

Certificate of Analysis

Cerilliant Quality

ISO GUIDE 34

CERTIFICATE AR1353

ISO/IEC 17025

CERTIFICATE AT1352

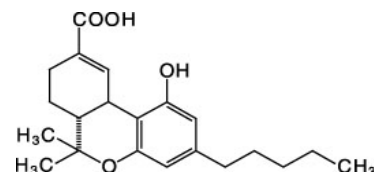
ISO 9001:2008

CERTIFICATE 3854

(-)-11-nor-9-Carboxy- Δ^9 -THC

(6aR-trans)-6a,7,8,10a-tetrahydro-1-hydroxy-6,6-dimethyl-3-pentyl-6H-dibenzo[b,d]pyran-9-carboxylic acid

Catalog Number: T-019
Solution Lot: FE042111-02
Expiration Date: April 2016
Solvent: Methanol
Volume per Ampule: Not less than 1 mL
Storage: Store in freezer.
Intended Use: For R&D/ analytical purposes only. Not suitable for human or animal consumption.
Regulatory: USDEA Exempt | Canadian TK # 61-257



Safety: Flammable, Poison

- Expiration Date has been established through real time stability studies.
- Ampules are overfilled to ensure a minimum 1 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration.

Component	Chromatographic Purity	Concentration
(-)-11-nor-9-Carboxy- Δ^9 -THC	99.3%	1.000 \pm 0.006 mg/mL
<ul style="list-style-type: none"> Uncertainty of the concentration is expressed as an expanded uncertainty in accordance with ISO 17025 and Guide 34 at the approximate 95% confidence interval using a coverage factor of k = 2 and has been calculated by statistical analysis of our production system and incorporates uncertainty of the purity factor, material density, and balance and weighing technique. Concentration is corrected for chromatographic purity, residual water, residual solvents and residual inorganics. 		

Solution Standard Verification and Homogeneity

Standard Solution	Lot Number	Verified Concentration (mg/mL)		%RSD - Homogeneity	
		Actual Results	Acceptance Criteria	Actual Results	Acceptance Criteria
New Lot	FE042111-02	0.991	\pm 3%	0.9	\leq 3%
Previous Lot	FE052109-05	1.000	\pm 3%	0.6	\leq 3%
<ul style="list-style-type: none"> Concentration is verified through multiple analyses and is calculated as the average of multiple analyses compared to an independently prepared calibration solution. Homogeneity of the New Lot is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The % RSD of samples pulled from across the lot demonstrate homogeneity of the New Lot. The % RSD of the Previous Lot represents variability of the analysis performed at the time of release. 					

Traceability

- Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo using NIST traceable weights. Calibration verification performed weekly and prior to each use utilizing NIST traceable weights. Each balance has been assigned a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure weighing complies with USP tolerances of no more than 0.1% relative error.
- Concentration is verified against an independently prepared calibration solution gravimetrically prepared using balances calibrated to NIST.
- In addition, each neat material utilized has been identified and thoroughly characterized through the use of multiple analytical techniques. Spectral data is provided on subsequent pages of the COA.

Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration/retest date when stored unopened as recommended. Product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.



Lara Sparks

Lara Sparks, Quality Assurance Director

May 18, 2011

Date

Standard Solution Assay Parameters

Analysis Method: HPLC/UV
Column: Betasil Phenyl 5 μ 4.6 x 150 mm
Mobile Phase: Acetonitrile::10mM Potassium Phosphate Buffer (75::25)
Flow Rate: 0.8 mL/min
Wavelength: 214 nm

