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STUDY OF THE ANTI-INFLAMMATORY ACTIVITY OF «ETICOX» FILM-COATED TABLETS

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ABSTRACT

This article presents the results of experimental studies conducted to evaluate the bioequivalence of the non-steroidal anti-inflammatory drug «Eticox» (film-coated tablets, 60 mg, 90 mg, and 120 mg), manufactured by NOVUGEN PHARMA LLC (Uzbekistan), and the reference drug «Arcoxia®» (film-coated tablets, 60 mg, 90 mg, and 120 mg), manufactured by Merck Sharp & Dohme B.V. (Netherlands). As part of the bioequivalence studies, a comparative assessment of the anti-inflammatory activity of the drugs was conducted using a formalin-induced acute inflammation model. The study results demonstrated no statistically significant differences ($p > 0.05$) between the «Eticox» drug and the reference drug regarding anti-inflammatory efficacy, as well as their bioequivalence in terms of specific pharmacological activity.

ИССЛЕДОВАНИЕ ПРОТИВОВОСПАЛИТЕЛЬНОЙ АКТИВНОСТИ ТАБЛЕТОК «ЭТИКОКС», ПОКРЫТЫХ ПЛЁНОЧНОЙ ОБОЛОЧКОЙ

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ABSTRACT

В данной статье представлены результаты экспериментальных исследований по оценке биологической эквивалентности нестероидного противовоспалительного препарата «Этикокс» (таблетки, покрытые плёночной оболочкой, 60 мг, 90 мг и 120 мг), производимого ООО «NOVUGEN PHARMA» (Узбекистан), и референтного препарата «Аркоксиа®» (таблетки, покрытые плёночной оболочкой, 60 мг, 90 мг и 120 мг), выпускаемого компанией «Merck Sharp & Dohme B.V.» (Нидерланды).

В рамках исследования биологической эквивалентности была проведена сравнительная оценка противовоспалительной активности

эквивалентность, генерический препарат, референтный препарат.

препаратов на модели острого воспаления, индуцированного формалином. Результаты исследования показали отсутствие статистически значимых различий (p > 0,05) между препаратом «Этикокс» и референтным препаратом по противовоспалительной эффективности, что свидетельствует об их биологической эквивалентности по специфической фармакологической активности.

Introduction. Inflammation is a complex biological protective response of the organism to infectious agents, mechanical injury, chemical factors, and autoimmune processes. Although this process is aimed at repairing damaged tissues and eliminating pathogenic factors, its prolonged nature or uncontrolled activation is recognized as a significant pathogenetic factor in the development of numerous chronic diseases [1, 2].

In particular, in rheumatic diseases such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and gout, the excessive production of inflammatory mediators leads to increased pain, impaired joint function, and a significant reduction in patients' quality of life. Furthermore, chronic inflammatory processes play a key role in the progression and development of complications associated with conditions such as atherosclerosis, ischemic heart disease, and Alzheimer's and Parkinson's diseases [2, 3].

Thus, anti-inflammatory drugs are an integral part of modern pharmacotherapy. These agents are widely used to reduce pain, suppress the inflammatory response, and alleviate the clinical course of the disease. However, long-term use of traditional non-steroidal anti-inflammatory drugs increases the risk of adverse events affecting the gastrointestinal tract, kidneys, and cardiovascular system. Consequently, recent years have seen a particular focus on the development of next-generation drugs characterized by high efficacy and an improved safety profile [4, 5, 6].

To foster the development of the domestic pharmaceutical industry, create import-substituting medicines, and meet the population's need for modern pharmaceutical products, «Eticox» film-coated tablets—available in 60 mg, 90 mg, and 120 mg dosages—were developed through the collaboration of scientists from the Tashkent Pharmaceutical Institute and «NOVUGEN PHARMA» LLC. The scientific assessment of the efficacy and safety of a domestically produced drug is one of the key stages in its introduction into industrial production.

The aim of this study is to evaluate the specific pharmacological activity of the developed film-coated «Eticox» tablets under experimental conditions and to conduct a comparative analysis of the obtained results with data from the reference drug.

Methods and materials. The experimental part of the study

investigated the specific anti-inflammatory activity of film-coated «Eticox» (etoricoxib) tablets (at dosages of 60, 90, and 120 mg) developed jointly by the Tashkent Pharmaceutical Institute and «NOVUGEN PHARMA» LLC. «Arcoxia®» film-coated tablets (60 mg, 90 mg, and 120 mg) manufactured by Merck Sharp & Dohme B.V. (Netherlands) were used as the comparator drug.

The anti-inflammatory activity of the preparations was evaluated using a model of acute experimental inflammation—the formalin-induced rat paw edema method. This model is considered one of the reliable and widely used experimental methods for determining the pharmacological efficacy of non-steroidal anti-inflammatory drugs [7].

