linneo health

Dronabinol DAC Therismos Kit 500mg

Dronabinol Kit
THC Pure Extract (95%) in 1.00 mL ITC syringe – 500mg

Document type:	Certificate Of Analysis (CoA)
Scope:	Quality Control (QC)
CoA Number:	*18-24-0039-02*
Batch number:	**F.6010402.001/M.01**
Packaging date:	19/02/2024
Retest date:	**12/2024**
Specification reference:	**ES-EXTK-001_01**

Producto / Product	Especificación / Specification	Resultado/ Result
Jeringa tipo I (acondicionamiento primario) Type I syringes (primary packaging)	Jeringas de vidrio de borosilicato tipo I (1 mL o 2,25 mL) con tapa de punta integrada y un émbolo con tapón. Borosilicate glass type I syringes (1 mL or 2.25 mL) with integrated tip cap and a plunger rod with a stopper.	Cumple Complies
Caja de cartón blanco (acondicionamiento secundario) White cartón case (secondary packaging)	Cartón reciclado de doble capa, blanco. 28,5 x 75,5 x 30 mm (A x L x A) Double-layer recycled cardboard, white 28.5 x 75.5 x 30 mm (W x L x H)	Cumple Complies
Tube Eppendorf Eppendorf tube	1.5 mL	Cumple Complies
Aguja hipodérmica Hypodermic needle	09 x 40 mm (20G)	Cumple Complies
Test identificación THC Test ID THC	Prueba simple de screen de drogas (orina) Drug Screen single test (urline)	Cumple Complies
Caja kit Kit box	Caja de cartón. 78 x 129 x 41 mm (A x L x A) Cardboard box 78 x 129 x 41 mm (W x L x H)	Cumple Complies

CoAs: Ga00117/ F.V. 6010402.001/M.01

Function	Name/Position	Conclusion	Signature/Date
Prepared by:	Raquel Hernández Quality Control Validation Technician		06/03/24
Reviewed by:	Soledad Pérez Quality Assurance Technician	Complies	06/03/2024
Approved by:	Maria de Gracia González Quality Assurance Manager	Complies	06/03/2024

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THC Pure Extract (95%) in 1.00 mL ITC syringe – 500mg

Document type:	Certificate Of Analysis (CoA)
Scope:	Quality Control (QC)
CoA Number:	*18-24-0037-02*
Batch number:	**F.6010402.001/M**
Cas nº:	**1972-08-3**
Manufacturing date:	12/2023
Packaging date:	01/2024
Retest date:	**12/2024**
Specification reference:	ES-EXT-004_01

Ensayo / Test	Método / Method	Especificación / Specification	Resultado/ Result
Apariencia Appearance	DAC 2012/2 D 100 Inspección visual DAC 2012/2 D 100 Visual inspection	Líquido de color casi incoloro a amarillo claro, ocasionalmente aceitoso de color púrpura pálido o masa resinosa en la superficie. Almost colourless to light yellow in colour, occasionally pale purple oily liquid or resinous mass on the surface	Conforme Complies
Identificación THC: IR Identificación THC: HPLC Identification THC: IR Identification THC: HPLC	DAC 2012/2 D 100 Farmacopea Europea 2.2.24 Farmacopea Europea 2.2.29 DAC 2012/2 D 100 European Pharmacopoeia 2.2.24 European Pharmacopoeia 2.2.29	Positivo Positive	Conforme Complies Conforme Complies
Solubilidad Solubility	DAC 2012/2 D 100 Inspección visual DAC 2012/2 D 100 Visual inspection	Prácticamente insoluble en agua; Parcialmente soluble en Etanol 96%, Parcialmente soluble en Glicerol 85%; Soluble en aceites. Practically insoluble in wáter; slightly soluble in Ethanol 96% and Glycerol 85%; Fatty oils soluble	Conforme Complies
Pureza cromatográfica Cromatography Purity	DAC 2012/2 D 100 Farmacopea Europea 2.2.29 DAC 2012/2 D 100 European Pharmacopoeia 2.2.29	El dronabinol contiene un mínimo de 95,0 y un máximo de 100,0 por ciento (6aR, 10aR)-6a,7,8,10a-tetrahidro-6,6,9-trimetil-3-pentil-6H-dibenzo[b,d]pirano- 1-ol (Δ9-tetrahidrocannabinol) Dronabinol contains a minimum of 95.0 and a maximum of 100.0 percent (6aR, 10aR)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol (Δ9-Tetrahydrocannabinol)	98.4%
Sustancias Relacionadas Relative Substances	DAC 2012/2 D 100 Farmacopea Europea 2.2.29 DAC 2012/2 D 100 European Pharmacopoeia 2.2.29	Impureza D área corregida (CBN) < 1,0% Impurity D corrected área (CBN) < 1.0%	Imp. D: 0.26 %
		Impureza E (Δ^8-THC) < 2,0% Impurity E (Δ^8-THC) < 2.0%	Imp. E: 0.41 %
		Otras impurezas < 1,0% Other impurities < 1.0%	RRT-0.39: 0.07% RRT-0.41: 0.17%

