

# Certificate of Analysis

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## Sample Identification

**Sample Name** Epithalon 10 mg  
**Batch Number** 2321092  
**Date Published** 2026-07-27 16:19

## Results for LYO-0400

| Peptides                                                                                           | Result | Unit  | Uncertainty | Acceptable Range |
|----------------------------------------------------------------------------------------------------|--------|-------|-------------|------------------|
| Epithalon Assay<br>Peptide Screening 0.1% TFA                                                      | 8.96   | mg    | [± 0.04]    |                  |
| Epithalon Purity<br>Peptide Screening 0.1% TFA                                                     | 98.1   | %     | [± 0.5]     |                  |
| Epithalon Identification by<br>Spectrum (FTIR)<br>Peptide Screening 0.1% TFA                       | 982    |       | [± 5]       |                  |
| Epithalon Identification by RT<br>Peptide Screening 0.1% TFA                                       | 1.000  |       | [± 0.005]   |                  |
| Microbiology                                                                                       | Result | Unit  | Uncertainty | Acceptable Range |
| Bacterial Endotoxin Chromgenic<br>USP<85>/ Eur. Ph. 2.6.14. Bacterial<br>Endotoxin Chromgenic Test | 0.040  | EU/mg | [± 0.001]   | 0 - 0.5          |
| Mass Spectrometry                                                                                  | Result | Unit  | Uncertainty | Acceptable Range |
| Molecular Ion Mass Identification<br>(MS Deconvolution)<br>Mass Spectrometry Identity              | 390    | g/mol | [± 1]       |                  |

|                                                                                   |                                 |                             |  |
|-----------------------------------------------------------------------------------|---------------------------------|-----------------------------|--|
|  | <b>Method Specification</b>     |                             |  |
| <b>Determination of identity, content and purity of Epithalon</b>                 |                                 |                             |  |
| <i>Document number</i><br><b>EPI_006_2026</b>                                     | <i>Superseded document</i><br>- | <i>Number of pages</i><br>4 |  |

## 1. Content Assessment

### 1.1. Instrumentation

| Module            | Name                 | Serial Number |
|-------------------|----------------------|---------------|
| System Controller | Shimadzu CBM-40 Lite | L221226351398 |
| Degassing Unit    | Shimadzu DGU-403     | NA            |
| Pump              | Shimadzu LC-40B XR   | L22146350580  |
| Autosampler       | Shimadzu SIL-40C XR  | L22216351622  |
| Colum Thermostat  | Shimadzu CTO-40S     | L22236351602  |
| PDA Detector      | Shimadzu SPD-M40     | L22276352808  |
| SQ MS Detector    | Shimadzu LCMS-2050   | O12476200760  |

### 1.2. Chromatographic conditions

| Chromatographic conditions |                                                    |
|----------------------------|----------------------------------------------------|
| Eluent A                   | 0.1% TFA in Water (HPLC, Gradient Grade)           |
| Eluent B                   | 0.1% TFA in Acetonitrile (HPLC, Gradient Grade)    |
| Flow rate                  | 0.4 mL/min                                         |
| Program                    | Gradient elution                                   |
| Injection volume           | 2 µL                                               |
| Colum Temperature          | 60°C                                               |
| Column                     | Phenomenex Biozen Peptide Polar C18, 150x2.1mm 3µm |
| Detection wavelength       | 225nm                                              |

