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ASSESSMENT OF THE PHARMACEUTICAL QUALITY OF DICLOFENAC TABLETS SOLD IN PHARMACIES IN THE REPUBLIC OF UZBEKISTAN

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Abstract
The pharmaceutical quality of drugs is of great importance in ensuring their safety, efficacy, and therapeutic effect [2,4]. In particular, the assessment of the quality indicators of diclofenac preparations, which is one of the most widely used non-steroidal anti-inflammatory drugs [5,8]. The aim of this study is to assess the pharmaceutical quality of diclofenac tablets sold in pharmacies of the Republic of Uzbekistan using modern analytical methods. During the study, diclofenac tablets from different manufacturers were selected and their quality indicators were studied using the high-performance liquid chromatography (HPLC) method.

Keywords: Diclofenac, NSAID, pharmaceutical quality, generic drugs, Pharmacopoeia, High-performance liquid chromatography (HPLC).

Introduction

Relevance of the topic:

In recent years, the issues of standardization and quality control of medicines have become relevant worldwide [3,4]. This problem is especially relevant for non-steroidal anti-inflammatory drugs (NSAIDs), in particular diclofenac sodium [6]. Since diclofenac is one of the most widely used pain and inflammation reducing agents, it is produced in several pharmaceutical forms (tablets, capsules, gel, injections, suppositories) by various manufacturers on the Uzbek pharmaceutical market. One of the key documents on the quality control of medicines is the Presidential Decree No. PQ-411 dated October 26, 2022 "On measures to further improve the system for providing the population with quality medicines and medical devices", which introduced new procedures for registering medicines, conducting clinical trials and strengthening quality control, which is aimed at increasing the safety and effectiveness of medicines [1]. However, in practice, differences in the in vitro properties of medicines may occur as a result of different technologies of foreign and domestic manufacturers. Therefore, it is an urgent issue to verify the pharmaceutical quality of brands of diclofenac tablets on the Uzbek market, assess their bioequivalence and confirm the reliability of generic drugs.

Research Objective:

This study aimed to assess the pharmaceutical quality of 50 mg and 25 mg diclofenac tablets produced by foreign and local manufacturers, which are commercially sold in pharmacies of the Republic of Uzbekistan. The study examined local and imported brands in terms of weight difference, active ingredient content, disintegration and dissolution rates.

Materials and Methods:

The study was conducted on diclofenac tablets of different brands purchased from pharmacies in Andijan. Analytical methods included qualitative analysis (using high-performance liquid chromatography) and physicochemical properties [6,7].

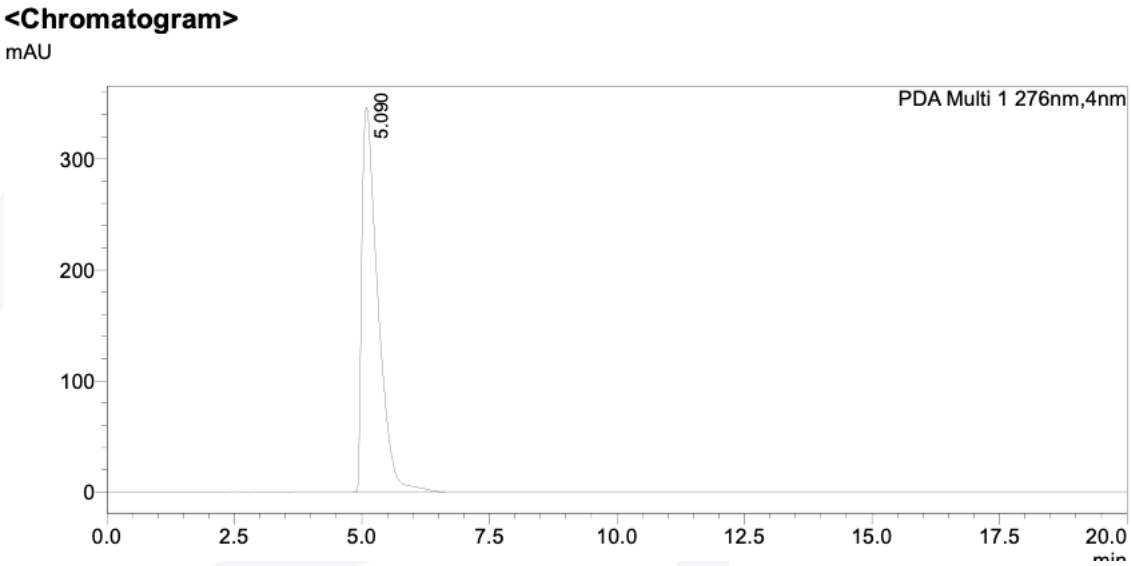

Figure 1: Diclofenac sodium standard sample in the chromatogram of the HPLC.

