Сертификат анализа

[illegible]	**ПИНОСОЛ®**		
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible] 3 7 5 2 [illegible] / 1 0		
[illegible]	[illegible]		
[illegible]	[illegible]	[illegible]	[illegible]

G u i z h o u p r o v i n c e , C h i n a

Г в а й азулен	[illegible]	[illegible]
Тимол	[illegible]	[illegible]
Масло мяты перечной	[illegible]	[illegible]

Испытание	**Нормы**	**Результаты**	**Оценка**
Описание	[illegible]	[illegible]	[illegible]
Подлинность	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
Микробиологическая чистота			
. [illegible]. 5 . 1 . 4			
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

Saneca Pharmaceuticals

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ljh^mdl	IBGHKHE		
Ghf_j ijh^mdlZ	1200477	K_jby /,06 +9	727 172
Ghf_j k_jbb	3010121	JZaf_j \uims_gq k_jbb	61 200
>habjh\dZ	0,17, 0,05, 0,002, 0,1, 0, , 0,0032		
E_dZjkl_ggZy			
JZaf_j miZdh\c	10	>ZlZ ijh_^_gby	07.02.2021
>ZlZ ijhba\h^k	11.01.2021	Ki_pbnbdZpby	N015768/03-110110
>ZlZ bkl_q_gb]h^ghklb	31.122023	Ghf_j j_]bkljZpl m^hklh_j_:gby	N015768/03
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*0,'	682492		
:NB	:evn-Zhdhn_jheZ Z _lZl Khkgu h[udgh\fZkgehc FZkeh w\dZeb-h\h_	238A, 065 11	
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	FZkeh fylu i_j- ghc	238A, 065 11	

	0,068%	0,177%	
	0,369%	0,422%	
	0,029%	0,033%	
	0, 0,0144%	0,0122%	
Dhebq_kl_ggh_ hij_^_e_g W_@O	1,53 ,87%	1,70%	
Khhl_lkl\m_l lj_[h\Zgbyf ki_pbnbdZpbb			

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ljhba\h^kl_ggZy iehsZ^dZ	DhgljhdZq_kl\Z b \uimkdZxsZy iehsZ^dZ
-15/2019	-15/2019
19 20	19 20

Ml_j'^_gh mihegh ihe_gb fh / ih^ibkv >ZlZ 08.02.2021

Certificate of analysis

Saneca Pharmaceuticals

Product	**PINOSOL ®**		
Product number	12004772	*Batch LIMS HV*	727 172
Batch number	3010121	*Released quantity*	61 200 PACKS
Dosage strength	0,17g, 0,05g, 0,002g, 0,1g, 0,3752g, 0,0032g,/10 g		
Dosage form	nasal drops		
Packaging size	10 ml	*Date of analysis*	7. 2. 2021
Manufacture date	11. 1. 2021	*Specification*	P N015768/03-110110
Expiry date	31. 12. 2023	*Marketing authorisation No.*	P N015768/03
Importing country	Russia		
GMID	682492		

API: TOCOFEROLI ALFA ACETAS, BASF SE, Carl Bosch Strasse 38, 67056, Ludwigshafen, DE

PINE SYLVESTRIS OIL- CALENDULA A.S., SK, Nová Ľubovňa 238 A , 065 11 Slovak Republic
EUCALYPTUS OIL - Guizhou Kaily Jian Perfumery Co. Ltd. Wanchao Industrial Area, Kaili city, Guizhou province, China
GUAIAZULENE - SYMRISE GMBH&CO. KG, GE, Muehlenfeldstrasse 1, 37603 Holzminden, Germany
THYMOL - SYMRISE GMBH&CO. KG, GE, Muehlenfeldstrasse 1, 37603 Holzminden, Germany
PEPPERMINT OIL - CALENDULA A.S., SK, Nová Ľubovňa 238 A , 065 11 Slovak Republic

Test	Limits	Results	Evaluation
Appearance			
Appearance	clear liquid,blue to green-blue colour with characteristic odour of menthol and eucalypt	complies	complies
Identification			
1.8 cineole	concordance of chromatograms	positive	complies
Fenchon	concordance of chromatograms	positive	complies
Alpha pinene	concordance of chromatograms	positive	complies
Bornylacetate	concordance of chromatograms	positive	complies
Butylhydroxyanisol	concordance of chromatograms	positive	complies
Menthol	concordance of chromatograms	positive	complies
Thymol	concordance of chromatograms	positive	complies
α-Tocoferol acetate - HPLC	concordance of chromatograms	positive	complies
Guaiazulene (spectrally)	maximum at 604 nm ± 2 nm, respect.650 nm ± 2 nm,720 nm ± 2 nm	positive	complies
Relative density	0.910 to 0.925	0.916	complies
Fill volume of 1 package	NLT 10.0 ml	10.0 ml	complies
Microbiological quality			
Microbiological quality, Ph.Eur. 5.1.4.			
Total aerobic microbial count (TAMC)	NMT 10^2 CFU/g	0 CFU/g	complies
Total combined yeats/moulds (TYMC)	NMT 10^1 CFU/g	0 CFU/g	complies

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Absence of Staphylococcus aureus	absence in 1 g	absence in 1g	complies
Absence of Pseudomonas aeruginosa	absence in 1 g	absence in 1g	complies
Bile-tolerant gram-negative bacteria	absence in 1 g	absence in 1g	complies
Content GC			
Alpha pinene	NLT 0.676 %	1.507 %	complies
1.8-cineole	NLT 0.315 %	0.934 %	complies
Bornylacetate	NLT 0.068 %	0.177 %	complies
Menthol	NLT 0.369 %	0.422 %	complies
Thymol	NLT 0.029 %	0.033 %	complies
Butylhydroxyanisol	0.0096 % to 0.0144 %	0.0122 %	complies
Content HPLC			
α-Tocoferol acetate	1.53 % to 1.87 %	1.70 %	complies

Conformity with the specification.

I hereby certify that the above information is authentic and accurate. This batch product has been manufactured including packaging and quality control at the below mention site in full complience with the GMP requirements of the local Regulatory Authority and with the the specifications in the Marketing Authorization of the importing country - Normative Document specifications. The batch processing, packaging and analysis records have been reviewed and found to comply with GMP. Labelling is in full compliance with the last approved by Ministry of Health of the Russian Federation version of packaging and leaflet artworks.

Released for sale

Certificate of analysis

Saneca Pharmaceuticals

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PEPPERMINT OIL - CALENDULA A.S., SK, Nová Ľubovňa 238 A , 065 11 Slovak Republic

Manufacturing site:

Saneca Pharmaceuticals a.s, Nitrianska 100
920 27 Hlohovec, Slovak republic
Authorisation number : V-15/2019
GMP Certificate No : SK/019V/2020

Quality control and release site:

Saneca Pharmaceuticals a.s, Nitrianska 100
920 27 Hlohovec, Slovak republic
Authorisation number : V-15/2019
GMP Certificate No : SK/019V/2020

Certified by QP: Vicenová Mária

Certified on: 8. 2. 2021

Saneca Pharmaceuticals
Saneca Pharmaceuticals a.s.
Nitrianska 100
920 27 Hlohovec
Slovenská republika
IČO: 46 833 323
IČ DPH: SK2023599842 55