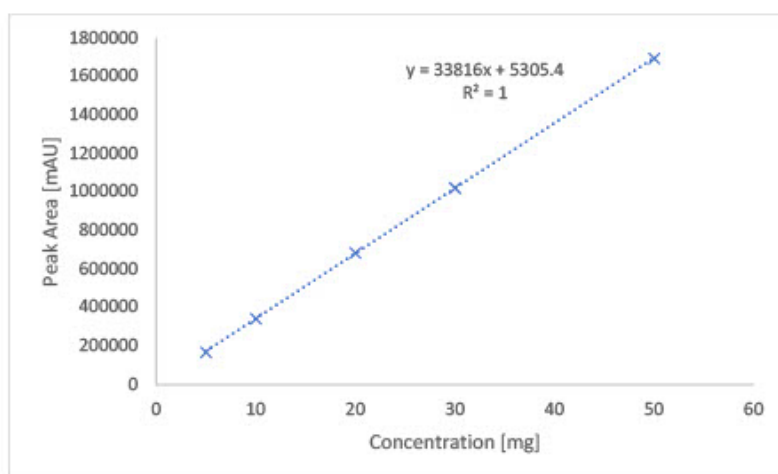
| Gradient Program |       |       |
|------------------|-------|-------|
| Time [min]       | A [%] | B [%] |
| 3                | 100   | 0     |
| 18               | 45    | 55    |
| 20               | 1     | 99    |
| 21               | 1     | 99    |
| 21.01            | 100   | 0     |
| 26               | end   |       |

### 1.3. Sample preparation

Whole amount of container was dissolved in 2mL of water (LCMS Grade). 100 µL of sample was transferred to HPLC vial and diluted by 900 µL water (LCMS Grade) and submitted for analysis.

### 1.4. Calibration curve

| Calibration curve detail     |                   |
|------------------------------|-------------------|
| Quantitative method          | External Standard |
| Calibration Type             | Linear            |
| Number of calibration points | 5                 |
| Force through Zero           | Enabled           |
| Weighting Method             | None              |



## 2. Purity assessment

### 2.1 Instrumentation

| Module            | Name                 | Serial Number |
|-------------------|----------------------|---------------|
| System Controller | Shimadzu CBM-40 Lite | L221226351398 |
| Degassing Unit    | Shimadzu DGU-403     | NA            |
| Pump              | Shimadzu LC-40B XR   | L22146350580  |
| Autosampler       | Shimadzu SIL-40C XR  | L22216351622  |
| Colum Thermostat  | Shimadzu CTO-40S     | L22236351602  |
| PDA Detector      | Shimadzu SPD-M40     | L22276352808  |
| SQ MS Detector    | Shimadzu LCMS-2050   | O12476200760  |

### 2.2 Chromatographic conditions

| Chromatographic conditions |                                                    |
|----------------------------|----------------------------------------------------|
| Eluent A                   | 0.1% TFA in Water (HPLC, Gradient Grade)           |
| Eluent B                   | 0.1% TFA in Acetonitrile (HPLC, Gradient Grade)    |
| Flow rate                  | 0.4 mL/min                                         |
| Program                    | Gradient elution                                   |
| Injection volume           | 2 µL                                               |
| Colum Temperature          | 60°C                                               |
| Column                     | Phenomenex Biozen Peptide Polar C18, 150x2.1mm 3µm |
| Detection wavelength       | 225nm                                              |

| Gradient Program |       |       |
|------------------|-------|-------|
| Time [min]       | A [%] | B [%] |
| 3                | 100   | 0     |
| 18               | 45    | 55    |
| 20               | 1     | 99    |
| 21               | 1     | 99    |
| 21.01            | 100   | 0     |
| 26               | end   |       |

### 2.3 Purity assesment

Purity of compound assesed by area normalization method, comparing area of each peak to sum of area of all peaks detected at wavelenght of 225 nm.

### 3. Identity Assessment

#### 3.1 Instrumentation

| Module            | Name                 | Serial Number |
|-------------------|----------------------|---------------|
| System Controller | Shimadzu CBM-40 Lite | L221226351398 |
| Degassing Unit    | Shimadzu DGU-403     | NA            |
| Pump              | Shimadzu LC-40B XR   | L22146350580  |
| Autosampler       | Shimadzu SIL-40C XR  | L22216351622  |
| Column Thermostat | Shimadzu CTO-40S     | L22236351602  |
| PDA Detector      | Shimadzu SPD-M40     | L22276352808  |
| SQ MS Detector    | Shimadzu LCMS-2050   | O12476200760  |

