

Determination of the Specific Activity of “Vaidaz” Gel

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Annotation: This study investigates the specific activity and antimicrobial properties of “Vaidaz” gel (15%, Sample 01, Shelf Life 3 years), developed by the Department of Pharmaceutical Production Organization and Quality Management of Medicines at Tashkent Pharmaceutical Institute. The primary objective was to evaluate the gel's anti-inflammatory and antimicrobial effects through both biological and microbiological methods. The research demonstrated that “Vaidaz” gel exhibits significant anti-inflammatory activity, comparable to “Fastum gel”, with a reduction in paw volume by 53.5% to 75.2% in rats after histamine-induced inflammation. In addition, the antimicrobial efficacy of “Vaidaz” gel was assessed through the agar diffusion method, showing a 2.35-fold lesser inhibition zone compared to the standard drug “Ofloxacillin”. These findings confirm that “Vaidaz” gel not only provides anti-inflammatory benefits but also possesses minor antibacterial activity. The results were documented in accordance with GOST and O'zDSt 2762:2018 “Good Laboratory Practice,” validating its potential as a promising therapeutic agent.

Keywords: Specific activity, gel, “Vaidaz”.

Relevance of the problem: The problem of drug provision, rational and safe pharmacotherapy has become one of the most pressing tasks for the activities of clinicians and pharmacists. This is due, on the one hand, to the constantly growing drug market and the volume of scientific information, and on the other hand, to the need to determine the most sought-after groups and classes of drugs. In the context of existing healthcare resources, rational use of high-quality, effective, safe drugs and the creation of new drugs by combining previously known drugs with an innovative approach is a priority task for pharmacy.

Objective of the study: Determination of the specific activity of “Vaidaz” gel.

Materials and methods of the study: “Vaidaz” drug - 15% gel, biological and microbiological methods.

Objective of the study: To study the specific activity of the “Vaidaz” drug - 10% gel (Sample 01, Shelf Life 3 years), developed at the Department of Pharmaceutical Production Organization and Quality Management of Medicines at Tashkent Pharmaceutical Institute in an experiment on white rats.

Results and Discussion:

The anti-inflammatory effect of the gel was studied using the “histamine edema” method on 18 white rats weighing 180-200 g of both sexes, compared with the “Fastum gel” drug produced by A. Menarini Manufacturing Logistics and Services S.r.L, Italy. The paw volume of the rats was measured in the norm beforehand. The compared drugs were applied once topically in a thin layer 1 time a day before histamine administration and every hour during the experiment.^[4] For the experiment, the rats were divided into groups of 6 individuals each.

The drugs were administered as follows: 1st group (control) - 0.1 ml of 1% histamine solution; 2nd group (experimental) - “Vaidaz” drug in a thin layer + 0.1 ml of 1% histamine solution. 3rd group (experimental) - “Fastum gel” drug produced by A. Menarini Manufacturing Logistics and Services S.r.L, Italy in a thin layer + 0.1 ml of 1% histamine solution.

An acute inflammatory reaction (edema) was reproduced by subplantar (between the 1st and 2nd toes of the left hind paw) administration of 0.1 ml of 1% histamine solution. The severity of the inflammatory reaction was assessed 1, 2, and 3 hours after the induction of inflammation by measuring the paw volume using a plethysmograph.

The anti-inflammatory effect (AE) was calculated using the following formula:

$$AE = (V_{exp} - V_{cont} / V_{cont}) \times 100, \text{ where}$$

V_{exp} – edema volume in the experimental group;

V_{cont} – edema volume in the control group.

The results were processed using the method of variation statistics.^[2] The results obtained when studying the anti-inflammatory effect of the compared drugs showed that in rats of the control group, the paw volume after dextran solution administration increased by 62.8% after 1 hour, by 59.5% after 2 hours, and by 48.8% after 3 hours compared to the initial paw volume. With the prophylactic use of “Vaidaz” gel, the paw volume after drug administration was 25.8% less after 1 hour, 33.6% less after 2 hours, and 30.5% less after 3 hours compared to the control indicators. The AE in rats was 53.5-75.2%.

Similar data was obtained when studying the anti-inflammatory activity of the “Fastum gel” drug produced by A. Menarini Manufacturing Logistics and Services S.r.L, Italy. With drug administration, the paw volume after drug administration was 16.2% less after 1 hour, 30.5% less after 2 hours, and 30% less after 3 hours compared to the control indicators. The AE in rats was 24.8-68.5%.

