Sagar Pardeshi, Dhanashree Pillai, Prabhanjan Giram,
Chandrakantsing Pardeshi, Amol Gholap, Jitendra Naik

Chapter 15
Nanocarriers for ocular drug delivery

Abstract: Researchers studying pharmaceuticals find it difficult to get medications into the tissues of the eyes. The main obstacles to medicine transport to the anterior and posterior regions include physiological barriers, anatomic barriers, efflux pumps, and metabolic barriers. It has been discovered that the issues with traditional ocular formulation can be effectively addressed by nanocarriers. For better penetration and effective targeted drug delivery to different ocular tissues, a number of nanocarriers – including liposomes, niosomes, nanomicelles, lipidic nanocarriers, polymeric nanoparticles, and dendrimers – have been investigated. Furthermore, to treat illnesses associated with the posterior parts of the eye, nanorobots can actively swim to the retina. We looked at the obstacles related to the eye structure in this chapter. In this chapter, we explored the barriers associated with the eye structure. This followed with a discussion on current developments that have the potential to improve translational medicine's ocular residence duration, distribution, and penetration to the anterior and posterior segments.

Keywords: Ocular, barriers, nanocarriers, nanomedicines, mucoadhesion, diagnostics

15.1 Introduction

Ocular diseases are a pressing concern that significantly impact both the vision and overall quality of life for patients. It's alarming to note that over 250 million people worldwide are currently grappling with visual impairment [1], and the outlook for morbidity prediction remains rather grim. In fact, if we don't see improvements in

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Chapter 1
Introduction to Quality by Design

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Abstract The pharmaceutical sector is concerned with product efficacy, safety, and quality. FDA decided to implement various Designs of Experiments (DoE) in the pharmaceutical industries. Quality by Design helps in the development of high-quality products and guides to manage product quality across its entire life cycle. This method quickly gains popularity worldwide due to its many benefits and use of numerous high-quality statistical tools. QbD is a meticulous, proactive, risk-based strategy for pharmaceutical development that commences with predetermined goals and emphasizes product and process understanding and process control based on reliable research. The QTPP, knowledge of product and process design, scale-up, control strategy, and constant improvement are considered as crucial components of pharmaceutical QbD. After approval, during the product lifecycle management process, the competency of the product and the process is evaluated and continuously enhanced.

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CHAPTER

3D printing-assisted colon-targeted drug delivery systems

15

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Abbreviations

3D	Three dimension
FDM	Fused deposition modeling
GIT	Gastrointestinal tract
HME	Hot melt extrusion
IVF	Injection volume filling
PVA	Polyvinyl alcohol
SLS	Selective laser sintering
SSE	Semisolid extrusion
DOP	Drop-on-powder

15.1 Introduction

Ease of drug administration and high patient compliance makes oral administration a much-preferred choice over other routes. Although restricted drug delivery to the desired site and limited absorption in the gastrointestinal tract (GIT) poses a great challenge for oral drug delivery, colon-targeted drug delivery finds great attention by the scientists worldwide owing to the benefits it offered for the treatment of variety of disorders *viz.* colorectal cancer, ulcerative colitis, Crohn's disease, and colorectal

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CHAPTER

9

Nasal Drug Delivery

Chandrakantsing V Pardeshi, Ganesh B Shevalkar, Rakhee Kapadia, Swapnil Jain, Srinivas Hebbar, Gundawar Ravi, Namdev Dhas

INTRODUCTION

Traditionally, nasal route has been exploited for delivery of drugs for the treatment of local diseases like nasal allergy, sinusitis, nasal infections, and nasal congestion. But, since last few decades, nasal route has attracted wider attention as a reliable, safe (being non-invasive), and convenient route to accomplish faster and higher levels of drug absorption. It is also evident that the therapy through intranasal administration was an accepted form of treatment in the Ayurvedic system of Indian medicine. The selection of an appropriate dosage form is critical because a dosage form with poor drug delivery can make a useful drug worthless. Intranasal administration seems to be an ideal alternative to the injectables for systemic drug delivery (Pardeshi et al. 2013).

The reasons behind interest in nasal route are highly vascularized epithelium of nasal mucosa, porous endothelial membrane, ready accessibility, large surface area for rapid drug absorption, rapid onset of action, lower enzyme levels compared to GI tract and liver, high total blood flow per cm^3, direct drug transport to systemic circulation and to the brain, thereby avoiding first-pass hepatic metabolism, and enhancing the bioavailability (Jadhav et al. 2007).

