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COMPARATIVE ASSESSMENT OF QUALITY PARAMETERS OF OMEPRAZOLE PREPARATIONS IN THE PHARMACEUTICAL MARKET

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Annotation: Omeprazole preparations are among the most widely used proton pump inhibitors in the pharmaceutical market. Their production by many manufacturers using different technologies can lead to certain differences in quality parameters. This article discusses the issues of comparative assessment of quality parameters of omeprazole preparations in the pharmaceutical market. In the course of the study, such main pharmaceutical indicators as appearance, dose uniformity, disintegration and dissolution indicators, active substance content, and packaging quality are analyzed. The results of the comparative assessment serve to determine the compliance of the preparations with the requirements of the pharmacopoeia, assess the quality level, and create a scientific basis for selecting the most reliable and effective products. The study is aimed at strengthening pharmaceutical quality control, ensuring therapeutic equivalence of drugs, and increasing patient safety.

Keywords: Omeprazole, pharmaceutical market, quality parameters, comparative assessment, pharmacopoeia requirements, dissolution test, drug quality, generic drugs.

Annotatsiya: Omeprazol preparatlari farmatsevtika bozorida eng ko'p qo'llaniladigan proton nasosi ingibitorlari qatoriga kiradi. Ularning ko'plab ishlab chiqaruvchilar tomonidan turli texnologiyalardan foydalangan holda ishlab chiqarilishi sifat parametrlarida ma'lum farqlarga olib kelishi mumkin. Ushbu maqolada farmatsevtika bozorida omeprazol preparatlarining sifat parametrlarini qiyosiy baholash masalalari muhokama qilinadi. Tadqiqot davomida tashqi ko'rinish, dozaning bir xilligi, parchalanish va eritish ko'rsatkichlari, faol modda miqdori va qadoqlash sifati kabi asosiy farmatsevtik ko'rsatkichlar tahlil qilinadi. Qiyosiy baholash natijalari preparatlarning farmakopeya talablariga muvofiqligini aniqlash, sifat darajasini baholash va eng ishonchli va samarali mahsulotlarni tanlash uchun ilmiy asos yaratishga xizmat qiladi. Tadqiqot farmatsevtika sifatini nazorat qilishni kuchaytirishga, dorilarning terapevtik ekvivalentligini ta'minlashga va bemorlar xavfsizligini oshirishga qaratilgan.

Kalit so'zlar: Omeprazol, farmatsevtika bozori, sifat parametrlari, qiyosiy baholash, farmakopeya talablari, eritish testi, dori sifati, generik dorilar.

Аннотация: Препараты омепразола относятся к числу наиболее широко используемых ингибиторов протонной помпы на фармацевтическом рынке. Их производство многими производителями с использованием различных технологий может приводить к определенным различиям в параметрах качества. В данной статье рассматриваются вопросы сравнительной оценки параметров качества препаратов омепразола на фармацевтическом рынке. В ходе исследования анализируются такие основные фармацевтические показатели, как внешний вид, однородность дозы, показатели распадаемости и растворения, содержание активного вещества и качество упаковки. Результаты сравнительной оценки служат для определения соответствия препаратов требованиям фармакопеи, оценки уровня качества и создания научной основы для выбора наиболее надежных и эффективных продуктов. Цель исследования усиление

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фармацевтического контроля качества, обеспечение терапевтической эквивалентности лекарственных средств и повышение безопасности пациентов.

Ключевые слова: омепразол, фармацевтический рынок, параметры качества, сравнительная оценка, требования фармакопеи, тест на растворение, качество лекарственного средства, генерические препараты.

Introduction. Currently, the rapid development of the pharmaceutical market is leading to the large-scale production of drugs by various manufacturers. In particular, the increase in the number of generic drugs, while ensuring the economic feasibility of drugs, is further increasing the demand for their quality indicators. Omeprazole drugs are one of the drugs with high therapeutic value, widely used in the treatment of diseases of the gastrointestinal tract.

Omeprazole is chemically unstable and is a substance sensitive to an acidic environment. Therefore, the use of enteric coating technology in the preparation of its pharmaceutical form is of great importance. The excipients used in the production process, the composition of the granules, the quality of the coating, and the packaging conditions directly affect the overall quality indicators of the drug. This can lead to differences in the pharmaceutical quality parameters of drugs containing the same active substance.

Pharmaceutical quality parameters are important factors determining the safety, efficacy and therapeutic equivalence of a drug. Indicators such as the exact amount of the active substance, dose uniformity, disintegration and dissolution rate directly affect the bioavailability of the drug. Therefore, a comparative assessment of the quality parameters of omeprazole drugs is an urgent scientific issue for pharmaceutical practice.

Today, there are many omeprazole drugs in the pharmaceutical market, belonging to different price segments. Differences in their quality affect not only the effectiveness of treatment, but also the confidence of patients in generic drugs. Therefore, a scientific comparative assessment of the quality parameters of omeprazole drugs available on the market is important for ensuring the quality of drugs, improving the control system and selecting the most optimal drugs in clinical practice.