Calibration Curve

Calibration Curve: Linear Regression
Number of Points: 4
Linearity (r): 0.999

Neat Material Data

Compound Name: (-)-11-nor-9-Carboxy- Δ^9 -THC
Compound Lot: FC051209-02

Chemical Formula: C₂₁H₂₈O₄
CAS Number: 56354-06-4
Molecular Weight: 344.45

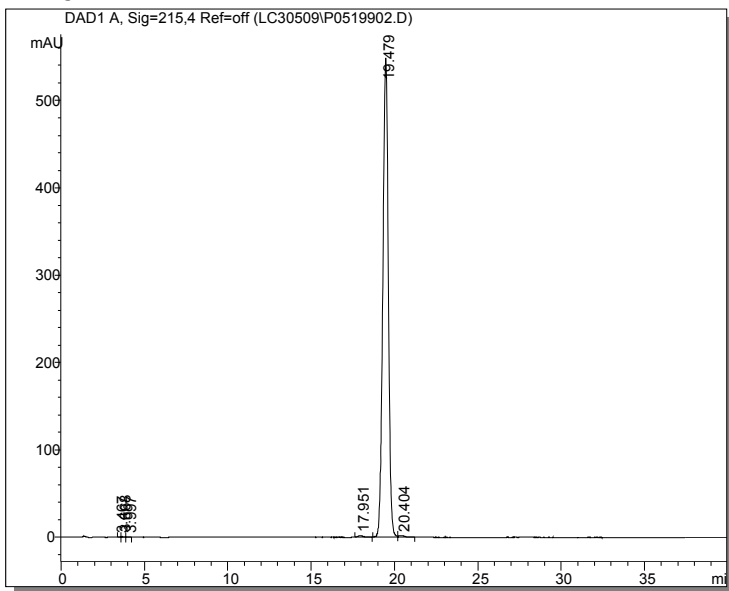
Neat Material Characterization Summary

Analytical Test	Method	Results		
Primary Chromatographic Purity by HPLC/PDA Analysis	SP10-0102	99.3%		
Secondary Purity Analysis by Thin Layer Chromatography	SP10-0106	Single Spot, R _f = 0.39		
Chiral Purity by HPLC/PDA Analysis	AM1075	0.4% (+)-Trans-THC-COOH		
Identity by GC/MS Analysis	SP10-0105	Consistent with Structure		
Identity by ¹ H-NMR Analysis	SP10-0116	Consistent with Structure		
Residual Solvent Analysis by GC/FID Headspace	AM1087	None Detected		
Residual Water Analysis by Karl Fischer Coulometry	SP10-0103	0.08%		
Elemental Analysis	Outsourced	Calculated	Analyzed	
		C	73.23%	73.24%
		H	8.19%	8.23%
Purity Factor		99.2%		

- ♦ Primary purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.
- ♦ The primary chromatographic purity value is used to calculate the Purity Factor.
- ♦ A secondary chromatographic purity method is utilized as a control.
- ♦ Purity Factor = [(100 - wt% residual solvent - wt% residual water - wt% residual inorganics) x Chromatographic Purity/100].
- ♦ Purity factor does not include adjustment for chiral and/or isotopic purity.

