Bogotá, D.C. 22 de Mayo de 2024

OFV-220524-1

Señores:
INSTITUTO NACIONAL DE MEDICINA LEGAL Y CIENCIAS FORENSES
Dra. MARÍA VICTORIA ESTUPIÑAN MARTINEZ
COORDINADORA
Grupo Nacional de Ciencias Forenses

REF. CONTRATO 0147-SG-2023

Cordial Saludo.

Nos dirigimos respetuosamente a ustedes para solicitar la aceptación de la entrega de los siguientes productos con una fecha de vencimiento inferior a lo pactado en el contrato. Esta situación implica que no se cumpliría la fecha mínima de vigencia estipulada en el contrato *(mínimo 1 año de vigencia).*

La solicitud se hace debido a la urgencia y requerimiento de la entidad para la utilización de estas sustancias. No obstante, **QUÍMICA M.G. S.A.S.** se compromete a reponer las unidades si, al llegar la fecha de vencimiento del producto, estas no han sido consumidas.

- **LOTE 4 ITEM 192:** una (1) unidad del producto **APROBARBITAL, CONCENTRACIÓN 1,0 MG/ML, TIPO 34029, A-150-1ML** o su equivalente el cual se realizó cambio de referencia a **34029** perteneciente a la marca **RESTEK** de acuerdo al otrosí # 1; el ítem con lote A0191870 con fecha de vencimiento 30 de Noviembre del 2024.

LOTE	ITEM	ESPECIFICACIÓN TÉCNICA	UNIDAD DE MEDIDA (PRESENTACION)	CANTIDAD	MARCA	REFERENCIA	PRESENTACION	
4	***192***	**Aprobarbital, concentración 1,0 mg/mL, tipo 34029, A-150-1ML o su equivalente.**	**Ampolla x 1 mL**	**1**	**RESTEK**	**34029**	**Ampolla x 1 Ml**	**1 Und con fecha de vencimiento 30/11/2024**
4	***192***	**Aprobarbital, concentración 1,0 mg/mL, tipo 34029, A-150-1ML o su equivalente.**	**Ampolla x 1 mL**	**24**	**RESTEK**	**34029**	**Ampolla x 1 Ml**	**24 Und listas para despacho. FECHA DE VENCMIENTO: 31/MARZO/2026**

- **LOTE 9 ITEM 241:** AB-FUBINACA Referencia IDO 60211, Ampolla 100ug/mL **;** el ítem con lote **1621.1B1.2L1A con fecha de vencimiento Noviembre del 2024 -** cantidad 2 ampollas.

Aclaramos que para los ítems pendientes de entrega del contrato no se requieren, ni se van a solicitar recursos adicionales, ya que los posibles imprevistos fueron considerados y contemplados en la oferta y esto con el ánimo de poder dar cumplimiento satisfactoriamente a la respectiva ejecución del presente contrato.

Se espera poder contar con su total comprensión sobre la situación planteada, puesto que siempre ha sido la intensión de *QUIMICA M.G. S.A.S*. dar cumplimiento cabal a las obligaciones contraídas con EL INSTITUTO NACIONAL DE MEDICINA LEGAL Y CIENCIAS FORENSES, desde hace varios años.

Agradecemos su comprensión y colaboración en este asunto. Quedamos atentos a su respuesta para proceder con la entrega.

Cordialmente.

_____

IVAN MUÑOZ ZULETA
Representante Legal

Certificate of Analysis
Reference Material

Lipomed Document QC-CA-1621L01
Version: 003-02.Feb.2021 Supersedes: 002-08.Jul.2016

Product name: **1 ml AB-FUBINACA solution** (0.1 mg/1 ml methanol)
N-[(1S)-1-(Aminocarbonyl)-2-methylpropyl]-1-[(4-fluorophenyl)-methyl]-1H-indazole-3-carboxamide

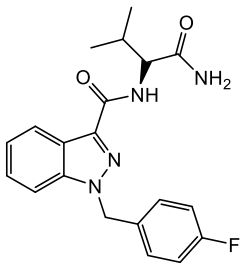
Lot No: 1621.1B1.2L1A
Art. No: FUB-1621-0.1LM

Release date: November 21, 2014
Last testing date: January 28, 2021
Expiry date: **November 2024**

