

Certificate of Analysis

Certificate No.: 13137

Product:	Animedazon Spray 211ml RO	Dosage form:	Spray
		Package size:	211 ml
Product:	49593	Marketing authorisation holder:	aniMedica GmbH
Batch:	00625215 Split: 0	Registration number:	140146
Quantity:	756 Units		
Manufacturing date:	25.06.2020		
Expiry date:	30.06.2023		

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	131,8 g
Pressure testing (20°C)	3,0 ... 4,5 bar	3,5 bar
Pressure testing (50°C)	6,0 ... 7,5 bar	6,7 bar
Particle size	$>20\% \leq 10\mu\text{m}$	36,28%
Particle size	$>50\% \leq 30\mu\text{m}$	67,05%
Particle size	$>90\% \leq 100\mu\text{m}$	96,10%
Particle size	$100\% \leq 250\mu\text{m}$	100%
Application test, UV ratio 368/638nm	1,90 ... 2,10	1,95
Application test, delivery rate	1,00 ... 1,70	1,51 g/sec
Spray pattern, outer diameter	5,5 ... 9,0 cm	7,0 cm
Spray pattern, inner/outer diameter	Min. 0,5	0,8
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	3,20 g/container
Assay: tetracycline-HCl	Max. 8,0 %	5,5 %
Impurity 4-epichlortetracycline-HCl	Max. 4,0 %	2,2 %
Total other impurities (without 4-epichlortetracycline-HCl and tetracycline-HCl)	Max. 1,0 %	0,2 %
Microbiological purity: TAMC	Max. 100 CFU/mL	< 10 CFU/mL
Microbiological purity: TYMC	Max. 10 CFU/mL	< 10 CFU/mL
Microbiological purity: staphylococcus aureus	Absent/ml	0
Microbiological purity: pseudomonas aeruginosa	Absent/ml	0

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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.

14. JULI 2020

Date, Signature Head of Quality Control

Batch certificate

Certificate No.: 13137

Product: Animedazon Spray 211ml RO

Dosage form: Spray

Product: 49593

Package size: 211 ml

Batch: 00625215 Split: 0

Marketing authorisation holder: aniMedica GmbH

Quantity: 756 Units

Registration-No.: 140146

Manufacturing: 25.06.2020

Expiry date: 30.06.2023

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:

Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange☐ Gudrun Pruß☐ Dr. Jürgen Schlüter☐