

Certificate of Analysis

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Sample Identification

Sample Name Berberine 500 mg
Batch Number 010326
Date Published 2026-05-26 10:48

Results for ORAL-0013

Vitamins	Result	Unit	Uncertainty	Acceptable Range
Capsule Mass Polar Compound Screening 10mM ammonium formate buffer	348.0	mg	[± 7]	
Elemental Impurities	Result	Unit	Uncertainty	Acceptable Range
Arsenic Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Cadmium Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Quicksilver Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Lead Elemental Impurities screening USP (232) / Ph. Eur. 5.20 / 2.4.20	< 0.001	ppm		
Supplements	Result	Unit	Uncertainty	Acceptable Range
Berberine Assay Polar Compound Screening 10mM ammonium formate buffer	< 20	mg/ capsule		

	Method Specification		
Determination of Berberine content in capsules			
<i>Document number</i> BER_005_2026	<i>Superseded document</i> -	<i>Number of pages</i> 2	

1. Content Assesment

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% Formic acid in 10mM Aqueous Ammonium Formate
Eluent B	0.1% Formic Acid in 10mM Acetonitrile Ammonium Formate
Flow rate	1 mL/min
Program	Gradient elution
Injection volume	5 µL
Colum Temperature	40°C
Column	Phenomenex Kinetex C18, 100x4.6mm 5µm
Detection wavelength	415 nm

Gradient Program		
Time [min]	A [%]	B [%]
1	95	5
10.00	100	0
11.00	100	0
11.01	95	5
13	end	

1.3. Standard preparation

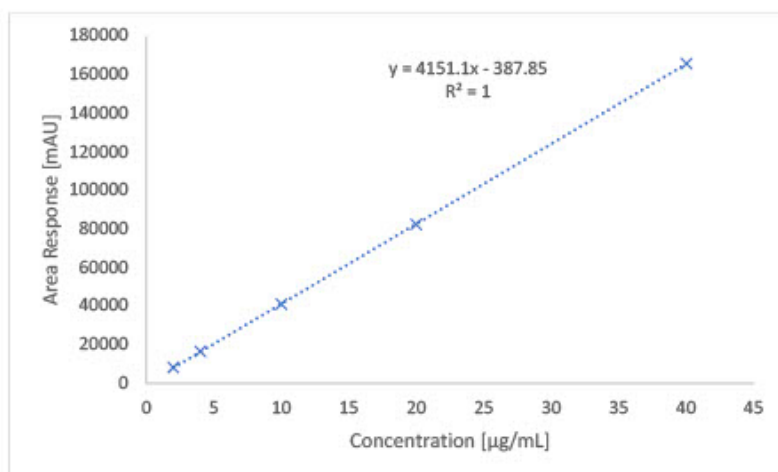
Approximately 25 mg of Berberine(CRM, Pure) was weighed and exact mass used was recorded. Whole amount of standard was quantitatively transferred to 25 mL volumetric flask and dissolved in DMSO (HPLC Grade) using ultrasonic bath. After full dissolution, flask was filled up to mark by DMSO(HPLC, Grade) and well mixed. Standard solution was diluted in mobile phase A solution to concentration 1 µg/mL and placed for analysis.

1.4. Sample preparation

Whole content of capsule was weighed and exact mass used was recorded. Whole amount of sample was quantitatively transferred to 5 mL volumetric flask and dissolved in DMSO (HPLC Grade) using ultrasonic bath. After extraction, flask was filled up to mark by DMSO(HPLC, Grade) and well mixed. Whole content of volumetric flask was centrifuged at 3000g for 5 minutes to remove insoluble particles and subsequently 1 mL of supernatant was diluted 10x in Methanol (HPLC, Gradient Grade). 10 µL of solution was transferred into 990 µL of mobile phase A and placed for analysis.

1.5. Calibration curve

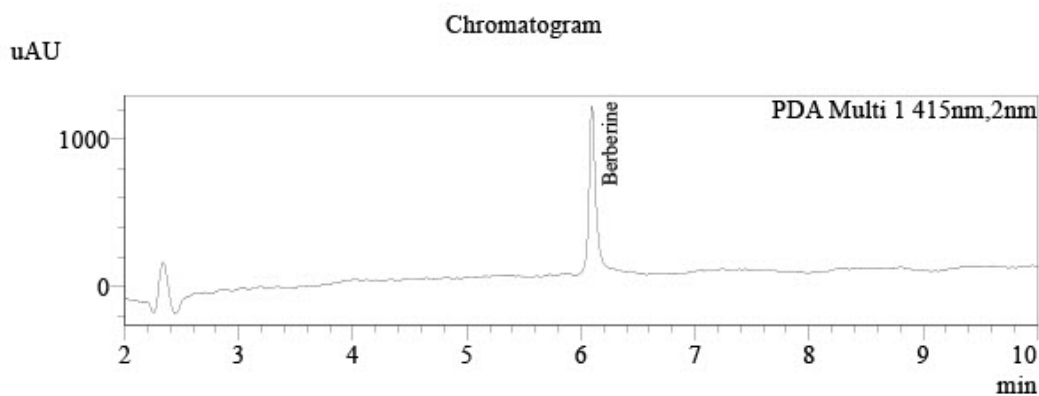
Calibration curve detail	
Quantitative method	External Standard
Calibration Type	Quadratic
Number of calibration points	4
Force through Zero	Disabled
Weighting Method	None



Analysis Report



Sample Information
Injection Volume : 5
Data File : ORAL-0013_003.lcd
Method File : SMS_V01.00_UV.lcm
Date Acquired : 5/26/2026 10:22:57 AM



Peak Table

PDA Ch1 415nm					
Peak#	Name	Ret. Time	Conc.	Unit	Area%
1	Berberine	6.096	6.135	mg/caps	100.000
Total					100.000

Responsibles



Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.

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