

Certificate of Analysis

Certificate No.: 9166

Product:	Busol 0,004mg/ml inj 5x10ml RO	Manufacturing date:	10-04-19
		Expiry date:	31-03-21
Product-No.:	49578		
Batch-No.:	19D104		
Split:	0		
Quantity:	495 Unit(s)		

Parameter	Specification	Result
Appearance	Clear, colourless solution, free of particles	Conforms
Colour	Not more intensiv coloured than G6	Conforms
pH-value	5,8 ... 6,2	6,1
Relative density	1,002 ... 1,014	1,005
Refractive index	1,330 ... 1,346	1,338
Particle	Particle free	Conforms
Tightness of the bottles	All bottles are tight	Corresponds to
Filling volume	10,1 ... 10,9 ml	10,2 ml
Identity buserelin acetate	Retention time and UV-spectrum of reference and sample complies	Corresponds to
Identity benzyl alcohol	Retention time and UV-spectrum of reference and sample complies	Corresponds to
Assay buserelin acetate	3,99 ... 4,41	4,17 µg/ml
Assay benzyl alcohol	19,0 ... 21,0	19,9 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 impurity, single	Max. 1,0 %	0,1 %
Total impurities	Max. 6 %	< 1 %
Sterility	Sterile	Corresponds to

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

Hereby it is confirmed for the named batch, that the above information is authentic and accurate. The batch was manufactured and tested in accordance to the GMP requirements and the current authorized procedures for manufacturing and testing.

During the manufacture and testing

- ☒ no deviations/irregularities have been observed.
☐ the following deviations/irregularities have been observed:

These deviations/irregularities do not affect the quality of the product, because

The named batch has the required quality and is released

- ☐ for dispatch
☒ for the market

Comments:

17.05.19
Date, Signature Qualified Person