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Pharmaceutical and Biopharmaceutical Characteristics of Montelukast Preparations Used in The Treatment of Bronchial Asthma

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Abstract

Bronchial asthma is considered one of the most widespread chronic inflammatory diseases globally, and leukotriene receptor antagonists occupy an important place in its pharmacotherapy. Montelukast sodium is one of the highly effective antileukotriene drugs widely used in the treatment of bronchial asthma and allergic rhinitis, and it is manufactured in generic forms by various pharmaceutical companies. Variations in excipient composition, manufacturing technology, stability indicators, and biopharmaceutical properties of preparations containing the identical active substance can significantly influence their therapeutic efficacy and overall quality. In this article, the pharmaceutical and biopharmaceutical characteristics of domestic and foreign montelukast-based tablet preparations were analyzed based on modern scientific literature. The literature review elucidates the chemical composition of the preparations, the role of excipients, dissolution profiles, bioequivalence, stability, and quality control methods, including HPLC and UV-spectrophotometric analytical methods. Furthermore, the key factors influencing the quality parameters of generic preparations were scientifically evaluated. The obtained data indicate that an in-depth study of the pharmaceutical equivalence of montelukast preparations and the optimization of their quality control are of profound importance.

Keywords: Bronchial asthma, montelukast sodium, generic preparations, pharmaceutical equivalence, biopharmaceutical properties, stability, dissolution test, quality control, HPLC analysis, leukotriene receptor antagonists, tablet preparations, bioequivalence.

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1. Introduction

Bronchial asthma represents one of the most pressing issues in modern medicine, characterized as a chronic inflammatory airway disease presenting with bronchial hyperresponsiveness. According to data from the World Health Organization, bronchial asthma affects a significant

proportion of the global population, contributing to rising morbidity and disability rates. Bronchospasm, mucus hypersecretion, and the activation of inflammatory mediators play pivotal roles in the pathogenesis of the disease. Consequently, the comprehensive use of anti-inflammatory and bronchodilator agents is essential for the effective management and control of bronchial asthma.

In recent years, leukotriene receptor antagonists have been widely utilized in the pharmacotherapy of bronchial asthma. Montelukast, a prominent representative of this therapeutic class, is well-established in clinical practice as an effective agent for the treatment of both bronchial asthma and allergic rhinitis. By selectively blocking cysteinyl leukotriene receptors, montelukast reduces bronchoconstriction, airway inflammation, and mucus secretion. The high therapeutic efficacy of the drug, coupled with the convenience of oral administration and its widespread application in pediatric practice, has driven the manufacture of numerous generic formulations across the pharmaceutical market.

Presently, domestic and foreign montelukast-containing preparations are extensively distributed throughout the pharmaceutical market; however, they may exhibit variations regarding manufacturing technologies, excipient compositions, stability profiles, and biopharmaceutical parameters. Investigating the pharmaceutical equivalence and quality parameters of preparations containing the identical active pharmaceutical ingredient (API) is currently one of the key frontiers in modern pharmacy. Evaluating the dissolution profiles, bioequivalence, stability, and quality control indicators of generic formulations is particularly critical to ensuring their therapeutic efficacy and safety.

High-performance liquid chromatography (HPLC), UV-spectrophotometry, dissolution testing, and stability analyses are widely employed in pharmaceutical quality control. These methodologies enable the accurate quantification of the active ingredient, the evaluation of degradation products, and the rigorous monitoring of the pharmaceutical quality of the drug preparations. Furthermore, the specific composition of excipients and the selection of packaging materials can also exert a significant impact on the physicochemical stability of the finished products.

This article provides a comprehensive analysis of the pharmaceutical and biopharmaceutical characteristics of domestic and foreign montelukast-based preparations used in the treatment of bronchial asthma, based on modern scientific literature, while scientifically elucidating the primary factors that influence the quality indicators of generic drug products.

