

Certificate of Analysis

Certificate No.: 15367

Product:	Animedazon Spray 211ml RO	Dosage form:	Spray
		Package size:	12x211ml
Product:	49593	Marketing authorisation holder:	aniMedica GmbH
Batch:	10108226 Split: 0	Registration number:	080068
Quantity:	3.528 Units	Distributor / Importer:	RO - BistriVet Rumänien
Manufacturing date:	08.01.2021		
Expiry date:	31.01.2024		

Parameter	Specification	Result
Appearance of spray	Evenly blue coloured spray	complies
Tightness test	No bubble formation, no blue colour occurs	complies
Leakage test, average leakage rate	$\leq 0,7\%$	Corresponds to
Leakage test, single container	$\leq 1,6\%$	Corresponds to
Fill weight	125,2 ... 137,0 g	133,1 g
Pressure testing (20°C)	3,0 ... 4,5 bar	3,5 bar
Pressure testing (50°C)	6,0 ... 7,5 bar	6,6 bar
Particle size	$>20\% \leq 10\mu\text{m}$	49%
Particle size	$>50\% \leq 30\mu\text{m}$	76%
Particle size	$>90\% \leq 100\mu\text{m}$	97%
Particle size	$100\% \leq 250\mu\text{m}$	202 μm
Application test, UV ratio 368/638nm	1,90 ... 2,10	2,02
Application test, delivery rate	1,00 ... 1,70	1,49 g/sec
Spray pattern, outer diameter	5,5 ... 9,0 cm	7,1 cm
Spray pattern, inner/outer diameter	Min. 0,5	0,7
Identity: chlortetracycline-hydrochloride	Retention times of standard and sample must correspond (+/- 10%)	Corresponds to
Identity: chloride 2.3.1, method a	Test for chloride must correspond	Corresponds to
Identity: patent blue V	UV-maximum at 638 +/- 2nm	Corresponds to
Assay: sum of CTC-HCl + TC-HCl	3,05 ... 3,37	3,26 g/container
Assay: tetracycline-HCl	Max. 8,0 %	5,6 %
Impurity 4-epichlortetracycline-HCl	Max. 4,0 %	2,2 %
Total other impurities (without 4-epichlortetracycline-HCl and tetracycline-HCl)	Max. 1,0 %	0,2 %

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Template: 1063

TAMC, TYMC, Staphylococcus aureus and Pseudomonas aeruginosa are tested periodically every 5th to 10th Batch but at least once a year

The finished product has been tested in accordance with the testing instruction and is of the required quality.

17. FEB. 2021

Date, Signature Head of Quality Control

Batch certificate

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I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the marketing authorisation as laid down in the manufacturing and quality control instructions. The batch processing, packaging and analytical documentation has been reviewed and is in full compliance with GMP guidelines. All deviations were evaluated before batch release.

This batch has the required quality and

- ☐ is released for delivery
- ☒ is released for the market

Remarks:

17.02.21 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange ☐ Gudrun Prusseit

☐ Dr. Jürgen Schlüter

☐