

## Investigation on the Study of the Biopharmaceutical Efficiency of the Recommended Tablets «Cerumax Forte»

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**Abstract:** In this research, we studied the influence of the pH of the medium on the rate of release of biologically active substances contained in the recommended tablets «Cerumax Forte» and the effect of the speed of rotation of the basket on the release of biologically active substances - metoclopramide, gingerol, pyridoxine hydrochloride from the contents of the tablets «Cerumax Forte» into the solvent Wednesday.

**Keywords:** biologically active substances (BAS), «Solubility» test, State Pharmacopoeia XIII, neutral medium, acidic medium, alkaline medium, and «Rotating basket» apparatus.

### Introduction

One of the main biopharmaceutical properties that largely determine the bioefficiency of the drug is the solubility of the drug, which determines the possibility of creating an effective dosage form of the drug, the kinetics of its release from the dosage form, the speed and completeness of absorption. When developing the «Solubility» test, studies were carried out to determine the intensity of release of biologically active substances, the optimal speed of rotation of the basket [1, 4-8].

### Materials and methods

The determination was carried out using a device of the «Rotating basket» type or a stirrer with a boat, listed in the XIII State Pharmacopoeia. The rate of release of biologically active substances contained in finished tablets into the dissolving medium is influenced by a number of factors. One of these factors is the pH of the solvent medium. The second factor is the rotation speed of the rotating basket [2, 3, and 7].

### Results and discussion

In the course of the study, these two cases were studied, and after the study, the «Solubility» test was developed. The optimal pH value of the dissolving medium was found when using several solvents. For this reason, a number of media were chosen as dissolving media for the study. These were: purified water as a neutral medium, 0.1 N as an acidic medium. Hydrochloric acid solution and 0.1 N sodium hydroxide solution - as an alkaline medium. The volume of the dissolving medium during the studies was chosen based on the sensitivity index of the developed method for the quantitative determination of active substances and was 1000 ml.

According to the research results, it was noted that the environmental pH directly affects the release rate of the bioactive substance from the composition of the «Cerumax Forte» tablets. Based on the results obtained, we can say: in neutral and alkaline environments, the release of the bioactive

substance from the composition of the recommended tablets was less than 75% in almost all formulations in forty-five minutes. For example, in a neutral environment, these figures ranged from 45.91% to 69.22%, and in an alkaline environment - from 38.42% to 48.54%. But at this very moment, in tablets made from almost all ingredients in an acidic environment, this figure showed a sum of 79.04% to 81.25%.

According to the requirements for tablets, this figure should be more than 75%.

It was established that the results of the analysis of the indicators presented in Table 1 showed that the tablets obtained as part of the CF-5 tablets «Cerumax Forte» gave a positive result in an acidic environment. Also, in tablets with different contents, almost the same results were observed in all environments.

It was established that the indicators obtained during the research correspond to the requirements of the III State Pharmacopoeia for tableted medicines.

Based on the foregoing, it was decided to use an acidic medium in further studies - a solution of hydrogen chloride.

**Table 1 The results of the study of the intensity of the release of bioactive substances from the composition of the tablets «Cerumax Forte» in three different media (n=5)**

Con- tents	BAS	Studied environments								
		Quantity in a neutral medium (purified water), %			Amount in acid medium (0.1 N HCl solution), %			Quantity in alkaline medium (0.1 N NaOH solution), %		
		Time, minute								
		15	30	45	15	30	45	15	30	45
CF-1	M	15,02	30,23	46,22	29,76	54,32	67,32	19,43	25,63	33,67
	G	21,89	27,86	32,65	38,43	62,89	67,88	27,76	31,33	48,65
	PH	31,90	36,98	38,21	43,65	59,98	68,11	33,21	38,76	45,21
CF-2	M	16,98	32,89	52,44	37,11	57,21	64,98	23,94	29,67	39,97
	G	24,65	25,11	29,98	41,23	67,87	69,22	35,32	41,76	46,32
	PH	32,92	38,21	41,36	45,85	58,73	67,95	32,99	37,84	43,65
CF-3	M	21,56	29,76	58,19	34,96	54,56	58,45	28,19	34,87	42,64
	G	29,87	32,54	39,23	48,11	57,74	57,54	31,54	35,73	43,94
	PH	34,14	37,88	39,76	42,98	55,12	64,98	31,02	36,54	46,11
CF-4	M	25,52	31,78	54,32	31,19	49,43	74,67	21,84	38,51	49,89
	G	33,56	36,21	37,98	47,54	55,21	59,76	37,21	39,93	45,87
	PH	39,22	45,65	59,21	46,44	59,05	69,52	41,54	47,43	56,98
CF-5	M	29,97	36,42	52,97	32,21	45,98	79,77	28,99	37,54	48,54
	G	34,32	39,88	45,91	53,98	75,43	79,04	34,65	37,90	43,65
	PH	37,21	45,65	69,22	39,41	52,89	81,25	29,45	31,32	38,42

