures, improving aesthetics, etc. One such broad category of medical devices is respiratory devices. These devices aid in breathing, ventilation, and oxygenation and can be used in home or clinical settings. Respiratory devices encompass those that help deliver drugs and/or support life. These devices include continuous ventilators, bilevel positive airway pressure machines (BPAP), continuous positive airway pressure machines (CPAP), and aerosol delivery devices. Aerosol delivery devices include metered dose inhalers, dry powder inhalers, and nebulizers [2].

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1.1 Nebulizers

A nebulizer is a device that holds liquid medication and converts it into an aerosol by using a small air compressor that is delivered directly to the patient for breathing. A nebulizer essentially consists of a drug reservoir with a lid, an air compressor, a mouthpiece/face mask, and tubing. The air compressor is attached to the drug reservoir through tubing over which a lid is placed that connects to a mouthpiece/face mask. The air compressor converts the air to a fine mist that carries the drug from the reservoir through tubing to be inhaled by the patient. With the use of a nebulizer, a drug is directly delivered to the respiratory system. This delivery method if used properly helps the drug reach both the small and large airways and increases the efficacy of the treatment. Nebulizers are often used by children, old persons, very ill people, or those who find it difficult to use an inhaler [3].

Nebulizers have been developed in design to suit the needs of the treatment and type of drug to be delivered, reduce wastage of drugs, and increase the effectiveness of the therapy. Consequently, there are different types of nebulizers available including (pneumatic) jet nebulizers (JNs), ultrasonic nebulizers (USN), and vibrating mesh nebulizers (VMNs). JNs are further divided into constant-output nebulizers (CON), breath-enhanced nebulizers (BENs), breath-actuated nebulizers (BANs), and dosimetric nebulizers [4,5]. Diverse designs of nebulizers are available for different types as per the manufacturer specifications and thus show different efficacy in delivering the aerosol [6].

1.1.1 Jet nebulizers (JNs)

These nebulizers work on the principle of the venturi effect. The major component of these types of nebulizers is the drug reservoir or the nebulizing chamber that has an inlet for compressed air. The inlet pipe is constricted as it enters the nebulizing chamber. The constricted end has an orifice or the nozzle through which the air comes out. The nozzle has a nozzle cover, placed over the nozzle at a fixed distance creating a capillary. When the air enters this constricted pipe, there is a drop in pressure as it moves out of the orifice or nozzle. This creates a low-pressure area that is distributed with the help of baffles in the nebulizing chamber. Because of the subatmospheric pressure created in the nebulizing chamber, the medication in the liquid or suspension form rises upward toward the orifice by capillary action or the Bernoulli effect and is aerosolized with the help of the air from the compressor. This aerosol accumulates in the upper part of the chamber and can be inhaled through the face mask or a mouthpiece [7]. CON generates aerosol during inhalation and exhalation, thus contributing to the wastage of the drug during the exhalation phase whereas BEN generates aerosol only during the inhalation phase, and during the exhalation phase the gas generating the aerosol returns back to the power gas supply. With dosimetric and BAN, aerosol is released only upon inhalation [8].

1.1.2 Ultrasonic nebulizers (USN)

Developed during the 1960s [9], these nebulizers use ultrasonic waves produced by the vibration of piezoelectric crystals. The high-frequency source is used to generate the ultrasonic waves in the piezoelectric crystals, which are transmitted to the drug solution or suspension directly or through a coupling liquid. These ultrasonic waves produce smaller or larger