

# OLEOLITES (PHYTOCANNABINOIDS) FOR THERAPEUTIC USE BY GC/MS

**REF GC88810**

CANNABIDIOL (CBD), CANNABIDIOLIC ACID (CBDA), CANNABIGEROL (CBG), CANNABINOL (CBN), TETRAHYDROCANNABINOLIC ACID (THCA), TETRAHYDROCANNABINOL (THC), TETRAHYDROCANNABIVARIN (THCV)

This product fulfills all the requirements of Directive 98/79/EC on in vitro diagnostic medical devices (IVD).  
The declaration of conformity is available upon request.



## INSTRUCTION FOR USE

**IVD**

For *in vitro* diagnostic use

**CE**



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## INDEX

|                                                                       |    |
|-----------------------------------------------------------------------|----|
| INTENDED USE .....                                                    | 3  |
| KIT CONTENT FOR 100 TESTS .....                                       | 3  |
| ACCESSORIES AND CONSUMABLES AVAILABLE SEPARATELY .....                | 4  |
| INSTRUMENTS .....                                                     | 4  |
| MATRIX – COLLECTION AND STORAGE PROCEDURE .....                       | 5  |
| PREANALYTICAL PROCEDURE .....                                         | 5  |
| ANALYTICAL PROCEDURE .....                                            | 6  |
| .....                                                                 | 6  |
| SETTING OF THE MASS SPEC (for Ion trap) .....                         | 7  |
| SETTING THERMAL PROGRAM .....                                         | 7  |
| ANALYTES AND DEUTERATED INTERNAL STANDARDS USED FOR CALIBRATION ..... | 8  |
| TECHNICAL FEATURES - PART I .....                                     | 8  |
| TECHNICAL FEATURES – PART II .....                                    | 10 |
| TECHNICAL FEATURES - PART III .....                                   | 10 |
| REFERENCE CHROMATOGRAMS .....                                         | 11 |
| GENERAL WARNINGS .....                                                | 14 |
| ABBREVIATIONS .....                                                   | 15 |
| BIBLIOGRAPHY .....                                                    | 16 |
| REFERENCE STANDARDS .....                                             | 17 |
| IVD SYMBOLS .....                                                     | 18 |

## INTENDED USE

*In vitro* diagnostic medical device for the detection and monitoring of CANNABIDIOL (CBD), CANNABIDIOLIC ACID (CBDA), CANNABIGEROL (CBG), CANNABINOL (CBN), TETRAHYDROCANNABINOLIC ACID (THCA), TETRAHYDROCANNABINOL (THC), TETRAHYDROCANNABIVARIN (THCV) as a titration for therapeutic oils.

Manual method for professional use.

## KIT CONTENT FOR 100 TESTS

| CONTENT                    | DESCRIPTION                | PACKAGING      | WARNINGS                                                                                              |
|----------------------------|----------------------------|----------------|-------------------------------------------------------------------------------------------------------|
| Reagent A                  | Derivatization Solution A  | 1 x 10 ml      | Store at +15 °C    |
| Reagent B                  | Derivatization Solution B  | 1 x 3 ml       | Store at +15 °C   |
| Reagent C                  | Extracting Solution        | 2 x 500 ml     | Store at +2 °C   |
| Reagent D                  | Diluent Solution           | 1 x 90 ml      | Store at +2 °C   |
| Reagent E                  | Stabilization Solution     | 1 x 100 ml     | Store at +2 °C   |
| Reagent F                  | Test Solution              | 1 x 1 ml       | Store at +2 °C   |
| Reagent G                  | Internal Standard Solution | 1 x 5 ml       | Store at -25 °C  |
| Multiparametric Calibrator |                            | 6 x 1 x 600 µl | (Packed separately – Code GC88816 – see data sheet)                                                   |