In further studies, the influence of the basket rotation speed on the release of BAS from the composition of the «Cerumax Forte» tablets was studied, which is not indifferent to the release of BAS into the dissolving medium.

At the next stage of research, we studied the effect of the basket rotation speed on the release of bioactive substances - metoclopramide, gingerol, pyridoxine hydrochloride from the composition of «Cerumax Forte» tablets into a dissolving medium.

During the study, we determined the rotation speed of the basket as 50, 100, 150, 200 and 250 rpm.

The results of the study are presented in table. 2.

The obtained results show that, depending on the rotation speed of the basket, the bioactive substances are released from the contents of the tablet into the dissolving medium of the bioactive substances. In studies, it was observed that the liftoff speed was more intense than the basket speed.

From the results of Table. 1 show that the release of bioactive substances into the dissolving medium increased at a basket rotation speed of 100 rpm. But these numbers are below 75% in 45 minutes. For this reason, the following speeds have been studied and research has been continued.

At the next speed, that is, at a basket speed of 150 rpm, it was found that the release of metoclopramide was 78.08%, the release of gingerol was 78.94%, and pyridoxine hydrochloride was 77.83%. With an increase in this speed, it was observed that the release of BAS into the dissolving

**Table 2 the results of the study of the influence of the speed of rotation of the basket on the intensity of the release of the active substance from the tablets «Cerumax Forte»**

Con- tent	BAS	Studied environments									
		Quantity in a neutral medium (purified water), %			Amount in acid medium (0.1 N HCl solution), %			Quantity in alkaline medium (0.1 N NaOH solution), %			
		<i>Basket rotation speed, 50 rpm</i>									
		15	30	45	15	30	45	15	30	45	
CF- 5	M	27,32	37,76	56,11	29,96	53,65	75,21	29,78	39,55	50,32	
	G	36,44	41,45	48,43	52,76	59,09	64,22	38,85	41,45	48,08	
	PH	35,99	49,57	71,05	48,43	62,27	73,68	32,65	35,24	41,32	
	<i>Basket rotation speed, 100 rpm</i>										
	M	29,54	39,53	61,54	33,67	59,22	66,87	34,98	45,25	57,56	
	G	46, 76	48,95	54,22	65,22	71,79	69,43	45,11	49,99	55,74	
	PH	39,53	55,27	69,53	54,87	69,11	74,87	34,98	43,65	54,74	
	<i>Basket rotation speed, 150 rpm</i>										
	M	35,37	46,78	73,56	55,76	72,98	78,08	39,54	55,74	68,73	
	G	46, 76	48,95	54,22	58,11	75,54	78,94	52,54	56,76	69,11	
	PH	39,53	55,27	69,53	53,57	69,92	77,83	41,77	58,83	74,43	
	<i>Basket rotation speed, 200 rpm</i>										
	M	37,68	54,69	74,37	53,22	72,98	74,32	45,76	63,33	74,09	
	G	53, 65	56,22	59,54	63,78	75,11	68,21	54,87	64,07	72,65	
	PH	43,65	58,11	73,43	56,24	72,57	67,57	45,87	64,78	74,98	
	<i>Basket rotation speed, 250 rpm</i>										
	M	38,11	53,98	74,47	58,98	74,67	74,89	49,45	69,94	74,93	
	G	55,26	56,98	61,09	64,87	75,97	68,94	55,93	66,11	74,27	
	PH	47,21	61,78	74,32	58,65	73,11	67,98	46,92	65,83	74,99	

Medium did not increase intensively, even at a basket speed of 200 rpm and 250 rpm, the tablet was dissolved, but the amount of BAS in the dissolving medium decreased. relatively.

### Conclusion

Thus, on the basis of the obtained research results, an acidic environment and a basket rotation speed of 150 rpm were chosen as the conditions for the «Solubility» test for «Cerumax Forte» tablets, and further studies were carried out according to these standards.

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