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			RRT-0.53: 0.05% RRT-0.60: 0.23% RRT-0.77: 0.20% RRT-0.85: 0.06% RRT-1.36: 0.13%
		Impurezas totales excepto impureza E < 3,0% Total Impurities except impurity E < 3.0%	1.2%
Disolventes Residuales Residual Solvents	Farmacopea Europea 2.9.10 Farmacopea Europea 2.9.11 European Pharmacopoeia 2.9.10 European Pharmacopoeia 2.9.11	2- Propanol ≤ 500 ppm (0,05%) 2- Propanol ≤ 500 ppm (0.05%)	No detectado Not detected
		Heptano ≤ 5000 ppm (0,5%) Heptane ≤ 5000 ppm (0.5%)	No detectado Not detected
		Etanol ≤ 5000 ppm (0,5%) Ethanol ≤ 5000 ppm (005%)	<10 ppm (LOQ)
		Metanol ≤ 3000 ppm (0,3%) Metanol ≤ 3000 ppm (0.3%)	<10 ppm (LOQ)
TAMC (Aerobios totales) TAMC (Total Aerobic Microbial Count)	Farmacopea Europea, 5.1.8 y 5.1.4 European Pharmacopoeia 5.1.8 and 5.1.4	≤ 10^4 UFC/g ≤ 10^4 UFC/g	<10^2 UFC/g
TYMC (Hongos y levaduras) TYMC (Total Combined Yeast and Moulds Count)		≤ 10^2 UFC/g ≤ 10^2 UFC/g	<10^2 UFC/g
Enterobacterias Bile-tolerant Gram (-) bacteria		≤ 10^2 UFC/g ≤ 10^2 UFC/g	<10 UFC/g
Escherichia coli		Ausencia/g Absence/g	Absence/g
Staphyloccoccus aureus		Ausencia/g Absence/g	Absence/g
Pseudomonas aeruginosa		Ausencia/g Absence/g	Absence/g
Salmonella spp.		Ausencia/25g Absence/25g	Absence/25g
Parámetros de acondicionado Packaging parameters: Estanqueidad Pressure decay	USP 1207.2	t = 1h, P = 200 mbar	Conforme Complies

CoAs: Ga00117/ F.V. 6010402.001/M

Function	Name/Position	Conclusion	Signature/Date
Prepared by:	Raquel Hernández Quality Control Validation Technician		06/03/24
Reviewed by:	Soledad Pérez Quality Assurance Technician	Complies	06/03/2024
Approved by:	Maria de Gracia González Quality Assurance Manager	Complies	06/03/2024

Scope: Quality Assurance (QA)

CoC Number: *E24-001*

CERTIFICADO DE CONFORMIDAD
CERTIFICATE OF COMPLIANCE

PRODUCTO/PRODUCT	LOTE/BATCH	UND / UND
DRONABINOL KIT – 1.00 mL ITC syringe -500 mg	F.6010402.001/M.01	1000

FABRICANTE/MANUFACTURER	ENVASADO POR/ PACKAGED BY	LABORATORIO CONTROL CALIDAD/ QUALITY CONTROL LABORATORY
ALCALIBER S.A.	ALLOGA	ALCALIBER S.A.

CLIENTE/CUSTOMER	LOGO	PAÍS/COUNTRY
Therismos GMBH	---	Germany

Fecha De Fabricación/Manufacturing Date:
Ver certificado de análisis adjunto/See attached certificate of analysis

TO WHOM IT MAY CONCERN

On behalf of Linneo Health S.L., declare:

1. This batch of product has been manufactured, including packaging/labelling quality control analysis in full compliance with the GMP ~~Part I~~ / Part II (cross the one which does not apply) requirements of the local Regulatory Authority and with the specification of the importing country or product specification.

2. The batch processing and analysis records were reviewed and found to be in compliance with GMP.

3. All deviations and OOS have been evaluated and approved based on fixed internal procedures
   a. No release relevant deviation or OOS.
   b. Additional quality relevant information for the mentioned batch is enclosed

I hereby certify that the above information is authentic and accurate.

Aprobado por
Approved by:

Firma / Signature:

Fecha aprobación/Approval date 23rd of February 2024

María de Gracia González
QA Manager & QP