

Certificate of Analysis

Certificate No.: 14612

Product: Animedazon Spray 211ml RO

Manufacturing date: 06-03-18

Product-No.: 49593

Expiry date: 31-03-21

Batch-No.: 80306165

Split: 0

Quantity: 4.536 Unit(s)

Parameter	Specification	Result
Appearance	constant blue coloured spray	constant blue coloured spray
Batch packaging record	batch packaging record complies	Corresponds to
Tightness	no blistering, no leak of blue colour	Corresponds to
Leakage (everage leakage)	0,7%	Corresponds to
Leakage (single leakage)	1,6%	Corresponds to
Filling quantity	125,2 ... 137,0 g	131,6 g
Pressure test (20°C)	3,0 ... 4,5 bar	3,7 bar
Pressure test (50°C)	6,0 ... 7,5 bar	6,7 bar
Particle size > 20%	10µm	42,69%
Particle size > 50%	30µm	72,68%
Particle size > 90%	100µm	97,46%
Particle size 100%	250µm	159,80µm
Applicationtest UV-Rate 368/638nm	1,90-2,10	1,94
Applicationtest emission rate	1,0-1,70 g/sec.	1,45
Spray pattern (external diameter)	5,5-9,0 cm	8,0
Spray pattern (inner/external diameter)	0,5	0,6
Identity: Chlortetracyclin-HCl	Retention time of standard and sample must comply (+/- 10,0%)	Corresponds to
Identity: Chloride	Identity reaction a of Chloride must comply	Corresponds to
Identity: Patentblue V	UV-Maximum bei 638 +/- 2 nm	Corresponds to
Assay(Sum of Chlortetracyclin-HCl + Tetracyclin-HCl) per tin	3,05 ... 3,37 g	3,19 g
Assay Tetracyclin HCl	Max. 8,0 %	4,6 %
Related substances: 4-Epichlortetracyclin-HCl	Max. 4,0 %	1,9 %
Sum of unknown Impurities(without 4-Epichlortetracyclin-HCl and Tetracyclin-HCl)	Max. 1,0 %	0,3 %
Microbial purity: TAMC	Max. 100 KBE/ml	< 10 KBE/ml
Microbial purity: TYMC	Max. 10 KBE/ml	< 10 KBE/ml
Microbial purity: Staphylococcus aureus	Max. 0 KBE/ml	0 KBE/ml
Microbial purity: Pseudomonas aeruginosa	Max. 0 KBE/ml	0 KBE/ml

Certificate of Analysis

Certificate No.: 14612

Product: Animedazon Spray 211ml RO

Manufacturing date: 06-03-18

Product-No.: 49593

Expiry date: 31-03-21

Batch-No.: 80306165

Split: 0

Quantity: 4.536 Unit(s)

Parameter	Specification	Result
-----------	---------------	--------

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

Hereby it is confirmed for the named batch, that the above information is authentic and accurate. The batch was manufactured and tested in accordance to the GMP requirements and the current authorized procedures for manufacturing and testing.

During the manufacture and testing

- ☒ no deviations/irregularities have been observed.
- ☐ the following deviations/irregularities have been observed:

These deviations/irregularities do not affect the quality of the product, because

The named batch has the required quality and is released

- ☐ for dispatch
- ☒ for the market

Comments

27.5.18
Date, Signature Qualified Person