Parenteral drug administration has a lot of advantages compared to the other routes of drug administration. The superiority of these routes stems from reduced drug metabolism and degradation, a higher degree of utilization of the administered dose, programmable drug dosing within the therapeutic index, and so on. However, parenteral routes, especially intravenous injection, have some major disadvantages such as low patient compliance, health hazards, higher cost of therapy due to the use of highly qualified healthcare workers, and expensive equipment / tools. In comparison, extensive drug metabolism especially in the liver is seen after oral administration. Furthermore, the bioavailability is usually much less with the non-parenteral routes.

A very rapid rate of absorption can be achieved following the nasal application of some drugs (Graff and Pollack, 2005). Frequently (depending on the physicochemical characteristics of the drug) this is accompanied by high bioavailability. This recognition of the potential has led to an explosion of research (both fundamental and applied) in this field in the last few years. The list of nasal drug products in the market or at various stages of preclinical and clinical development is ever increasing. Many drugs have been shown to achieve a better systemic bioavailability by self-medication through the nasal route rather than by oral administration. The systemic bioavailability by

CHAPTER 1

Importance of nanomedicine in human health

Sagar R. Pardeshi[1], Mahesh P. More[2], Roshani Pagar[3], Eknath B. Kole[1], Tulshidas S. Patil[4], Prabhanjan S. Giram[3], Chandrakantsing V. Pardeshi[5], Shilpa R. Mandpe[1], Prashant K. Deshmukh[2], Pritam B. Patil[6] and Jitendra B. Naik[1]

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1.1 Introduction

Developments in the emerging area of nanotechnology provide probable techniques for improving health-care needs of patients. The combinational approaches possibly screen, diagnose, stage, and treat the multifactorial disease [1]. The nanomedicine-based novel techniques provide collective clearance of diseases and satisfy the multiresistant population in the 21st century [2]. The designing nanomaterials for advanced research find diverse applications in various fields. The technical advances are not limited to drug delivery, environmental remediation, solar energy, communication, energy conservation, etc., and so on [3]. Engineering or tuning nanomaterials for multivariate applications provides multilateral benefits in improving the health of human being [4]. Widest designing of nanomaterials was considered within 1−100 nm size for biomedical applications considered to be a finest small size. Reducing the size provides more promising characteristics starting from macro−micro−nano−pico−femto, etc. The reducing size opens new avenues with unique fine-tuning of characteristics [5]. Nanoengineered material or devices perform multiple functions at a single point of time in biomedical applications starting from site specificity, eradication to elimination from the body. The optimum activity of nanomedicines provides improved efficiency along with reduction in side effects associated with conventional drug delivery systems (DDS). Additional research task force is consistently working on designing and developing models, devices, and instruments for prompt utilization of novel nanomaterials. The developments in instrument design for biomedical purpose support utilization of noninvasive or less invasive therapies for patients suffering from multiple diseases. The surgical operations performed using

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CHAPTER

3D printing-assisted colon-targeted drug delivery systems

15

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Abbreviations

3D Three dimension
FDM Fused deposition modeling
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15.1 Introduction

Ease of drug administration and high patient compliance makes oral administration a much-preferred choice over other routes. Although restricted drug delivery to the desired site and limited absorption in the gastrointestinal tract (GIT) poses a great challenge for oral drug delivery, colon-targeted drug delivery finds great attention by the scientists worldwide owing to the benefits it offered for the treatment of variety of disorders *viz*. colorectal cancer, ulcerative colitis, Crohn's disease, and colorectal infections. Colon drug delivery is also a promising approach for the systemic delivery of therapeutic proteins and peptides, which otherwise may be de-

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16 NUTRITIONAL MANAGEMENT OF IRRITABLE BOWEL SYNDROME

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ABSTRACT

The most common functional gastrointestinal illness that pediatricians and consultants see is irritable bowel syndrome (IBS). The pathogenesis of irritable bowel syndrome is complicated and includes changes in the enteric microbiota, abdominal hypersensitivity, gut immune/barrier function, control of the hypothalamic-pituitary-adrenal axis, neurotransmitters, stress response, and other factors. In this review, we describe the modifiable dietary risk factors. Diagnosis, treatment based on symptoms, and nutritional herbs used in the treatment of IBS. This review also provides information about which type of diet to avoid in IBS. Nutrient deficiency, and the symptoms of IBS. Food sources that contain low fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAP) diet help to maintain appropriate pH levels of stomach acid and help improve muscle function of the digestive tract. Understanding the dietary management techniques for irritable bowel syndrome will direct nutritionists and healthcare professionals to provide the best results.

