

Certificate of Analysis

Certificate No.: 22704

Product:	Busol 0,004mg/ml inj 5x10ml RO		
Article number:	49578	Dosage form:	Solution for injection
Batch:	23E123 Split: 0	Package size:	5x10ml
Quantity:	596 Units	Marketing authorisation holder:	T.P.Whelehan Son & Co.Ltd.
Manufacturing date:	12.05.2023	Registration number:	140137
Expiry date:	30.04.2025	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear, colourless liquid, free of particles	corresponds to
Clarity	Clear solution	corresponds to
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	corresponds to
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	20,2 mg/ml
Assay: buserelin acetate	3,99 ... 4,41	4,19 µg/ml
Impurity: (D-His2)-buserelin	Max. 3,0 %	0,4 %
...purity: (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 %	0,2 %
Unknown impurity, 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: 1529

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

15 JUNI 2023
Date, Signature Head of Quality Control