Available online www.jocpr.com

Journal of Chemical and Pharmaceutical Research, 2017, 9(2):201-203

Research Article

ISSN : 0975-7384
CODEN(USA) : JCPRC5

Determination Microbiological Purity of the Gel "Anticandid"

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ABSTRACT

This abstract presents of results of the study microbiological purity gel under the code name "Anticandid" based on substances derived 4H-pyrido[4',3':5,6]pyrano[2,3-d]pyrimidine derivatives with antifungal activity. The practical value and originality are concluded in the study the number of microorganisms in samples of gels by different methods. The research results showed the high quality of the samples in terms of "Microbiological purity."

Keywords: Gel; Sabouraud dextrose agar; Casein soy broth; Mannitol-salt agar test strains; Surface sowing

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INTRODUCTION

Microbiological purity is one of the most important quality indicators during the determination study of developed drug. The microbiological purity test includes quantative of viable bacteria and fungi, as well as identification of specific types of microorganisms, the presence of which is unacceptable in non-sterile drug means.

According to microbiological purity, it is necessary to develop rules that restrict the level of microbial contamination of the excipient. However, their microbiological purity is directly dependent on the microbiological purity of the air of industrial premises, transportation conditions and storage time in the clear on the packaging stage. The most of drugs are not subjected to sterilization, can be contaminated by microorganisms. The microorganisms in viscous media developed is more slower than in liquid media, but they are a long time can survive and reproduce in the drug.When the course of preparation - the primary contamination of a number of different microorganisms can get into medicine. The sources of microbial contamination can be water, raw materials, air, equipment, primary packaging and a variety of external factors. The most rational and promising directions in solving the problem of reducing microbial contamination of drugs, active substances and excipients are: to improve the culture of production and improvement of production technologies that meet modern requirements for microbiological purity.

The development of new drugs with one of the most important aspects is the assessment of the quality indicators and their standardization, which ensures the security and stability of the drug throughout the shelf life.

In this context, the optimization of the composition and the search for new drugs in the first place due to the selection of the optimal framework is an urgent problem of pharmacy.

MATERIALS AND METHODS

To study the microbiological purity of the gel under the code name "Anticandid" was obtained by the model of gel. Samples were determined immediately after preparation, every 6 months in the refrigerator storage conditions (temperature between 2 ° C to 8 ° C) and at a temperature (15 ° C to 25 ° C) for 24 months.

In determining the microbiological purity of samples of the gel "Anticandid" used the methods proposed in the State Pharmacopoeia of the Republic of Kazakhstan: determination of the total number of viable aerobic mesophilic bacteria and fungi - a method of drilling depth, the surface plating method determining the presence of the bacteria Staphylococcus aureus, Pseudomonas aeruginosa and Enterobacteriaceae family.

Tests allow quantification of mesophilic bacteria and fungi that can grow under aerobic conditions. As test strains of microorganisms was used from the American Culture Collection: Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 9027 and Escherichia Coli ATCC 25922.

According to recommendations of the following solid and liquid culture media were used: soybean-casein agar (to determine the number of live bacteria) Sabouraud dextrose agar (determine the amount of mushrooms), soy casein broth (for pre-incubation in determining the presence of certain microorganisms), mannitol -solevoy agar (for the identification of Staphylococcus aureus), tsetrimidny agar (for the identification of Pseudomonas aeruginosa).

In the study were used for each nutrient is more than 6 petri dishes, the result of the study was defined as the arithmetic average of the numbers of colonies that grew on all the parallel cups. Cups with casein-soya agar plates were incubated at a temperature from 300C to 350C during 5 days, the cup of Sabouraud dextrose agar - at a temperature from 200C to 25C - 7 days.

Waste sample of 10 g of gel was dissolved in 100 ml of 0.9% saline, the sample is not heated 400C temperature thoroughly mixed by maintaining the temperature in a water bath. Added the required amount of pre-warmed-solvent to optain dilutions 1:10 of the sample test. Then was stirred until necessary desired emulsion.

In accordance with the requirements of the State Pharmacopoeia of the Republic Kazakhstan I, vol. 1, 2/6/12, tolerance of: aerobic bacteria not more than 1000, fungi (in total) of not more than 100. 1 g of the drug tolerance of: and other gram-negative enterobacteria not more than 100. As well as in 1 g of the drug is not allowed to have *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

RESULTS AND DISCUSSION

The composition of the "Anticandid" based on substances derived 4H-pyrido [4 ', 3': 5,6]pyrano[2,3-d] pyrimidine derivatives is shown in Table 1.

Table 1: The composition of the "Anticandid" gel with antifungal effect

I	*Active substance:*	
	Substance derived	3%
	4H-pyrido [4 ', 3': 5,6] pyrano [2,3-d] pyrimidine 3%	
II	*Excipients:*	
	DMSO	3%
	Propylene glycol	50.00%
	CarbopolUltrez 20	1.00%
	Triethanolamine	1.00%
	Purified Water	42.00%

Incubation of the samples prepared gel (1:10) in the mannitol-salt agar (300C to 350C temperature - 72 hours) showed "the absence of bacteria *Staphylococcus aureus* and *Pseudomonas aeruginosa* in 1 g of the test gels". The results are presented in the table below (table 2).

Table 2: The results of the study of microbiological purity of the gel "Anticandid"

S No	Index	Research Method	Storagetime, temperature, month									
			t=2^0C - 8^oC					t=15^0C - 25^oC				
			0	6	12	18	24	0	6	12	18	24
1	Total number of aerobic microorganisms, CFU/g.	Deep sowing	10	10	10	10	20	10	10	10	20	20
		Surfacesowing	10	10	10	20	20	10	10	20	20	20
2	Number of yeasts and molds, CFU/g.	Deep sowing	8	8	10	10	10	8	10	10	10	10
		Surfacesowing	8	10	10	10	10	8	8	10	10	10
3	The presence of Enterobacteriaceae gram-negative, gram-positive bacteria	Staphylococcusaureus	Missing									
		Pseudomo-nasaerugi-nosa	Missing									
		E. Coli	Missing									

Note: CFU (colony-forming unit)1 g of the drug.

Determination of microbiological purity by the methods of superficialand deep sowing the concentration of bacteria content from 10 to 20 colony forming units per 1 g (TEM / g), yeast and mold fungi - from 8 to 10 CFU / g. The obtained results shows the absence of the sample ofgel gram positive cocci *Staphylococcus aureus* and

gram-negative bacteria *Pseudomonas aeruginosa* and *Escherichia Coli* during storage for 24 months at a temperature of from 20C to 25C.

CONCLUSIONS

According to study the level of microbial contamination doesn't exceed the permissible limits: not more than 10,000 CFU aerobic bacteria and 100 CFU of fungi in 1 g. of the gel in the absence of intestinal *Escherichia Coli* bacteria - less than 1 CFU per 100 g. (mL), and bacteria of the family *Staphylococcus aureus* and *Pseudomonas aeruginosa* was not discovered and showed microbiological purity and stability over the storage period.

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