The study was conducted on 18 white laboratory rats of both sexes, weighing 180–200 g. Prior to the experiment, the animals were kept under quarantine conditions in the vivarium for 14 days. The following housing conditions were maintained: an air temperature of 20–22°C, a relative humidity of no more than 50%, an air exchange rate of 8–10 times per hour, and a natural lighting regimen (day–night cycle). The animals were housed in standard plastic cages and fed a standard diet intended for laboratory animals [7, 8].

The test doses and routes of administration were selected in accordance with the recommendations of the «Guidelines for the Experimental (Preclinical) Study of New Pharmacological Substances». All stages of the study were conducted in compliance with bioethical principles for working with experimental animals and in accordance with the requirements of the «European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes»."

Before the start of the experiment, the volume of the left hind paw of all animals was measured three times using a plethysmometer, and the mean of the obtained results was taken as the baseline value.

A model of acute inflammation in experimental animals was induced by injecting 0.1 ml of a 2% formalin solution into the plantar region between the first and second digits of the left hind paw. Formalin exposure enhanced the release of inflammatory mediators—such as histamine, serotonin, bradykinin, and prostaglandins—leading to the development of local edema and an inflammatory response.

The drugs were administered once intragastrically (per os) at a dose of 100 mg/kg, 120 minutes prior to formalin administration. Animals in the control group received an equivalent volume of purified water [7, 8].

The intensity of the inflammatory response was assessed using a plethysmometer three hours after formalin administration. Measurements were performed using a plethysmometer equipped with a water chamber (24 mm in diameter) and a curved outlet tube. The increase in paw volume was taken as the primary criterion reflecting the degree of inflammation.

The anti-inflammatory activity (AIA) of the preparations was calculated using the following formula:

$$AIA=\frac{(\Delta Vk-\Delta Vd)}{\Delta Vk}\times 100\%$$

Here:

AIA — anti-inflammatory activity;

ΔV_k — mean edema volume in the control group (pathology control);

ΔV_d — mean edema volume in the experimental group.

The obtained results were subjected to statistical analysis, and the significance of differences between groups was assessed using parametric statistical methods. A p-value of < 0.05 was considered statistically significant.

Allocation of animals into groups. The rats used in the experiment were randomly assigned to three groups of six animals each.

Group 1 (pathological control): the animals were administered 2 ml of purified water orally. After 120 minutes, 0.1 ml of a 2% formalin solution was injected into the plantar surface of the left hind paw to induce a model of acute inflammation.

Group 2 (experimental): the animals were orally administered the drug «Eticox» (film-coated tablets in dosages of 60, 90, and 120 mg; manufacturer: NOVUGEN PHARMA LLC, Uzbekistan) at a dose of 100 mg/kg. One hundred and twenty minutes after drug administration, 0.1 ml of a 2% formalin solution was injected into the left hind paw.

Group 3 (comparison): animals were orally administered the drug «Arcoxia®» (film-coated tablets in dosages of 60, 90, and 120 mg; manufacturer: Merck Sharp & Dohme B.V., Netherlands) at a dose of 100 mg/kg. One hundred and twenty minutes after drug administration, 0.1 ml of a 2% formalin solution was injected into the left hind paw.

Assessment of the inflammatory process. The anti-inflammatory efficacy of the drugs was evaluated using an oncometric (plethysmometer) method based on measuring changes in paw volume. Paw volume was recorded as a baseline value prior to formalin administration and measured again 180 minutes after the induction of inflammation. An increase in paw volume indicated the degree of inflammation, whereas a reduction in edema reflected the anti-inflammatory activity of the drug.

The obtained results were statistically analyzed using STATISTICA for Windows 9.5 software. The calculated data are presented as the arithmetic mean (M) and standard error (m). The statistical significance of differences between groups was assessed using Student's t-test. A p-value < 0.05 was considered indicative of a statistically significant difference.

Results obtained. The anti-inflammatory activity of «Eticox» film-coated tablets was evaluated using a rat paw edema model induced by formalin injection ($n = 6$). The results were compared with those of the reference drug «Arcoxia®» .

The study results demonstrated that the developed drug exhibited pronounced anti-inflammatory activity at all doses tested. In the groups treated with the drug, a significant reduction in formalin-induced paw edema was observed compared to the pathological control group.

In particular, following oral administration at a dose of 100 mg/kg, the «Eticox» tablet (60 mg, film-coated) reduced paw edema by 42% three hours

post-administration in a formalin-induced inflammation model, compared to the pathological control group.

The comparator drug—«Arcoxia®» film-coated tablets (60 mg)—also demonstrated a pronounced anti-inflammatory effect upon oral administration at a dose of 100 mg/kg. In this group, anti-inflammatory activity (AIA) was 51% (Table 1).

