

Certificate of Analysis

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Sample Identification

Sample Name DSIP 5 mg
Batch Number NDS-007
Date Published 2026-08-17 14:25

Results for LYO-0515

Peptides	Result	Unit	Uncertainty	Acceptable Range
DSIP Assay Peptide Screening 0.1% TFA	5.24	mg	[± 0.03]	(RT)
DSIP Purity Peptide Screening 0.1% TFA	99.1	%	[± 0.5]	(RT)
DSIP Identification by Spectrum (FTIR) Peptide Screening 0.1% TFA	978		[± 5]	(RT)
DSIP Identification by RT Peptide Screening 0.1% TFA	0.990		[± 0.005]	(RT)
Microbiology	Result	Unit	Uncertainty	Acceptable Range
Bacterial Endotoxin Chromgenic USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromgenic Test	0.056	EU/mg	[± 0.001]	
Mass Spectrometry	Result	Unit	Uncertainty	Acceptable Range
Molecular Ion Mass Identification (MS Deconvolution) Mass Spectrometry Identity	848	Da	[± 1]	(RT)

	Method Specification	
Determination of identity, content and purity of DSIP		
<i>Document number</i> DSIP_006_2026	<i>Superseded document</i> -	<i>Number of pages</i> 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	0.05% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.0425% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.9 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	55°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	280nm

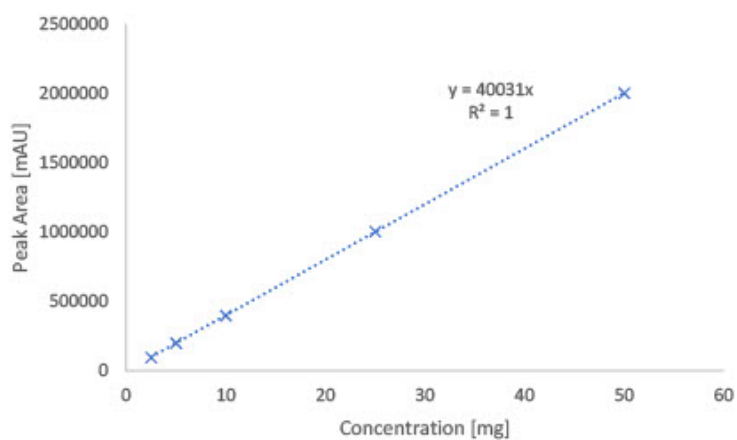
Gradient Program		
Time [min]	A [%]	B [%]
1.5	95	5
13	45	55
13.5	1	99
14.5	1	99
14.51	95	5
16	end	

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	0.05% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.0425% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.9 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	55°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Detection wavelength	225nm

Gradient Program		
Time [min]	A [%]	B [%]
1.5	97.5	2.5
13	45	55
13.5	1	99
14.5	1	99
14.51	97.5	2.5
16	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 214 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
Colum 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	0.05% TFA in Water (HPLC, Gradient Grade)
Eluent B	0.0425% TFA in Acetonitrile (HPLC, Gradient Grade)
Flow rate	0.9 mL/min
Program	Gradient elution
Injection volume	2 µL
Colum Temperature	55°C
Column	Waters XSelect CSH C18, 100x2.1mm 2.5µm
Mass spectrometry	Scan: positive 280-2000 Da

Gradient Program		
Time [min]	A [%]	B [%]
1.5	97.5	2.5
13	45	55
13.5	1	99
14.5	1	99
14.51	97.5	2.5
16	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



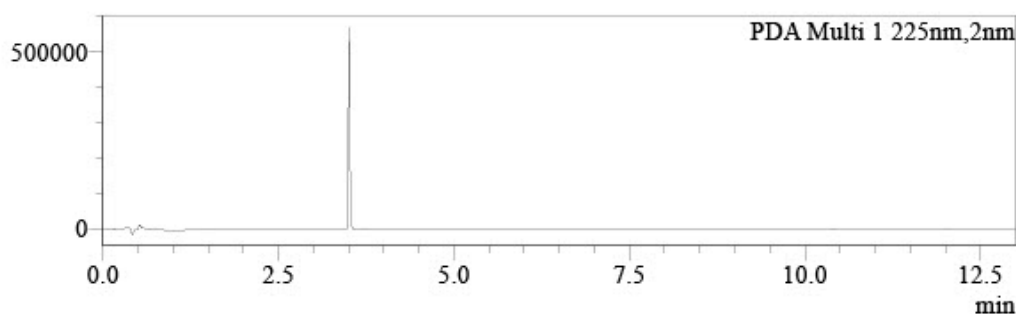
Analysis of quantity and purity of active ingredient by UHPLC with UV detection

