

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

S.C. BISTRI-VET SRL
 LIBERTATII STR. 13
 420155 BISTRITA (JUD. BISTRITA-NASAUD)
 ROMANIA

Hoogstraten, 24.01.2019

ORIGINAL

Material

F862016-001079-01 OTOSPECTRINE 15ML

Pharmaceutical Form:

Non sterile suspension

Batch 4003510 / Manufacturing Date 10.2018 Expiry date 10.2020

Inspection lot 40000039561 from 11.2018

CERTIFICATION STATEMENT: I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Formula: Neomycinesulphate 5000 IU - Dexamethasone 1 mg - Polymyxine B sulphate 10000 IU - Monosulfiram 50 mg - Lidocaine HCl 40 mg excipients q.s. ad 1 ml

Aspect: yellow suspension

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (15 ml)	%	98,53	95,00	105,00
pH		5,49	4,00	7,00
Relative density		1,067	1,060	1,080
Refractive index		1,460	1,450	1,500
Id: Neomycin sulphate		Complies		
Id: Lidocaine HCl		Complies		
Id: Dexamethason		Complies		
Id: Monosulfiram		Complies		
Id: Polymyxin B sulphate		Complies		
Assay: Dexamethasone	%	99,12	95,00	105,00
Assay: Lidocaine HCl	%	99,81	95,00	105,00
Assay: Monosulfiram	%	98,33	95,00	105,00
Assay: Polymyxin B sulphate	%	97,29	90,00	110,00
Assay (Micro): Neomycin	%	102,10	90,00	110,00
Micr.qual: TAMC	CFU/G	0		100
Micr.qual: TYMC	CFU/G	0		10
Micr.qual: P. aeruginosa		Absent		
Micr.qual: S. aureus		Absent		

Dig. Sign.: Van Buggenhout Kris
 23.01.2019 13:18:28

Qualified Person

Conclusion:
 Quality test complied



focus on health

ORIGINAL

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