NOVARTIS
ANIMAL HEALTH

Novartis Animal Health Inc.
26, rue de la chapelle
68330 Huningue, France

Tel + 33 3 68 06 33 00
Fax + 33 3 68 06 34 00

BATCH CERTIFICATE

Product Name :	DENAGARD 45% granulátum - 1112 g		
Dosage Form	Water soluble granules	Conc. of Tiamulin:	450 mg/g
Material Number:	610697-354A00	Manufacturing Date:	09/2014
Substance Number:	A-8812 A	Expiry Date:	09/2017
Quantity	477		
Importing Country:	Hungary	Marketing Authorisation Nr.:	2073/3/06 ÁOGYTI

Sites involved in the Manufacture		*Manuf. Author. Nr.*
Manufacturing	Sandoz GmbH BTP Schaftenau, Biochemiestraße 10 6336 Langkampfen, Austria	481368

Tests

◦ See Certificate of Analysis Sandoz (Annex)	Batch B273009
◦ See Certificate of Packaging Eurovet Animal Health (Annex)	Batch 061233

Comments:

Lot meets Novartis Animal Health Inc. Quality Requirements.

The shelf life of the bulk material may be different from the shelf life of the registered finished product.

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

Legrand
Kevin

Digitally signed by Legrand Kevin
DN: SERIALNUMBER=1375536 +
CN=Legrand Kevin, OU=AH,
OU=people, DC=novartis, DC=com
Reason: Batch release
Date: 2014.12.05 15:04:24 +01:00

Pharmacist, Deputy, Qualified Person

Certificate issued on *05/12/2014*

This document was electronically signed according to Novartis digital signature standards

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Certificate of Packaging

Name of the product: Denagard 45% granulátum

Product number	: 840503	Our ref. number	: JT
Batch number	: 061233	Packing instruction	: 94050302
Manufacturing date	: 09-2014	Packing / Batch size	: 1.112 kg / 477
Expiry date	: 09-2017	Date of analysis	: 27-11-2014
Novartis form. code	: A-8812 A	Testing method Eurovet	: QM-SC-LAB84050
Testing Method NAH	: BE-296.H5	CoA version	: SC94050302.3.0
Batch number API	: B273009/ 936711		

Eurovet manufacturing authorisation number : 855-BVEAKI
Novartis marketing authorization number : 2073/3/06 AOGYTI

DETERMINATIONS	SPECIFICATIONS	RESULTS
TIAMULIN HYDROGEN FUMARATE (IDENTIFICATION BY HPLC)	Corresponds to comparison	Corresponds to comparison
AVERAGE FILLING MASS (g)	1128 - 1162	1151
INDIVIDUAL FILLING MASS (g)	1112 – 1178	pass

Alexander Diamandidis

03 DEC 2014

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