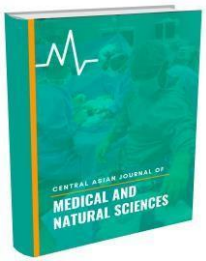

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Article

Study Of Quality Indicators Of Tablets "Enformin" and "Sitmet" With Antidiabetic Effect

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Abstract: This study evaluates the quality indicators of two antidiabetic tablet formulations, "Enformin" and "Sitmet," focusing on their technological properties and compliance with pharmacopoeial standards. The research aimed to identify compositions that optimize tablet quality through the addition of auxiliary substances. Five compositions for each tablet were analyzed for properties such as hardness, friability, dissolution rate, and moisture absorption. Rigidity and disintegration tests revealed that "Enformin" composition ET-3 and "Sitmet" composition ST-5 consistently met or exceeded quality standards. Moisture absorption studies confirmed low hygroscopicity for both formulations, while residual moisture and compression pressure studies established optimal manufacturing parameters for producing high-quality tablets. Results indicate that specific compositions and manufacturing conditions directly influence the physicochemical properties, ensuring tablet stability and efficacy. These findings provide a basis for scaling up production to meet growing local demands for antidiabetic drugs, in alignment with Uzbekistan's pharmaceutical development goals.

Keywords: Diabetes, Granule, Pressable Mass, Gravimetric Method, Tablet

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1. Introduction

In our republic, priorities are established in ensuring the development of the domestic pharmaceutical industry in the pharmaceutical industry, on the basis of which the tasks set are competitive, bioeffective, inexpensive, the creation of stagnant drug preparations is of particular importance.

The second application of the new Uzbekistan development strategy for 2022-2026, paragraph 85, "to increase the production volume of products of the pharmaceutical industry by 3 times and bring the level of supply of the local market by 80%...."the establishment of such important tasks will be instrumental in the further development of the domestic pharmaceutical industry in our republic, the establishment of the production of original preparations technology and the implementation of scientific research on the localization of production and the satisfaction of consumer needs [1,4,6,12,14,16,18].

There are many urgent tasks facing the health systems of the countries of the world community, including the Republic of Uzbekistan, among which is the identification of the

provision of drugs for patients with diabetes. According to the WHO (World Health Organization) forecasts of World Scientists, the incidence of diabetes is constantly growing [1,2].

Also, according to the data presented in the literature, the consumption of antidiabetic drugs has regional characteristics. This fact, as well as differences in the socio-economic status of its various subjects, the presence of territorial features in the formation of Health composition and the formation of local pharmaceutical markets, requires a comprehensive study of the provision of drugs for patients with diabetes mellitus at the level of a separate Region [1].

The purpose of this stage of the study was to study the qualitative indicators of the recommended antidiabetic tablets "Sitmet" and "Enformin".

2. Materials and Methods

Observing that the technological properties of the initial raw materials with a negative technological property, which were presented in previous published works, were positively compared with auxiliary substances, the technological properties of the composition ET-3 for "Enformin" tablets and ST-5 for "Sitmet" tablets were found to be positive.

For the purpose of assessing the quality of the recommended tablets, research has been continued with 5 compositions that are recommended and show the same indicators.

The results obtained were presented in Table 1.

From the results presented in Table 1, it can be seen that the results of appearance, average weight and deviation in almost all types of tablets with quality indicators being evaluated meet the requirements imposed on the tablets.

However, the ratio of the height of the" Enformin " tablets to the diameter is 41-43% above the level of demand in the compositions ET-2 and ET-3. This result stands at the limit of demand, indicating 39% in tablets taken in the composition ET-2 and ET-5. Tablets containing ET - 3, on the other hand, have been observed to be on demand, indicating 37%.

It was also observed that the ratio of the height to the diameter of the "Sitmet" tablets showed a positive indicator in all tablets taken with the content of ST-3 (41%), and that tablets taken with the content of ST-1 and ST-4 received indicators at the demand limit. Tablets containing ST-5, on the other hand, are 37% on demand.