Bulk Product Information: 1621.1B1.2

Chemical formula: $C_{20}H_{21}FN_4O_2$ Molwt: 368.41

CAS Registry No: 1185282-01-2



TEST	SPECIFICATIONS	RESULTS
1. Appearance	clear colorless solution	conforms
2. Identity	HPLC R_t corresponds to R_t of reference standard (± 0.5 min)	R_t standard = 13.7 min R_t test = 13.7 min
3. Purity	HPLC > 98.0 %	98.602 ± 0.015 %
4. Concentration of calibrated ampoule	0.0950 – 0.1050 mg/ml	0.0997 ± 0.0016 mg/ml (mean value)
5. Solvent purity (GC)	methanol > 99.9 %	> 99.9 %
6. Extractable volume	> 1 ml	conforms

Storage Conditions: For maximum stability store airtight at 2 - 8 °C in a dark location.

Lipomed certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria throughout the retest/expiry date when stored unopened and compliant to the above stated storage conditions. The product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.

FOR ANALYTICAL PURPOSES ONLY: NOT FOR HUMAN OR ANIMAL USE!

Issued by Dr. L. Prévot

Date sign: Arlesheim,

February 02, 2021

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Standard Solution Calibration:

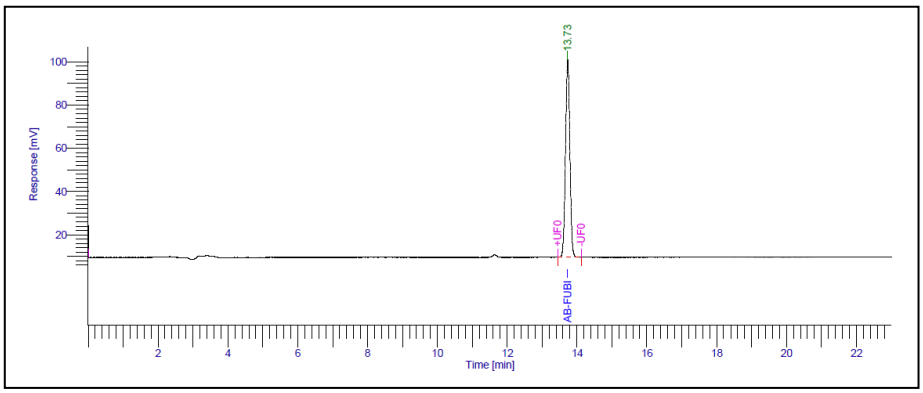
Bulk Reference Solutions	Prepared concentration in mg/ml
Reference 1	0.1003 mg/ml
Reference 2	0.1016 mg/ml

Ampoules	Analyzed concentration in mg/ml
First sample	0.0990 mg/ml
Second sample	0.1002 mg/ml
Third sample	0.0999 mg/ml

Lot to Lot Consistency:

Standard solution	Lot Number	Concentration
Actual Lot	1621.1B1.2L1A	0.0997 ± 0.0016 mg/ml
Previous Lot	N/A	N/A

HPLC Data:



Analytical conditions:

column:
YMC Pack Pro C18 (250*4.6)mm
mobile phase:
A: 0.1H3PO4 in nanopure H2O
B: 0.1H3PO4 in Acetonitrile
Gradient:
1 min 60%A / 40%B
18 min 10%A / 90%B
3 min 10%A / 90%B
flow rate: 1.0 ml/min
wavelength: 300 nm
injection volume: 5 ul

Peak #	Component Name	Time [min]	Area [uV*sec]	Area [%]
1	AB-FUBINACA	13.73	788164.3	100.000

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GENERAL INFORMATION

Quality Documentation:

This certificate is designed in accordance with ISO Guide 31 (Reference Materials – Contents of Certificates and Labels) and ISO Guide 35 (Reference Materials – General and Statistical Principles for Certification).

Quality Standards for Arlesheim production site:

ISO 9001 Quality Management System. Manufacturing, analysis, packaging and distribution of Analytical Reference Materials and Pharmaceuticals. IQNet/SQS Certification: 37199

ISO/IEC 17025 General requirements for the competence of Testing Analytical Reference Standards. ANAB Certificate number: AT-1760

ISO 17034 General requirements for the competence of Reference Material Producer. ANAB Certificate number: AR-1761

Quality Control Assessment:

The product quality is controlled by regularly performed analytical control tests/retests.

