

CERTIFICATE OF ANALYSIS

Veterinary Product: BIHELDON tablets
Packs: Each pack contains 50 tablets, Romania
Quantity: 7260 pk.
Batch No: 220120
Expiry date: January 2023

1. Physico-chemical Specification

TESTS	REQUIREMENTS	RESULTS
1. Appearance	Flat, round smooth tablets, 13-mm dia., Two crossed break lines on one side	Conforms
2. Colour	Pale yellow	Conforms
3. Taste	Bitter	Conforms
4. Odour	Slight, characteristic	Conforms
5. Mass, g	0.600 (0.570 to 0.630)	0,595
6. Mass uniformity, per cent	For 18 – 20 tablets ± 5 For NMT 2 tablets ± 10	Conforms
7. Disintegration, min	NMT 15	12
8. Friability, per cent	NMT 0.3	0,17
9. Hardness, kg	5 to 10	8,5
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.III	Conforms
12. Assay		
Praziquantel, mg	50 \pm 5 % (47.5 to 52.5)	49,80
Pyrantel Pamoate, mg	150 \pm 5 % (142.5 to 157.5)	150.00
13. Microbiological quality	As per Ph. Eur. III (P.P 287-288 – Preparations for Oral and Rectal Usage)	Conforms
14. Primary packaging	to pass the packaging specification	Conforms
15. Secondary packaging	to pass the packaging specification	Conforms
16. Expiry term, year	Three years (3) from the date of manufacture	Conforms

Conclusion:

The product Biheldon tablets meet the requirements of Registration documentation

Bulgaria, January 2020

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