3. Results and Discussion

The results of the study of the degree of hardness of the tablets obtained showed: the hardness of tablets of all composition studied in the "Enformin" tablets to friction is obtained in all compositions except for the content of ET-3 and ET-5 (99.62%, 99.01%). The results of the study of the degree of hardness of the tablets obtained showed: the hardness of tablets of all composition studied in the "Enformin" tablets to friction is obtained in all compositions except for the content of ET-3 and et-5 (99.62%, 99.01%) showed below-demand rates (96.88-98.85%). The hardness to the fracture, on the other hand, was found to be in demand, indicating indicators in the range of 39-60 N. The largest percentage of hardness compared to fracture was in tablets containing ET-3.

Tablet hardness in" Sitmet " tablets was found to be 97.45-99.05% when compared to rubbing when studied, and all but tablets (99.05%) with ST-5 content were not on demand. "Sitmet" tablets were found to have a fracture toughness of 45 N, 41 N,39 n,48 N, and 55 N, respectively, and these indicators were on demand.

It has been observed in studies that the solubility and quantitative analysis of both tablets, the quality of which is being evaluated, are positive.

From the results of the above study, the fragility of one of the qualitative indicators of the tablets obtained in the recommended compositions in subsequent studies was studied.

The decay factor is an indicator characterized by a high impact on direct biosamarity, and its positive indicators provide the corresponding pharmacological effect [7,9,10,13,17].

The results obtained were given in Figure 2.

From the results obtained, the breakdown indicators of "Enformin" tablets obtained in the composition ET-3, ET-4, ET-5 showed at the level of demand and 10, 9 and 10 minutes, respectively. Tablets containing ET - 1 have been found to display 14 minutes at the demand level limit as well as tablets containing ET-2 exhibiting an indicator equal to the demand level.

Thus, based on the results of the research carried out, the tablets taken on the basis of the composition, which showed positive results from all studied quality indicators, were taken as a basis for further research, tablets taken with the content of ET-3 for the "Enformin" tablets and ST-5 for the "Sitmet" tablets.

Table 1

The results of the study of the quality indicators of the recommended tablets" Enformin "and" Sitmet"

Studied quality indicators		"Enformin" tablets					"Sitmet" tablets				
		ET -1	ET -2	ET -3	ET -4	ET -5	ST -1	ST -2	ST -3	ST -4	ST -5
Appearance		White color tablets	White color tablets	White color tablets	White color tablets	White color tablets	Virgin color tablets	Virgin color tablets	Virgin color tablets	Virgin color tablets	Virgin color tablets
Average weight and deviation from, mg		1142±2,92	1258±2,08	1145±3,11	1151±4,07	1147±3,54	1046±2,54	1045±0,21	948±3,11	1045±1,27	1047±0,15
The ratio of tablet height to diameter %		38	41	37	39	43	40	38	41	39	37
Rigidity	In relation to friction, %	96,88	97,87	99,62	98,85	99,01	97,45	98,73	98,22	98,11	99,05
	Relative to fracture, N	39	41	60	48	59	45	41	39	48	55
Thaw,%		87,23	76,91	88,84	81,01	86,05	89,65	77,98	78,11	85,26	88,76

(45 minutes)										
The amount of substance acting, %	99,03	98,97	99,03	99,25	99,11	MGX	99,54	99,21	98,79	99,02	99,56
						SG	99,35	98,97	99,00	98.74	99,25
						GD	99,22	99,06	98,93	98,95	99,14