Pharmacological importance of bronchial asthma and montelukast

Bronchial asthma is a chronic inflammatory disease of the airways characterized by bronchial hyperreactivity, reversible bronchospasm, and airway obstruction. Immunological and biochemical processes play an important role in the pathogenesis of the disease. The release of allergic mediators leads to inflammation of the bronchial wall, increased mucus secretion, and spasm of bronchial smooth muscles. These changes result in the development of clinical symptoms such as dyspnea, coughing, wheezing, and chest tightness.

Eosinophils, mast cells, T-lymphocytes, and inflammatory mediators play a significant role in the pathogenesis of bronchial asthma. In particular, cysteinyl leukotrienes (LTC4, LTD4, and LTE4) are considered major mediators in the development of bronchial asthma. These biologically active substances are formed through the metabolism of arachidonic acid via the 5-lipoxygenase pathway.

The biosynthesis of leukotrienes occurs through the following process:

$$Arachidonic\ acid \xrightarrow{5-lipoxygenase} Leukotrienes$$

Generated leukotrienes stimulate bronchoconstriction (contraction of bronchial smooth muscles), increase vascular permeability, augment mucus secretion, and promote the migration of inflammatory cells. Especially LTD4 is considered one of the most active mediators in terms of its bronchoconstrictor effect. Therefore, blocking leukotriene receptors is recognized as one of

the crucial directions in the pharmacotherapy of bronchial asthma.

Montelukast belongs to the group of leukotriene receptor antagonists and exerts its effect by selectively blocking CysLT1 receptors. The drug restricts the binding of LTD4 to bronchial receptors, consequently reducing bronchospasm, inflammation, and mucus secretion.

The primary pharmacological action of montelukast is mediated through the following mechanism:

$$LTD_4 + CysLT1\ receptor \rightarrow Bronchoconstriction$$

As a result of blocking CysLT1 receptors, montelukast causes relaxation of the bronchi and improves airway

permeability. This effect of the drug has important clinical significance in controlling the symptoms of bronchial asthma.

Montelukast is an orally administered drug that is well absorbed from the gastrointestinal tract and extensively binds to plasma proteins. The drug is mainly metabolized in the liver by cytochrome P450 enzymes, particularly CYP3A4 and CYP2C9. Its metabolites are primarily excreted from the body through bile. The pharmacokinetic properties of the drug allow its administration once daily. One of the important advantages of montelukast is that it is administered in tablet form rather than by inhalation. This provides convenience especially in pediatric practice and in patients who experience difficulties using inhalers. In addition, the drug is effective in bronchial asthma associated with allergic rhinitis. In clinical practice, montelukast is widely used in mild and moderate persistent asthma, in reducing nocturnal asthma symptoms, and in the prevention of exercise-induced bronchospasm.

In recent years, generic preparations based on montelukast have become widespread in the pharmaceutical market. Although preparations manufactured by different companies contain the same amount of active substance, they may differ in excipient composition, manufacturing technology, dissolution profile, and stability parameters. Therefore, comprehensive investigation of the pharmaceutical and biopharmaceutical properties of montelukast preparations is considered one of the important scientific directions of modern pharmacy.

Pharmaceutical and biopharmaceutical properties of montelukast preparations

Concept of generic preparations and pharmaceutical equivalence.

As a result of the development of the modern pharmaceutical industry, generic forms of medicinal products have become widespread in the pharmaceutical market. Generic preparations play an important role in increasing economic efficiency in healthcare systems, ensuring the accessibility of medicines, and maintaining the continuity of pharmacotherapy. Especially in chronic diseases such as bronchial asthma, the necessity for long-term treatment requires extensive use of generic preparations.

A generic preparation - is a medicinal product manufactured by other pharmaceutical companies after the expiration of the patent of the original drug and containing exactly the same active substance. Generic medicinal products must have the same dosage, dosage form, route of administration, and therapeutic purpose as the original preparation. However, generic preparations may differ from the original product in terms of manufacturing technology, excipient composition, packaging materials, and pharmaceutical properties.

