NOVARTIS

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BATCH CERTIFICATE

Product Name :	ECONOR 10 % Premix - 25 kg		
Dosage Form	Premix (powder)	Conc. of Valnemulin:	100 mg/g
		Manufacturing Date:	02/2015
Substance Number:	A - 12120 A	Expiry Date:	02/2020
Importing Country:	Hungary	Marketing Authorisation Nr.:	EU/2/98/010/018
	Poland		EU/2/98/010/018

Sites involved in the Manufacture		*Manuf. Author. Nr.*
Manufacturing / Testing & Packaging	Eurovet Animal Health BV, Handelsweg 25, 5531 AE BLADEL , the Netherlands	855-BVEAK

Tests	
◦ See Certificate of Analysis Eurovet Animal Health (Annex)	Batch 068078

Comments:

Lot meets Novartis Animal Health Inc. Quality Requirements.

I hereby certify that the above information is authentic and accurate. This batch of Product has been fabricated/manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Signature

Roy Gaelle

Digitally signed by Roy Gaelle
DN: SERIALNUMBER=1747961 +
CN=Roy Gaelle, OU=AH,
OU=people, DC=novartis, DC=com
Reason: batch release
Date: 2015.07.01 14:15:29 +02:00

Pharmacist, Deputy, Qualified Person

Certificate issued on 01/07/2015

This document was electronically signed according to Novartis digital signature standards

Novartis Animal Health d.o.o.
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Certificate of Analysis

Name of the product: Econor 10% Premix

eurovet Animal Health

Product number	: 78018	Our ref. number	: KB
Batch number	: 068078	Packing instruction	: 98018104
Manufacturing date	: 02-2015	Packing / Batch size	: 25 kg / 71
Expiry date	: 02-2020	Date of analysis	: 03-06-2015
Novartis form. code	: A-12120A	Testing method Dechra	: QM-SC-LAB78018
Testing Method NAH	: BE-334.H1	CoA version	: SC98018104.1.0
Novartis material number	: 610712126A00	Country	: Hungary / Poland
Batch number API	: B297025 / 940031		

Dechra manufacturing authorisation number : 855-BVEAKI
Novartis marketing authorization number : EU/2/98/010/018

DETERMINATIONS	SPECIFICATIONS	RESULTS
1. APPEARANCE	White to slightly yellowish powder	White to slightly yellowish powder
2. WATER CONTENT (%)	Not more than 5.5	4.1
3. PH	3.5 – 6.0	5.0
4. VALNEMULIN (IDENTIFICATION BY TLC)	Confirmed	Confirmed
5. VALNEMULIN (IDENTIFICATION BY HPLC)	Confirmed	Confirmed
6. UNIFORMITY OF MASS (KG)		
(AVERAGE)	Not less than 25	25
(INDIVIDUAL)	24.75 – 25.25	
7. VALNEMULIN (%) (ASSAY BY HPLC)	95 - 105 of declared content	99
8. RELATED SUBSTANCES		
Valnemulin Sulfoxide (%)	≤ 1.0	0.1
Pleuro-DMC (%)	≤ 2.0	0.3
Valyl-Valnemulin (%)	≤ 2.0	0.4
Unknown individually (%)	≤ 0.2	0.1
Unknown in total (%)	≤ 1.0	0.1
Known in total (%)	≤ 3.0	0.8
Known and unknown in total (%)	≤4.0	0.9

Alexandar Diamandidis

08 JUN 2015

Manager Quality Assurance - Qualified Person

Conclusion : **Conform specifications.**

This product has been manufactured and tested on behalf of Novartis Animal Health Inc. Basel/Switzerland. I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site in full compliance with the GMP requirements of the Dutch Regulatory Auhority and in compliance with the documentation and specifications provided by Novartis Animal Health. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

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Dechra