## ACCESSORIES AND CONSUMABLES AVAILABLE SEPARATELY

| CODE     | DESCRIPTION                                                                       | PACKAGING      |
|----------|-----------------------------------------------------------------------------------|----------------|
| GC88816  | Calibrator for Oleolites (Phytocannabinoids) for therapeutic use                  | 6 x 2 x 600 µl |
| GC88819  | Control for Oleolites (Phytocannabinoids) for therapeutic use – Levels 1 and 2    | 2 x 1 x 1 ml   |
| ZRE13623 | Analytical Column Rxi-5silMS (30 x 0,25 mm - 0,25 µm)                             | 1 Pc           |
| GC88830  | Deuterated Internal Standard Mix Solution                                         | 1 x 5 ml       |
| S29057U  | Standard glass vials of 2 ml with screw caps for Autosampler                      | 1 x 100 Pcs    |
| S24717   | Glass insert for vials of 2 ml                                                    | 1 x 100 Pcs    |
| Z1636/26 | 10 ml Pyrex Tubes with cap SWL (for hydrolysis, till 300°C-washable and reusable) | 1 x 40 Pcs     |

## INSTRUMENTS

| DESCRIPTION          | WARNINGS |
|----------------------|----------|
| GC/MS Instrument     | Required |
| Operational Computer | Required |
| Autosampler          | Required |

## MATRIX – COLLECTION AND STORAGE PROCEDURE

| MATRIX                                            | PROCEDURE |
|---------------------------------------------------|-----------|
| Galenic oil preparations for therapeutic purposes | N.A.      |

## PREANALYTICAL PROCEDURE

| STEP      | DESCRIPTION                                                                                                                                                                                                                                                                                                                  |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|           | <p>Dispense 100 µl of <b>Reagent F</b> into a Pyrex tube.</p> <p>Dry under nitrogen flow or rotary evaporator WITHOUT EXCEEDING the temperature of 40 °C.</p> <p>Add 100 µl of <b>Reagent A</b> and 30 µl of <b>Reagent B</b>.</p> <p>Incubate for 30 minutes at 65°C.</p> <p>Transfer it into a glass vial with insert.</p> |
| Injection | Inject from 1 to 5 µl according to the sensitivity of the instrument.                                                                                                                                                                                                                                                        |

## ANALYTICAL PROCEDURE

| STEP                                                              | DESCRIPTION                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1                                                                 | Dispense 100 µl of the sample + 9900 µl of <b>Reagent C</b> into a Pyrex tube.<br><br>Vortex for 30 seconds.                                                                                                                                                                                                                                                                |
| 2                                                                 | Dispense 100 µl of the extract (Step 1) and 900 µl of <b>Reagent D</b> into an Eppendorf tube.<br><br>Vortex for 10 seconds.                                                                                                                                                                                                                                                |
| 3                                                                 | Dispense 50 µl of the previously obtained solution (Step 2) and 950 µl of <b>Reagent E</b> into an Eppendorf tube.<br><br>Vortex for 10 seconds.                                                                                                                                                                                                                            |
| 4                                                                 | Dispense 100 µl of the previously obtained solution (Step 3) and 50 µl of <b>Reagent G</b> into a Pyrex tube.<br><br>Vortex for 10 seconds, then dry under nitrogen flow or rotary evaporator WITHOUT EXCEEDING the temperature of 40 °C.                                                                                                                                   |
| 5                                                                 | Add 100 µl of <b>Reagent A</b> and 30 µl of <b>Reagent B</b> .<br><br>Incubate for 30 minutes at 65°C.<br><br>Transfer it into a glass vial with insert.                                                                                                                                                                                                                    |
| Injection                                                         | Inject from 1 to 5 µl according to the sensitivity of the instrument.                                                                                                                                                                                                                                                                                                       |
| Construction of the calibration curve and preparation of controls | Dispense 100 µl of every level and 50 µl of <b>Reagent G</b> into a Pyrex tube.<br><br>Vortex for 10 seconds, then dry under nitrogen flow or rotary evaporator WITHOUT EXCEEDING the temperature of 40 °C.<br><br>Add 100 µl of <b>Reagent A</b> and 30 µl of <b>Reagent B</b> .<br><br>Incubate for 30 minutes at 65°C.<br><br>Transfer it into a glass vial with insert. |
| Injection                                                         | Inject from 1 to 5 µl according to the sensitivity of the instrument.                                                                                                                                                                                                                                                                                                       |

