



DEVELOPMENT OF A " DISSOLUTION " TEST FOR "STIGMACHOLE" CAPSULES

Mamatkulov Zukhriddin Urmonovich

Rizaev Kamal Saidakbarovich

*e-mail: mzu_77@mail.ru

<https://doi.org/10.5281/zenodo.13885438>

In this article, the "Dissolution" test, which is one of the most important indicators in the production process of "STIGMACOLE" capsules, was developed. To do this, the "in vitro" method was used in laboratory conditions. In the development of the solubility test of "STIGMACHOLE" capsules based on scientific results, using the method presented in the first edition of the State Pharmacopoeia of the Republic of Uzbekistan, the "Rotating" device was used. The rate of release of active biologically active substances (BFM) contained in the capsule and the pH index of the environment were analyzed using the "rotating equipment" device. During the study, purified water (pH=5.8), 0.1 molar hydrochloric acid (pH=1.3), 0.1 molar solution of sodium bicarbonate (pH=8), 0.01 molar sodium tetraborate (pH=9, 2) was performed using such solutions. As a result of the research, the "in vitro" method developed a suitable "Dissolution" test for "STIGMACHOLE" capsules.

Keywords: "STIGMACHOLE" capsule, "in vitro", "rotating equipment" device, "Dissolving" test, flavanoid.

As a result of the development of the pharmaceutical industry, the concept of biopharmaceutics entered the pharmaceutical science in the second half of the 21st century. Biopharmaceutics is a direction that scientifically studies different dosage forms of drugs, as well as the physical, physico-chemical properties of bioactive and auxiliary substances in drugs with the same dosage, and their effect on pharmacotherapeutic properties [4,6].

At the same time, determining the properties of solid drug forms is carried out by their disintegration and dissolution properties in a solvent medium. From the point of view of biopharmaceutics, the rate of absorption of the active substance depends on the rate of its decomposition or dissolution. Determination of the bioefficacy test of any solid drug form is carried out using in vitro and in vivo experiments. In order to determine the quality of medicinal products, conducting in vivo experiments in enterprise conditions has some difficulties, so one of the simple, fast and accurate methods, i.e. the in vitro method, can be used [3,5].

Today, there are several methods that determine the dissolution rate of solid drug forms. Usually they differ from each other by the size of the solvent medium, whether it moves or not, and pH of the solvent medium. The amount of active substance that has changed from a solid type of medicine to a solution in a certain time is called the dissolution of a tablet or capsule. In order to determine the dissolution of tablets or capsules, the device "rotating equipment" presented in SP XI is used [2,6].

The main reasons for the widespread use of the "rotating equipment" method are the high correlation of the obtained research results with the results of in vivo experiments in many cases, the simplicity of the method, the ease of implementation and the low cost [6].

In the dissolution test for the capsule dosage form according to SP XI, the release of the bioactive substance is affected by the temperature, the speed of rotation of the device, the volume and nature of the dissolution medium [2].

Based on the above, determining the biopharmaceutical parameters of "STIGMACHOLE" capsules with choleretic properties in in vitro experiments was determined as **the aim of our scientific research**.

Experiment part.

Research materials and methods.

"STIGMACHOLE" capsules, which have a fire-driving property, were selected as the object of our scientific research. It was conducted based on the requirements of the article "Solubility test for solid drug forms" in the SP I edition of the Republic of Uzbekistan [1,7]. In order to determine the bioefficacy of "STIGMACHOLE" capsules, a dissolution test was introduced in "in vitro" conditions from the "Erweka DT" rotating device.

"STIGMACHOLE" capsules was carried out at 4 different rotation speeds of the rotating device were 50, 100, 150 and 200 rpm respectively.

Research results and their discussion.