INTRODUCTION

Irritable bowel syndrome (IBS) is one of the most diagnosed gastrointestinal diseases. The prevalence of IBS in children and adolescents is high. Various studies have reported prevalence to be approximately 8 to 12% in children, and 3 to 17% in adolescents. [1, 4]

IBS, in the absence of any other causative disease, is defined as the presence of abdominal pain or discomfort with altered bowel habits with a change in stool form and frequency. The most important single risk factors are female sex, younger age, and preceding gastrointestinal infections. Clinical symptoms of IBS include abdominal pain or discomfort, stool irregularities, and bloating, as well as other somatic, visceral, and psychiatric comorbidities. [1, 2]

The epidemiology, clinical presentation, and management of irritable bowel syndrome (IBS) may vary in different geographical regions due to differences in diet, gastrointestinal infection and infestations, socio-cultural and psycho-social factors, religious and illness beliefs, symptom perception, and reporting. Asia is geographically and socio-demographically diverse. [3]

The pathophysiology of IBS is most likely multifactorial involving visceral hypersensitivity, abnormal gut motility, intestinal microbiota, inflammation and immune disturbance, genetic factors, abnormal gas handling, psychosocial factors, intestinal infections, central nervous system, and serotonin. [1]

Pharmacological treatment of IBS varies from antidepressants including tricyclic antidepressants and selective serotonin reuptake inhibitors to antispasmodics5-hydroxytryptamine-3 receptor (5-HT3) antagonists, 5-HT4 agonists, antibiotics, probiotics, and melatonin. [5, 6]

Based on the different mechanisms in the etiology, treatment focuses on controlling symptoms. Due to the longtime syndrome, inadequacy of current treatments, financial burden for patients, and pharmacologic effects, several patients have turned to the use of complementary and alternative medicine (CAM). Complementary and alternative treatments for IBS include hypnosis, acupuncture, cognitive behavior therapy, yoga, and herbal medicine. Herbal medicines can have therapeutic effects on IBS. This study aimed to evaluate the efficacy of herbs, and nutritional supplements in the control of IBS, and their possible mechanisms of action were reviewed. [5, 7]

Diagnosis of IBS:

1. **Colonoscopy**: Using a short, flexible tube, the doctor looks at the colon's whole length.
2. **CT scan**: This test generates images of the abdomen and pelvis that may rule out other symptoms and causes, particularly if there is abdominal pain.
3. **Upper endoscopy**: The esophagus, the tube that connects the mouth to the stomach, is accessed by inserting a long, flexible tube down into the throat. The upper digestive tract can be seen by the provider thanks to a camera on the tube's end. A tissue sample (biopsy) may be taken during an endoscopy. It is possible to take a sample of the fluid to check for bacterial overgrowth. If celiac disease is suspected, an endoscopy may be suggested.

LABORATORY TESTS FOR IBS:

1. **Lactose intolerance tests**: Lactase is an enzyme that is required for the digestion of sugar contained in dairy products. If it does not manufacture lactase, it may have symptoms comparable to IBS, such as stomach pain, gas, and diarrhea. It may order a breath test or request that milk and milk products be removed from the diet for several weeks.
2. **Breath test for bacterial overgrowth**: A breath test can also identify whether or not you have bacterial overgrowth in your small intestine. Bacterial overgrowth is more likely in patients who have had intestinal surgery, have diabetes, or another ailment that causes digestion to slow down.
3. **Stool tests**: Stool tests may be performed to look for germs, parasites, or the presence of bile acid. Bile acid is a digestive liquid that is produced by the liver.

CAUSES & RISK FACTORS:

There is an indication that several factors, including food, the intestinal microbiota, low-grade chronic intestinal inflammation, and aberrant gastrointestinal endocrine cells, are key players in the pathogenesis of IBS shown in Figure 16.1. [3]

CHAPTER 5

ROLE OF DIETARY FIBER IN CORONARY HEART DISEASE (CHD)

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ABSTRACT

The purpose of this review is to study the role of dietary fiber in coronary heart disease (CHD). Excessive LDL cholesterol, low HDL cholesterol, high blood pressure, family records, diabetes, smoking are the chance

Food Supplements and Dietary Fiber in Health and Disease. Bhushan R. Rane, Raj K. Keservani, Durgesh Singh, Nayan A. Gujarathi, and Ashish S. Jain, (Eds.)

