NOVARTIS
ANIMAL HEALTH

Novartis Animal Health Inc.
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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:	05/2014
Substance Number:	A-8812 A	Expiry Date:	05/2017
Quantity	472		
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 B255570
◦ See Certificate of Packaging Eurovet Animal Health (Annex)	Batch 054107

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: 2014.08.29 11:08:32 +02:00

Pharmacist, Deputy, Qualified Person

Certificate issued on 29/08/2014

This document was electronically signed according to Novartis digital signature standards

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Novartis Animal Health d.o.o.

7

SANDOZ

+43 (0) 5338 200

CERTIFICATE OF ANALYSIS

Order No. 4320012284/10

Material No. 450019

KNGL

Product
DENAGARD 45% WATERSOLUBLE GRANULES AD US.VET.

Batch	Manufacture date	Expiry date
B255570	MAY 2014	MAY 2017

Tests	Specifications	Results
APPEARANCE	WHITE TO YELLOWISH GRANULES	COMPLIES
IDENTIFICATION TIAMULIN HYDROGENFUMARATE (HPLC)	CORRESPONDING	COMPLIES
DISSOLVING TIME	NOT MORE THAN 5 min	1
BULK DENSITY (PH.EUR.)	0.50 - 0.65 g/ml	0.60
TAPPED DENSITY (PH.EUR)	0.60 - 0.80 g/ml	0.74
LOSS ON DRYING (PH.EUR)	NOT MORE THAN 2.0 %	1.0
COLOUR OF SOLUTION (PH.EUR)	COLOURLESS TO SLIGHTLY YELLOWISH, NOT DARKER THAN Y6	COMPLIES
PH	3.0 - 4.0	3.5
BY-PRODUCTS (WITH REFERENCE TO THE DECLARED CONTENT OF ACTIVE SUBSTANCE) (HPLC)		
BY-PRODUCTS		
IMPURITY B	NOT MORE THAN 1.5 %	< 0.1
IMPURITY H	NOT MORE THAN 1.5 %	< 0.1
IMPURITY I	NOT MORE THAN 1.0 %	0.3
IMPURITY F	NOT MORE THAN 1.0 %	0.2
IMPURITY D	NOT MORE THAN 1.0 %	0.5
ANY OTHER IMPURITY	NOT MORE THAN 0.5 %	< 0.1
TOTAL IMPURITES	NOT MORE THAN 3.0 %	1.0
MICROBIAL COUNT		
AEROBIC BACTERIA	NOT MORE THAN 1000 CFU PER g	< 100
YEASTS AND MOULDS	NOT MORE THAN 100 CFU PER g	0
ESCHERICHIA COLI	NOT DETACTABLE IN 1 g	COMPLIES
ASSAY TIAMULIN HYDROGENFUMARATE (PH.EUR) (HPLC)	42.8 - 47.2 %	44.9
FULLY COVERS TESTS AND SPECIFICATIONS OF TM 2909		

We certify that the above mentioned product conforms with the specifications:
CP-NO. 2909.6

DATE OF RELEASE 27.06.2014

SANDOZ GmbH
A-6250 KUNDL/AUSTRIA

RELEASED BY

DR. MARCEL HOLZER

NOVARTIS
Novartis Animal Health d.o.o.

KUNDL, 02.07.2014

i.V. Dr. Schütz

Dr. Johannes Schütz

SANDOZ QUALITY ASSURANCE