"STIGMACHOLE" capsules, the experiments were carried out in the following order: by placing one "STIGMACHOLE" capsule in a rotating cajava device, in order to study the effect of the release of BFM contained in the capsule and the rate of rotation of cajava, purified water (pH=5.8), 0.1 Molar hydrochloric acid (pH=1.3), 0.1 molar solution of sodium bicarbonate (pH=8), and sodium tetraborate (pH=9.2) were poured into containers of different volumes, and the rotary cajava device was pumped at different speeds per minute. (50, 100, 150 and 200 times). The volume of the solvent was 900 ml. The sensitivity of the quantitative analysis method was also taken into account. During the experiment, the temperature was $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$. Each media containing STIGMACHOLE capsules was sampled every 10 minutes and the amount of exposed BAC was measured. The release of BAC when using purified water in a rotating device as a solvent showed higher release than other solvent media. After that, slightly lower results were obtained when 0.1 M hydrochloric acid solution was used as a medium compared to purified water. The parameters obtained in the medium of solutions containing 0.1 m sodium hydroxide and 0.1 m sodium tetraborate were shown to be unsatisfactory [2].

Taking into account the results of the research, it was considered appropriate to use purified water as a solvent medium. The obtained experimental results are given in Table 1.

Table 1

pH of the solvent on the rate of release of biologically active substances from
"STIGMACHOLE" capsules into the solvent

Factors under study		"STIGMACHOLE" capsule,%
Environments under study	Duration of the experiment, per minute	
Purified water (pH =5.8)	10	49%
	20	80%
	30	86%
0.1 molar HCl (pH =1.2)	10	45%
	20	72%
	30	77%
0.1 molar NaHCO ₃ (pH =7.8)	10	7%
	20	9%
	30	13%
0.01 mol/l Na ₂ B ₄ O ₇ (pH= 9.18)	10	2. 1%
	20	3. 2%
	30	7. 1%

The results of the assessment of the influence of the pH environment of the solvent on the rate of release of biologically active substances from "STIGMACHOLE" capsules into the solvent environment are presented 80% and 86%.

In our further studies, the effect of the total release of BACs contained in the capsule, which is considered as the second indicator, on the rotation speed of the rotating equipment, experiments were carried out for every 50, 100, 150 and 200 revolutions per minute. The results of the experiment are shown in Table 2.

Table 2

Results of the study of the effect of device speed on the complete release of
biologically active substances included in the capsule "STIGMACHOLE"

Factors under study		"STIGMACHOLE" capsule,%
Rotational speed, rpm	Time, minute	
50	10	5 1.4%
	20	5 6.9%
	30	6 9.1%
100	10	60.7%
	20	75.6%
	30	89.8 %
150	10	6 2.2%
	20	7 7.4%
	30	86.5%
200	10	6 3.7%
	20	8 0.1%
	30	85.9%

In the rotating cajava device, the rate of transition from the content of the STIGMACHOLE capsule to the available solvent of BAC was shown in the maximum 30 minutes, and the percentage of released substances was found to be 69.1%.

When the number of revolutions in the device was increased to 100 per minute, the percentage of release of BACs contained in the "STIGMACHOLE" capsule into the solvent medium was 84%, 87% and 89.8%. After that, when the number of rotations was increased to 150 and 200, the amount of released BACs was 86.5% and 85.9%, accordingly. When the number of rotations was increased to 100 per minute, the yield of release of BACs from "STIGMACHOLE" capsules showed its highest intensity at 30 minutes.

In conclusion, it was shown that more than 75% of flavanoids were released into the dissolution medium within 45 minutes at the speed of rotating equipment [7]. Also, according to the results of the release rate of BACs when using in vitro purified water, 0.1 molar HCl, 0.1 molar sodium bicarbonate and 0.01 molar sodium tetraborate solutions, purified water was selected as the solvent medium in the dissolution test. In this case, taking 1000 ml of purified water as a medium was also considered to be effective in the experiments.

As a result of different degrees of rotation per minute of the rotary device, the percentage of release of BACs contained in the "STIGMACHOLE" capsule into the solvent medium was 89.8%. The results of this experiment became the basis for setting the rotation speed of the equipment equal to 100 per minute.

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