

BIOMECTIN 1% INJ. 50ML
 Gysz: 6B3531B Lej: 19/10/12
 Kisz: 50ml Me.: Doboz
 SZÉKELY KFT részére

Medimpex Gy. Zrt.
 1158 Budapest
 Rákospalotaihatárút2
 Tel: +36-1-414-6477
 Fax: +36-1-414-6479

Biomectin 1% injekció (HU) A.U.V.
 Gysz: 6B3531B Lej: 19/10/12
 Kisz: 50ml Me.: darab
 MEDIMPEX GYÓGYSZER ZRT. részére

2151 Fót
 Keleti Márton u. 19.
 Tel: 27/537-100
 Fax: 27/537-100



BATCH CERTIFICATE FOR MEDICINAL PRODUCT

Name, strength/potency, dosage form	Biomectin 1%, 10mg/ml, solution for injection
Package size	50 ml
Batch number of the finished product	6B3531B /
Name of the destination country / countries of the batch	Hungary
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 [when within the EU] with the requirements of the Marketing Authorisation(s) of the destination country/countries.	
Name of the Qualified Person certifying the batch	Mariola Kiszewska
Signature of Qualified Person certifying the batch	
Date of signature	2015-11-28

Vetoquinol Biowet Sp. z o.o.
 Adres: ul. Kos. Gdynskich 13-14,
 15-148/95/ 728 55 20 + G1,
 5-letni Logistyczny Sprzedaży
 Toruń, ul. Dąbrowski
 e-mail: info.pl@vetoquinol.com

PL-64-400 004 204 0141P
 tel: +48/95/ 728 55 37
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ANKA Bank BGZ BNP Paribas S.A.
 EUR PL29 1400 1094 0004 0000 0000 0000 0000 0000 0000 0000 0000
 USD PL52 1400 1094 0004 0000 0000 0000 0000 0000 0000 0000 0000
 CHF PL28 1400 1094 0004 0000 0000 0000 0000 0000 0000 0000 0000
 P. 37 1400 1094 0004 0000 0000 0000 0000 0000 0000 0000 0000
 REKEN 210521414 NIP 597111810
 Wysokość kapitału zakładowego: 1 000 000 000

BIOMECTIN 1% INJ. 50ML

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Kisz:50ml

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Lej:19/10/12

Me.:Doboz

Medimpex Gy. Zrt.

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CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT		
Product name : BIOMECTIN 1% 50ML HU	Manufacturing date : 12/10/2016 /	
Batch number : 6B3531B /	Expiration date : 12/10/2019 /	
TESTS	SPECIFICATIONS	RESULTS
Product appearance	Clear, colorless solution	Pass
Content in unit container 50ml	$\geq 50 \leq 55$ ml	51 ml
Relative density	$\geq 1,080 \leq 1,200$ g/ml	1,109 g/ml
Viscosity in 20°C	$\geq 25 \leq 35$ cP	28 cP
Identification Ivermectin		
TLC method	Confirm with Rf	Pass
Spectrophotometric method	Confirm with spectrum	Pass
HPLC method	Confirm with RT	Pass
Identification Glycerol formal		
TLC method	Confirm with Rf	Pass
GC method	Confirm with RT	Pass
Identification Propylene glycol		
TLC method	Confirm with Rf	Pass
GC method	Confirm with RT	Pass
H2B1a compound assay	≥ 90 % m/v	87 % m/v
Assay Ivermectin		
Total of H2B1a and H2B1b	$\geq 0,95 \leq 1,05$ % m/v	1,00 % m/v
Propylene glycol assay	$\geq 54 \leq 66$ % m/v	58 % m/v
Glycerol formal assay	$\geq 38 \leq 44$ % m/v	41 % m/v

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Vetoquinol Biowet Sp. z o.o.
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Sz: Repnowy w Zielonej Górze Via wydział Gospodarczy KRŚ o numerze 0200064275 Wykaski kasztan: zakisidawngi 3 500 000 71

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

Meoszám:190400228MBT

5.pld. Kiadva: 19/06/19

MEDIMPEX GYÓGYSZER ZRT.
1158 Bp., Rákospalotai határút 2.
Nagyné Kán Éva
Minőségbiztosító szakasszisztens
Csak a piros szín hiteles

gel

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vetoquinol
ACHIEVE MORE TOGETHER
CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT

Product name : BIOMECTIN 1% 50ML HU	Manufacturing date : 12/10/2016	
Batch number : 0B3531B	Expiration date : 12/10/2019	
TESTS	SPECIFICATIONS	RESULTS
HPLC purity		
Impurities of RRT 1,3-1,5	<= 2.5 %	1.8 %
Any other impurity	<= 1 %	0 %
Total	<= 3 %	3 %
Sterility	Sterile	Pass

I hereby certify that this lot is manufactured, packed and labelled under conditions as stated in current European Union rules for Good Manufacturing Practice, for medicinal products for veterinary use, and the finish product in all aspects meets marketing authorization requirements.

Approved by QC : Przemysław KOWALSKI	Released by Qualified Person : Mariola KISZEWSKA
Date : 25/11/2016 16:11:01	Date : 28/11/2016 14:16:48
	Decision : FULL RELEASE

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

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Vetoquinol Biowet Sp. z o.o. Adres: ul. Kos. Goyniskich 13-14, Tel: +48/95/729 55 00 Fax: +48/95/729 55 00 5a:1 Rejmowice, Zielonej Górze VIII wódz of Gospodarczy KRS 000044225 Wysokość kapitału zakładowego 9 500 000 Zł	PI - 64-400 00020W WLKP e-mail: info@vetoquinol.com www.vetoquinol.pl NIP 559-01-08-568
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Meoszám:161200592/07/T 8.pld. Kiadva: 19/03/29

Meoszám:190400228MBT 5.pld. Kiadva: 19/06/19

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Csak a piros szín hiteles