Spectral and Physical Data

HPLC

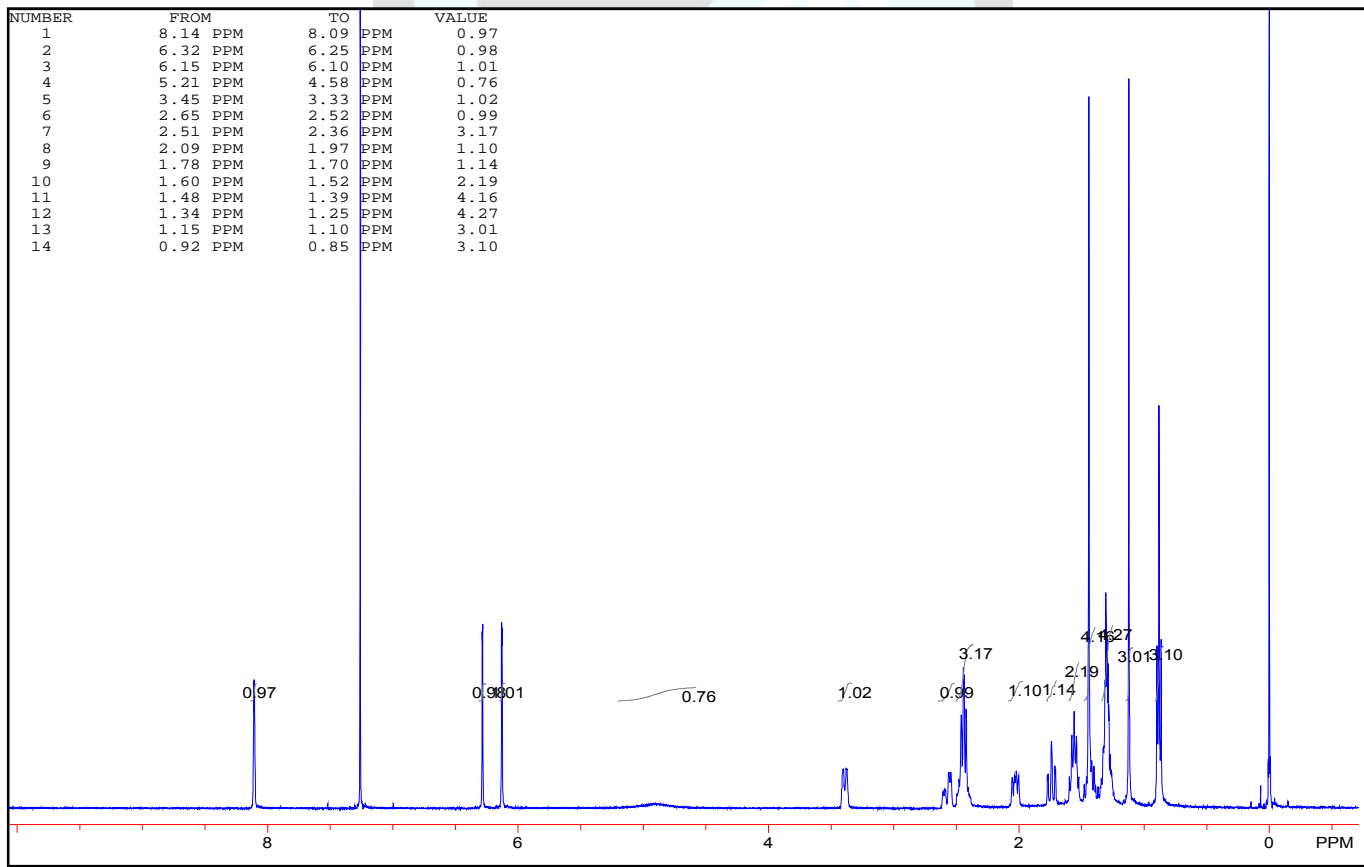


Column: Prodigy ODS, 4.6 x 250 mm
Mobile Phase: Acetonitrile::0.01M Potassium phosphate buffer (55:45)
Flow Rate: 1.5 mL/min
Wavelength: 215 nm
Data File Name: S:\HPLC\HPLC3\2009\LC30509\P0519902.D
Operator: TNT
Instrument: LC#3
Sample Name: FC051209-02
Method File: AM1291.M
Acquired: May 19, 2009 10:10 AM

Peak #	Ret Time	Area	Height	Area %
1	3.47	0.95	0.19	0.01
2	3.67	5.08	0.72	0.04
3	4.00	2.30	0.33	0.02
4	17.95	47.54	2.03	0.38
5	19.48	12428.30	548.66	99.14
6	20.40	52.20	2.02	0.42

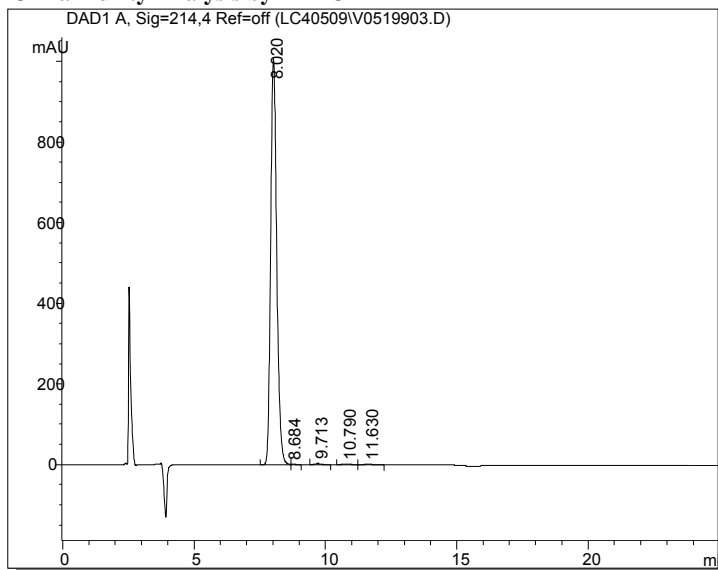
¹H NMR

Instrument: JEOL ECX 400
Solvent: Chloroform-D



Spectral and Physical Data (cont.)