Sample Information

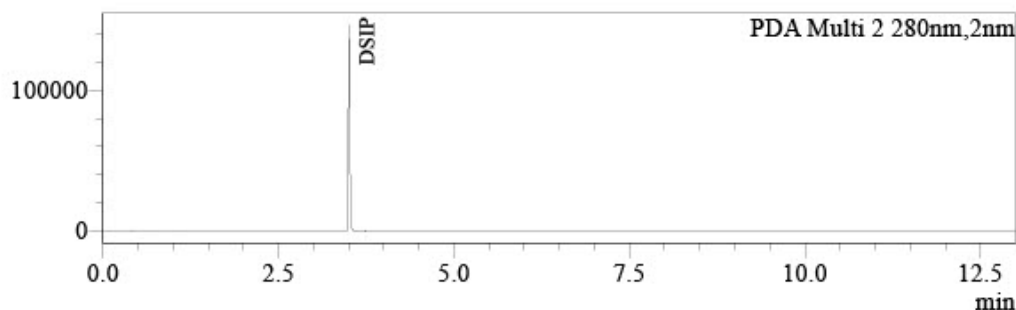
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Method File : Peptide screening_V7_Group D.lcm
Date Acquired : 8/5/2026 9:01:33 PM

Chromatogram

uAU



uAU



Peak Table

PDA Ch1 225nm

Name	Ret. Time	Area	Conc.	Unit	Area%
	2.704	1360	0.000		0.159
	3.239	1559	0.000		0.183
	3.399	265	0.000		0.031
	3.504	845846	0.000		99.088
	3.735	2548	0.000		0.298
	3.802	760	0.000		0.089
	3.908	551	0.000		0.065
	4.072	295	0.000		0.035
	4.422	143	0.000		0.017
	4.854	302	0.000		0.035
		853627			100.000

Peak Table

PDA Ch2 280nm

Name	Ret. Time	Area	Conc.	Unit
	2.704	356	0.000	
	3.237	349	0.000	
	3.399	52	0.000	

Name	Ret. Time	Area	Conc.	Unit
DSIP	3.504	213021	5.241	mg
	3.735	560	0.000	
	3.802	169	0.000	
	3.909	129	0.000	
	4.074	65	0.000	
	4.423	30	0.000	
	4.852	60	0.000	
	5.070	34	0.000	
	5.240	20	0.000	
		214848		

Analysis Report

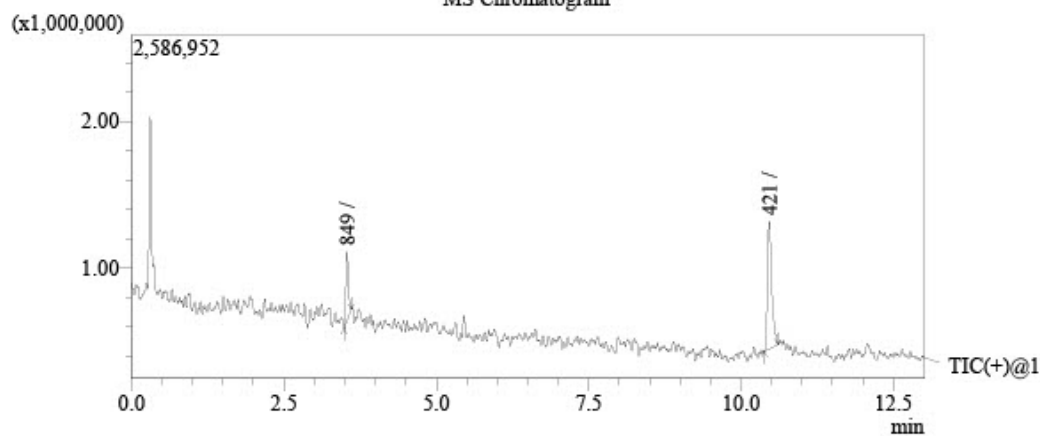


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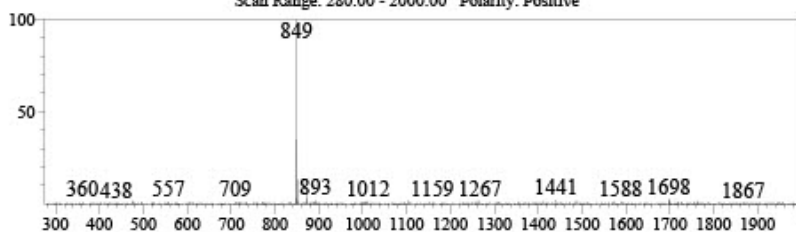
Analysis of identity of active ingredient by UHPLC with mass spectrometric detection