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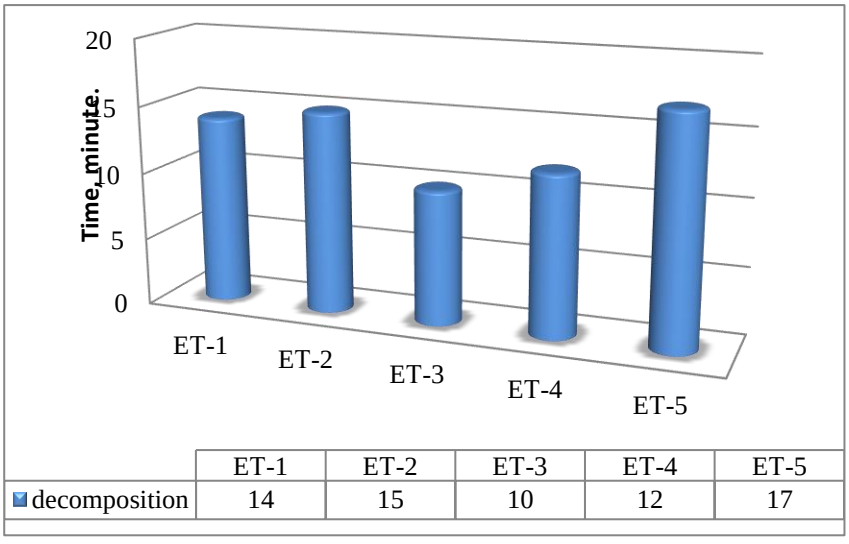
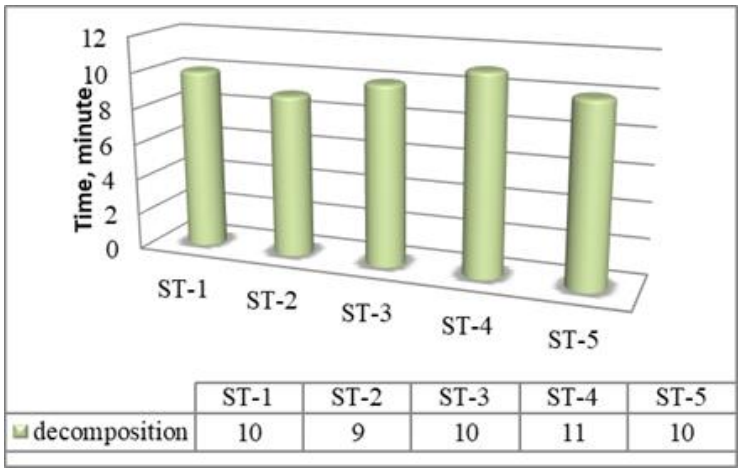
Thus, based on the results of the research carried out, the tablets taken on the basis of the composition, which showed positive results from all studied quality indicators, were taken as a basis for further research, tablets taken with the content of ET-3 for the "Enformin" tablets and ST-5 for the "Sitmet" tablets.



«Enformin»



«Sitmet»

Figure 1. Results of studies of the fragility of" Enformin "and" Sitmet " tablets

Factors affecting the quality of the recommended tablets. During the storage of ready-made drug preparations for a certain period of time, factors affecting the quality of the finished product will definitely be studied in the creation of a new drug based on internal and external factors and their constant interaction. The quality of the finished product will depend primarily on the physical chemical structure of the initial raw material, the effect of external mucus, the conduct of the technological process. The relative and absolute humidity and temperature of the finished product storage rooms, light, etc.can affect the quality of quality preparations. The study of wet absorption kinetics of drug preparations helps to create storage conditions corresponding to the physicochemical properties of substances, as well as to select packaging that will ensure the strength of quality both during storage and during transportation.

The study of wet ingestion kinetics of the recommended tablets. From the above, the pressed masses of the recommended preparations and the moisture-absorbing properties of the ready-made recommended tablets were studied. We have also studied the effects of different relative humidity of the environment on tablet quality by S.A.Nosovitskay and co - authors. The ability to absorb moisture was also studied by the gravimetric method.

In studies, pre-weighed granules are samples of pressable mass (0.5 g each) and Tablets (0.1 g each) in diameter 2,0-2,6-3,3 settled in the sm. Ready-made buoys were placed in a dryer containing a saturated solution of sodium bromide (relative humidity 58%), ammonium chloride solution (relative humidity 78%), zinc sulfate (relative humidity 90%) and purified water (relative humidity 100%). Over time, an increase in the amount of moisture was determined by the gravimetric method. For 7 days, every 24 hours, the Bulls were taken, closed with a lid and weighed on the analytical scales with an accuracy of +0,0001 g.

