

Ref: 00000072214

Certificate of Analysis

Product Name: DENAGARD 45% N AT15 GR UD GE
Customer prod. Name: DENAGARD 45% WATERSOLUBLE GRANULES AD US.VET.
Material No: 450019 Sandoz Batch: B288746
Inspection Lot No.: 000406805458
Manufacturing Date: JAN-2015 Expiry Date: JAN-2018
Printed expiry date 1: January 2018
Specification No.: 2909.6

Tests	Requirements	Results
APPEARANCE	WHITE TO YELLOWISH GRANULES	Complies
IDENTIFICATION TIAMULIN HYDROGENFUMARATE (HPLC)	CORRESPONDING	Complies
DISSOLVING TIME	<= 5 min	1 min
BULK DENSITY (PH.EUR.)	0.50 - 0.65 g/mL	0.58 g/mL
TAPPED DENSITY (PH.EUR.)	0.60 - 0.80 g/mL	0.71 g/mL
LOSS ON DRYING (PH.EUR.)	<= 2.0 %	1.1 %
COLOUR OF SOLUTION (PH.EUR.)	COLOURLESS TO SLIGHTLY YELLOWISH, NOT DARKER THAN Y6	Complies
PH-VALUE	3.0 - 4.0	3.6
BY-PRODUCTS (WITH REFERENCE TO THE DECLARED CONTENT OF ACITVE SUBSTANCE): IMPURITY B (HPLC)	<= 1.5 %	< 0.1 %
BY-PRODUCTS (WITH REFERENCE TO THE DECLARED CONTENT OF ACITVE SUBSTANCE:) IMPURITY H (HPLC)	<= 1.5 %	< 0.1 %
BY-PRODUCTS (WITH REFERENCE TO THE DECLARED CONTENT OF ACITVE SUBSTANCE): IMPURITY I (HPLC)	<= 1.0 %	0.2 %

Ref: 000000072214

Certificate of Analysis

Product Name: DENAGARD 45% N AT15 GR UD GE
Customer prod. Name: DENAGARD 45% WATERSOLUBLE GRANULES AD US.VET.
Material No: 450019 **Sandoz Batch:** B288746

Tests	Requirements	Results
BY-PRODUCTS (WITH REFERENCE TO THE DECLARED CONTENT OF ACITVE SUBSTANCE); IMPURITY F (HPLC)	<= 1.0 %	0.1 %
BY-PRODUCTS (WITH REFERENCE TO THE DECLARED CONTENT OF ACITVE SUBSTANCE); IMPURITY D (HPLC)	<= 1.0 %	0.6 %
BY-PRODUCTS (WITH REFERENCE TO THE DECLARED CONTENT OF ACITVE SUBSTANCE); ANY OTHER IMPURITY (HPLC)	<= 0.5 %	0.2 %
BY-PRODUCTS (WITH REFERENCE TO THE DECLARED CONTENT OF ACITVE SUBSTANCE); TOTAL IMPURITIES (HPLC)	<= 3.0 %	1.1 %
AEROBIC BACTERIA	<= 1000 cfu/g	< 100 cfu/g
YEASTS AND MOULDS	<= 100 cfu/g	0 cfu/g
ESCHERICHIA COLI	NOT DETECTABLE IN 1 G	Complies
ASSAY TIAMULIN HYDROGENFUMARATE (HPLC, PH.EUR.)	42.8 - 47.2 %	44.8 %

Confirmation:

The product has been manufactured and packaged in compliance with cGMP (GMP Guideline Volume 4 Parts I and II (ICHQ7)), the product registration, applicable laws or regulations and tested according to the approved specifications. FULLY COVERS TESTS AND SPECIFICATIONS OF TM 2909.

Sales Order Number: 4376043654

Origin: Austria

Data authorized by:**MICHAEL PRIMIK**
QC Release Manager**Date of release:**

30-JAN-2015

Certificate creation date:

05-FEB-2015

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:	01/2015
Substance Number:	A-8812 A	Expiry Date:	01/2018
Quantity	476		
Importing Country:	Hungary	Marketing Authorisation Nr.:	2073/3/06 ÁOGYTI

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

Tests

- See Certificate of Analysis Sandoz (Annex) Batch B288746
- See Certificate of Packaging Eurovet Animal Health (Annex) Batch 067726

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

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: 2015.06.23 13:09:19 +02:00

Pharmacist, Deputy, Qualified Person

Certificate issued on 23/06/2015

This document was electronically signed according to Novartis digital signature standards

Novartis Animal Health d.o.o.

7

Certificate of Packaging

Name of the product: Denagard 45% granulátum

Product number	: 840503	Our ref. number	: TH
Batch number	: 067726	Packing instruction	: 94050302
Manufacturing date	: 01-2015	Packing / Batch size	: 1.112 kg / 476
Expiry date	: 01-2018	Date of analysis	: 02-06-2015
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	: B288746/940207		

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)
INDIVIDUAL FILLING MASS (g)

1128 - 1162
1112 - 1178

1152
Passes

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 Authority 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.



Eurovet Animal Health BV
P.O. Box 179, 5530 AD Bladel, the Netherlands. Handelsweg 25, 5531 AE Bladel, the Netherlands,
Phone +31 (0)497 54 43 00, Fax +31 (0)497 54 43 02, Rabobank, IBAN: NL45 RABO 0120 2375 71
BIC: RABONL2U, VAT NL 0075.63.401.B01, Chamber of Commerce Eindhoven, reg. no. 17054289

All offers and deliveries are made in accordance with our general terms and conditions of sale deposited with the Chamber of Commerce at Eindhoven.

Els de Meijer
Novartis Animal Health d.o.o.

22 JUN 2015

Qualified Person

Dechra