#### 3.2 Chromatographic conditions

| Chromatographic conditions |                                                    |
|----------------------------|----------------------------------------------------|
| Eluent A                   | 0.1% TFA in Water (HPLC, Gradient Grade)           |
| Eluent B                   | 0.1% TFA in Acetonitrile (HPLC, Gradient Grade)    |
| Flow rate                  | 0.4 mL/min                                         |
| Program                    | Gradient elution                                   |
| Injection volume           | 2 µL                                               |
| Column Temperature         | 60°C                                               |
| Column                     | Phenomenex Biozen Peptide Polar C18, 150x2.1mm 3µm |
| Mass spectrometry          | Scan: positive 280-2000 Da                         |

| Gradient Program |       |       |
|------------------|-------|-------|
| Time [min]       | A [%] | B [%] |
| 3                | 100   | 0     |
| 18               | 45    | 55    |
| 20               | 1     | 99    |
| 21               | 1     | 99    |
| 21.01            | 100   | 0     |
| 26               | end   |       |

#### 3.3 Molecular Ion Mass evaluation

Molecular ion mass was determined by deconvolution of multiply charged ESI-MS spectra to calculate the average neutral (zero-charge) molecular mass by equation:

$$M(\text{neutral}) = (z_i((mz_i) - H)) - ME$$

Where:

$mz_i$  - Measured mass of charged particle

$z_i$  - charge

H - proton mass (1.0076 Da)

ME - mass error

# Analysis Report



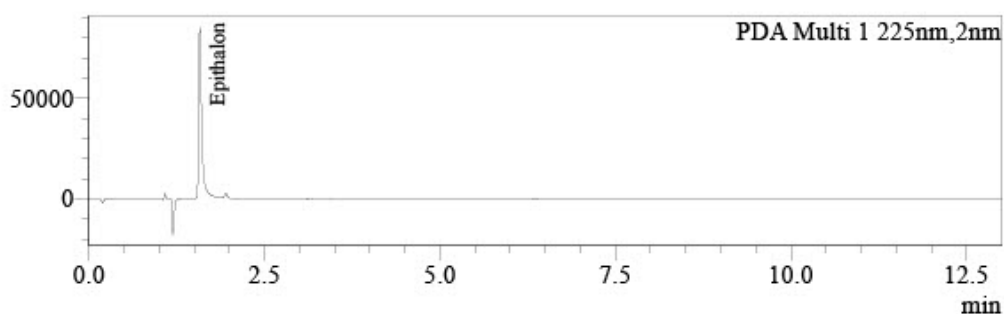
## Analysis of quantity and purity of active ingredient by UHPLC with UV detection

### Sample Information

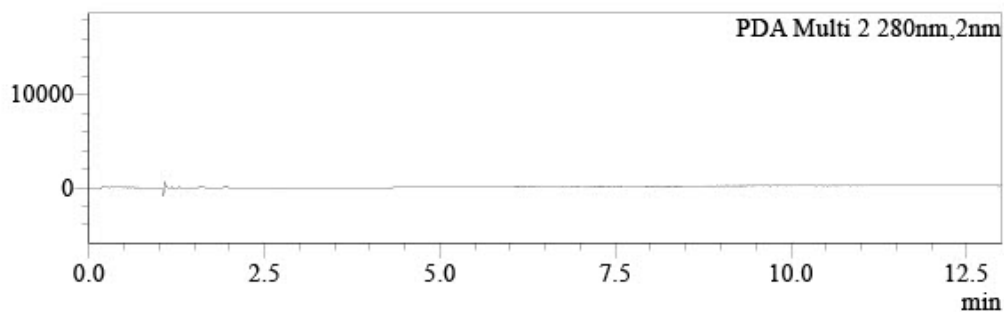
Injection Volume : 2  
Data File : LYO-0400\_\_003.lcd  
Method File : Peptide screening polar\_Group C.lcm  
Date Acquired : 7/23/2026 2:13:19 PM

