CERTIFICATE OF ANALYSIS

Dales Pharmaceuticals

PRODUCT: Vetoryl 60mg Capsules (CZ/HU/PL/SK)
BATCH NO: 82558
DATE OF MANUFACTURE: June 2016
DATE OF TESTING: July 2016
EXPIRY DATE: May 2019

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

Test	Specification	Result
1. Appearance		
a) Capsule	Size 3 hard gelatine capsules with an ivory coloured body/black cap. Logo on capsule body. "Vetoryl 60mg"	Complies
b) Granule	Fine white powder	Complies
2. Identification: Trilostane	Trilostane present	Complies
3. Average Weight of Capsules Contents	223.3 - 246.8mg/capsule	235.8mg/capsule
4. Weight Uniformity	Conforms to Ph. Eur	Complies
5. Disintegration	≤ 15 minutes	3 minutes
6. Assay: Trilostane	57.0-63.0mg/capsule	59.2mg/capsule
7. Dissolution	≥ 75% in 45 minutes, and no unit < 60% in 45 minutes	104% Complies
8. Related Substances	Individual Unidentified ≤ 0.1 % Impurity A ≤ 0.5 % Stage III ≤ 0.5 % Ketotrilostane ≤ 1.0 % Total ≤ 2.0 %	ND 0.1% ND 0.44% 0.54%
9. Microbial Purity*	TVC ≤ 1000 cfu/g TFC ≤ 100 cfu/g E. Coli absent in 1g	N/A N/A N/A

* every 10th batch or 1 per year

Signed .....
R D Burton BSc CBiol MRSB
Qualified Person

Date 01 Nov 16

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 60 mg Capsules (CZ/HU/PL/SK)

Packed Product Code: 91551

Lot Number: 82558 Packaging Date: July 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: 01 AUG 16

R D Burton BSc CBiol MRSB
Qualified Person