

CERTIFICATE OF ANALYSIS

PRODUCT: Veteryl 10mg Capsules (CZ/HU/PL/SK)
STOCK CODE: 91549

BATCH NO: 107214
MARKETING AUTH N^o: CZ: 96/041/07-C HU: 2231/1/07 MgSzH-ÁTI
PL: 1772/07
SK: 96/036/DC/07-S

DATE OF MANUFACTURE: May 2018
DATE OF TESTING: June 2018

EXPIRY DATE: April 2021

Manufacturing and test site: Dales Pharmaceuticals, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, United Kingdom, BD23 2RW

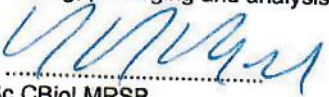
Analytical Report Ref: 422 (19)

<u>Test</u>	<u>Specification</u>	<u>Result</u>
1. Appearance		
a) Capsule	Size 4 hard gelatine capsules with an ivory body and black cap. Black print on body: 'Veteryl 10mg'	
b) Granule	White to off-white granule, free from visible contamination	Complies
2. Identification:		Complies
Trilostane	Trilostane present	Complies
3. Average Weight of Capsules Contents	74.4 – 82.2 mg/capsule	75.82mg/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	9.5 – 10.5 mg/capsule	9.6mg/capsule
8. Dissolution	> 75% in 45 minutes	101%
9. Related Substances		
	Individual Unidentified ≤ 0.1%	ND
	Impurity A ≤ 0.5 %	0.02%
	Stage III ≤ 0.5%	ND
	Ketotrilostane ≤ 1.0%	0.45%
	Total ≤ 2.0%	0.47%
10. Microbial Purity*		
	TVC ≤ 1000 cfu/g	N/A
	TFC ≤ 100 cfu/g	N/A
	E. Coli absent in 1g	N/A

This product is in compliance with the specification.
I hereby certify that the above information is authentic and accurate.

This batch of product has been manufactured, including packaging/labelling 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 Authorisation of the importing country or product specification file for Investigational Medicinal Products.

The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Signed: 
R D Burton BSc CBiol MRSB
Qualified Person
(Second Issue Title Amended)

Date: 20 July 18



ESTABLISHED IN 1989

Dales Pharmaceuticals Manufacturing is a trading business of Dechra Ltd. Snaygill Ind Estate, Keighley Rd, Skipton, N Yorks, BD23 2RW
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