## SETTING OF THE MASS SPEC (for Ion trap)

### Parameters SIM

| PARAMETERS | SETTING     |                         |                         |
|------------|-------------|-------------------------|-------------------------|
|            | RT<br>(min) | Quantifier Ion<br>(m/z) | Quantifier Ion<br>(m/z) |
| CBD        | 5.26        | 390                     | 337-301-458             |
| CBD-D3     | 5.26        | 393                     |                         |
| CBDA       | 6.40        | 491                     | 453-492-559             |
| CBG        | 6.01        | 337                     | 337-391-460             |
| CBN        | 6.30        | 367                     | 368-369-382             |
| CBN-D3     | 6.30        | 370                     |                         |
| THCA       | 7.06        | 487                     | 488-489-502             |
| THC        | 5.89        | 371                     | 386-315-303             |
| THC-D3     | 5.89        | 374                     |                         |
| THCV       | 5.03        | 343                     | 358-315-275             |

## SETTING THERMAL PROGRAM

### THERMAL PROGRAM

| TEMPERATURE          | TIME                                    |
|----------------------|-----------------------------------------|
| 200°C                | 2 min                                   |
| Increase of 20°C/min | Until it reaches 300°C<br>for 3 minutes |

### TEMPERATURES AND EXERCISE FLOWS

| PARAMETERS   | SETTING  |
|--------------|----------|
| Injector     | T=250°C  |
| Split Ratio  | 1:10     |
| Transferline | T=250°C  |
| Helium Flow  | 1 ml/min |
| T° source    | 230°C    |
| T° quad      | 150°C    |

## ANALYTES AND DEUTERATED INTERNAL STANDARDS USED FOR CALIBRATION

| ANALYTES | DEUTERATED INTERNAL STANDARDS USED FOR CALIBRATION |
|----------|----------------------------------------------------|
| CBD      | CBD-D3                                             |
| CBDA     | CBD-D3                                             |
| CBG      | CBN-D3                                             |
| CBN      | CBN-D3                                             |
| THCA     | THC-D3                                             |
| THC      | THC-D3                                             |
| THCV     | THC-D3                                             |

## TECHNICAL FEATURES - PART I

| CONCENTRATIONS | MEANING                                   |
|----------------|-------------------------------------------|
| C LLOQ         | Concentration at low limit quantification |
| C1             | Low concentration                         |
| C2             | Medium concentration                      |
| C3             | High concentration                        |
| Max C          | The highest concentration                 |

| ANALYTES | CONCENTRATIONS USED TO CALCULATE REPRODUCIBILITY AND ACCURACY (mg/ml) |    |    |    |       |
|----------|-----------------------------------------------------------------------|----|----|----|-------|
|          | C LLOQ                                                                | C1 | C2 | C3 | MAX C |
| CBD      | 1                                                                     | 2  | 5  | 10 | 20    |
| CBDA     | 1                                                                     | 2  | 5  | 10 | 20    |
| CBG      | 1                                                                     | 2  | 5  | 10 | 20    |
| CBN      | 1                                                                     | 2  | 5  | 10 | 20    |
| THCA     | 1                                                                     | 2  | 5  | 10 | 20    |
| THC      | 1                                                                     | 2  | 5  | 10 | 20    |
| THCV     | 1                                                                     | 2  | 5  | 10 | 20    |