Intended Use:

The product covered by this certificate is designed for calibration or for use in quality control procedures for the specified chemical compound listed on the first page. This product can be used for quantification and/or identification. All solutions should be thoroughly mixed prior to use. If dilution is required, use only diluent compatible with the substance and solvent in this preparation.

Expiration/Retest Date:

Expiration/retest date of the unopened ampoule stored at the recommended storage conditions is the last day of the month.

A retest will be performed 6 months prior to the stated retest date. Upon successful retesting, a new retest date or expiration date is set for the product. The certificate of analysis is then updated and made available on our website. For our products, the extension of the shelf life is capped to 10 years after release as the maximum period.

Gravimetric Preparation:

All balances are calibrated annually by an ISO/IEC 17025 accredited calibration service. Calibration verification is performed weekly with certified and traceable weights. For each balance, a minimum weighing value has been assigned.

Purity:

- Purity and/or chemical identity are determined by one or more of the following techniques: HPLC/UV, GC/FID, LC/MS, IR, UV, 1H NMR, Karl Fischer, melting point, and optical rotation if applicable
- Purity of isomeric compounds is reported as the sum of the isomers
- Purity values are rounded to the last decimal place given
- The salt form, purity, residual water, and residual solvents are already taken into account for the given content value.

Uncertainty Statistics:

The uncertainties are determined in accordance with ISO 17034 and ISO/IEC 17025. Uncertainty is given for a minimum injection volume of 1 µl. The certified uncertainty value (including characterization uncertainty, homogeneity between ampoules uncertainty, storage stability uncertainty and shipping stability uncertainty) is combined using the following formula:

$$U(y) = \sqrt{U^2_{characterization} + U^2_{homogeneity} + U^2_{storage\ stability} + U^2_{shipping\ stability}}$$

For expanded uncertainty with confidence interval of 95% multiply combined uncertainty, here above, by coverage factor k=2. The filling volume is the minimum sample size for which the uncertainty is valid. The ampoules are over-filled to ensure that the minimum filling volume can be sufficiently transferred.

Homogeneity:

Homogeneity of the lot is confirmed by a duplicate analysis of at least 12 ampoules. At least 4 ampoules are taken at start, middle and end of the filling process. The number of ampoules to be analyzed depends on the lot size. The analyzed concentration at each position is the average value obtained from duplicate analysis of 4 ampoules.

Stability:

The manufacturer guarantees the stability of this product throughout its intended shelf life, when handled and stored accordingly to the given storage conditions.

Legal and Safety Notice:

This product is for routine laboratory analysis and research purposes only. Due to the hazardous nature, only trained personnel should handle this product. The General Terms and Conditions of Lipomed apply.

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CERTIFIED REFERENCE MATERIAL

ilac-MRA
A2LA ACCREDITED
ISO 17034 Accredited
Reference Material Producer
Certificate #3222.01

ilac-MRA
A2LA ACCREDITED
ISO/IEC 17025 Accredited
Testing Laboratory
Certificate #3222.02

Certificate of Analysis

chromatographic plus

FOR LABORATORY USE ONLY-READ SDS PRIOR TO USE.

This Reference Material is intended for Laboratory Use Only as a standard for the qualitative and/or quantitative determination of the analyte(s) listed.

Catalog No. : 34029 **Lot No.:** A0191870

Description : Aprobarbital Standard

Aprobarbital 1000µg/mL, P&T Methanol, 1mL/ampul

Container Size : 2 mL **Pkg Amt:** > 1 mL

Expiration Date : November 30, 2024 **Storage:** 10°C or colder

Ship: Ambient

CERTIFIED VALUES

Elution Order	Compound	CAS #	Lot #	Purity	Grav. Conc. (weight/volume)	Expanded Uncertainty * (95% C.L.; K=2)
1	Aprobarbital	77-02-1	59C0208	99%	1,004.0 µg/mL	+/- 14.0215

* Expanded Uncertainty displayed in same units as Grav. Conc.

Solvent: P&T Methanol
CAS # 67-56-1
Purity 99%

Quality Confirmation Test

Column:
30m x 0.25mm x 0.25µm
Rtx-5 (cat.#10223)

Carrier Gas:
hydrogen-constant pressure 10 psi.

Temp. Program:
75°C (hold 1 min.) to 330°C
@ 20°C/min. (hold 10 min.)

