

Certificate of Analysis

Certificate No.: 29270

Product:	Busol 0,004mg/ml inj 5x10ml RO		
Article number:	49578	Dosage form:	Solution for injection
Batch:	25C204 Split: 0	Package size:	5x10ml
Quantity:	236 Units	Marketing authorisation holder: T.P.Whelehan Son & Co.Ltd.	
Manufacturing date:	20.03.2025	Registration number:	140137
Expiry date:	28.02.2027	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	6,0
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	20,3 mg/ml
Assay: buserelin acetate	3,99 ... 4,41	4,26 µg/ml
Impurity: (D-His2)-buserelin	Max. 3,0 %	0,3 %
Impurity: (D-Tyr5)-buserelin	Max. 1,0 %	< 0,1 %
Impurity: (D-Ser4)-buserelin	Max. 3,0 %	< 0,1 %
Impurity: (D-Glp1)-buserelin	Max. 1,0 %	0,1 %
Impurity: (Des-Glp1, Des-His2)-buserelin	Max. 1,0 %	0,4 %
Unknown impurity, single	Max. 1,0 %	0,8 %
Total impurities	Max. 6 %	< 3 %
Sterility	Sterile	Corresponds to

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

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Along with you



aniMedica GmbH
a LIVISTO company

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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.

13. MAI 2025

Date, Signature Head of Quality Control

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