| ANALYTES | ACCURACY INTRA SERIE<br>(RELATIVE ERROR %) |           | ACCURACY INTER SERIE<br>(RELATIVE ERROR %) |           |
|----------|--------------------------------------------|-----------|--------------------------------------------|-----------|
|          | C1<br>(%)                                  | C3<br>(%) | C1<br>(%)                                  | C3<br>(%) |
| CBD      | 5,38                                       | 4,25      | 6,23                                       | 6,30      |
| CBDA     | 10,09                                      | 4,76      | 13,49                                      | 5,96      |
| CBG      | 12,95                                      | 7,72      | 14,29                                      | 9,29      |
| CBN      | 5,69                                       | 4,84      | 7,27                                       | 6,66      |
| THCA     | 6,87                                       | 1,54      | 7,16                                       | 6,23      |
| THC      | 6,33                                       | 7,42      | 8,20                                       | 7,72      |
| THCV     | 4,91                                       | 5,75      | 7,69                                       | 6,34      |

## TECHNICAL FEATURES – PART II

| ANALYTES | REPRODUCIBILITY INTRA SERIE<br>(COEFFICIENT OF VARIATION %) |         |            | REPRODUCIBILITY INTER SERIE<br>(COEFFICIENT OF VARIATION %) |         |            |
|----------|-------------------------------------------------------------|---------|------------|-------------------------------------------------------------|---------|------------|
|          | C LLOQ<br>%                                                 | C2<br>% | Max C<br>% | C LLOQ<br>%                                                 | C2<br>% | Max C<br>% |
| CBD      | 2,29                                                        | 2,20    | 1,15       | 3,10                                                        | 3,14    | 3,08       |
| CBDA     | 6,23                                                        | 5,60    | 5,66       | 11,22                                                       | 8,21    | 10,22      |
| CBG      | 1,28                                                        | 2,90    | 1,31       | 3,26                                                        | 5,50    | 2,95       |
| CBN      | 2,33                                                        | 2,35    | 1,40       | 6,62                                                        | 3,72    | 3,28       |
| THCA     | 4,58                                                        | 2,10    | 3,20       | 11,34                                                       | 9,68    | 10,16      |
| THC      | 2,63                                                        | 1,19    | 1,88       | 3,18                                                        | 3,06    | 3,51       |
| THCV     | 2,88                                                        | 3,16    | 1,92       | 4,38                                                        | 6,27    | 3,50       |

## TECHNICAL FEATURES - PART III

| ANALYTES | LLOD<br>(mg/ml) | LINEARITY<br>(mg/ml) | COEFFICIENT OF<br>CORRELATION<br>R2 + DEV STD |
|----------|-----------------|----------------------|-----------------------------------------------|
| CBD      | 0,3             | 1 - 200              | 0,9972 ± 0,0011                               |
| CBDA     | 0,3             | 1 - 200              | 0,9928 ± 0,0028                               |
| CBG      | 0,3             | 1 - 200              | 0,9918 ± 0,0025                               |
| CBN      | 0,3             | 1 - 200              | 0,9969 ± 0,0018                               |
| THCA     | 0,3             | 1 - 200              | 0,9902 ± 0,0052                               |
| THC      | 0,3             | 1 - 200              | 0,9959 ± 0,0004                               |
| THCV     | 0,3             | 1 - 200              | 0,9965 ± 0,0004                               |