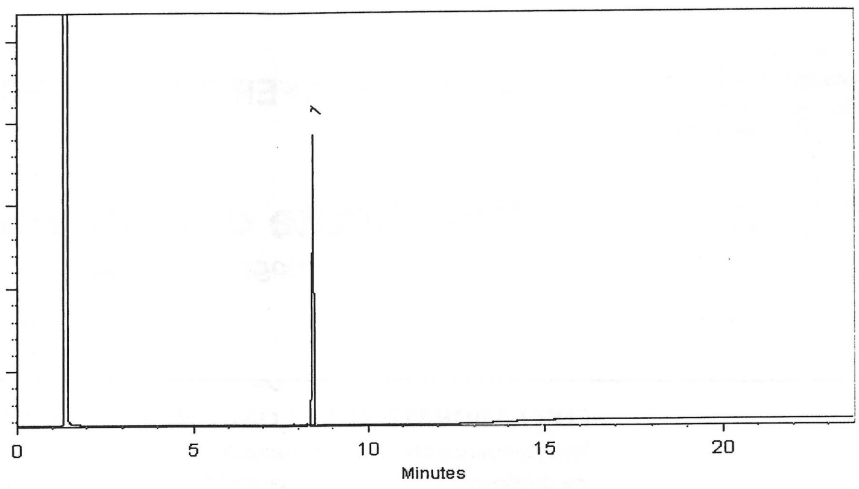
Inj. Temp:
250°C

Det. Temp:
330°C

Det. Type:
FID

Split Vent:
10 ml/min.

Inj. Vol
1µl



This chromatogram represents a general set of testing conditions chosen for product acceptance. For optimal results in your lab, conditions should be adjusted for your specific instrument, method, and application.

Sam Moodler - Operations Tech I

Date Mixed: 21-Nov-2022 **Balance Serial #** 1127510105

Marlina Cowan -- Operations Tech II ARM QC

Date Passed: 28-Nov-2022

Manufactured under Restek's ISO 9001:2015 Registered Quality System Certificate #FM 80397

General Certified Reference Material Notes

Expiration Notes:

- Expiration date valid for unopened ampul stored in compliance with the recommended conditions.
- Uncertainty, concentration, and expiration of the CRM are based on the unopened product being stored according to the recommended condition found in the storage field.

Purity Notes:

- Purity and/or chemical identity are determined by one or more of the following techniques: GC/FID, HPLC, GC/μECD, GC/MS, LC/MS, RI, and/or melting point.
- Compounds with a listed purity of less than 99% have been weight corrected to compensate for impurities and/or salts. A correction factor is used to calculate the amount of compound necessary to achieve the desired concentration of the parent compound in solution.
- Purity of isomeric compounds is reported as the sum of the isomers.
- Purity values are rounded to the nearest whole number.

Certified Uncertainty Value Notes:

- The uncertainties are determined in accordance with ISO 17034 and Guide 35. The certified expanded uncertainty value includes gravimetric uncertainty, homogeneity between-ampul uncertainty, storage stability uncertainty and shipping stability uncertainty and were combined using the following formula:

$$U_{combined\ uncertainty} = k\sqrt{u^2_{gravimetric} + u^2_{homogeneity} + u^2_{storage\ stability} + u^2_{shipping\ stability}}$$

  k is a coverage factor of 2, which gives a level of confidence of approximately 95%.

- The packaged amount is the minimum sample size for which uncertainty is valid. The ampuls are over-filled to ensure that the minimum packaged amount can be sufficiently transferred.

Manufacturing Notes:

- Concentration is based upon gravimetric preparation using either a balance whose calibration has been verified daily using NIST traceable weights, and/or dilutions with Class A glassware.

Handling Notes:

- Stability of the unopened product, when stored in compliance with the recommended conditions, is guaranteed through the expiration displayed on the product label and certificate. Contact Restek for additional opened product stability information, with the knowledge/understanding that open product stability is subject to the specific handling and environmental conditions to which the product is exposed. For your convenience Restek supplies deactivated vials with most standards packed in 2mL ampuls. Larger volume deactivated vials are available through Restek as a custom ordered item. Additionally, Restek sells DMDCS for the purpose of glassware deactivation as catalog number 31861, which includes complete instructions.
- If any undissolved material is visible inside the ampul, sonicate the unopened ampul until the material is completely dissolved.