The excicators were thermostated at a temperature of 22 ±10 0C.

The wet absorption magnitude (%) was determined by the following formula in relation to the samples taken:

$V = (m - m0) / m0) \cdot 100,$

here:

m is the mass of the sample over a certain period of time, g;

m0 is the initial mass of the sample, g.

The results obtained were presented in Table 2.

Table 2

Results of studies of wet absorption kinetics of pressable mass and recommended model tablets of different relative humidity

Recommended compositions	The amount of moisture absorbed at different humidity of the environment, at relative humidity, %								
	Duration of study, day	58% (natrium bromide)		78% (ammonium chloride)		90% (zinc sulfate)		100% (purified water)	
		Tablet mass	Tablet	Tablet mass	Tablet	Tablet mass	Tablet	Tablet mass	Tablet
"Enformin" tablets									
ET-1	1	3,82	1,82	4,49	3,99	3,97	2,11	5,23	4,74
	2	4,45	1,98	4,77	4,29	4,72	2,24	4,98	5,59
	3	5,03	2,13	5,44	4,53	5,45	2,54	5,89	5,86
	4	6,07	2,48	5,80	5,13	6,39	3,99	6,43	5,24
	5	6,65	3,76	6,43	5,45	6,97	4,44	6,78	5,97
	6	7,15	4,27	6,97	5,72	7,48	4,69	7,32	6,05
	7	7,98	4,56	7,11	5,87	8,21	4,95	8,51	6,21
Tablets "Sitmet"									
ST-5	1	3,12	2,75	4,54	3,60	3,43	2,99	4,96	3,87
	2	3,89	2,98	5,21	3,84	4,65	3,64	5,98	4,02
	3	4,07	3,94	5,95	4,02	4,58	4,05	6,75	4,64
	4	4,89	4,07	6,07	4,87	5,11	4,32	6,26	4,99
	5	5,05	4,28	6,65	5,12	5,57	4,62	6,88	5,49
	6	5,79	4,95	7,15	5,76	5,91	4,99	7,38	5,93
	7	5,96	4,98	7,76	6,08	6,37	5,42	7,98	6,21

Table 2-the indicators of the analysis presented were observed to indicate that the mass to be pressed and the moisture absorbed by the tablets are different. Another factor affecting the moisture - absorbing properties of drugs is the size of the sample surface.

Studies have been carried out by gravimetric method in conditions where the relative humidity of the environment created by a saturated solution of sodium bromide is 58%. The pre-pulled amount of the mass to be pressed was placed in buoys of different diameters. The designers, whose composition included buoys, were put in a thermostat at a temperature of 22 0 C.

Surface-dependent S (g/m2) absorbed moisture was calculated by the following formula:

$$У = (m – m0) / S,$$

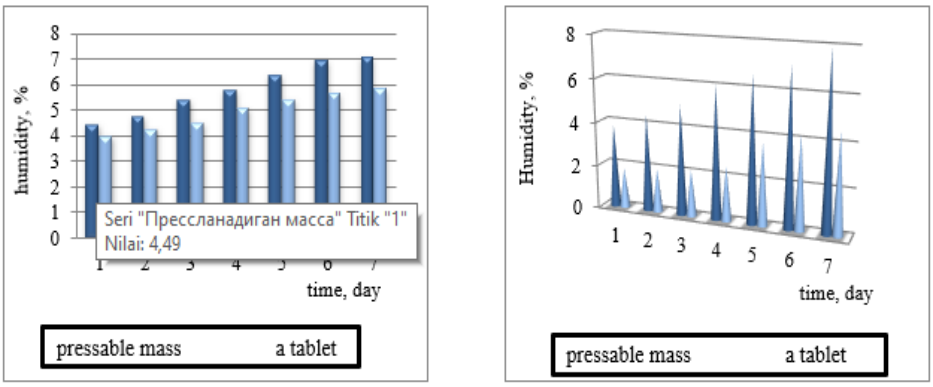
Here,

m - is the mass of the sample over a certain period of time, g;

m0 - is the initial mass of the sample, g.