In pharmaceutical practice, the concepts of pharmaceutical equivalence and bioequivalence are important in evaluating the quality of generic preparations. Pharmaceutical equivalence refers to the pharmaceutical similarity of preparations containing the same active substance, the same dosage, and the same dosage form. Although such preparations are equivalent in terms of active substance content, they may differ in excipient composition and manufacturing technology.

Pharmaceutical equivalence is evaluated according to the following main criteria:

- active substance content;
- uniformity of dosage form;
- dissolution profile;
- disintegration time;
- physicochemical stability;
- quality control parameters.

The concept of bioequivalence is particularly important in assessing the therapeutic efficacy of generic preparations. Bioequivalence refers to the similarity in the rate and extent of biological absorption of two preparations after administration into the body. Bioequivalent preparations are expected to produce the same therapeutic effect. Therefore, bioequivalence studies are considered an essential requirement of international pharmaceutical standards for generic medicines.

Although pharmaceutical equivalence and bioequivalence are interrelated concepts, they do not have the same meaning. A pharmaceutically equivalent preparation is not always completely bioequivalent. This is because excipients, granulation technology, tablet density, coating materials, and stabilizers may affect the solubility and absorption rate of the active substance.

This issue is especially relevant in preparations based on montelukast sodium. Although montelukast preparations manufactured by different companies contain the same amount of active substance, differences may be observed in dissolution profiles, stability parameters, and biopharmaceutical properties. This may affect the therapeutic efficacy and pharmacokinetic characteristics of

the preparations to a certain extent.

Modern analytical methods are widely used in evaluating the pharmaceutical quality of montelukast preparations. In particular, high-performance liquid chromatography (HPLC), UV spectrophotometry, dissolution testing, and stability analyses are important in determining the quality parameters of preparations. These methods are used to evaluate active substance content, degradation products, solubility, and physicochemical stability of the preparations.

In recent years, interest in studying the pharmaceutical equivalence of local and foreign montelukast preparations has been increasing. This has important scientific and practical significance in improving the quality of generic preparations, enhancing their therapeutic efficacy, and developing pharmaceutical quality control systems.

Chemical composition of montelukast preparations and pharmaceutical importance of excipients

Montelukast is a synthetic antileukotriene drug widely used in the treatment of bronchial asthma and allergic rhinitis. The drug reduces bronchospasm and inflammatory processes through selective blockade of cysteinyl leukotriene receptors. The pharmacological efficacy of montelukast depends not only on the properties of the active substance but also on the excipients contained in the dosage form, the manufacturing technology, and physicochemical stability. Therefore, studying the chemical composition of preparations and the pharmaceutical significance of excipients is considered one of the important directions of modern pharmaceutical analysis.

In pharmaceutical practice, montelukast is mainly used in the form of its sodium salt — montelukast sodium. This form increases the water solubility and bioavailability of the drug. The substance is a white or yellowish hygroscopic powder with lipophilic properties. The physicochemical properties of montelukast directly affect its dissolution profile and biological absorption.

The molecular formula of montelukast is expressed as follows:

$C_{35}H_{36}ClNO_3S$

The montelukast molecule contains aromatic rings, a thioether group, and a carboxyl fragment, all of which play an important role in receptor binding. The lipophilic nature of the drug facilitates its passage through cell membranes; however, its limited water solubility necessitates the appropriate selection of excipients.

Table 1

Main phsicochemical properties of monteculast

Parameters	Descriptions
Chemical name	Montelukast sodium
Molecular formula	$C_{35}H_{36}ClNO_3S$
Molecular weight	586.2 g/mol
Pharmacological group	Leukotriene receptor antagonist
Solubility	Limited in water, readily soluble in organic solvents
Physical state	Hygroscopic powder
Lipophilicity	High
Main metabolism	Hepatic metabolism via CYP_3A_4 and CYP_2C_9

The efficacy of pharmaceutical preparations largely depends on the composition of excipients. Excipients play an important role in controlling the disintegration, solubility, mechanical strength, stability, and biopharmaceutical properties of a preparation. In modern pharmaceutical technology, excipients are considered not merely as inert components but as important factors shaping the quality of the preparation.

