

CERTIFICATE OF ANALYSIS

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

BATCH NO. 100370

DATE OF MANUFACTURE: October 2017

DATE OF TESTING: November 2017

EXPIRY DATE: September 2020

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	235.0mg/capsule
4. Weight Uniformity	Conforms to Ph. Eur	Complies
5. Disintegration	≤15 minutes	3minutes
6. Uniformity of content	Conforms to Ph. Eur	Complies
7. Assay: Trilostane	28.5 – 31.5 mg/capsule	29.5mg/capsule
8. Dissolution	> 75% in 45 minutes	104%
9. Related substance	Individual unidentified ≤ 0.1%	0.1%
	Impurity A ≤ 0.5%	0.1%
	Stage iii ≤ 0.5%	ND
	Ketotrilostane ≤ 1.0%	0.3
	Total ≤ 2.0%	0.5%
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 
Abdul Ghafoor
Qualified Person

Date 26 Jan 2018