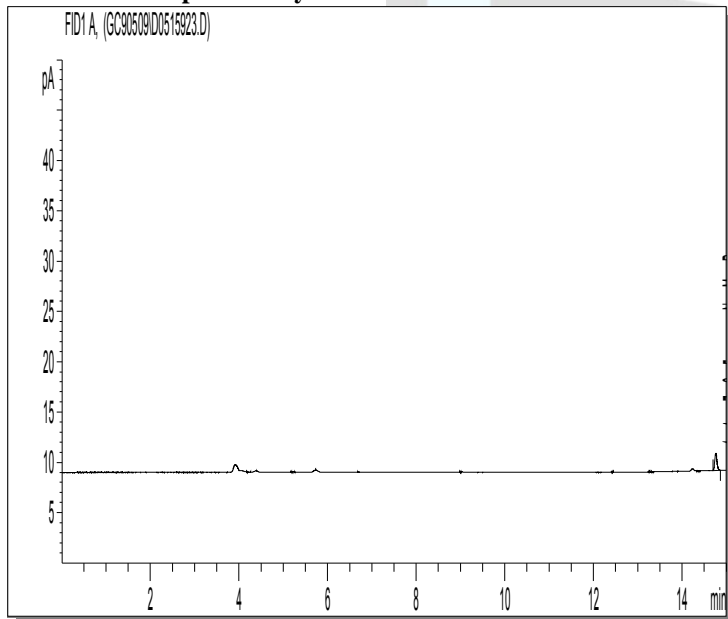
Chiral Purity Analysis by HPLC



Column: Lux 5µ Cellulose-I, 4.6 x 250 mm
Mobile Phase: Hexane::Ethanol::TFA (950::50::0.005)
Flow Rate: 1.2 mL/min
Wavelength: 214 nm
Data File Name: S:\HPLC\HPLC4\2009\LC40509\0519903.D
Operator: TNT
Instrument: LC#4
Sample Name: FC051209-02
Method File: AM1075.M
Acquired: May 19, 2009 11:50 AM

Peak #	Ret Time	Area	Area %	
1	8.02	16308.00	98.95	(-)-THC Acid
2	8.68	10.52	0.06	
3	9.71	46.47	0.28	
4	10.79	61.10	0.37	(+)-THC Acid
5	11.63	54.90	0.33	

GC/FID Headspace Analysis



Column: DB-ALC1 30m x 0.53mm x 3µm film thickness
Temp Program: 40°C (12 min) to 220°C at 40°C/min (5.5 min)
Carrier Gas: Helium
Flow Rate: 2.0 mL/min
Detector Temp: 250°C
Injector: Headspace Sampler
Injector Temp: 200°C
HS Oven Temp: 200°C
Injection Volume: 1.0 mL
Incubation Time: 10 minutes
Method: AM1087

Data File Name: S:\GC\GC-HS9\GC90509\0515923.D
Operator: KRS
Instrument: GC#9
Sample Name: FC051209-02
Acquired: May 15, 2009 10:58 PM

Peak	Compound	Area	Weight %
1	NMP	NA	NA
Total			ND

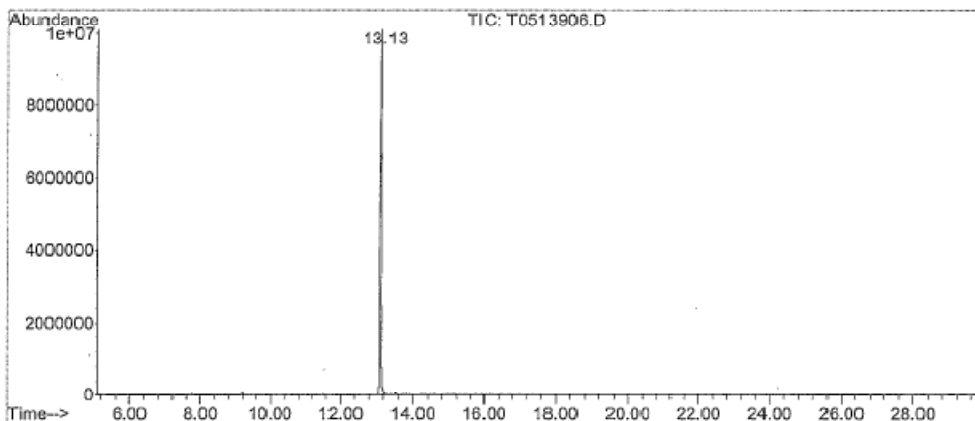
ND - Not Detected

Spectral and Physical Data (cont.)

Identity by GC/MS Analysis

Compound Name : (-)-11-Nor-9-carboxy-delta9- THC/di-TMS
Lot Number : FC051209-02
Instrument : Agilent 5973N MSD/6890N GC
Operator-Inst ID : RPC - C10477
Date Reported : Thu May 14 10:08:03 2009
Column Type : DB-5ms, 30m x 0.25mm ID, 0.25um film thickness
Temp. Program : 50°C to 200°C@40°C/min, 200°C to 300°C@10°C/min, 16min hold
Injector Temp. : Cool on-column
Carrier Gas : Helium
Flow Rate (mL/min) : 0.80 mL/min
Transfer Line Temp. : 280°C
Scan Range : 50-600

Total Ion Chromatogram



Mass Spectrum

