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Pharmacological studies of the phytogel “Imbirol”

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Abstract

With technological, structural, mechanical, physical and chemical properties of the gel was developed a gel base that meets modern foundations local action. A further task was to support the optimal concentration of active material - essential oils.

Keywords: gel, essential oils, upper respiratory tract infection, microbiological activity and acute toxicity.

1. Introduction

An important task of the modern pharmacy is to provide population with effective medications, including the treatment and prevention of infectious and inflammatory diseases of the upper respiratory tract. It is proved that the nature of soft core has an active influence on release of active materials. Due to this a well distributed and absorbed into mucous gel was chosen as a form of release which leads to higher bioavailability of active materials^[1]. On the basis of literature and microbiological research the following essential oils were selected as active ingredients: ginger, clary, marjoram and tea tree^[2, 3]. The essential oil of ginger (*Olei Zingiber officinale*) has a wide range of actions, including: anti-inflammatory, warming, antiseptic. As essential oils have also pathogenic activity, it helps to lower high temperature. The essential oil of marjoram (*Olei Majorana hortensis L.*) has antibacterial, antifungal and antiseptic properties. It is very good for rhinitis, inflammation of the sinuses and others. The essential oil of Salvia (*Olei Salvia sclarea L.*) is a strong analgesic, has a strong bactericidal anti-virus and anti-inflammatory action^[4, 5]. Tea tree essential oil (*Olei Melaleuca alternifolia L.*) is a powerful antiseptic, has a strong anti-viral and anti-inflammatory action. Also it provides wound-healing effect^[6-10]. The purpose of this study was to support the optimal concentrations of selected essential oils in gels and learning of general toxic properties of the product.

2. Materials and methods

For screening of antibacterial action 5 gel samples were prepared with different concentration of essential oil. Gel sample number 1 - gel base + 1% essential oils of ginger, 1% of clary, 0.5% of marjoram. The gel sample number 2 - gel base + 1% essential oils of clary, 0.5% of tea tree, 0.5% of marjoram. Gel sample number 3 - gel base + 1% essential oils of ginger, 1% of clary, 0.5% of tea tree. Gel sample number 4 - gel base + 1% essential oils of ginger, 0.5% of tea tree oil, 0.5% of marjoram. Gel sample number 5 - gel base + 1% essential oils of ginger, 1% of clary, 0.5% of tea tree oil, 0.5% of marjoram. Gel sample number 6 - gel base + 1% essential oils of ginger, 1% of clary, 1% of marjoram, 1% of tea tree. Antimicrobial activity test specimens studied in vitro using agar diffusion method ("wells"). This method is based on the ability of active materials to diffuse in agar medium, which is pre-sown mikroorganisms. According to the WHO test strains of *Staphylococcus aureus* were used to assess the activity of medications, *Escherichia coli*, *Basillus subtilis*, *Candida albicans*. Microbial load was 107 microbial cells per 1 ml of substance and established according to the standard McFarland. The 18-24 hour cells of mikroorganisms were taken into research. Determination of antibacterial medications carried out on two layers of dense nutrient medium, water, salt). The bottom layer is the 10 mm substrate which horizontally set 3-6 thin-walled stainless steel cylinder with a 8 mm diameter and 10 height. The top layer consisting of a nutrient agar medium, melted and cooled to 40 °C where appropriate standard daily culture test microbe is poured around cylinders. Previously, the top layer is well mixed to form homogenous mass After freezing cylinders were removed and placed in a hole formed in the test substance on the basis of its volume (0.3 mL). The amount of medium for the upper layer ranged from 14 to 16 ml. Cups were dried for 30-40 minutes at room temperature and placed

in an incubator for 18-24 h^[11]. To determine the medium lethal dose (LD50) an acute toxicity study gel № 5 was conducted. The acute toxicity was studied by Pastushenko rapid test TV on five groups of white male rats weighing 200-250 g 3 animals in each group in the range of doses of 7500-9400 mg/kg with intragastric administration with the observation of the animals for two weeks^[12]. Rats were grown in a vivarium of the Central Research Laboratory of the National University of Pharmacy (Pharmacy CSRL) and before the experiment acclimatization was carried out under conditions of room for testing within 7 days. Animals were treated according to the current rules on devices, equipment and vivarium maintenance. Animals received standard food in accordance with the applicable rules. The animals treated according to the

rules of the "European Convention" for vertebral animals protection used for experimental and scientific purposes^[13].