Thus, the developed drug «Eticox» demonstrated high pharmacological activity in a model of acute inflammation induced by formalin administration and showed therapeutic efficacy comparable to that of the reference drug.

Table 1

Determination of the anti-inflammatory activity of the «Eticox» 60 mg preparation

Body weight, gr	Dose		Average volume of a healthy foot, ml	Paw volume (ml) 3 hours after formalin injection	Increase in paw volume compared to normal, ml	AIA, %
	mg/kg	ml				
Control group (NaCl)						
189 ± 6,4	-	2	1,05±0,1	1,5 ± 0,06	0,45 ± 0,05	-
«Eticox» tablets (NOVUGEN PHARMA LLC, Uzbekistan)						
188,3±4,3	100	2	1,0±0,07	1,28±0,07	0,26±0,05	42
«Arcoxia®» tablets («Merck Sharp & Dohme B.V.», Netherlands)						
187±5,6	100	2	1,08±0,07	1,3±0,08	0,22±0,07	51

«Eticox» tablets (90 mg, film-coated), manufactured by «NOVUGEN PHARMA» LLC (Uzbekistan), when administered orally at a dose of 100 mg/kg in a formalin-induced acute inflammation model, significantly reduced rat paw edema by 44% after 3 hours compared to the pathological control group [7, 8].

Under similar experimental conditions, the comparator drug—«Arcoxia®» film-coated tablets, 90 mg (manufacturer: Merck Sharp & Dohme B.V., Netherlands)—also demonstrated a pronounced anti-inflammatory effect upon oral administration at a dose of 100 mg/kg. The anti-inflammatory activity (AIA) of the preparation three hours after formalin administration was 49% (Table 2).

Table 2

Determination of the anti-inflammatory activity of the drug «Eticox» 90 mg

Body weight, gr	Dose		Average volume of a healthy foot, ml	Paw volume (ml) 3 hours after formalin injection	Increase in paw volume compared to normal, ml	AIA, %
	mg/kg	ml				
Control group (NaCl)						

189 ± 6,4	-	2	1,05±0,1	1,5 ± 0,06	0,45 ± 0,05	-
«Eticox» tablets (NOVUGEN PHARMA LLC, Uzbekistan)						
190±6,8	100	2	1,05±0,08	1,28±0,07	0,25±0,05	44
«Arcoxia®» tablets («Merck Sharp & Dohme B.V.», Netherlands)						
187±5,8	100	2	1,02±0,07	1,25±0,08	0,23±0,08	49

«Eticox» film-coated tablets (90 mg dosage; manufacturer: NOVUGEN PHARMA LLC, Uzbekistan) demonstrated a pronounced anti-inflammatory effect in a formalin-induced acute inflammation model following oral administration at a dose of 100 mg/kg. It was found that three hours after formalin administration, paw edema in rats was significantly reduced—by 44% compared to the pathological control group [8, 9].

Arcoxia® 90 mg (Merck Sharp & Dohme B.V., Netherlands), used as a comparator drug, also demonstrated high anti-inflammatory activity upon oral administration at a dose of 100 mg/kg. The anti-inflammatory activity (AIA) of this preparation was 49% three hours after formalin administration (Table 3).

The results obtained demonstrated that the developed film-coated «Eticox» tablets (90 mg) exhibit anti-inflammatory activity comparable to that of the reference drug Arcoxia® (90 mg) in a model of acute inflammation induced by formalin administration [10, 11].

Table 3

Determination of the anti-inflammatory activity of the drug «Eticox» (120 mg)

Body weight, gr	Dose		Average volume of a healthy foot, ml	Paw volume (ml) 3 hours after formalin injection	Increase in paw volume compared to normal, ml	AIA, %
	mg/kg	ml				
Control group (NaCl)						
189 ± 6,4	-	2	1,05±0,1	1,5 ± 0,06	0,45 ± 0,05	-
«Eticox» tablets (NOVUGEN PHARMA LLC, Uzbekistan)						
188±7,1	100	2	1,0±0,1	1,3±0,06	0,26±0,05	42
«Arcoxia®» tabletks («Merck Sharp & Dohme B.V.», Netherlands)						
188,5±5,6	100	2	1,03±0,08	1,26±0,1	0,23±0,08	49

Conclusion: Studies have shown that «Eticox» film-coated tablets in dosages of 60 mg, 90 mg, and 120 mg, developed by «NOVUGEN PHARMA» LLC (Uzbekistan), exhibit pronounced anti-inflammatory activity in a model of acute inflammation induced by formalin administration. A comparative assessment against the reference drug «Arcoxia®» («Merck Sharp & Dohme B.V.», Netherlands)

revealed no statistically significant differences in anti-inflammatory activity between the products ($p > 0.05$). The results confirm that the developed «Eticox» tablets are bioequivalent to the reference drug.

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