

Certificate of Analysis

Certificate No.: 9229

Product: Animedazon Spray 211ml RO Manufacturing date: 25-04-19
 Product-No.: 49593 Expiry date: 30-04-22
 Batch-No.: 90425187
 Split: 0
 Quantity: 7.116 Unit(s)

Parameter	Specification	Result
Appearance	equal blue coloured spray	equal blue coloured spray
Tightness test	no blistering, no leakage of blue colour	no blistering, no leakage of blue colour
Leakage test (average leakage rate)	0,7%	0,1%
Leakage test (single unit)	1,6%	0,1%
filling weight	125,2 ... 137,0 g	132,3 g
pressure test (20°C)	3,0 ... 4,5 bar	3,5 bar
pressure test (50°C)	6,0 ... 7,5 bar	6,4 bar
Particle size (laser diffraction)	250µm	205µm
Particle size (laser diffraction)	10µm	34,34%
Particle size (laser diffraction)	30µm	60,56%
Particle size (laser diffraction)	100µm	91,86%
Applicationtest UV-Rate 368/638 nm	1,90 - 2,10	1,99
Emission rate	1,0 - 1,70 g/sec.	1,52
Spray area (exterior diameter)	5,5 - 9,0cm	7,5 cm
Spray area (interior/exterior diameter)	0,5	0,7
Identity CTC-HCl	retention time of standard and sample must be identical	Corresponds to
Chloride	conforms to the test a of chloride	Corresponds to
patent blue V	UV-Maximum at 638 +/- 2 nm	Corresponds to
Sum CTC-HCl + TC-HCl per can	3,05 ... 3,37 g	3,26 g
TC-HCl	Max. 8,0 %	5,0 %
4-Epichlortetracyclin-HCl	Max. 4,0 %	1,4 %
Unknown impurities, total	Max. 1,0 %	0,2 %

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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:

 28/5/2019
Date, Signature Qualified Person