### Chromatogram

uAU



uAU



### Peak Table

#### PDA Ch1 225nm

| Name      | Ret. Time | Area   | Conc. | Unit | Area%   |
|-----------|-----------|--------|-------|------|---------|
| Epithalon | 1.576     | 279056 | 8.965 | mg   | 98.100  |
|           | 1.947     | 5405   | 0.000 |      | 1.900   |
|           |           | 284461 |       |      | 100.000 |

### Peak Table

#### PDA Ch2 280nm

| Name | Ret. Time | Area | Conc. | Unit |
|------|-----------|------|-------|------|
|      |           |      |       |      |

# Analysis Report

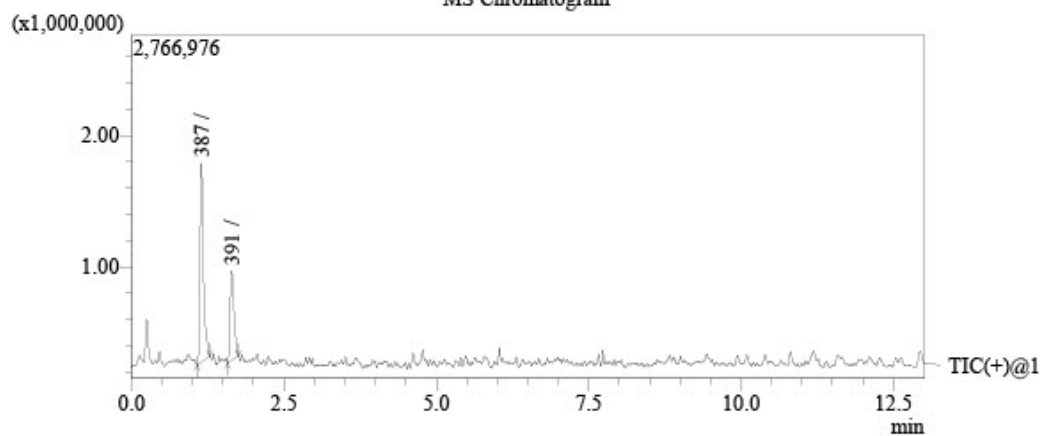


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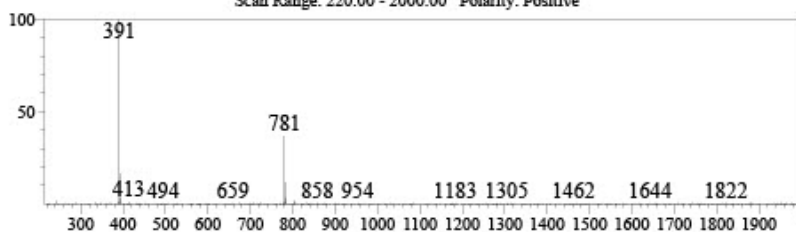
## Analysis of identity of active ingredient by UHPLC with mass spectrometric detection

MS Chromatogram

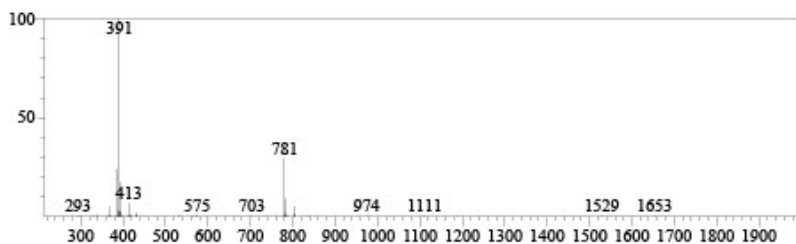


Library Search

Detected compound  
Ret. Time: 1.576 Base Peak: 391  
Scan Range: 220.00 - 2000.00 Polarity: Positive



Library: Peptide screening lib  
Formula: C<sub>14</sub>H<sub>22</sub>N<sub>4</sub>O<sub>9</sub> CAS: 307297-39-8 Mol. Weight: 390 Ret. Index: 0  
Compound Name: Epithalon



## Responsibles



**Mr. Ján Galbavý**  
*CEO*

Analysis results relate only to the samples tested.

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