S - specific surface depends on the surface moisture absorption, g/m2

The results obtained were given in Figures 2 and 3.

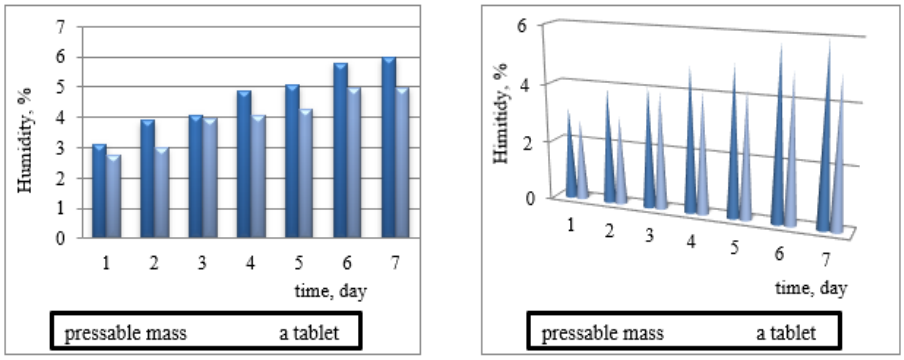


A **B**

A- relative humidity 58 %
Б- relative humidity 100 %

A- relative humidity 58 %
Б- relative humidity 100 %

Figure 2. Wet absorption kinetics of "Enformin" tablets at different relative humidity



A **B**

A- relative humidity 58 %
B- relative humidity 100 %

Figure 3. Wet absorption kinetics of "Sitmet" tablets at different relative humidity

As can be seen in the results obtained, wet swallowing Kinetics in all studied samples went intensively during the incubation period, but the moisture ingested was very low and did not affect the quality of the samples being studied.

Tablet masses and tablets taken in the recommended composition, based on the results of the above study, can be classified as among drugs with a low moisture absorption Kinetics, non-hygroscopic.

To study the effect of residual moisture on the quality of the recommended tablets. The effect of the residual moisture of the tablet mass on the quality indicators of the tablets was carried out using tablets of the composition selected for both recommended tablets.

The results obtained were given in Figures 4 and 5.

Figures from Figures 4 and 5 show that the specific residual moisture content of the tablet mass is 3-5% for "Enformin" tablets and 1-3% for "Sitmet" tablets. The moisture in the range of these indicators indicates the positive scattering of the pressed mass, as well as the effect of the scattering on the manifestation of density. This in turn indicates that a certain residual moisture has a special place in obtaining

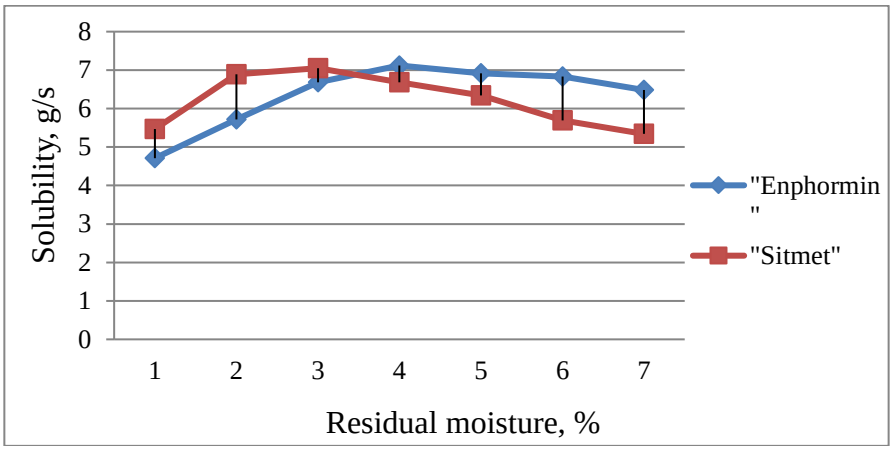


Figure 4. Results of studies of the effect of pressed mass residual moisture on volatility indicators