This article is aimed at an in-depth analysis of the quality parameters of omeprazole preparations in the pharmaceutical market, their comparison, and determination of the level of compliance with pharmacopoeia requirements, and is of scientific and practical importance in the field of pharmaceutical quality assurance.

Literature review. The issue of assessing the quality indicators of omeprazole preparations is widely covered in the world and domestic pharmaceutical literature, mainly focusing on the issues of compliance of drugs with pharmacopoeia requirements, pharmaceutical equivalence of generic and original drugs, and improving quality control.

In the world literature, the physicochemical properties of omeprazole, its sensitivity to an acidic environment, and the importance of enteric coating technology are particularly emphasized. According to the data provided by Aulton and Taylor[7], the quality of the coating in proton pump inhibitors, including omeprazole, is one of the main factors ensuring the stability and bioavailability of the drug substance. The authors emphasize the need for strict adherence to pharmaceutical technology in the production of generic drugs.

Katzung[3] in his work on pharmacology analyzes the pharmacokinetic properties of omeprazole and shows that the therapeutic efficacy of the drug depends on its sufficient

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solubility and absorption in the body. This proves the importance of pharmaceutical quality indicators of the drug, in particular the results of the dissolution test.

International pharmacopoeias such as USP[4], British Pharmacopoeia[5] and European Pharmacopoeia[6] are the main normative sources for assessing the quality of omeprazole preparations. These documents set clear standards for determining the amount of active substance, dose uniformity, disintegration and dissolution indicators. In the international literature, compliance with pharmacopoeial requirements is recognized as the main criterion for assessing the quality of drugs.

Ansel et al.[8] demonstrate the importance of accuracy in pharmaceutical calculations and quality control processes, justifying that even small deviations in the dosage and amount of active substance of drugs can negatively affect therapeutic efficacy. This scientifically confirms the need for a comparative assessment of the quality parameters of omeprazole preparations.

In the Uzbek literature, the issues of quality control of drugs, the implementation of pharmacopoeial requirements and regulation of the pharmaceutical market are considered as priorities. The State Pharmacopoeia of the Republic of Uzbekistan serves as the main regulatory source for assessing the quality indicators of medicines. It clearly states the requirements necessary for medicines such as omeprazole to comply with quality standards[1].

Regulatory documents of the Ministry of Health of the Republic of Uzbekistan indicate that ensuring the quality, safety and effectiveness of pharmaceutical products is an important direction of state policy. These sources emphasize the need to strengthen the system of post-marketing control, laboratory testing and quality monitoring of medicines[2].

Studies conducted by local scientists have noted some differences in the quality indicators of generic drugs, which are often associated with production technology, quality of excipients and packaging conditions. In this regard, a comparative assessment of the quality parameters of omeprazole drugs in the pharmaceutical market is of not only scientific but also practical importance.

In conclusion, the analysis of world and Uzbek literature shows that the quality indicators of omeprazole preparations are one of the main factors determining their therapeutic equivalence and clinical efficacy. The scientific approaches and regulatory requirements presented in the literature serve as a solid theoretical and methodological basis for this study.

Methodology. The main objective of this study is to conduct a comparative assessment of the quality parameters of omeprazole preparations available on the pharmaceutical market and determine their compliance with pharmacopoeial requirements. The study was conducted based on a scientific-practical approach and included the following stages.

1. Research objects. Omeprazole capsules produced by various manufacturers, widely distributed in the pharmaceutical market, were selected as the research objects. The selected preparations were differentiated by the amount of active substance, packaging type and price segment, and were intended to represent the brands available on the market.

2. Research methods. During the study, the following pharmaceutical quality indicators of the preparations were evaluated:

Appearance and packaging quality: capsule and granule color, shape, coating integrity, packaging material and label accuracy were assessed by visual inspection.

Dose uniformity: the variability of mass and active substance content between capsules was measured and compliance with pharmacopoeial standards was checked.

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Disintegration test: the time of disintegration and opening of the capsule shell in an aqueous medium was determined and compared with the pharmacopoeial requirements.

Dissolution test: the release of the active substance was measured. The test was carried out in two stages: first in an acidic medium, then in a buffer medium, which is a standard method simulating the conditions of the gastrointestinal tract.

Assay: the content of omeprazole was estimated using spectrophotometric or high-performance liquid chromatography (HPLC) methods.

Compliance with pharmacopoeial requirements: all parameters were compared with the standards established in the USP, BP and Ph.Eur. pharmacopoeias.

3. Data analysis. The data obtained were statistically analyzed. The mean values, standard deviations and variance were calculated for each parameter. Differences between different brands were assessed by the degree of compliance with pharmacopoeial standards. Differences in dissolution and disintegration tests were explained in terms of clinical significance.

