Biomectin 1% injekció (HU) A.U.V.
Gysz:6B3375B Lej:19/09/29
Kisz:100ml Me.:doboz
DR. SZÉKELY KFT. részére

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

vetoquinol
ACHIEVE MORE TOGETHER

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.
Adres: ul. Kos. Edyńskich 13-14,
tel. +48/957 728 55 00 + 01
Dział Logistyki Sprzedaży
Łańcuch Dostaw
e-mail: info.pl@vetoquinol.com
Sąd Rejestrowy w Zielonej Górze VIII Wydział Gospodarczy KRS o numerze 0000064226

P.O. 66-400 GORZÓW WLKP.
fax +48/957 735 90 45
tel./fax +48/957 728 55 57
tel./fax +48/957 728 55 50
www.vetoquinol.pl

Konto: Bank BGZ BNP Paribas S.A.
EUR PL75 1600 1084 0004 0[illegible]
USD PL52 1600 1084 0004 0[illegible]
CHF PL25 1600 1084 0004 0[illegible]
PL31 1600 1084 0004 0[illegible]
REGON 210527414 NIP 599[illegible]
Wysokość kapitału zakładowego [illegible]

vetoquinol
ACHIEVE MORE TOGETHER

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name : BIOMECTIN 1% 100ML HU
Batch number : 6B33756

Manufacturing date : 29/09/2016
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 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	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.

Vétoquinol Biowet Sp. z o.o.
Adres: ul. Kos. Szyńskich 13-14,
Tel: +48/95/728 55 00
fax: +48/95/728 55 30
Sąd Rejonowy w Zielonej Górze VIII wydział Gospodarczy KRS o numerze 0000064225 Wysokość kapitału zakładowego 3.600.000 Zł

PL- 66-400 GORZÓW WLKP
e-mail: info@vetoquinol.com
www.vetoquinol.pl
NIP 599-01-09-560

vetoquinol
ACHIEVE MORE TOGETHER

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name : BIOMECTIN 1% 100ML HU
Batch number : 6B3375B

Manufacturing date : 29/09/2016
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
Date : 04/11/2016 10:28:44

Released by Qualified Person : Mariola KISZEWSKA
Date : 08/11/2016 14:10:57
Decision : FULL RELEASE

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

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

Vétoquinol Biowet Sp. z o.o.
Adres: ul. Kos. Gdyńskich 13-14,
Tel. +48/95/728 55 00 ext 1,
fax +48/95/728 55 30
Sąd Rejonowy w Zielonej Górze VIII wydział Gospodarczy KRS o numerze 0000064225 Wysokość kapitału zakładowego: 8 500 000 zł
PL- 66-400 GORZÓW WLKP
e-mail: info@vetoquinol.com
www.vetoquinol.pl
NIP 599-01-09-560

Min. biz.