NUTRITIONAL MANAGEMENT OF DIGESTIVE SYSTEM DISEASES,

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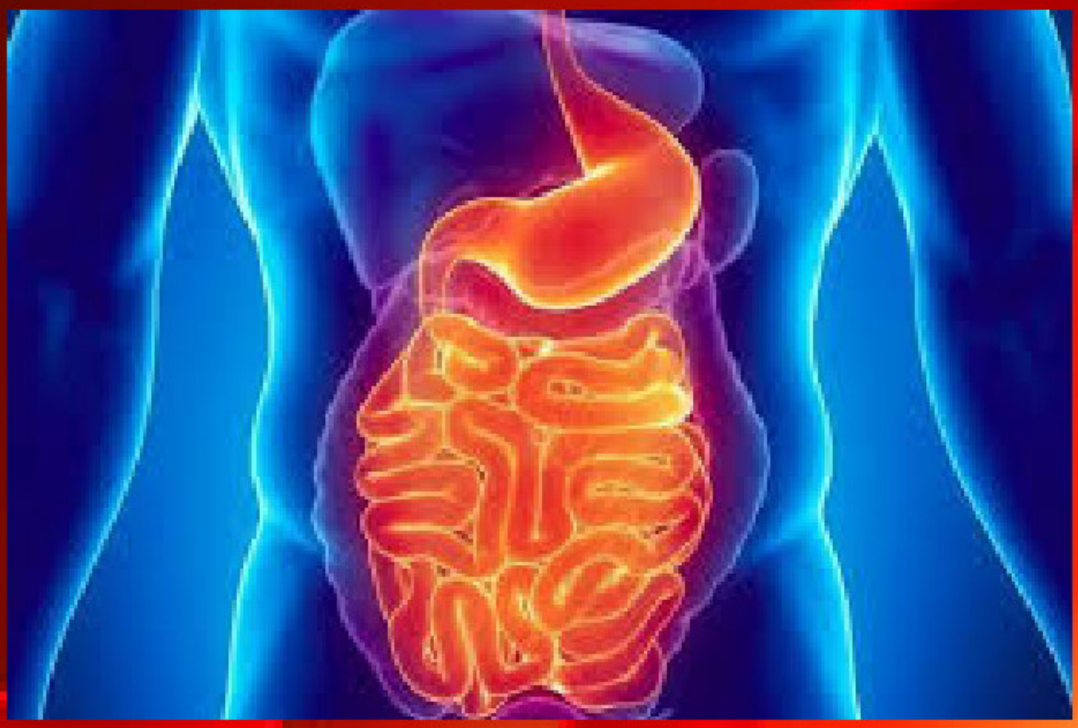

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ALZHEIMER'S DISEASE AND ADVANCED DRUG DELIVERY STRATEGIES

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Bhupendra Gopalbhai Prajapati
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Prakash N. Kendre

CHAPTER

1

Etiology, pathogenesis of Alzheimer's disease and amyloid beta hypothesis

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1. Introduction

The group of prevalent and disabling neurodegenerative ailments include Alzheimer's, Huntington's and Parkinson's disease. Additionally, neurodegeneration is the primary cause of multiple sclerosis's irreversible neurological impairment [1]. It is anticipated that by the end of the next 28 years, there would be 152 million patients, up from the present 50 million [2]. With an estimated 60%–70% of cases globally, Alzheimer's Disease (AD) is frequent source of dementia with predicted prevalence of 10% in individuals under the age of 65; however, it surges to 32% in population of age above 85 years, when its yearly incidence is anticipated to be 6.48%. The verbal, visuospatial, and executive domains of cognition gradually deteriorate in AD patients, as well as memory. Amyloid beta (Aβ) plaques and tau tangles (TTs) are pathological AD indicators [3]. Neuronal loss, the progressive buildup of neurofibrillary tangles (NFTs) along with presence of amyloid fibers in neuritic plaques and blood vessel walls are the hallmarks of AD. Even though amyloid pathology and NFT are both typical characteristics of AD, it is unclear how these two diseases are related. However, both illnesses are the ultimate outcome of protein aggregation: Aβ becomes fibrillated and produces amyloid plaques, whereas tau get aggregated following hyperphosphorylation and causes NFTs. Numerous studies have demonstrated a connection between these two clinical AD indicators and an attack via free radicals, or oxidative stress. The amyloid precursor protein (APP), presenilin 1 (PSEN1) and presenilin 2 (PSEN2) genes are situated on chromosome 21, 14 and 1, individually. Additionally, the apolipoprotein E4 gene's epsilon 4 allele (*APOE* ε4) on chromosome 19 is connected with improved danger of AD [4].

2. Etiology of Alzheimer's disease

As depicted in Fig. 1.1; cardiovascular diseases related cerebral ischemic injury, aging, genetic predisposal, and oxidative stress are the main etiology for the advancement of neurodegenerative disorders like AD.

