

Certificate of Analysis

Certificate No.: 23570

Product:	Busol 0,004mg/ml inj 5x10ml RO		
Article number:	49578	Dosage form:	Solution for injection
Batch:	23J094 Split: 0	Package size:	5x10ml
Quantity:	446 Units	Marketing authorisation holder:	T.P.Whelehan Son & Co.Ltd.
Manufacturing date:	09.10.2023	Registration number:	140137
Expiry date:	30.09.2025	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	5,9
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	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	20,1 mg/ml
Assay: buserelin acetate	3,99 ... 4,41	4,19 µg/ml
Impurity: (D-His2)-buserelin	Max. 3,0 %	< 0,1 %
Impurity: (D-Tyr5)-buserelin	Max. 1,0 %	< 0,1 %
Impurity: (D-Ser4)-buserelin	Max. 3,0 %	< 0,1 %
Impurity: (D-Glp1)-buserelin	Max. 1,0 %	< 0,1 %
Impurity: (Des-Glp1, Des-His2)-buserelin	Max. 1,0 %	< 0,1 %
Unknown impurity, single	Max. 1,0 %	< 0,1 %
Total impurities	Max. 6 %	< 1 %
Sterility	Sterile	Corresponds to

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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.

28. NOV. 2023

Date, Signature Head of Quality Control

Batch certificate

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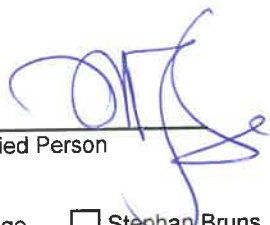
I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the marketing authorisation as laid down in the manufacturing 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:

Four horizontal lines for handwritten remarks, each with a diagonal slash mark.

28.11.2023 

Date, Signature Qualified Person

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