## REFERENCE CHROMATOGRAMS

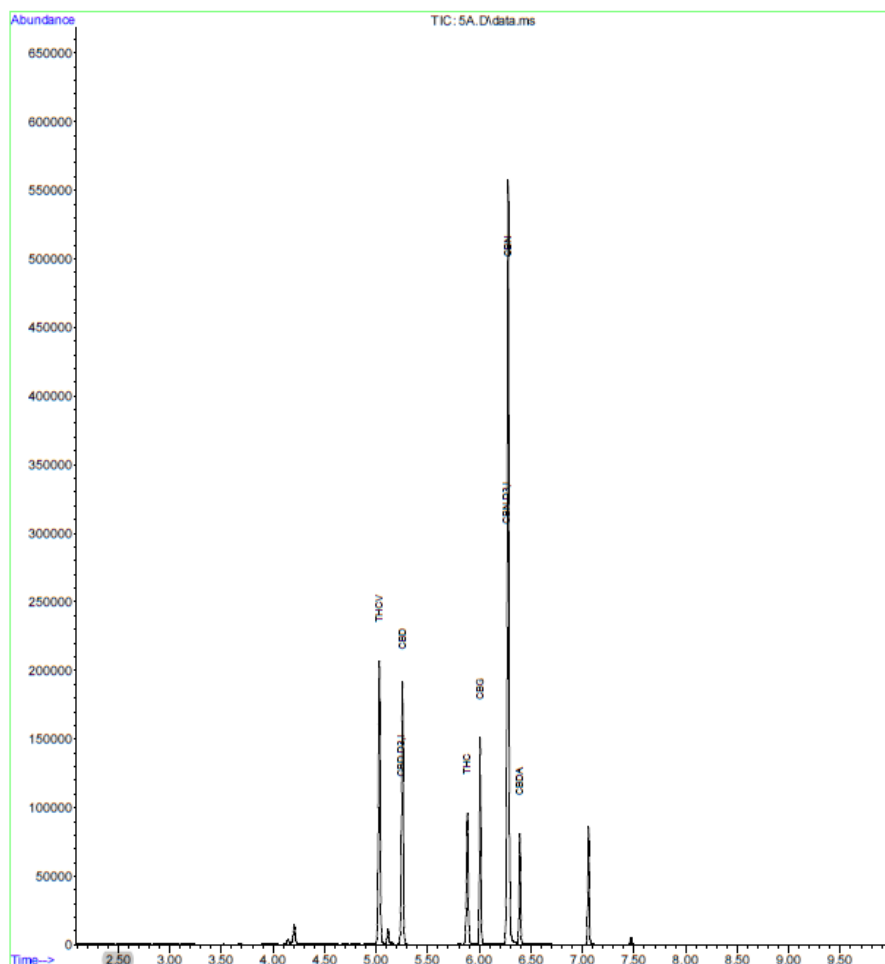


Fig. 1 Calibrator for Oleolites (Phytocannabinoids) for therapeutic use: 20 mg/l