The AD is triggered through several central nervous system (CNS) insults, including brain trauma. Increased cytokine production and inflammation are brought on by these insults [4]. At first glance, AD and cerebral ischemic injury could seem to be two quite different CNS conditions. Nevertheless, it has been shown that both start at parallel predispositions and share path that culminates in cell death. There are similarities between the pathophysiology of brain ischemia and AD which have recently highlighted, and such resemblance contributes for buildup of Aβ peptide and consequent neuronal toxicity [5]. The relationship between trauma brain injury (TBI) and AD has been confirmed by the identification of conditions that resemble AD, such as abnormal tau aggregation and buildup after lesions in animal models and TBI survivors [6]. In general, the term neuro-inflammation refers to an inflammatory reaction inside central nervous system (CNS) triggered by many pathogenic events, including infection, trauma, ischemia, and toxins. Neuro-inflammation is one of the causes of AD [3].

Alzheimer's Disease and Advanced Drug Delivery Strategies
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NATURAL COSMECEUTICALS CONTRIBUTION TO SKIN CARE PREPARATIONS: A REVIEW

Abstract

The present chapter is based on the use of natural cosmeceuticals in skin care preparations. Nowadays, natural cosmeceuticals are introduced in the market as many people are looking for natural alternatives to synthetic chemicals found in traditional skincare. Cosmeceutical means a combination of cosmetics and pharmaceuticals which are applied topically, as cosmetics yet contain therapeutic or bioactive ingredients that affect the skin's biological function. The use of bioactive extracts or phytochemicals from a variety of botanicals can be accomplished in skin care preparations that act as an antioxidant, anti-inflammatory, antibacterial, anti-acne, sun protective, and skin whitening agent. In the present review, extensive literature research was undertaken to summarize suitable natural cosmeceuticals that can be suggested for the contribution to skin care preparations. Various ayurvedic medicinal plants and herbs are beneficial for contributing to skin care preparations and in addition to skin healing benefits, future research should attempt to determine this directly.

Keywords: Natural cosmeceuticals; ayurvedic medicinal plants; antioxidant; anti-inflammatory; antibacterial; sun-protective agent; skin whitening; skin care preparations

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1

NOVA MEDICINE AND HEALTH

NATURAL PRODUCTS

An Answer to Cardiovascular Complications

AMAN B. UPAGANLAWAR
TANUJ JOSHI
Editors

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Chapter 19

Multifunctional Pentacyclic Triterpenoids: A Natural Product Remedy for the Prevention of Cardiovascular Complications

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Abstract

Reactive oxygen species (ROS) are detrimental as they can damage a wide range of molecules, including proteins and lipids. This ROS trait can cause cardiovascular disorders and consequences including hypertension, ischemia, and reperfusion injury to multiple tissues. Many pentacyclic triterpenoids (PTs) exist in plants, and both their semi-synthetic derivatives and synthetic analogues feature molecular diversity that allows them to interact with multiple biological targets. All pentacyclic triterpenes have a 30-carbon skeleton with either five, six-membered rings like ursanes and lanostanes or four, six-membered rings and one five-membered ring such as lupanes and hopanes. Squalene epoxide molecules are combined to produce pentacyclic triterpenes. These compounds are typically present in the fruits, leaves, roots and other parts of several medicinal plants. Pentacyclic triterpenoids were evaluated for cardio protective and antioxidant effects in addition to their organ protective effects on vital organs including kidney and heart. Pentacyclic triterpenoids are known to have antioxidant and Nrf2 translocation activity.

Keywords: pentacyclic triterpenes, cardiovascular disorders, ROS, herbs

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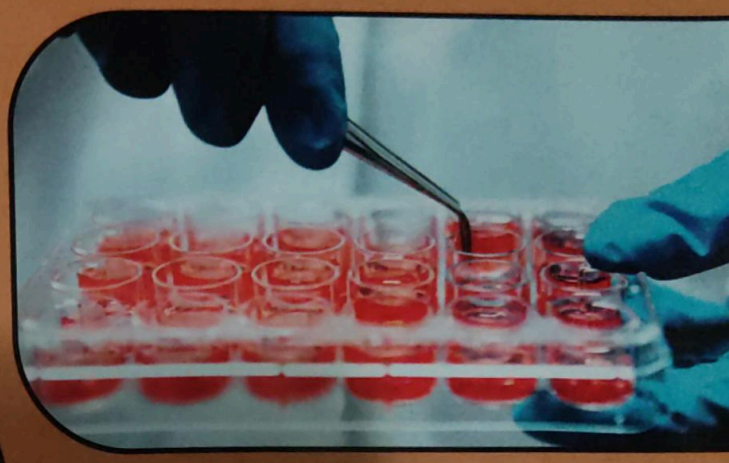

