



LIVISTO

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a LIVISTO company

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CERTIFICATE OF ANALYSIS

Product:	Busol 0,004 mg/ml, RO	PV-No.:	39561-02
Dosage form:	Injection solution	Batch No.:	19A03304
Manufac. Date:	01/2019	Expiry Date:	12/2020

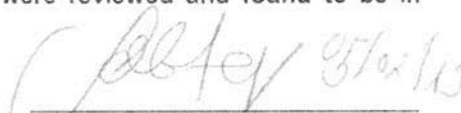
Parameter	Specification	Result
Appearance	clear, colourless solution, particle free	clear, colourless solution, particle free
Colour	< Y6	brighter Y7
Refraction index	1,330 – 1,346	1,338
Relative density	1,002 – 1,014	1,006
pH	5,8 – 6,2	6,1
Tightness of bottles	all bottles are tight	conforms
Volume	10,1 – 10,9 ml	10,2 ml
Purity		
Sterility	sterile	sterile
Identity		
Buserelin acetate	must conform	conforms
Benzyl alcohol	must conform	conforms
Related substances		
(D-His ²)-Buserelin	≤ 3,0 %	0,5 %
(D-Tyr ⁵)-Buserelin	≤ 1,0 %	< 0,1 %
(D-Ser ⁴)-Buserelin	≤ 3,0 %	0,2 %
(D-Glp ¹)-Buserelin	≤ 1,0 %	0,1 %
(Des-Glp ¹ , Des-His ²)-Buserelin	≤ 1,0 %	< 0,1 %
Unknown impurities	single ≤ 1,0 %	< 0,1 %
	total ≤ 6 %	< 0,1 %
Assay		
Buserelin acetate	3,99 – 4,41 µg/ml	4,20 µg/ml
Benzyl alcohol	19,0 – 21,0 mg/ml	19,9 mg/ml

"I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site in full compliance with the GMP requirements of local Regulatory Authority and with specifications in the Marketing Authorisation. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP."

"This batch has been released for sale."

Date: 2019-02-04

Amtsgericht Coesfeld
HRB-Nr. 7210
Geschäftsführer:


- Qualified Person -

Along with you