Montelukast tablets commonly contain excipients such as lactose monohydrate, microcrystalline cellulose (MCC), croscarmellose sodium, magnesium stearate, and hydroxypropyl methylcellulose (HPMC). These substances are used to optimize tablet formation, disintegration rate, and dissolution profile.

Lactose monohydrate is one of the most widely used filling agents. It provides the tablet with the required volume and improves compression properties. However, lactose may affect the stability of certain preparations under hygroscopic

conditions. Microcrystalline cellulose increases the mechanical strength of tablets and optimizes the granulation process.

Croscarmellose sodium is an important disintegrant that reduces the disintegration time of the preparation. This substance swells upon contact with water and facilitates rapid tablet disintegration. As a result, the dissolution rate of the active substance increases and its biological absorption improves.

Table 2

Main exipients found in montekulast preparation and their pharmaceutical importance

Excipients	Pharmaceutical Function	Effect on Product Quality
Lactose monohydrate	Filler	Forms the tablet mass
Microcrystalline cellulose (MCC)	Binder and strengthening agent	Increases mechanical strength
Croscarmellose sodium	Disintegrant	Ensures rapid tablet disintegration
Magnesium stearate	Lubricant	Facilitates the compression process
HPMC (Hypromellose)	Film-forming agent	Improves stability and external protection
Opadry	Film coating material	Protects against moisture and light

Magnesium stearate is one of the most widely used lubricants in pharmaceutical technology. It reduces the adhesion of tablet mass to compression molds during the tableting process. However, when used in high concentrations, it may form a hydrophobic layer that can negatively affect the solubility of the active substance.

Coating agents such as hypromellose (HPMC) and Opadry protect the preparation from environmental influences. In particular, the susceptibility of montelukast to degradation under the influence of light and moisture increases the importance of coating technology. Packaging materials also play an important role in ensuring the stability of the preparation.

Table 3

Comperative composition of selected monteculast preparation

Product name	Manufacturer	Active substances	Main exepients
Monteksa	Nika Pharm	Montelukast sodium 10 mg	Lactose, MCC, magnesium stearate
Singlon	Gedeon Richter	Montelukast sodium 10 mg	Lactose, HPMC, croscarmellose
Monte	AmantisMed Belarus	Montelukast sodium 10 mg	MCC, stearatlar
Montezid	Zota Healthcare Ltd	Montekulast sodium 10 mg	Hypromellose, MCC
L-gis	Jayhun Invest	Montekulast sodium 10 mg	Lactose, MCC,croscarmellose

Although local and foreign montelukast preparations available in the pharmaceutical market are compositionally similar, they may differ in the ratio of excipients and manufacturing technologies. These differences may affect the dissolution profile, disintegration time, and biopharmaceutical characteristics of the preparations.

Excipients used in different preparations may affect the dissolution rate, physicochemical stability, and biological absorption parameters. Therefore, in evaluating the

pharmaceutical equivalence of montelukast preparations, it is important to consider not only the amount of active substance but also the qualitative and quantitative composition of excipients.

In modern pharmaceutical research, high-performance liquid chromatography (HPLC), UV spectrophotometry, dissolution testing, and stability analysis are widely used to evaluate the quality of montelukast preparations. These methods are used to assess the chemical composition, degradation products, solubility, and pharmaceutical quality parameters of the preparation. This makes it possible to scientifically compare the pharmaceutical and biopharmaceutical properties of local and foreign generic preparations.

Biopharmaceutical properties and dissolution profile of montelukast preparations

In modern pharmaceutical research, studying the biopharmaceutical properties of medicinal products is of great importance in evaluating their therapeutic efficacy. The biological absorption of a drug in the body directly depends on its physicochemical properties, dosage form, excipient composition, and dissolution profile. Especially in the evaluation of generic preparations, biopharmaceutical parameters make it possible to identify pharmaceutical and therapeutic differences between preparations.

