

Certificate of Analysis

Certificate No. 13873

Product	Buserin 0.004mg/ml inj; 5x10ml HU	Dosage form	
		Package size	10m.
Product	49315	Marketing authorisation holder	T.P.Whelehan Son & Co.Ltd
Batch	20H122 Split. 0	Registration number	2449/1/09/MgSzH AT1
Quantity	496 Units		
Manufacturing date	12.08.2020		
Expiry date	31.07.2022		

Parameter	Specification	Result
Appearance	clear, colourless liquid, free of particles	clear, colourless liquid, free of particles
Clarity	clear solution	clear solution
Colour	< G6	G7
pH-value	5.8 - 6.2	6.0
Relative density	1.002 ... 1.014	1.006
Refractive index	1.330 ... 1.348	1.338
Particle contamination	particle free	particle free
Tightness test	all bottles are tight	leak tight
Filling volume	10.1 - 10.9 ml	10.2 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	20.3 mg/ml
Assay: buserelin acetate	3.99 ... 4.41	4.20 µg/ml
Impurity (D-His2)-buserelin	Max. 3.0 %	< 0.1 %
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 %	< 0.1 %
Total impurities	Max. 6 %	< 1 %
Sterility	sterile	Corresponds to

Certificate of Analysis


Certificate No. 13873

Product	Busol 0.004mg/ml inj, 5x10ml HU	Dosage form.	
		Package size.	10ml
Product	49316	Marketing authorisation holder	T P Whelehan Son & Co Ltd
Batch	20H122 Split 0	Registration number	2449/1/08/MgSzH ATI
Quantity	496 Units		
Manufacturing date	12.08.2020		
Expiry date	31.07.2022		

Parameter	Specification	Result
-----------	---------------	--------

Template 1175

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


Date, Signature Head of Quality Control**KERESKEDELMI CÉLRA
FELSZABADÍTVA**
DR LENGYEL TAMÁS
minőségügyi felelős