

6/06057

Certificate of Analysis

Certificate No.: 12448

Product: Animedazon Spray 211ml RO

Dosage form:

Package size:

Product: 49593

Marketing authorisation holder: aniMedica GmbH

Batch: 00408209 Split: 0

Registration number:

Quantity: 168 Units

Manufacturing date: 08.04.2020

Expiry date: 30.04.2023

140146-080068 6/06056

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	132,7 g
Pressure testing (20°C)	3,0 ... 4,5 bar	3,8 bar
Pressure testing (50°C)	6,0 ... 7,5 bar	7,2 bar
Particle size	$>20\% \leq 10\mu\text{m}$	37%
Particle size	$>50\% \leq 30\mu\text{m}$	65%
Particle size	$>90\% \leq 100\mu\text{m}$	94%
Particle size	$100\% \leq 250\mu\text{m}$	100%
Application test, UV ratio 368/638nm	1,90 ... 2,10	1,93
Application test, delivery rate	1,00 ... 1,70	1,41 g/sec
Spray pattern, outer diameter	5,5 ... 9,0 cm	7,2 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	3,23 g/container
Assay: tetracycline-HCl	Max. 8,0 %	5,6 %
Total other impurities (without 4-epichlortetracycline-HCl and tetracycline-HCl)	Max. 1,0 %	0,1 %



Certificate of Analysis

Certificate No.: 12448

aniMedica Herstellungs GmbH
a LIVISTO company

6/06052

Product: Animedazon Spray 211ml RO

Dosage form:

Package size:

Product: 49593

Marketing authorisation holder: aniMedica GmbH

Batch: 00408209 Split: 0

Registration number: ~~140146~~

080068

Quantity: 168 Units

6/06052

Manufacturing date: 08.04.2020

Expiry date: 30.04.2023

Parameter	Specification	Result
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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.

30. APR. 2020

Date, Signature Head of Quality Control



aniMedica ~~Herstellungs~~ GmbH
a LIVISTO company

406052

Batch certificate

Certificate No.: 12448

Product: Animedazon Spray 211ml RO

Dosage form:

Package size:

Product 49593

Marketing authorisation holder: aniMedica GmbH

Batch: 00408209 Split: 0

Registration-No.:

Quantity: 168 Units

Manufacturing 08.04.2020

Expiry date: 30.04.2023

140146-080068 69 06052

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.

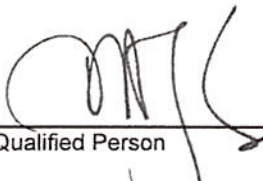
This batch has the required quality and

☐ is released for delivery

☒ is released for the market

Remarks:

Four horizontal lines for remarks, each with a diagonal slash through it.

06052 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange

☐ Gudrun Pruß

☐ Dr. Jürgen Schlüter

☐