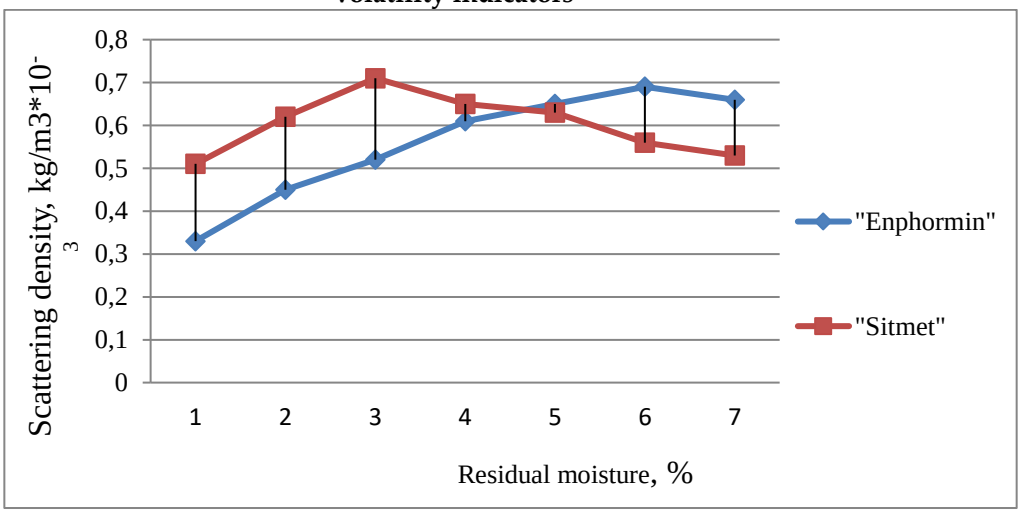


Figure 5. The results of the study of the effect of the residual moisture of the pressable mass on the density indicators of the hairdryer

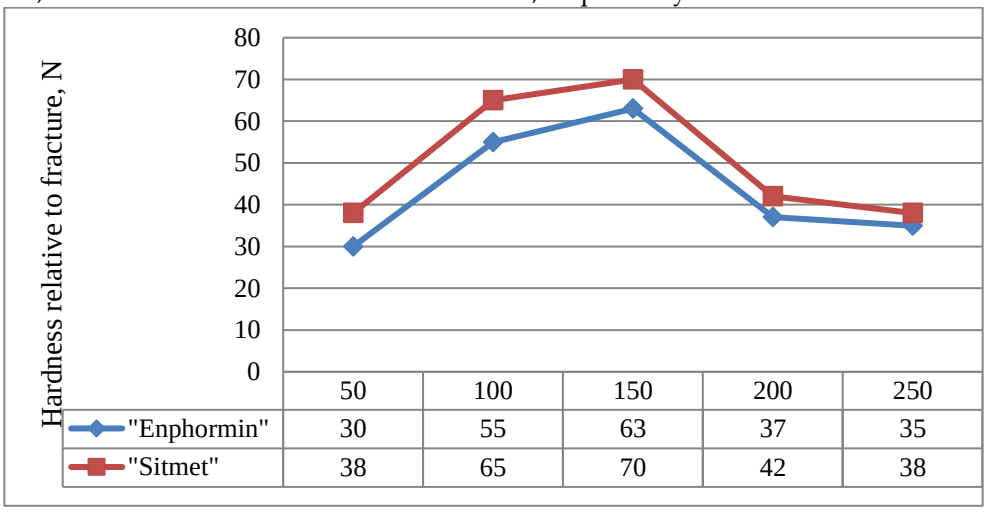
To study the effect of pressing pressure on the quality of the recommended tablets. It is of great importance to determine the pressing pressure when organizing the large-scale production of the recommended tablets. Therefore, the study of this factor is considered relevant. In laboratory studies where new content and technology is being developed, the force of pressing pressure is mainly studied by being carried out on hand presses. But according to the literature, this indicator changes in production on an industrial scale and affects the quality of the tablet. In the development of tablet technology, the process of pressing the mass is complex, and the effect of pressing pressure will be greater. These factors are: internal pressure of the pressable mass falling on the poansons, lateral pressure, coefficient of friction, temperature, etc., affect the quality of the tablet [3,5,8,11,15].