The chromatogram of the standard diclofenac sodium showed a single, clear and symmetrical peak with a retention time of approximately 5.09 minutes. No additional peaks attributable to impurities were detected, indicating a high level of chemical purity of the standard substance.

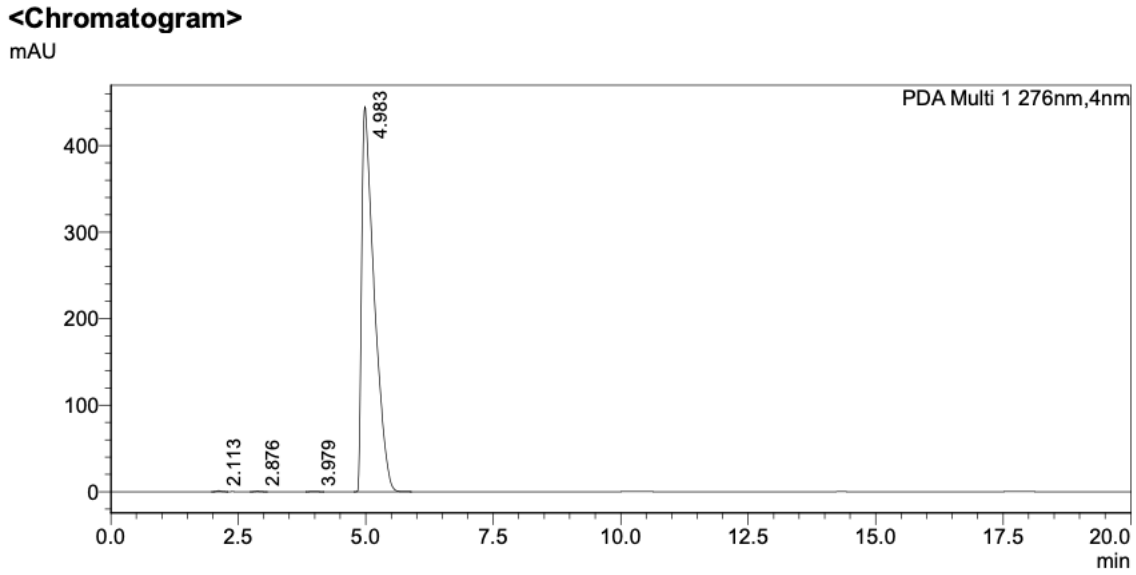

Figure 2: Ortofen tablet in the chromatogram of the HPLC.

The retention time of the main peak in the chromatogram of Ortafen tablets corresponded to that of standard diclofenac, confirming the identification of the active substance. The area of the main peak was more than 99% of the total area, and the impurities did not exceed the standards established by the pharmacopoeia requirements. The results obtained confirm the chemical purity and stability of diclofenac sodium in the preparation.

