



LIVISTO

aniMedica GmbH
a LIVISTO company

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CERTIFICATE OF ANALYSIS

Product: Animedazon , RO
Dosage form: Spray
Manufac. Date: 01/2019

Batch No.: 90129181
PV-No.: 39580-03
Expiry Date: 01/2022

Parameter	Specification	Result
Appearance of Spray	Evenly blue coloured spray	Evenly blue coloured spray
Leakage test	≤ 0.7 % (average leakage rate) ≤ 1.6 % (single container)	0,4 % 1,0 %
Tightness test	No bubble formation, no blue colour occurs	conforms
Fill weight	125.2 g – 137.0 g	132,2 g
Pressure testing (20° C)	3 – 4.5 bar	3,4 bar
Pressure testing (50° C)	6 – 7.5 bar	6,4 bar
Particle size (laser diffraction method using a dry dispersion module; pressure: 1.5 bar)	> 20 % ≤ 10 µm > 50 % ≤ 30 µm > 90 % ≤ 100 µm 100 % ≤ 250 µm	45,78 % 76,13 % 98,42 % ≤ 150,664µm
Identity		
- Chlortetracycline hydrochloride (HPLC) - Chloride -Patent blue V (colouring agent)	Rt (sample) (Chlortetracycline) ≡ Rt (Standard) (Chlortetracycline) (± 10%) Reaction of chlorides positive UV maximum at 638±2 nm	Conforms
Application test		
UV ratio 368/638 nm	1.90 – 2.10	1,99
Delivery rate	1.00 – 1.70 g/sec	1,54 g/sec
Spray pattern	Outer diameter 5.5 to 9.0 cm Inner/outer diameter ≥ 0.5	7,7 cm 0,7



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Product:

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Batch No.: 90129181

Content		
- Sum Chlortetracyclin x HCl + Tetracyclin x HCl	3.05 – 3.37 g per container	3,19 g per container
- Tetracyclin x HCl ¹⁾	≤ 8.0 %	4,6 %
Impurities ¹⁾		
4-Epichlortetracycline x HCl:	≤ 4.0%	2,1 %
Total other impurities ²⁾	≤ 1.0%	0.4 %
Microbiological purity ³⁾		
Ph.Eur 5, Supplement 5.6, 5.1.4 Method B (harmonised method) Criteria for cutaneous use - Staphylococcus aureus - Pseudomonas aeruginosa	TAMC: ≤ 10 ² CFU/ml TYMC: ≤ 10 ¹ CFU/ml absent absent	-----

¹⁾ relative to sum CTC x HCl and TC x HCl

²⁾ impurities except 4-Epichlortetracycline x HCl and Tetracycline x HCl

³⁾ Test on microbiological quality is determined periodically at each 5th to 10th batch, at least once year

"I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site in full compliance with the GMP requirements of local Regulatory Authority and with specifications in the Marketing Authorisation. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP."

"This batch has been released for sale."

Date: 01.02.18



- Qualified Person -