



aniMedica GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 17754

Product:	Busol 0,004mg/ml inj 5x10ml RO	Dosage form:	<i>Solution</i> ~~Suspension~~ for injection
Article number:	49578	Package size:	5x10ml
Batch:	21I204 Split: 0	Marketing authorisation holder:	T.P.Whelehan Son & Co.Ltd.
Quantity:	246 Units	Registration number:	140137
Manufacturing date:	20.09.2021	Distributor / Importer:	RO - BistriVet Rumänien
Expiry date:	31.08.2023		

Parameter	Specification	Result
Appearance	Clear, colourless liquid, free of particles	clear, colourless liquid, free of particles
Clarity	Clear solution	clear solution
Colour	Not more intensively coloured than reference solution 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
Particle contamination	Particle free	particle free
Tightness test	All bottles are tight	tight
Filling volume	10,1 ... 10,9 ml	10,3 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	19,9 mg/ml
Assay: buserelin acetate	3,99 ... 4,41	4,30 µg/ml
Impurity: (D-His2)-buserelin	Max. 3,0 %	0,4 %
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 impurities, single	Max. 1,0 %	0,8 %
Total impurities	Max. 6 %	< 2 %
Sterility	Sterile	Corresponds to

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

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Along with you



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6/031122

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.

27. Okt 2021
Date, Signature Head of Quality Control

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