MS Chromatogram

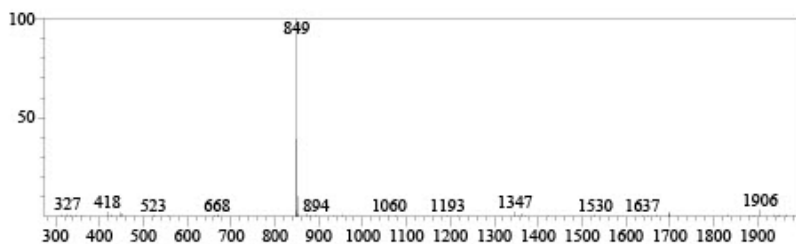


Library Search

Detected compound
Ret. Time: 3.488 Base Peak: 849
Scan Range: 280.00 - 2000.00 Polarity: Positive



Library: Peptide screening lib
Formula: C₃₅H₄₈N₁₀O₁₅ CAS: 62568-57-4 Mol. Weight: 848 Ret. Index: 0
Compound Name: DSIP



Endotoxin Determination Report

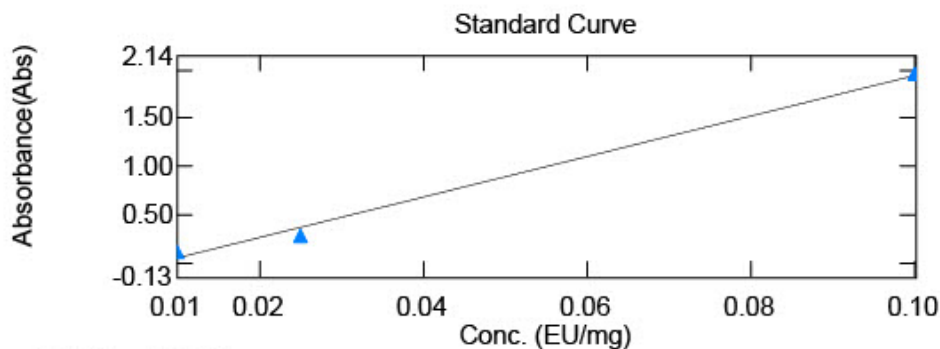


File Information

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Date/Time: 08/04/2026 04:55:58 PM

Instrument Information

Instrument Type: UV-1900 Series
Model (S/N): UV-1900i (A12536253123)



$$y = 20.9444x - 0.153119$$
$$r^2 = 0.99483$$

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
1	LYO-0448	1.610	0.6899	40.00
2	LYO-0449	1.987	0.8874	40.00
3	LYO-0450	3.261	1.5542	40.00
4	LYO-0451	0.579	0.4534	20.00
5	LYO-0514	0.223	0.0804	20.00
6	LYO-0515	0.292	0.1528	20.00
7	LYO-0516	0.816	0.7014	20.00
8	LYO-0517	0.143	0.1460	10.00
9	LYO-0518	3.211	1.5282	40.00
10	LYO-0519	3.780	1.8259	40.00
11	LYO-0520	0.188	0.0441	20.00
12	LYO-0521	14.507	1.3661	200.00
13	LYO-0462	3.678	1.7725	40.00
14	LYO-0466	0.310	0.1718	20.00
15	LYO-0467	0.741	0.6224	20.00
16	LIQ-0049	0.010	0.0526	1.00
17	LYO-0468	0.225	0.0822	20.00
18	LYO-0469	0.450	0.3181	20.00
19	LYO-0470	2.350	1.0776	40.00
20	LYO-0471	2.690	1.2555	40.00

	Sample Name	Conc	Raw_WL545.0	Dilution Rate
21	LYO-0472	0.248	0.1071	20.00
22	LYO-0473	0.565	0.4389	20.00
23	LYO-0474	2.342	1.0733	40.00
24	LYO-0475	0.381	0.2456	20.00
25	LYO-0476	13.044	1.2128	200.00
26	LYO-0477	0.266	0.1259	20.00

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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