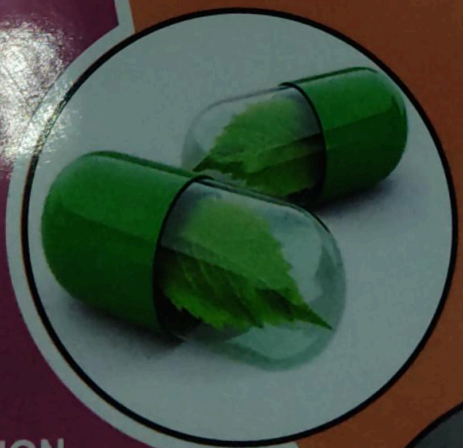

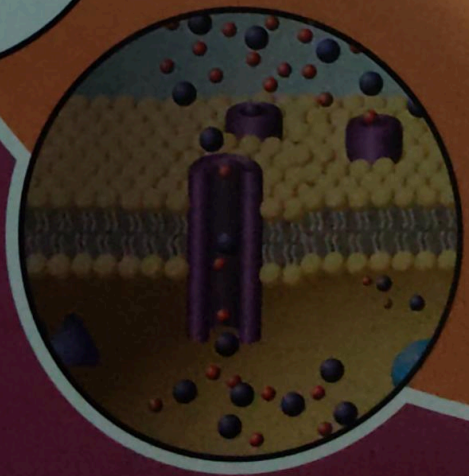

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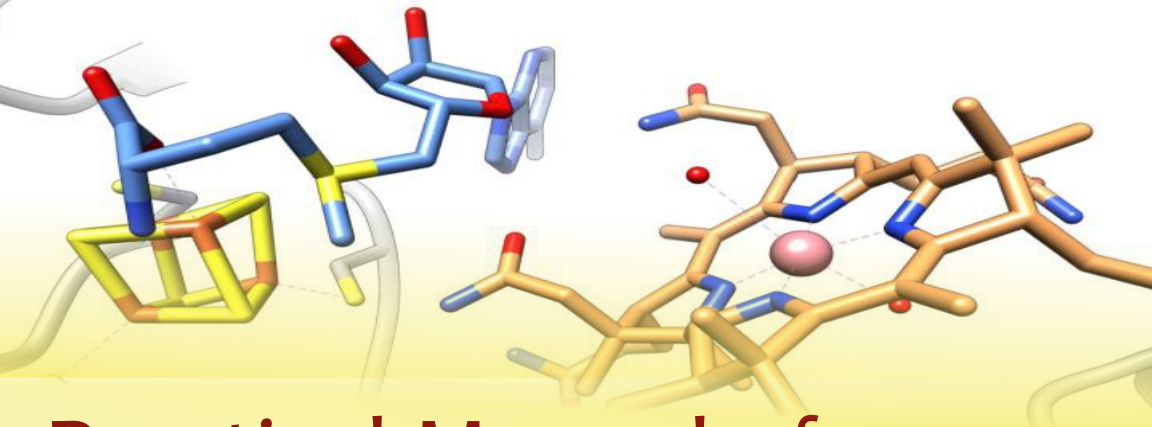

