

# Certificate of Analysis

Name of the product: Denagard 10% premix



Product number	: 78050	Our ref. number	: TH
Batch number	: 056306	Packing instruction	: 98050200
Manufacturing date	: 07-2014	Packing / Batch size	: 25 kg /99
Expiry date	: 07-2017	Date of analysis	: 25-11-2014
Novartis form. code	: A-20003 B	Testing method Dechra	: QM-SC-LAB-78050
Testing Method NAH	: BE-302.H.2	CoA version	: SC98050200.4.0
Batch number API	: 935743/B264346		

Dechra manufacturing authorisation number : 855-BVEAKI  
 Novartis marketing authorization number : 2126/5/06 AOGYTI

DETERMINATIONS	SPECIFICATIONS	RESULTS
1. APPEARANCE	Free flowing white to cream-coloured, grey tinged powder	Free flowing white to cream-coloured, grey tinged powder
2. TIAMULIN HYDROGEN FUMARATE (IDENTIFICATION BY HPLC)	Corresponds to comparison	Corresponds to comparison
3. LOSS ON DRYING (%)	Not more than 14.0	11.6
4. TOTAL AEROBIC COUNT, PER G	Not more than 1000	NOT PERFORMED
5. COMBINED YEAST AND MOULDS, PER G	Not more than 100	NOT PERFORMED
6. ESCHERICHIA COLI AND SALMONELLA, PER 10G	Not detectable	NOT PERFORMED
7. TIAMULIN HYDROGEN FUMARATE (ASSAY BY HPLC)	95.0 – 105.0 % of declared content	97.3
8. RELATED SUBSTANCES (%) (ASSAY BY HPLC)		
IMPURITY B	Not more than 1.5 %	NOT DETECTED
IMPURITY H	Not more than 1.5 %	NOT DETECTED
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 FURTHER IMPURITY	Not more than 0.5 %	0.1
TOTAL IMPURITIES	Not more than 3.0 %	1.4

Alexander Diamandidis

03 DEC 2014

Conclusion : Conform specifications.

Manager Quality Assurance - Qualified Person

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.



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Novartis Animal Health

