

CERTIFICATE OF ANALYSIS


PRODUCT: Cardisure 2.5mg Tablets (CZ/SK/HU)
BATCH NO: 95245
DATE OF MANUFACTURE: April 2017
DATE OF TESTING: May 2017
EXPIRY DATE: September 2019



Dales Pharmaceuticals

At the time of testing the results below were obtained for the above product.

<u>Test</u>	<u>Specification</u>	<u>Result</u>
1. Appearance	A light brown round tablet, quadrisect, diameter 12mm	Complies
2. Identification: Pimobendan	Pimobendan present by HPLC	Complies
	Pimobendan present by UV	Complies
3a Average tablet weight	428 – 473 mg/tablet	452mg/tablet
b Weight deviation Maximum	+5% of average	Complies
c Weight deviation Minimum	-5% of average	Complies
4. Friability	≤ 1%	0.07%
5. Resistance to crushing	100 to 140N	126N
6. Disintegration	NMT 15 minutes (FIO)	2 minutes
7. Assay: Pimobendan	2.38 to 2.63 mg/tablet (95 to 105% label claim)	2.52mg/tablet
8. Impurities		
Largest single	≤ 1.0%	N/A
Total	≤ 1.0%	N/A
9. Dissolution	EU Q=75% at 30mins (Ph. Eur 2.9.3)	100%
10. Uniformity of Dosage Units	Complies if L1 value of 15.0 is met for 10 tablets (L2 is 25.0 for 30 tablets) USP<905> and Ph.Eur 2.9.40	Complies
11. Microbial quality	TVC NMT 2000 cfu/g TFC NMT 200 cfu/g E. Coli absent in 1g	N/A N/A N/A

Signed 
R D Burton BSc CBiol MRSB
Qualified Person

Date 07 JUN 17



INVESTOR IN PEOPLE

Dales Pharmaceuticals, A trading business of Dechra Ltd. Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW
tel: 01756 791311 fax: 01756 798604 www.dechramanufacturing.com

Registered Office: Snaygill Industrial Estate, Keighley Road, Skipton, North Yorks. BD23 2RW Registered in England No. 4513124 VAT No. 687 8995 32



Dales Pharmaceuticals

CERTIFICATE OF CONFORMITY

Manufacturing Company: Dales Pharmaceuticals
Address: Snaygill Industrial Estate, Skipton, North Yorkshire, BD23 2RW

Manufactured For: Dechra Veterinary Products Ltd.
Address: Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
UK

Product Name: Cardisure 2.5mg Tablets (CZ/SK/HU)


Packed Product Code: 91624

Lot Number: 95245 Packaging Date: June 2017

It is hereby certified 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 GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country.

The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Signature: 
R D Burton BSc CBiol MRSB
Qualified Person

Date: 07 JUN 17



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