3. Results and discussion

Six phytogel samples were studied with the complex of essential oils. To obtain bases was selected «Ultrez-10 NF» gelling carbomer by company «Lubrizol», and it was neutralized with tromethamol in the ratio 1: 1. The complex of essential oils previously dissolved in PEG-40 hydrogenated castor oil (PEG – 40 HCO) with 96% ethanol, and then administered into a gel base.

The results of screening of antibacterial phytogel samples action are presented in Table

Table 1 Antimicrobial effect of experimental samples (n=5)

Sample number	Microorganisms cultures			
	S. aureus	E. coli	B. subtilis	C. albicans
	Zone diameters of mikroorganisms stunted growth, mm			
1	14,5±0,3	13,5±0,2	15,5±0,4	12,5±0,2
2	14,5±0,2	14,2±0,3	15,5±0,3	13,5±0,2
3	14,5±0,3	13,5±0,2	16,5±0,4	13,5±0,2
4	15,5±0,1	15,2±0,2	17,5±0,3	14,2±0,2
5	16,5±0,4	15,5±0,5	17,5±0,4	14,5±0,5
6	17,5±0,5	14,8±0,3	16,3±0,1	15,5±0,3

According to the results of microbiological tests high antibacterial activity of selected gel samples with essential oils (ginger, clary, marjoram and tea tree) were proved. As it can be seen from table sample number 5 and sample number 6 approximately have the same high values. The concentration of essential oils in sample number 6 is more, so we selected a sample number 5 from an economical point of view it is more advantageous, and the effect is almost the same. In this way the sample with essential oils such as 1% ginger, 1% of clary, 0.5% marjoram, 0.5% tea tree (sample number 5), which provides high antimicrobial activity against gram-positive

cultures and yeast fungi of the genus *Candida*, which play a great role in the pathogenesis of respiratory diseases. This sample was selected for further studies. For new medications besides efficiency there are higher requirements for their safety. In this regard, we conducted a study of acute toxicity and local irritant action of "Imbyrol" phytogel (sample number 5) compared to the "Pinosol" cream (AO Zentyva, Slovakia), part of a complex that also includes essential oils such as pine, eucalyptus and menthol. Research results of general toxicological properties of "Imbyrol" gel (sample №5) are presented in Table 2.

Table 2: Studies of acute toxicity of "Imbyrol" phytogel in intragastric administration to rats (n=5)

Group	Dose, mg/kg	Amount of animals	The death of animals / Amount of animals	Results of research
"Imbyrol" phytogel	6680	3	0/3	Within two weeks of animals were moving, actively eating and drinking water, behave appropriately, showedno signs of intoxication.
	7500	3	0/3	
	8400	3	0/3	
	8900	3	0/3	
	9400	3	0/3	
"Pinosol" cream	6680	3	0/3	Within two weeks of animals were moving, actively eating and drinking water, behave appropriately, showedno signs of intoxication
	7500	3	0/3	
	8400	3	0/3	
	8900	3	0/3	
	9400	3	0/3	

These data indicate that the LD50 value for "Imbyrol" gel is in the dose range 7500 ÷ 9400 mg / kg. According to the method in the slightest dose of the selected range we find in table LD50 value, which was 8100 (7390 ÷ 8800) mg/kg after oral administration. According to the classification "Imbyrol" phytogel for oral administration to rats is classified practically as non-toxic substances (5001 <LD50 <15000 mh / kg) according to the classification of substances toxicity by Sidorov K.^[14]. Thus, the results of conducted research show no toxic and local irritant action "Imbyrol" phytogel in single skinapplication to rats.

4. Conclusion

Studies have shown that the the complex of selected essential oils with selected concentrations has expressed antimicrobial and anti-inflammatory effects. It is proved that the developed gel has no toxicity.

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