

BIOMECTIN 1% INJ. 100ML
Gysz:6B3375B Lej:19/09/29
Kisz:100ML 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:6B3375B Lej:19/09/29
Kisz:100ml Me.:doboz
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	100 ml
Batch number of the finished product	6B3375B
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	2016-11-08

Vetoquinol Biowet Sp. z o.o.
Al. Wolności 13-14,
01-654 Warszawa
Kraj: Polska
Kraj: Logistyk/Sprzedaż
Kraj: Dostaw
e-mail: info.pl@vetoquinol.com
Kraj: Rejestracja w Krajowej Górze VIII Wydział Gospodarczy KRSe numerze 9000064226

Pol: 65-400 60 20 W PKP
fax +48/95/ 735 90 45
tel/fax +48/95/ 728 55 37
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www.vetoquinol.pl

Konta: Bank 302 BNP Paribas s.a
EUR PL75 1620 1084 0004 0000 0000 0000 0000
USD PL52 1620 1084 0004 0000 0000 0000 0000
CHF PL25 1620 1084 0004 0000 0000 0000 0000
PL07 1620 1084 0004 0000 0000 0000 0000
REGON 210527414 NIP 599 000 0000
Wysokość kapitału zakładowego: 3 000 000 zł



CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT		
Product name: BIOMECTIN 1% 100ML HU	Manufacturing date: 29/08/2016 /	
Batch number: 6B33756	Expiration date: 29/09/2019 /	
TESTS	SPECIFICATIONS	RESULTS
Product appearance	Clear, colorless solution	Pass
Content in unit container 100ml	>= 100 <= 110 ml	102 ml
Relative density	>= 1.080 <= 1.200 g/ml	1.109 g/ml
Viscosity in 20°C	>= 25 <= 35 cP	28 cP
Identification Ivermectin		
TLC method	Confirm with RT	Pass
Spectrophotometric method	Confirm with spectrum	Pass
HPLC method	Confirm with RT	Pass
Identification Glycerol formal		
TLC method	Confirm with RT	Pass
GC method	Confirm with RT	Pass
Identification Propylene glycol		
TLC method	Confirm with RT	Pass
GC method	Confirm with RT	Pass
H2B1a compound assay	>= 90 % m/v	98 % m/v
Assay Ivermectin		
Total of H2B1a and H2B1b	>= 0.95 <= 1.05 % m/v	1.00 % m/v
Propylene glycol assay	>= 54 <= 66 % m/v	60 % m/v
Glycerol formal assay	>= 36 <= 44 % m/v	41 % m/v

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

Vetoquinol Biowet Sp. z o.o.
 Adres ul. Kosz. Gdynskich 13-14,
 Tel: +48 79 572 28 53 (6 lin.)
 fax: +48 79 572 8 55 30
 Sąd Rejonowy w Zielonej Górze XII wydział Gospodarczy Kraj. S. numerze 2001064225 Wysokość kapitału zakładowego 3.500.000,00 zł

PL- 66-400 GORZÓW WL K/P
 e-mail: info@vetoquinol.com
 www.vetoquinol.pl
 NIP 599-01-09-540

BIOMECTIN 1% INJ. 100ML

Gysz:6B3375B

Kisz:100ML

SZÉKELY KFT részére

Lej:19/09/29

Me.:Doboz

Medimpex Gy. Zrt.

1158 Budapest

Rákospalotaihatárút2

Tel:+36-1-414-6477

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ACHIEVE MORE TOGETHER
CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT

Product name : BIOMECTIN 1% 100ML HU Manufacturing date : 28/09/2018
Batch number : 6B3375B Expiration date : 29/09/2019

TESTS	SPECIFICATIONS	RESULTS
HPLC purity		
Impurities of RRT 1,3-1,5	≤ 2.5 %	1.5 %
Any other impurity	≤ 1 %	1 %
Total	≤ 5 %	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 : Przemyslaw KOWALSKI Released by Qualified Person : Maciela KISZEWSKA
Date : 04/11/2018 10:26:44 Date : 08/11/2018 14:10:57
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. Kas. Gdyniskich 12-14,
Tel: +48957285500
Fax: +48957285500
Sąd Rejonowy w Zielonej Górze VIII Wydział Gospodarczy KR5 o numerze 380064225. Wysokość kapitału zakładowego: 2 500 000 zł

PL: 56-600 00R70W ZAKP
e-mail: info@vetoquinol.com
www.vetoquinol.pl
NIP 599-01-09-560

Meoszám:161200591/07/T 8.pld. Kiadva: 19/03/29

Meoszám:190400226MBT 6.pld. Kiadva: 19/06/13

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

al