

Certificate of Analysis

Certificate No.: 16444

Product: Busol 0,004mg/ml inj 5x10ml RO
Article number: 49578 Dosage form: *Solution* ~~Suspension~~ for injection
Batch: 21E057 Split: 0 Package size: 5x10ml
Quantity: 296 Units Marketing authorisation holder: T.P.Whelehan Son & Co.Ltd.
Manufacturing date: 05.05.2021 Registration number: 140137
Expiry date: 30.04.2023 Distributor / Importer: RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	clear, colourless liquid, free of particles	complies
Clarity	clear solution	complies
Colour	< G6	>G7
pH-value	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	complies
Tightness test	all bottles are tight	complies
Filling volume	10,1 ... 10,9 ml	10,2 ml
Identity: benzyl alcohol	Retention times and UV-spectra of standard and sample must correspond	Corresponds to
Identity: buserelin acetate	Retention times and UV spectra of standard and sample must correspond	Corresponds to
Assay: benzyl alcohol	19,0 ... 21,0 mg/ml	19,8 mg/ml
Assay: buserelin acetate	3,99 ... 4,41	4,40 µg/ml
Impurity: (D-His2)-buserelin	Max. 3,0 %	< 0,1 %
Impurity: (D-Tyr5)-buserelin	Max. 1,0 %	0,2 %
Impurity: (D-Ser4)-buserelin	Max. 3,0 %	0,5 %
Impurity: (D-Glp1)-buserelin	Max. 1,0 %	0,2 %
Impurity: (Des-Glp1, Des-His2)-buserelin	Max. 1,0 %	0,2 %
Unknown impurities, single	Max. 1,0 %	0,2 %
Total impurities	Max. 6 %	< 1 %
Sterility	sterile	Corresponds to

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Parameter	Specification	Result
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Template: 1184

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

07. JUN. 2021

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:

07.06.21 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange☐ Gudrun Prußeit☐ Dr. Jürgen Schlüter☐ Dr. Bernd Manfred Müller☐