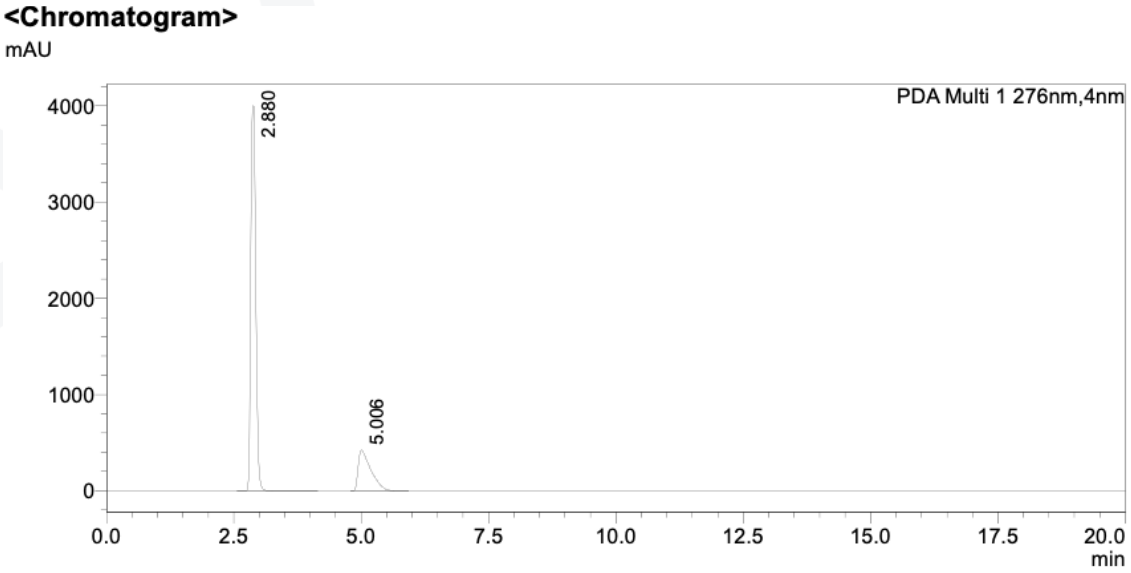

Figure 3: Diklogen tablet in the chromatogram of the HPLC.

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The retention time of the main peak in the chromatogram of the diclofenac tablet was consistent with the standard diclofenac sodium, confirming the identification of the active substance. The area of the main peak was more than 99% of the total area, and the impurities did not exceed the standards specified in the pharmacopoeial requirements.

	сред. Масса		Ortafen			сред. Масса		Diklogen		
1	0.107				1	0.645				
2	0.104				2	0.655				
3	0.102				3	0.640				
4	0.108				4	0.644				
5	0.110		сред.мас	0.105	5	0.648		сред.мас	0.646	
6	0.109		макс	0.110	6	0.642		макс	0.655	
7	0.106		мин	0.100	7	0.642		мин	0.640	
8	0.100		макс откл	4.712 %	8	0.643		макс откл	1.409 %	
9	0.108		мин откл	-4.807 %	9	0.646		мин откл	-0.913 %	
10	0.105				10	0.654				
11	0.104				11	0.645				
12	0.106			твёрдност	12	0.655				
13	0.105		1	82.6 N	13	0.640		Diklogen	твёрдност	
14	0.106		2	78.6 N	14	0.644		1	72.6 N	
15	0.103		3	84.8 N	15	0.648		2	72.6 N	
16	0.104		4	73.8 N	16	0.642		3	81 N	
17	0.105		5	80.6 N	17	0.642		4	73 N	
18	0.103				18	0.643		5	70.6 N	
19	0.104				19	0.646				
20	0.102				20	0.654				

Research results and their discussion:

The quality indicators of Diklogen and Ortafen (diclofenac) tablets were tested in laboratory conditions. The analyses were carried out using high-performance liquid chromatography (HPLC) and physico-mechanical tests. The results of the chromatographic analysis showed that the active substance was represented by clear and stable peaks in the tested sample [3,5]. Analysis of the retention time and areas of the peaks confirmed that the content of foreign impurities in the preparations was very low, and the active substance was within the regulatory range. This indicates the chemical purity and structural stability of the preparations. In tests conducted on the mass uniformity of the tablets, the average mass of the Diklogen preparation was 0.646 g, and the average mass of the Ortafen preparation was 0.105 g. In both preparations, the deviations of individual masses from the average value did not exceed the requirements of the pharmacopoeia, which indicates the stability of the production process. According to the results of mechanical strength tests, the hardness of Diclogen tablets was in the range of 70.6–81 N, and the hardness of Ortafen tablets was in the range of 73.8–84.8 N. These indicators confirm that the

tablets are resistant to mechanical damage during transportation, storage, and application [2,4].

Conclusion

Thus, the pharmaceutical quality indicators of diclofenac tablets sold in pharmacies of the Republic of Uzbekistan were assessed. The results of the analyzes showed that these drugs comply with the requirements established by the State Pharmacopoeia and regulatory legal acts [2,3]. The qualitative and quantitative indicators of the active substance - diclofenac sodium - were determined with high reliability by the high-performance liquid chromatography (HPLC) method [6,7]. During chromatographic studies, it was noted that the retention time of the main peak corresponds to the standard sample, the share of the main peak is more than 99% of the total chromatographic signal, and the amount of detected impurities does not exceed the permissible limits. This indicates a sufficient level of chemical purity and stability of the active substance in the tested preparations. The obtained scientific results confirm the selectivity, accuracy, and recovery of the applied USSX methodology, allowing us to assess the diclofenac tablets, which are the objects of the study, as qualitatively suitable for use in clinical practice.

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