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SCIENTIFIC JUSTIFICATION OF THE COMPOSITION OF THE BASES–CARRIERS OF VETMICODERM LINIMENT FOR TOPICAL APPLICATION

[1]Ogloblina M. V., [*2]Bushueva I. V., [2]Parchenko V. V.

[1]Petro Mohyla Black Sea National University, Ukraine.
[2]Zaporizhzhia State Medical and Pharmaceutical University, Ukraine.

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***Corresponding Author: Dr. Bushueva I. V.**
Professor Zaporizhzhia State Medical and Pharmaceutical University, Zaporizhzhia, Ukraine.
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ABSTRACT
The development of veterinary pharmaceuticals in Ukraine is a strategically important area for ensuring the health of animals, increasing the competitiveness of the national agro –industrial complex and reducing dependence on import deliveries. «Vetmicoderm» antifungal liniment for external use is an example of an innovative product that has the potential to expand the arsenal of highly effective veterinary pharmacotherapeutic agents. Therefore, the purpose of the presented work was to justify the rational composition of the topical «Vetmicoderm» for veterinary practice with the use of a biopharmaceutical approach to implement this issue.

KEYWORDS: Antifungal agent, liniment, «Vetmicoderm», base–carrier, composition, pharmaceutical development.

INTRODUCTION

The development of veterinary pharmaceuticals in Ukraine is a strategically important area for ensuring the health of animals, increasing the competitiveness of the national agro –industrial complex and reducing dependence on import deliveries. «Vetmicoderm» antifungal liniment for external use is an example of an innovative product that has the potential to expand the arsenal of highly effective veterinary pharmacotherapeutic agents.

Practical implementation of research on the creation of a liniment for external use of Vetmicoderm will allow to expand the arsenal of highly efficient veterinary pharmacotherapeutic means, reduce dependence on import deliveries and vice versa to create conditions for increasing exports of domestic scientific products with high value. The use of the maximum number of domestic components and the use of technologies known in the Ukrainian chemical and pharmaceutical industry will simplify the implementation of this project and reduce the time of its implementation, which is quite relevant for the real sector of the economy of our country.

Based on biopharmaceutical concepts, the composition of the basics is one of the dominant pharmaceutical factors. Its scientifically sound choice is the main fragment of laboratory development of liniment for external use.[1,2]

The purpose of this work is to justify the rational composition of the topical liniment «Vetmicoderm» for veterinary practice with the use of a biopharmaceutical approach to implement this issue.

MATERIALS AND METHODS

Biopharmaceutical studies of the liniment «Vetmicoderm» for topical use were performed using harmless bases, the application of which on the skin does not lead to allergic and locally–rapid manifestations, has

positive consumer characteristics and technology of production of which has no technological complications in the conditions of domestic chemical–paint.[3,4]

The composition of linimental compositions is given in Table 1.

Table 1: The composition of topical veterinary compositions–limits with 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine, as the active substance «Vetmycoderm».

The components	Of the base–carrier (NoNo)								
	1	2	3	4	5	6	7	8	9
4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine	10	10	10	10	10	10	10	10	10
Sodium–CMC	2								
Twin 80	2	2	2	2	2				2
Methylcellulose		5							
Propylene glycol	30	30	30	30	30	30	30	30	30
Polyethylenoxide 400			5						
Polyethylenoxide 1500			53						
Olive oil				10	10	10	10	10	10
Monoglycerides are distilled				4	8				
Emulsifier №1				7,5					
Vaseline oil					10				
Emulpharma 1000 emulsifier						7			
Kedan Ksantanova						1			
Olivem 1000 emulsifier							5		
Guarov gum							1		
Isoemulgator								5	9
Polawax emulsion wax					6			10	
Ercawax CE V emulsifier								7	
Water purified to	100	100		100	100		100	100	100