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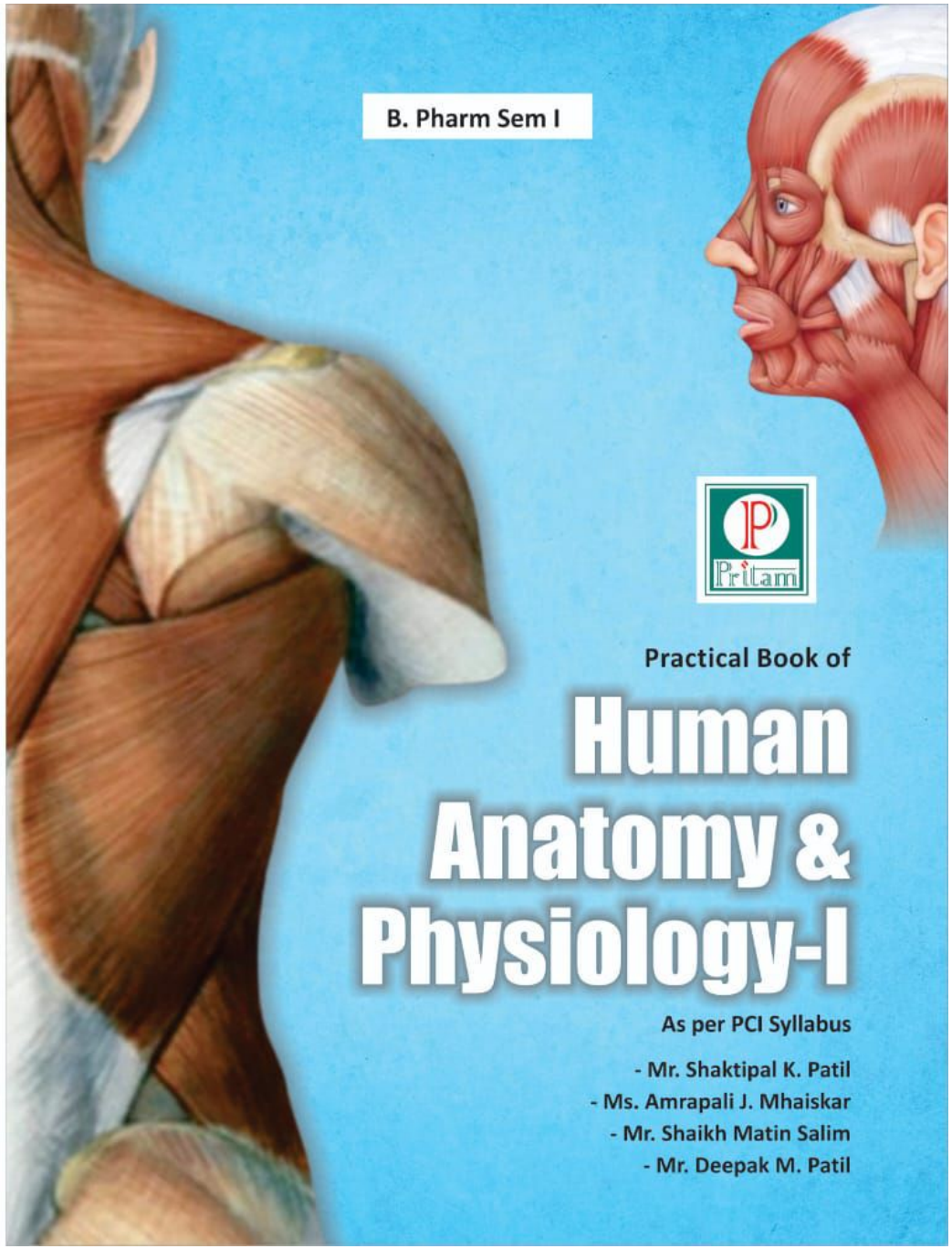

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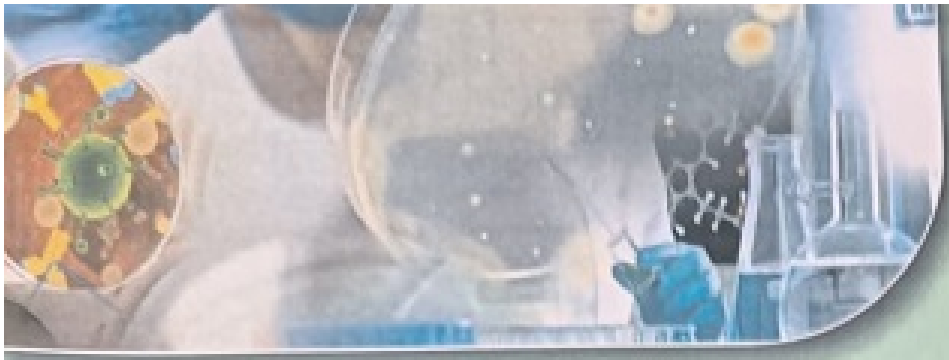

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Dr. Atul R. Bendale is presently working as a Professor at Shree Mahavir Education Society's, Mahavir Institute of Pharmacy, Nashik, Maharashtra. He is having 15 years of experience in academics. His research area of interest is green organic synthesis. He is the author of 16 books, holds 6 patents and published 50 papers in reputed journals. He is recipient of prestigious *Bharat Gaurav Puraskar* and *Best Educationist Award* for his remarkable contribution in the field of education. Actively he is working as reviewer and editor for several journals.

