



aniMedica GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 21725

Product: Busol 0,004mg/ml inj 5x10ml RO
Article number: 49578
Batch: 23A032 Split: 0
Quantity: 399 Units
Manufacturing date: 03.01.2023
Expiry date: 31.12.2024
Dosage form: Solution for injection
Package size: 5x10ml
Marketing authorisation holder: T.P.Whelehan Son & Co.Ltd.
Registration number: 140137
Distributor / Importer: RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear, colourless liquid, free of particles	clear, colourless liquid, free of particles
Clarity	Clear solution	clear solution
Colour	Less coloured than solution G6	>7
pH	5,8 ... 6,2	6,1
Relative density	1,002 ... 1,014	1,006
Refractive index	1,330 ... 1,346	1,338
Particle contamination	Particle free	particle free
Tightness test	All bottles are tight	leak tight
Filling volume	10,1 ... 10,9 ml	10,2 ml
Identity: benzyl alcohol	Retention times and UV spectrum of standard and sample must correspond	Corresponds to
Identity: buserelin acetate	Retention times and UV spectrum of standard and sample must correspond	Corresponds to
Assay: benzyl alcohol	19,0 ... 21,0 mg/ml	19,6 mg/ml
Assay: buserelin acetate	3,99 ... 4,41	4,30 µg/ml
purity: (D-His2)-buserelin	Max. 3,0 %	0,3 %
Impurity: (D-Tyr5)-buserelin	Max. 1,0 %	< 0,1 %
Impurity: (D-Ser4)-buserelin	Max. 3,0 %	0,2 %
Impurity: (D-Glp1)-buserelin	Max. 1,0 %	< 0,1 %
Impurity: (Des-Glp1, Des-His2)-buserelin	Max. 1,0 %	0,2 %
Unknown impurity, single	Max. 1,0 %	0,2 %
Total impurities	Max. 6 %	1 %
Sterility	Sterile	Corresponds to

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

Im Südfeld 9
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Deutschland

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Parameter	Specification	Result
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Template: 1529

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

08. FEB. 2023

Date, Signature Head of Quality Control

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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:

16.02.2023
Date, Signature Qualified Person

- ☒ Dr. Hans-Jörg Lange ☐ Stephan Bruns ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller ☐ Ulrich Kontny

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