

CERTIFICATE OF ANALYSIS

PRODUCT: Vetoryl 60mg Capsules (CZ/HU/PL/SK)
BATCH NO: 100381
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 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	231.8mg/capsule	
4. Weight Uniformity	Conforms to Ph. Eur	Complies	
5. Disintegration	≤ 15 minutes	5minutes	
6. Assay: Trilostane	57.0-63.0mg/capsule	59.6mg/capsule	
7. Dissolution	≥ 75% in 45 minutes, and no unit < 60% in 45 minutes	100% Complies	
8. Related Substances	Individual Unidentified Impurity A Stage III Ketotrilostane Total	≤ 0.1 % ≤ 0.5 % ≤ 0.5 % ≤ 1.0 % ≤ 2.0 %	0.1% 0.1% ND 0.3% 0.5%
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 
 Abdul Ghafoor
 Qualified Person

Date 26 Jan 2018