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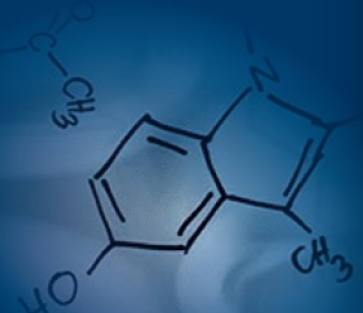

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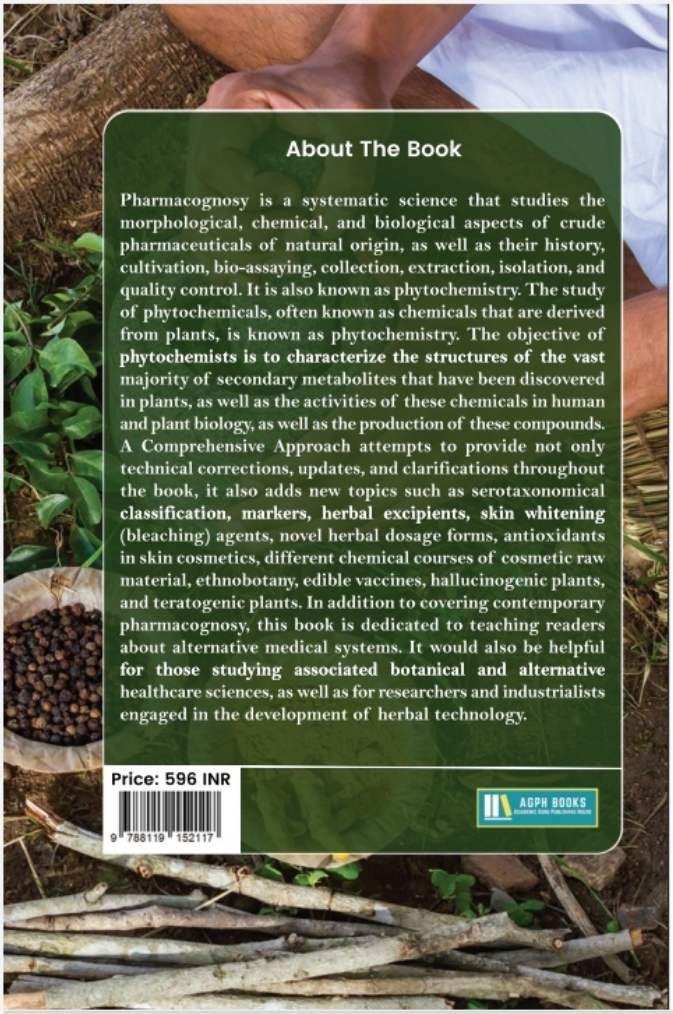

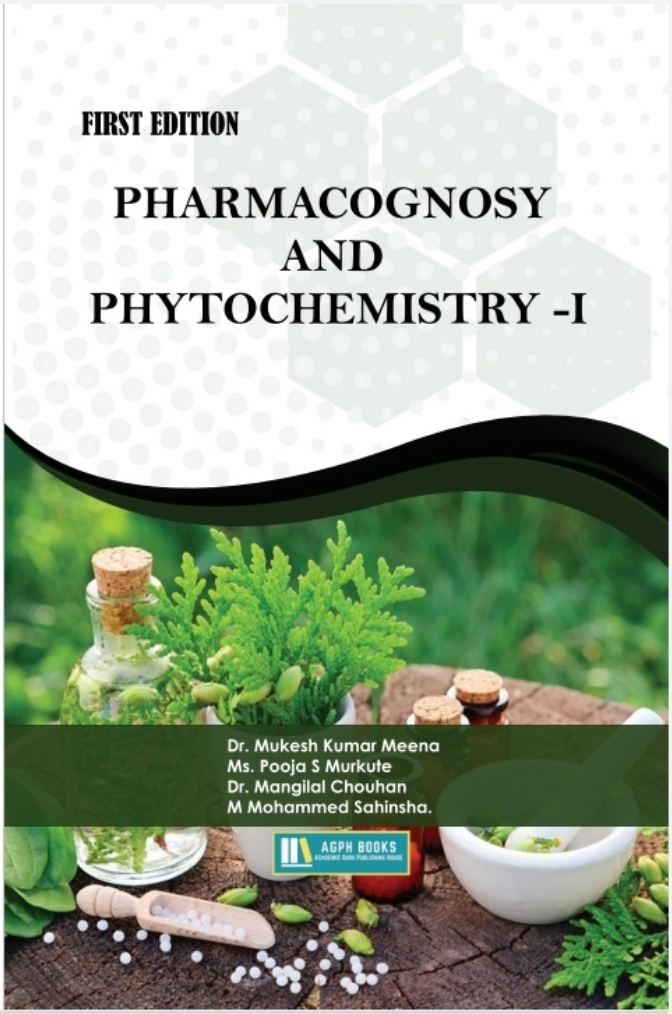

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