



aniMedica GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 43848

Product:	Animedazon Spray 211ml RO		
Article number:	49593	Dosage form:	Spray
Batch:	00421213 Split: 0	Package size:	211ml
Quantity:	2.196 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	21.04.2020	Registration number:	080068
Expiry date:	30.04.2023	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance of spray	Evenly blue coloured spray	complies
Batch packaging record	batch packaging record complies	Corresponds to
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	3,7 bar
Pressure testing (50°C)	6,0 ... 7,5 bar	7,1 bar
Particle size	$>20\% \leq 10\mu\text{m}$	40,09%
Particle size	$>50\% \leq 30\mu\text{m}$	68,73%
Particle size	$>90\% \leq 100\mu\text{m}$	96,21%
Particle size	$100\% \leq 250\mu\text{m}$	100%
Application test, UV ratio 368/638nm	1,90 ... 2,10	2,05
Application test, delivery rate	1,00 ... 1,70	1,54 g/sec
Spray pattern, outer diameter	5,5 ... 9,0 cm	7,1 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	3,22 g/container
Assay: tetracycline-HCl	Max. 8,0 %	5,6 %
Impurity 4-epichlortetracycline-HCl	Max. 4,0 %	1,6 %
Total other impurities (without 4-epichlortetracycline-HCl and tetracycline-HCl)	Max. 1,0 %	0,1 %

Amtsgericht Coesfeld
HRB-Nr. 7210
Geschäftsführer:
Dr. Enno Gottschalk

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Parameter	Specification	Result
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Template: 1743

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

11. OKT. 2021

Date, Signature Head of Quality Control

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