

CERTIFICATE OF ANALYSIS

Veterinary Product: *Pinox comprettes spumescences*

Pack: Each pack contains 40 compr., Romania

Quantity: 310 pack

Batch No: 260819

Expiry date: August 2021

TESTS	REQUIREMENTS	RESULTS
1. Appearance	Oblong, smooth, rounded ends tablet	Conforms
2. Colour	Light yellow with mild mosaic	Conforms
3. Taste	Bitter	Conforms
4. Odour	Specific	Conforms
5. Mass, g	11.735 (11.148 to 12.322)	11.690
6. Mass uniformity, per cent	For 18 – 20 tablets ± 5 For NMT 2 tablets ± 10	Conforms
7. Disintegration, min	NMT 30	27.0
8. Hardness, Kp	Not less 3 Kp	9.5
10. Loss on drying at 105°C, per cent	NMT 3	1.00
11. Identification	Positive	Conforms
12. Assay Oxytetracycline hydrochloride, mg	1250 ± 5 % (1156.25 to 1343.75)	1245.21
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	Two years from the date of manufacture	Conforms

Conclusion: The product *Pinox comprettae spumescences* meets the requirements of Registration documentation.

Bulgaria, January 2020

QQ :