Since the use of active pharmaceutical substances with a high degree of dispersion in soft dosage forms is more appropriate taking into account the biological availability factor[5] and solubility of 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine propylene glycol solution, which was obtained with moderate heating 70–80°C. All liniment compositions were prepared under identical conditions, stored for 2 weeks in a refrigerator, and the state of the experimental systems was organoleptically evaluated. All liniment compositions were prepared under identical conditions, stored for 2 weeks in a refrigerator, and the state of the experimental systems was organoleptically evaluated. Composition No. 9 liquefied during storage, which indicates a probable interaction of the ingredients and was therefore excluded from further experimentation. Compositions No. 1–8 were examined for their stability, which was determined by assessing colloidal and thermal stability according to State Standard 29188.3. It was found that linations from 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine on carriers № 6 and №7 are stratified under the influence of centrifugal forces and heat treatment and were also excluded. Biopharmaceutical evaluation of liniment compositions with 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine was carried out by assessing the intensity of release of the active pharmaceutical ingredient using the modified Kruvchinsky method. The equilibrium dialysis process was carried out using Franz diffusion cells (PermeGear, USA). «Cuprofan» film was used as a semipermeable membrane, and ethyl alcohol was chosen as the dialysis medium, taking into account the solubility of 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine. The dialysis temperature was 32±0.5˚C, the process time was 30 minutes, after which the amount of 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine in the dialysates was determined spectrophotometrically.[6] To increase the statistical reliability of the results and reduce the time of conducting the research, we used the mathematical model of variance analysis – a single–factor experiment with repeated observations.[7,8]

RESULTS

The carrier base determines:

- Physico–chemical properties, which ensure the stability of the active ingredient, such as an antifungal component, and promote its uniform distribution.
- Bioavailability, which affects the rate and depth of penetration of the active substance through the stratum corneum of the animal's skin, which is critically important for the effectiveness of «Vetmicoderm» liniment.
- Organoleptic characteristics that ensure ease of application, adhesion to the skin and comfort for animals, which reduces stress during application.

Scientifically based selection of the carrier base is a key stage in laboratory development.

Experimental studies have shown that bases with a high content of lipophilic components improve adhesion to the skin of animals with thick fur, while hydrophilic components promote rapid release of the active ingredient.[3] In addition, the choice of carrier base should take into account veterinary considerations such as the animal's skin type (e.g., epidermal thickness in cattle compared to small domestic animals) and application conditions (humidity, temperature). To ensure the stability of «Vetmicoderm» in various climatic conditions of Ukraine, antioxidants and preservatives that meet GMP (Good Manufacturing Practice) standards may be added to the composition. The analysis of variance matrix and the obtained experimental results are presented in Table 2.

Table 2: Amount of 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine released (%) from liniments for external use (time 30 minutes) according to the one–factor analysis of variance model with repeated observations.

No	Type of cream composition according to table 1 (factor A)	Test numbers			Together	Average value
		1	2	3		
1	8	47,19	44,33	47,19	138,71	46,24
2	5	31,46	30,03	31,46	92,95	30,98
3	4	17,16	18,59	21,45	57,2	19,07
4	2	16,9	16,9	15,47	49,27	16,42
5	1	14,3	17,16	17,16	48,62	16,21
6	3	5,72	10,01	8,58	24,31	8,1
Together					411,06	

Table 3 presents the results of the analysis of variance of the obtained experimental data.

Table 3: Analysis of variance data of 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine released after 30 min from experimental liniment formulations.

Source of variability	Number of degrees of freedom	Sum of squares	Mean square	$F_{exp.}$	$F_{table.}$
Composition type	5	2790,9	558,18	204,46	2,9
Error	12	32,74	2,73		
Total amount	17	2823,64			

The results of the analysis of variance using the Fisher test indicate that the calculated experimental value of the F–criterion ($F_{exp.}$) significantly exceeds its tabular value ($F_{tab.}$) for the corresponding degrees of freedom indicated in the table. This allows us to conclude that the type of matrix–carrier of the studied liniments has a statistically significant effect on the release profile of 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine from these pharmacotherapeutic compositions. Comparison of the average values of this optimization parameter using Duncan's multiple rank criterion allowed generating a number of its advantages, which allow updating the data of biopharmaceutical research and identifying the optimal composition of veterinary liniment with 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine (the composition numbers correspond to those in Table 1):
8 th > 5 th > 4 th (2 th (1 th) > 3 th

DISCUSSION

They prove the promising use for further research within the framework of pharmaceutical development of the liniment «Vetmicoderm» with 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine on emulsion base No. 8:
4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine 10,0
Propylene glycol 30.0
Olive oil 10.0
Isoemulsifier 5.0
Polawax emulsion wax 10.0
Emulsifier Ercawax CE V 7.0
Water purified to 100.0

CONCLUSION

It was found that the type of carrier base has a statistically significant effect on the release of 4–((5–(decylthio)–4–methyl–4H–1,2,4–triazol–3–yl)–methyl)morpholine from veterinary liniments for external use.

It was established that the oil/water emulsion matrix–base is the optimal carrier for the studied pharmacotherapeutic agent, as it provides the maximum level of release of the active substance and allows to reliably predict a high level of bioavailability of the liniment.

Conflict of interest: No.

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