Thus, the obtained results show that “Vaidaz” drug, developed at the Department of Pharmaceutical Production Organization and Quality Management of Medicines at Tashkent Pharmaceutical Institute, possesses anti-inflammatory activity and is not inferior in activity to the “Fastum gel” drug in an experimental aseptic arthritis in rats. The results of the experiment are presented in Table 1.

Table 1. Study of the anti-inflammatory effect of the drug “Vaidaz”

Group	Increase in paw weight, ml Anti-inflammatory effect in %			
	Baseline	1 hour	2 hour	3 hour
Control	1,21±0,05	1,97±0,13 ^x	1,93±0,13 ^x	1,80±0,11 ^x
“Vaidaz” (drug)	1,10±0,04	1,46±0,08 ^{xy} 53,5%	1,28±0,06 ^{xy} 75,1%	1,25±0,05 ^{xy} 75,2%
“Fastum gel” (drug)	1,08±0,04	1,65±0,05 ^x 24,8%	1,34±0,03 ^{xy} 63,0%	1,26±0,02 ^{xy} 68,5%

Note: ^x - significance of differences compared to initial values at $P < 0.05$; ^y - significance of differences compared to the control group values at $P < 0.05$.

The antimicrobial activity of the gel was determined by the agar diffusion method on a dense nutrient medium by comparing the sizes of the zones of inhibition of the growth of test-microbes formed during the testing of solutions of certain concentrations of the standard sample and the test drug.^[6]

Sterile Petri dishes with a flat bottom and the same diameter were used for the analysis. 20 ml of a nutrient medium of a certain composition infected with an 18-20-hour culture of the test strain (St. Aureus) were poured into the dishes placed on a horizontal table. Corresponding nutrient media were used for the studies.

Inoculum preparation: To prepare the inoculum, pure daily cultures of microorganisms grown on dense nutrient media were used. Several identical, clearly isolated colonies were selected. Using a loop, a small amount of material was transferred from the tops of the colonies to a tube with a sterile 0.9% NaCl solution, bringing the density of the inoculum exactly to 0.5 according to the MacFarland standard. The inoculum was used within 15 minutes after preparation.

Analysis: To conduct the test, a solution of the standard sample C1 from the drug “Oflomed” 250 mg / 5 ml produced by Innothera Chouzy, France, and a solution of the test sample I1 from the Vaidaz gel developed at the Department of Pharmaceutical Production Organization and Quality Management of Medicines at Tashkent Pharmaceutical Institute, were prepared. On the solidified agar surface, wells were made in the center with a glass cylinder. The tested drugs were introduced into the wells at the specified concentrations in six Petri dishes.

Incubation: The dishes were placed in a thermostat at a temperature of $(36 \pm 1)^\circ \text{C}$ for 18-24 hours.

After incubation in the thermostat, the zones of inhibition of the growth of microorganisms formed by the solutions of the compared drugs were measured with a microbiological ruler with an accuracy of 1 mm. The antimicrobial activity of the compared drugs was assessed based on the size of the zones.

The obtained data were statistically processed using the STATISTICA program for Windows 95.

After incubation in the thermostat, the zones of inhibition of the growth of microorganisms formed by the solutions of the compared drugs were measured with a microbiological ruler with an accuracy of 1 mm. The antimicrobial activity of the compared drugs was assessed based on the size of the zones.

The obtained data show that the size of the zones of inhibition of the growth of microorganisms under the influence of the tested gel is 2.35 times less compared to the “Oflomed” drug. The results of the experiment are presented in Table 2.

Table 2. Zones of inhibition of the growth of microorganisms under the influence of the tested Vaidaz gel

Preparations	Solution Concentration	• Zones of growth inhibition of microorganisms, mm
		St. aureus
Vaidaz gel	I1	$17,0 \pm 0,4$
Oflomed	C1	40,0

Conclusions: Thus, the study of the specific activity of the drug “Vaidaz” - 15% gel (Sample 01, Shelf Life 3 years), developed at the Department of Pharmaceutical Production Organization and Quality Management of Medicines at Tashkent Pharmaceutical Institute, shows that the drug possesses anti-inflammatory effects. The research results are documented in a scientific report on research work in accordance with the requirements of GOST and O’zDSt 2762:2018 “Good Laboratory Practice,” Tashkent 2018. The study of the antimicrobial activity of the drug “Vaidaz” - 15% gel (Sample 01, Shelf Life 3 years), developed at the Department of Pharmaceutical Production Organization and Quality Management of Medicines at Tashkent Pharmaceutical Institute, shows that the drug possesses anti-inflammatory and minor antibacterial effects.

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