In a study of the effect of pressing pressure on the quality of finished products when taking these preparations, tablets were pressed at pressing pressures of 50,100,150,200 and 250 MPa. In the studies carried out, pressing pressure was found to have a direct effect on the hardness of the recommended tablets relative to friction and fracture, and on the breakdown rate of the tablets. In studies, tablet masses were taken in the recommended compositions and the results of pressing at pressures of 50-300 MPa were analyzed.

Pressing pressure affects the hardness and breakdown performance of the tablets in relation to fracture and friction, and it is to these indications that we are taking the

recommended pills to press we studied the effects of pressure. The results obtained were the results of the study of the effect of pressing pressure on the hardness of the recommended tablets in relation to the fracture in Figure 6.

Figure 6 shows that pressing pressure increased intensively when it was 50-100 MPa and showed 30-50 MPa in "Enformin" tablets and 38-65 MPa in "Sitmet" tablets. The increase in pressure between 100-150 MPa was observed in studies as well as the increase in pressure between 55-63 N and 65-70 MPa, respectively, and a sharp decrease in the hardness of recommended tablets to break as a result of the increase in pressure to 200-250 MPa, and a result of 37-35 MPa and 42-38 MPa, respectively.



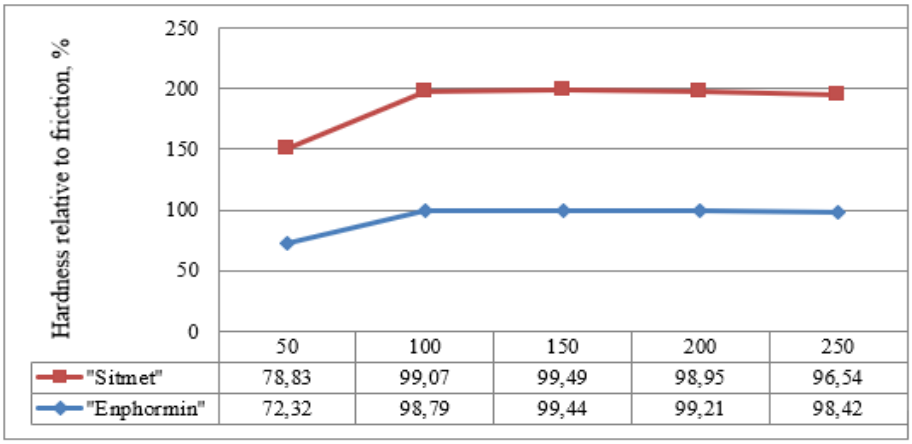
	50	100	150	200	250
"Enphormin"	30	55	63	37	35
"Sitmet"	38	65	70	42	38

Figure 6. The results of a study of the effect of pressing pressure on the hardness indicators of the recommended tablets in relation to the fracture

In subsequent studies, the effect of pressing pressure on the hardness of tablets against friction from the quality indicators of both recommended tablets was studied and presented in Figure 7.

The results of the study showed the following indicators: when the pressure of pressing in "Enformin" tablets increased from 100 MPa to 200 MPa, it was observed that the degree of hardness of the recommended tablet against friction decreased as the pressure of pressing increased, indicating a result of 99.44% at a pressure of 150 MPa. It was also observed that at a pressure of 250 MPa, the rate dropped to 99.21%.

"Sitmet" tablets, on the other hand, showed a variable increase in stiffness relative to friction at pressing pressures of 50,100 and 150 MPA (78.83%, 99.07% and 99.49%, respectively, when pressure of 200 MPa was given, and 98.95% showed a drop in demand by showing the result.