Montelukast is a synthetic antileukotriene drug with lipophilic properties. The drug has relatively limited water solubility, which is one of the important factors affecting its dissolution and biological absorption characteristics. The use of montelukast in the form of its sodium salt serves to increase its solubility and improve its bioavailability parameters.

The biopharmaceutical properties of montelukast are determined by its molecular structure, lipophilicity, and solubility. The drug is well absorbed through the intestinal mucosa and extensively binds to plasma proteins. The therapeutic efficacy of the drug is closely associated with the rate of release of the active substance from the dosage form and its dissolution in the gastrointestinal tract.

From a biopharmaceutical point of view, medicinal substances are classified according to the Biopharmaceutics Classification System (BCS) based on their solubility and permeability characteristics. Although montelukast has high permeability, it exhibits limited water solubility. Therefore, the dissolution profile of the preparation is considered one of the main factors determining its biological absorption.

Table 4

Main biopharmaceutical properties of montelukast

Parameters	Description
Lipophilicity	High
Water solubility	Limited
Permeability	High
Biological absorption	Good
Dosage form	Film-coated tablet
Main absorption site	Small intestine
Factors affecting bioavailability	Dissolution, excipients, coating technology

Dissolution testing is an important pharmaceutical analytical method used to evaluate the rate at which a drug releases its active substance into a dissolution medium over a certain period of time. This test is widely applied in predicting the biological absorption of a preparation, comparing generic products, and performing quality control.

The dissolution profile of montelukast preparations significantly depends on the composition of excipients and manufacturing technologies. Disintegrants such as croscarmellose sodium ensure rapid tablet disintegration, whereas magnesium stearate, due to its hydrophobic properties, may reduce the dissolution rate.

Dissolution tests are usually performed using USP apparatuses. One of the most commonly used methods is the paddle apparatus (USP II). During the study, the amount of active substance released into the solution at specific time intervals is determined. The dissolution profile is commonly evaluated at intervals of 15, 30, 45, and 60 minutes.

Pharmaceutically equivalent preparations may differ in their dissolution profiles. This is particularly important for

montelukast preparations because the drug has limited water solubility. Therefore, even minor differences in excipient composition and manufacturing technology may significantly affect the solubility and biological absorption of the active substance.

Table 5

Main factors affecting the dissolution profile

Factor	Effect on Dissolution Profile
Tablet Hardness	High hardness reduces the dissolution rate.
Croscarmellose Sodium	Accelerates disintegration.
Magnesium Stearate	May form a hydrophobic layer.
Coating Material	Affects solubility and stability.
Particle Size	Smaller particles dissolve faster.
Moisture Content	Affects both stability and dissolution.

Comparative analysis of the dissolution profiles of local and foreign montelukast preparations has important scientific significance in evaluating their pharmaceutical quality. Although some generic preparations are considered pharmaceutically equivalent in terms of active substance content, they may differ in dissolution rate and biopharmaceutical properties. This may affect the therapeutic efficacy and pharmacokinetic parameters of the preparations.

The dissolution profile is also an important parameter in evaluating the bioequivalence of generic preparations. Preparations with similar dissolution profiles may exhibit similar pharmacokinetic characteristics in the body. Therefore, dissolution testing is considered an integral part of modern pharmaceutical quality control.

Comprehensive investigation of the biopharmaceutical properties of montelukast preparations has important scientific and practical significance in evaluating the quality of generic products, selecting optimal excipients, and improving the therapeutic efficacy of preparations.

Modern approaches to quality control and stability evaluation of montelukast preparations

In the modern pharmaceutical industry, quality control and stability evaluation of medicinal products are considered important stages in ensuring their therapeutic efficacy and safety. Particularly for preparations such as montelukast, which are used for long-term pharmacotherapy of bronchial asthma, monitoring physicochemical stability and pharmaceutical quality parameters is of great importance. The increasing number of generic preparations further intensifies the need to evaluate their pharmaceutical equivalence and stability using modern analytical methods.

