

BIOMECTIN 1% INJ. 100ML

Gysz: 0E0129C

Kisz: 100ML

SZÉKELY KFT részére

Lej: 2023-01-12

Me: Doboz

Szállító:

Medimpex Gy. Zrt.

1158 Budapest

Rákospalotaihatárút2

Tel: +36-1-414-6477

e-mail: qa@mpx.hu



CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT	
Product name : BIOMECTIN 1% 100ML HU	Manufacturing date : 13/01/2020
Batch number : 0E0129C	Expiration date : 12/01/2023

TESTS	SPECIFICATIONS	RESULTS
Product appearance	Clear, colorless solution	Pass
Content in unit container 100ml	$\geq 100 \leq 110$ ml	102 ml
Density	$\geq 1.080 \leq 1.200$ g/ml	1.109 g/ml
Viscosity in 20°C	$\geq 25 \leq 35$ cP	27 cP
Identification Ivermectin TLC method Spectrophotometric method HPLC method	Confirm with Rf Confirm with spectrum Confirm with RT	Pass Pass Pass
Identification Glycerol formal TLC method GC method	Confirm with Rf Confirm with RT	Pass Pass
Identification Propylene glycol TLC method GC method	Confirm with Rf Confirm with RT	Pass Pass
H2B1a compound assay	≥ 90 %	97 %
Assay Ivermectin Total of H2B1a and H2B1b	$\geq 0.95 \leq 1.05$ % m/v	1.00 % m/v
Propylene glycol assay	$\geq 54 \leq 66$ % v/v	59 % v/v
Glycerol formal assay	$\geq 36 \leq 44$ % v/v	41 % v/v

This document has been produced electronically and is valid without a signature.

Vetoquinol Biowet Sp. z o.o.
Adres: ul. Kos. Gdynskich 13-14,
Tel. +48/95/728 55 00 +1,
fax +48/95/728 55 00
Sąd Rejonowy w Zielonej Górze VIII wydział Gospodarczy KRS o numerze 0000064225 Wysokość kapitału zakładowego 3.500.000 Zł

PL- 66-400 GORZÓW WLKP
e-mail: info@vetoquinol.com
www.vetoquinol.pl
NIP 599-01-08-560

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FINISHED PRODUCT		
Product name : BIOMECTIN 1% 100ML HU	Manufacturing date :	13/01/2020
Batch number : 0E0129C	Expiration date :	12/01/2023
TESTS	SPECIFICATIONS	RESULTS
HPLC purity		
Impurities of RRT 1,3-1,5	<= 2.5 %	2.0 %
Any other impurity	<= 1 %	1 %
Total	<= 5 %	4 %
Sterility	Sterile	Pass

The batch meets requirements release specification

Approved by QC : Przemyslaw KOWALSKI	Released by Qualified Person : Mariola KISZEWSKA
Date : 04/02/2020 15:45:30	Date : 23/04/2020 13:24:11
	Decision : FULL RELEASE

Not tested - According to the requirements of the marketing authorization the parameter is not tested routinely.

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