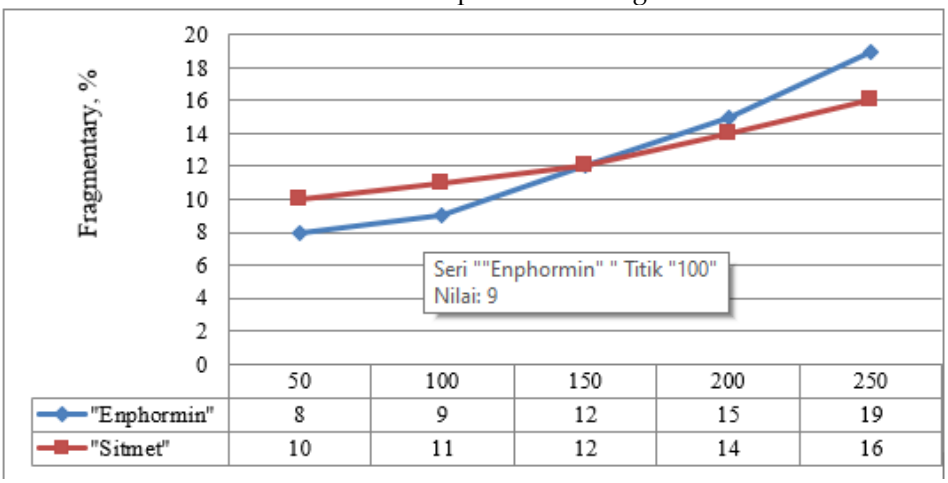


	50	100	150	200	250
"Sitmet"	78,83	99,07	99,49	98,95	96,54
"Enphormin"	72,32	98,79	99,44	99,21	98,42

Figure 7. The results of a study of the effect of pressing pressure on the hardness indicators of the recommended tablets with respect to friction

One of the indicators that ensure the quality of pill drug types is the breakdown indicator, and in subsequent studies the effect of pressing pressure on this indicator was studied.

The results of the study of the effect of pressing pressure on the breakdown indicators of the recommended tablets were presented in Figure 3.9.



	50	100	150	200	250
"Enphormin"	8	9	12	15	19
"Sitmet"	10	11	12	14	16

Figure 7. Results of studies of the effect of pressing pressure on the breakdown performance of the recommended tablets

In studies, there was an increase in fragility with an increase in pressing pressure when taking "Enformin" as well as "Sitmet" tablets. With a pressing pressure of 50 MPa, the decay rate was 8 minutes in "Enformin" tablets. This figure was 10 minutes in "Sitmet tablets". In the 100 MPa of pressing pressure, the breakdown of the tablets was 9.11 minutes, respectively. While "Enformin" tablets had decay rates of 12, 15, and 19 minutes as a result of the pressurization pressure being given at subsequent MPA forces, "Sitmet" tablets showed 12, 14, and 16 minutes respectively. As can be seen from the results obtained, the breakdown indicators of the "Enformin" tablets were found to give positive results in the strength of the pressing pressure of 50,100,150 and 200 MPa, as well as meet the requirements of the Republican state pharmacopoeia of Uzbekistan for the breakdown of tablets.

The fragmentation index of tablets given pressing pressure at a power of 250 MPa showed a high result in demand.In contrast," Sitmet " tablets have been found in studies to give demand-level indicators of 10.1-1.12 and 14 minutes at 50, 100, 150 and 200 MPa pressing pressures. The results of the study, obtained at an increase in pressing pressure to 250 MPa, showed that the breakdown rate of "Sitmet" tablets is not at the level of demand, indicating 16 minutes.

Thus, the quality of the" Enformin "and" Sitmet " tablets is directly affected by pressing pressure.

From the results of the above studies, the effect of pressurized mass in the range of 100-150 MPa for the recommended "Enformin" tablets and 150-200 MPA for "Sitmet" tablets on the receipt of quality tablets was guaranteed. It has been proven that this pressing pressure makes it possible to obtain quality pills according to the indicators studied.

4. Conclusion

Assessment of the quality of tablets taken in the proposed technology was carried out on the basis of the requirements of the state pharmacopoeia of the Republic of

Uzbekistan for tablets. It has been found that the recommended tablets meet the requirements in full according to the indicators studied, and for further research, these tablets were taken as a basis.

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