

CERTIFICATE OF ANALYSIS

Veterinary Product: NONOVULIN 10 mg tablets

Packs: Each pack contains 100 tablets, Romania

Quantity: 2442 pk.

Batch No: 010219

Expiry date : February 2022

1. Physico-chemical Specification

TESTS	REQUIREMENTS	RESULTS
1. Appearance	Fiat, round smooth tablets, 8-mm dia.	Conforms
2. Colour	white	Conforms
3. Taste	Tasteless	Conforms
4. Odour	odourless	Conforms
5. Mass, g	0.200 (0.185 to 0.215)	0.206
6. Mass uniformity, per cent	For 18 – 20 tablets ± 7.5 For NMT 2 tablets ± 15	Conforms
7. Disintegration, min	NMT 15	14.0
8. Friability, per cent	NMT 0.3	0.10
9. Hardness, kg	NLT 3	9.6
10. Loss on drying at 105°C, per cent	NMT 3	1.11
11. Identification	to pass the test by TLC as per Eur.Ph.VI	Conforms
12. Assay of Magesrol acetate, g	0.009 to 0.011	0.0103
13. Microbiological quality	As per Ph. Eur. III (P.P 287-288 – Preparations for Oral and Rectal Usage)	Conforms
13. Primary packaging	to pass the packaging specification	Conforms
14. Secondary packaging	to pass the packaging specification	Conforms
15. Expiry term, year	Three years (3) from the date of manufacture	Conforms

Conclusion:

The product Nonovulin 10 mg tablets meets the requirements of Registration documentation.

Bulgaria, January 2020

QQ: 