

Certificate of Analysis

Certificate No.: 73719

Product:	Busol 0,004mg/ml inj 5x10ml RO		
Article number:	49578	Dosage form:	Suspension for injection
Batch:	26029207 Split: 0	Package size:	5x10ml
Quantity:	200 Units	Marketing authorisation holder:	T.P.Whelehan Son & Co.Ltd.
Manufacturing date:	07.08.2026	Registration number:	140137
Expiry date:	31.07.2028	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear, colorless liquid, free of particles.	Clear, colorless liquid, free of particles
Clarity	Clear solution	Clear solution
Colour	Not more intensely colored than G6 (<G6)	G7
pH	5,8 ... 6,2	6,0
Relative density	1,002 ... 1,014	1,006
Refractive index	1,330 ... 1,346	1,338
Particulate matter	Particle free	Corresponds to
Tightness test	Bottles are tight	tight
Filling volume	10,1 ... 10,9 ml	10,3 ml
Identity: benzyl alcohol	Retention time and UV spectra of standard and sample must correspond	Corresponds to
Identity: buserelin acetate	Retention time and UV spectra of standard and sample must correspond	Corresponds to
Assay: benzyl alcohol	19,0 ... 21,0 mg/ml	19,5 mg/ml
Assay: buserelin acetate	3,99 ... 4,41	4,12 µg/ml
Related substances: [D-Tyr5]-Buserelin	Max. 1,0 %	< 0,1 %
Related substances: [D-Ser4]-Buserelin	Max. 3,0 %	< 0,1 %
Related substances: [D-Glp1]-Buserelin	Max. 2,0 %	< 0,1 %
Related substances: [D-His2]-Buserelin	Max. 3,0 %	0,3 %
Total unknown impurities, single, Buserelin	Max. 1,0 %	0,1 %
Total impurities, Buserelin	Max. 6 %	< 1 %
Sterility	Sterile	Corresponds to



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aniMedica GmbH
a LIVISTO company

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Parameter	Specification	Result
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Template: 4273

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

03. SEP. 2026

Date, Signature Head of Quality Control