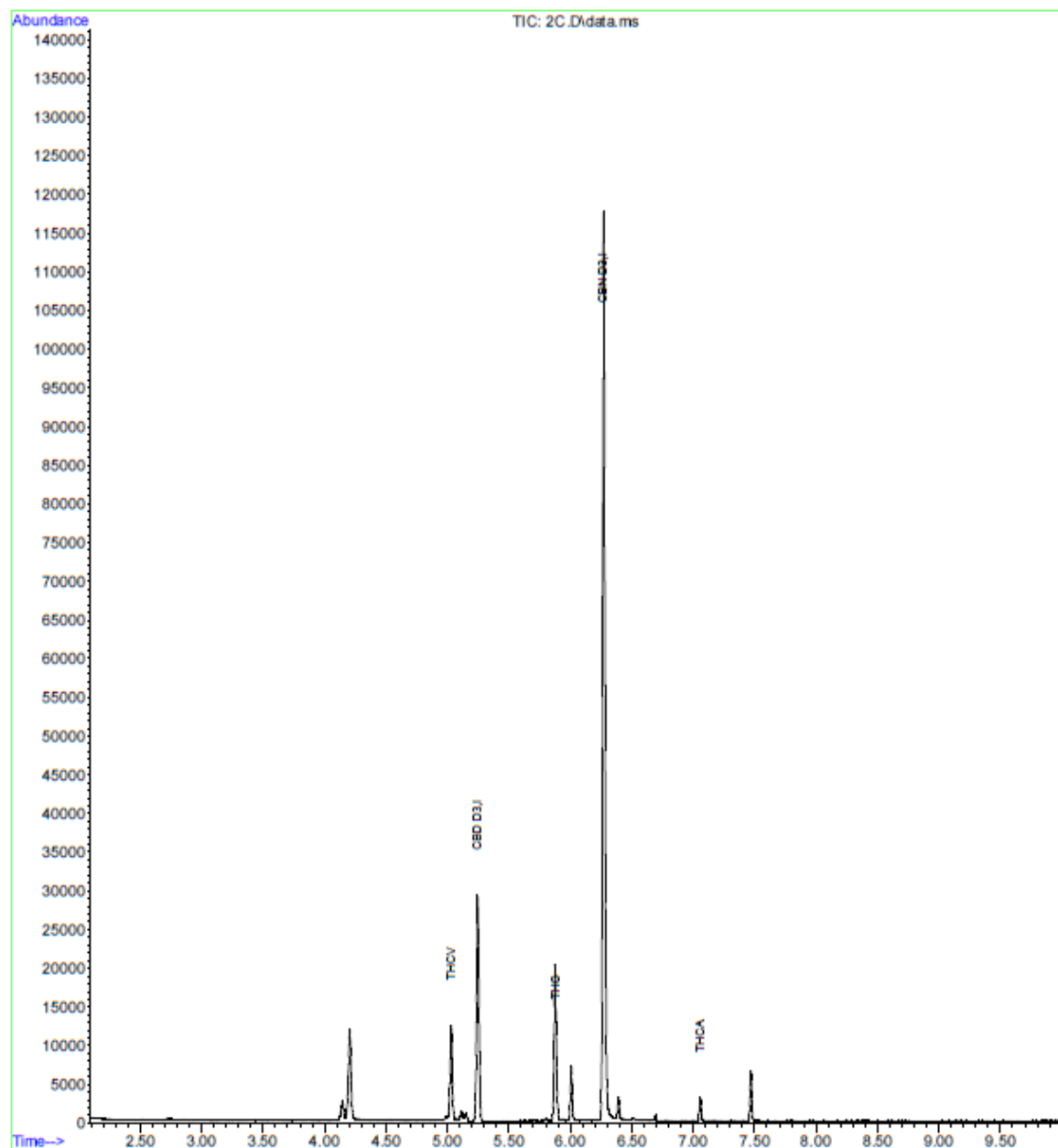


Fig. 2 Control for Oleolites (Phytocannabinoids) for therapeutic use Level 1: 3,5 mg/l

