

BIC 044030826

TEST REPORT

Sample № 10/10

19 October, 2016

Tested substance: EPITHALON – the peptide normalizing the functions of epiphysis. Purity: > 98%, 10 mg. ..: 01.08.2016; Expiration date: 01.08.2019.

Appearance: Lyophilized powder in a vial made of clear glass with a yellow lid (Figure 1).



Figure 1 – Tested sample

Method of analysis:

Purity determination: HPLC with Diode Array Detector (Thermo Dionex UltiMate3000RS, HPLC-DAD). Detection = 201 nm.

Quality determination: HPLC with quadrupole mass spectrometer (Thermo UltiMate 3000 RS with mass spectrometer TSQ Quantum Access Max).

Chromatography Test Conditions: column: Merck LiChrospher WP 300 RP-18 250*4 mm 5 μm; mobile phase: A: 100% H₂O/20 mM CH₃COONH₄, B: 2-propanol/20 mM CH₃COONH₄; liner gradient from 45% to 55% B; flow rate: 0,85 ml/min; temperature: thermostat at 45 °C; detection: UF 210 nm, In volume - 20μl.

Results



Figure 2 – Chromatogram of the tested sample

Figure 2 shows the chromatogram of the tested sample. UF spectrum is shown on Figure 3.

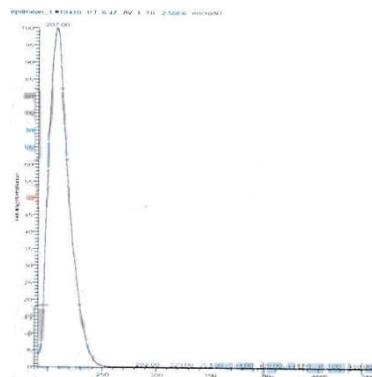


Figure 3 – UV spectrum of the tested sample

Table 1 shows the relative content of the tested sample. The content of the main component – 97%.

Table 1 – The results of chromatogram acquired by HPLC-DAD

№	Time, min	Volume, conv. un.	Rel. content, %
1	6,03	92,58	0,21
2	6,46	42345	96,99
3	7,72	1223	2,80
Summ		43660,58	

The results acquired by HPLC-MS:



Figure 4 –The mass spectrum of the tested sample, RT = 6,46 min

The mass spectrum (Figure 4) shows that one of the peaks of the sample EPITHALON mass peak with $m/z = 391,62 = 0,4$ and isotope distribution corresponds to the singly-charged ion of the peptide [EPITHALON II]. According to the results the molecular weight of the peptide is 390 DA.

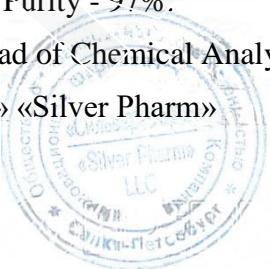
Conclusion:

The main component of EPITHALON – peptide Epithalon normalizing the functions of epiphysis. Purity - 97%.

Head of Chemical Analytical Laboratory

LLC«IPC» «Silver Pharm»

Customer



 Geybo D.S.