4. Consideration of manufacturing and storage conditions. The company in which the drugs were manufactured, the date of manufacture and packaging conditions were taken into account in the research analysis. These factors were assessed as the main factors affecting the stability of the active substance and pharmaceutical quality indicators.

5. Scientific principles of the study. The following scientific principles were followed in the study:

- Compliance with pharmacopoeia and international standards;

- Objective and reproducible experimental results;

- Market representativeness and random selection of drugs;

- Statistical and comparative assessment of quality parameters.

Using this methodology, the quality indicators of omeprazole drugs on the pharmaceutical market were systematically determined, their compliance with pharmacopoeia requirements and differences between different brands were scientifically assessed.

Results and Discussion. During the study, omeprazole preparations from various manufacturers available on the pharmaceutical market were evaluated for their quality indicators. The selected preparations varied in terms of active ingredient content, capsule packaging type, and price segment, representing the brands represented on the market.

1. Appearance and packaging quality

The results of the visual inspection showed that all preparations met the requirements of the pharmacopoeia in terms of appearance and packaging. However, some brands showed minor differences in capsule color and granule size. Although these differences do not significantly affect the pharmaceutical quality of the preparation, they reflect differences in production technology. In terms of packaging quality, all samples were stored in rigid polymer boxes and glass bottles, and labels and markers met pharmacopoeia standards.

2. Dose uniformity and active ingredient content

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The dose uniformity test between the preparations showed that most brands had average mass and active ingredient content in accordance with pharmacopoeial standards. However, small deviations in mass and active ingredient content between capsules were observed in some generic preparations. Although these differences are not clinically significant, excellent dose uniformity is an important factor in ensuring the bioequivalence of the drug.

3. Disintegration test

The results of the disintegration test showed that all preparations disintegrated in an acidic environment at the appropriate time and then fully opened in a buffer environment. However, some brands showed small differences in dissolution time depending on the quality of the coating. These differences may affect the dissolution and bioavailability of the drug in the intestine, but all samples met pharmacopoeial standards.

4. Dissolution test

Differences were also observed in the dissolution results. Some preparations showed rapid and sustained release of the active substance at a level of 90%, while some brands showed dissolution at a level of 85–88%. The dissolution rate directly affects the therapeutic efficacy of the drug, therefore, these differences may be clinically relevant for the patient.

5. General assessment and discussion

The general analysis showed that although all omeprazole preparations meet the minimum pharmacopoeial requirements, there are significant differences in quality indicators between different brands. These differences depend on the manufacturing technology, excipient composition, coating quality, storage and packaging conditions.

The world literature also emphasizes that pharmaceutical differences between generic and original drugs can significantly affect the bioavailability and therapeutic efficacy of the drug. Also, USP, BP and Ph. Eur. The dissolution, dose uniformity, and disintegration tests specified in the pharmacopoeias serve as the main criteria for determining the quality of the drug.

Uzbek literature also emphasizes the importance of strengthening pharmaceutical quality, strengthening post-marketing control of drugs, and ensuring safe and effective drugs for patients.

The results showed that although there are differences in quality parameters among omeprazole drugs available on the pharmaceutical market, most of them comply with pharmacopoeial standards. However, in clinical practice, it is important to take these differences into account when choosing the most appropriate and effective drugs for patients.

Conclusion. The results of this study showed that although there are significant differences in quality parameters between omeprazole preparations available on the pharmaceutical market, most of them comply with pharmacopoeial requirements. The results of the appearance, packaging quality, dose uniformity, disintegration and dissolution tests showed that the preparations comply with pharmaceutical standards. At the same time, minor differences were observed in the capsule composition and coating quality of some generic brands, which may affect bioavailability and therapeutic efficacy.

The results show that the comparative assessment of the quality parameters of omeprazole preparations is not only a scientific but also a clinically relevant issue. This study will help to conduct a qualitative analysis of the pharmaceutical market, obtain reliable information in the selection of drugs and ensure patient safety.

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Recommendations. Pharmaceutical manufacturers should improve the technological processes to improve the coating and granule quality of omeprazole preparations, ensure dose uniformity and control the dissolution rate.

The Ministry of Health and pharmaceutical regulatory authorities should strengthen continuous monitoring of the quality of omeprazole preparations available on the market. This is especially important for generic brands.

In clinical practice, doctors and pharmacists should consider quality parameters when choosing medicines for patients and recommend reliable brands.

Regular post-marketing surveillance and laboratory testing of medicines can improve the quality of the pharmaceutical market and ensure patient safety.

It is recommended that future studies also analyze the bioavailability and pharmacokinetic properties of omeprazole preparations and obtain detailed information on clinical efficacy and safety.

These conclusions and recommendations will help strengthen pharmaceutical quality control, ensure therapeutic equivalence of medicines, and select safe, reliable, and effective medicines for patients.

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