High-performance liquid chromatography (HPLC) is considered one of the most important analytical methods in the quality control of montelukast preparations. This method allows highly accurate evaluation of the active substance content, impurities, and degradation products contained in the preparation. The sensitivity and selectivity of the HPLC method contribute to its wide application in controlling the pharmaceutical quality of montelukast products. In addition, UV spectrophotometry is considered one of the simple and economically convenient methods used to determine the concentration of the active substance in the preparation.

Temperature, humidity, and light have significant effects on the stability of montelukast preparations. The lipophilic properties of the drug and the susceptibility of certain chemical groups to oxidation may intensify degradation processes under improper storage conditions. Therefore, stability studies of the preparations are conducted in accordance with the recommendations of the International Council for Harmonisation (ICH). During stability testing, the appearance of the preparation, active substance content, dissolution profile, and physicochemical parameters are monitored.

Excipients and packaging materials also play an important role in ensuring the stability of preparations. In particular, Alu-Alu blister packaging provides high protective properties for moisture-sensitive preparations. Packaging technology directly affects the shelf life and physicochemical stability of the preparation.

Table 6

Main methods used for quality control and stability evaluation of montelukast preparations

Method	Evaluated Parameter	Pharmaceutical Importance
HPLC	Active substance and impurities	High accuracy and selectivity
UV spectrophotometry	Concentration	Rapid and cost-effective method
Dissolution test	Dissolution profile	Evaluation of bioavailability
Stability analysis	Stability	Determination of shelf life
Friability test	Mechanical strength	Resistance to transportation
Hardness test	Tablet hardness	Affects disintegration and dissolution

Thus, evaluation of the quality control and stability of montelukast preparations using modern analytical methods has important scientific and practical significance in determining the pharmaceutical equivalence of generic preparations, ensuring their therapeutic efficacy, and improving pharmaceutical quality control systems.

2. Conclusion

Montelukast is considered one of the modern antileukotriene drugs that occupies an important place in the pharmacotherapy of bronchial asthma and allergic rhinitis. The mechanism of action of the drug, based on selective blockade of leukotriene receptors, provides high therapeutic efficacy in reducing bronchospasm, inflammation, and airway hyperreactivity. The oral administration of montelukast, its convenience in pediatric practice, and its importance in long-term control therapy contribute to its widespread use in the pharmaceutical market.

As a result of the development of the pharmaceutical industry, numerous generic preparations based on montelukast are being manufactured. However, preparations containing the same amount of active substance may differ in excipient composition, manufacturing technology, coating materials, and physicochemical properties. These differences may potentially affect the dissolution profile, stability, biopharmaceutical characteristics, and biological absorption of the preparations.

In modern pharmaceutical technology, excipients are considered not merely as inert components but as important factors influencing the quality of the preparation. Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, and coating-forming polymers significantly affect the disintegration, solubility, mechanical strength, and stability parameters of the preparation. Therefore, in evaluating generic preparations, it is important to thoroughly analyze not only the active substance content but also the composition of excipients.

Dissolution testing is an important analytical parameter in evaluating the biopharmaceutical properties of montelukast preparations. Differences in dissolution profiles may affect the bioavailability and therapeutic efficacy of the preparation. Furthermore, the susceptibility of montelukast to degradation under the influence of light, moisture, and temperature increases the relevance of stability studies. Therefore, special attention should be paid to storage conditions and packaging technology of the preparations.

The use of modern analytical methods such as HPLC, UV spectrophotometry, dissolution testing, and stability analysis is of great scientific and practical importance in evaluating the quality of generic montelukast preparations. These methods make it possible to determine the pharmaceutical equivalence, physicochemical stability, and quality parameters of the preparations. In particular, comparative evaluation of local and foreign preparations plays an important role in improving pharmaceutical quality control systems.

In future scientific studies, it is advisable to conduct in-depth investigations of the dissolution kinetics, long-term stability parameters, bioequivalence characteristics, and the effects of excipients on the biopharmaceutical properties of montelukast preparations. At the same time, evaluating the compliance of local generic preparations with international pharmaceutical standards and further improving pharmaceutical quality control systems remain among the актуal directions of modern pharmacy.

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