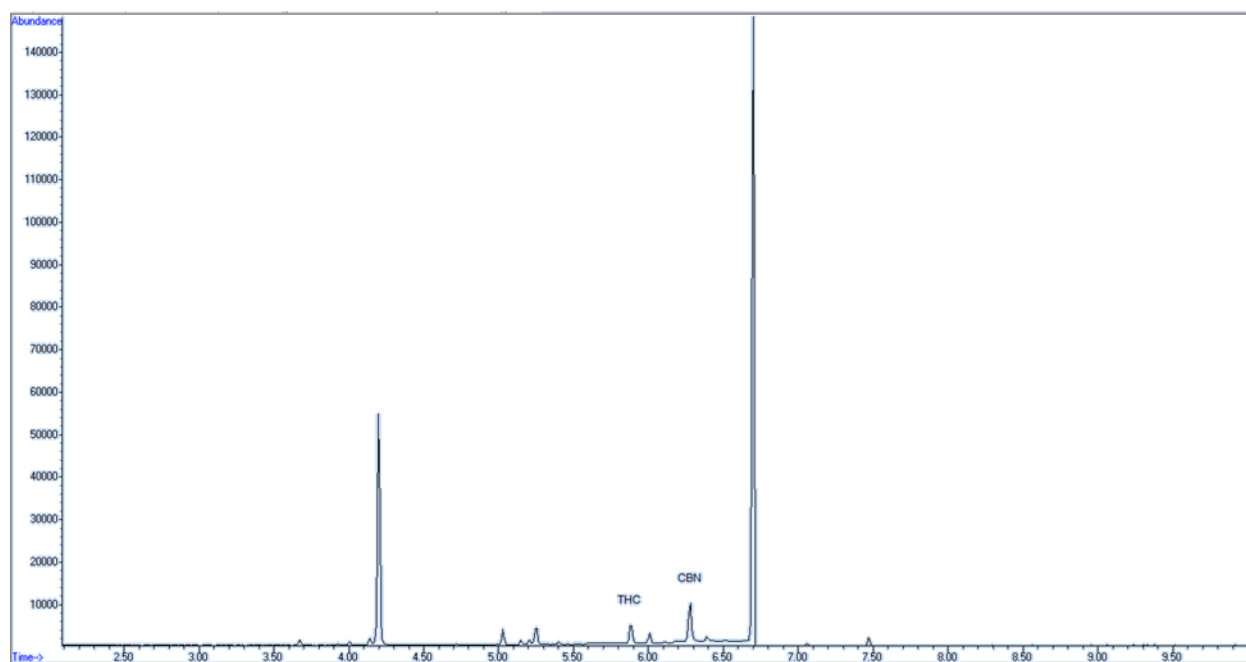


Fig. 3 Oleolite sample containing THC and CBN.

## GENERAL WARNINGS

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### 1. NEW COLUMN TREATMENT

Install the new analytical column Rxi-5silMS (30 x 0,25 mm x 0,25 µm).

Cut the column 2 cm from the ends with a suitable column cutter.

### 2. COLUMN CONDITIONING

Conditionate for 5 minutes at room temperature at a flow of 1 ml/min and for 1 hour at 10°C under the maximum exercise temperature at a flow of 1 ml/min.

DO NOT CONDITION WITH THE COLUMN ATTACHED TO THE MASS DETECTOR.

### 3. INJECTION NEEDLE WASHING

Hexane

## ABBREVIATIONS

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| ABBREVIATIONS     | MEANING                             |
|-------------------|-------------------------------------|
| e.g. 5 x 1 x 1 ml | N° of levels x N° of vials x volume |
| DEV STD           | Standard Deviation                  |
| LLOD              | Low limit of detection              |
| N.A.              | Not available                       |
| Pcs               | Piece/pieces                        |
| rpm               | revolutions per minute              |
| RT                | Retention Time                      |

## BIBLIOGRAPHY

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## REFERENCE STANDARDS

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**Quality Assurance System** compliant with regulations:

UNI CEI EN ISO 13485:2016,

UNI EN ISO 9001:2015

Any modification made to the Medical Device unless authorized by Eureka S.r.l. - Lab Division makes this declaration invalid.

We declare that the devices comply with the following **Technical Standards**:

EN ISO 13485:2016

EN ISO 13612:2002

EN ISO 14971:2012

EN ISO 15223-1:2016

EN ISO 18113-1:2011

EN ISO 18113-2:2011

We declare that the device is sold in a non-sterile package.

## IVD SYMBOLS

| NUMBER | SYMBOL                                                                              | DESCRIPTION                                       |
|--------|-------------------------------------------------------------------------------------|---------------------------------------------------|
| 1      |    | Manufacturer                                      |
| 2      |    | Product Model Number / Designation or Part Number |
| 3      |    | Caution, consult accompanying documents           |
| 4      |    | Product Lot Number                                |
| 5      |  | Use By (Expiry)                                   |
| 6      |  | Consult Operating Instructions                    |
| 7      |  | Date of manufacture                               |
| 8      |  | Temperature limitation                            |
| 9      |  | For <i>in vitro</i> diagnostic use                |
| 10     |  | European Union conformity                         |
| 11     |  | Packaging                                         |