Dales Pharmaceuticals

CERTIFICATE OF ANALYSIS

PRODUCT: Vetoryl 30mg Capsules (CZ/HU/PL/SK)

BATCH NO: 77741

DATE OF MANUFACTURE: December 2015

DATE OF TESTING: March 2016

EXPIRY DATE: November 2018

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

Test	Specification	Result
1. Appearance		
a) Capsule	Size 3 hard gelatin capsules with an ivory coloured body and black cap. Black print on body: 'Vetoryl 30mg'	Complies
b) Granule	White to off-white granule	Complies
2. Identification: Trilostane	Trilostane present	Complies
3. Average Weight of Capsules Contents	223.3 - 246.8 mg/capsule	239.3mg/capsule
4. Weight Uniformity	Conforms to Ph. Eur	Complies
5. Disintegration	≤15 minutes	3 minutes
6. Uniformity of content	Conforms to Ph. Eur	Complies
7. Assay: Trilostane	28.5 – 31.5 mg/capsule	30.3mg/capsule
8. Dissolution	> 75% in 45 minutes	106%
9. Related substance	Individual unidentified ≤ 0.1%	0.09%
	Impurity A ≤ 0.5%	0.09%
	Stage iii ≤ 0.5%	ND
	Ketotrilostane ≤ 1.0%	0.36%
	Total ≤ 2.0%	0.54%
10. Microbial Purity*	TVC ≤ 1000 cfu/g	N/A
	TFC ≤ 100 cfu/g	N/A
	E. Coli absent in 1g	N/A

* every 10th batch or 1 per year

Signed .....

Date 14 MAY 16

R D Burton BSc CBiol MRSB
Qualified Person

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: Vetoryl 30mg Capsules (CZ/HU/PL/SK)

Packed Product Code: 91550

Lot Number: 77741 Packaging Date: March 2016

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: ..... Date: 14 March 16

R D Burton BSc CBiol MRSB
Qualified Person