

**CERTIFICATE OF ANALYSIS**



Dales Pharmaceuticals

**PRODUCT:** Vetoryl 30mg Capsules (UK/IRE)

**BATCH NO:** 51142

**DATE OF MANUFACTURE:** June 2014

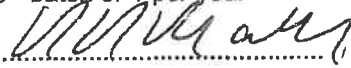
**DATE OF TESTING:** July 2014

**EXPIRY DATE:** May 2017

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) 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	230.8mg/capsule
4. Weight Uniformity	Conforms to Ph. Eur	Complies
5. Disintegration	≤15 minutes	2 minutes
6. Uniformity of content	Conforms to Ph. Eur	Complies
7. Assay: Trilostane	28.5 – 31.5 mg/capsule	29.6mg/capsule
8. Dissolution	> 75% in 45 minutes	103%
9. Related substance	Individual unidentified ≤ 0.1%	ND
	Impurity A ≤ 0.5%	0.0
	Stage iii ≤ 0.5%	ND
	Ketotrilostane ≤ 1.0%	0.7%
	Total ≤ 2.0%	0.7%
10. Microbial Purity*	TVC ≤ 1000 cfu/g	N/A
	TFC ≤ 100 cfu/g	N/A
	E. Coli absent in 1g	Absent

\* every 10<sup>th</sup> batch or 1 per year

Signed   
R D Burton BSc CBiol MSB  
Qualified Person

Date 29 JULY



INVESTOR IN PEOPLE

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