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Document type:	Certificate Of Analysis (CoA)
Scope:	Quality Control (QC)
CoA Number:	***15-25-0179-01***

Certificado de Análisis de Cannabis Flor var. IBT03.4 HK 20/1

Certificate Of Analysis of Cannabis Flower str. IBT03.4 HK 20/1

Batch number:	**N191A1X.01R**
Condition:	**e-beam Irradiated 5 KGY**
Manufacturing date:	**23/06/2025**
Expiry date:	**23/06/2026**
Specification reference:	**ES-IBT03-006_7.0**

Ensayo / Test	**Método / Method**	**Especificación / Specification**	**Resultado / Result**
Apariencia Appearance	Inspección visual: Ph. Eur. monografía flor de cannabis 3028, ed. vigente Visual inspection: Ph. Eur. Cannabis Flower monograph 3028, current ed.	De verde oscuro a amarillo pálido o de marrón claro a marrón rojizo From dark green to pale yellow or from light brown to reddish-brown	Cumple Complies
Identificación Identity	Macroscópica: Ph. Eur. monografía flor de cannabis 3028, ed. vigente Macroscopic: Ph. Eur. Cannabis Flower monograph 3028, current ed. Microscópica: Ph. Eur. monografía flor de cannabis 3028, ed. vigente Microscopic: Ph. Eur. Cannabis Flower monograph 3028, current ed. HPTLC: Ph. Eur. 2.8.25 / Ph. Eur. monografía flor de cannabis 3028, ed. vigente o HPLC, Ph. Eur. 2.2.29 HPTLC: Ph. Eur. 2.8.25 / Ph. Eur. Cannabis Flower monograph 3028, current ed. or HPLC, Ph. Eur. 2.2.29	Cumple Complies Cumple Complies Contiene THC Contains THC	Cumple Complies Cumple Complies Contiene THC Contains THC
Partículas extrañas Foreign matters	Ph. Eur. 2.8.2 / Ph. Eur. monografía flor de cannabis 3028, ed. vigente Ph. Eur. 2.8.2 / Ph. Eur. Cannabis Flower monograph 3028, current ed.	≤ 2% No contiene semillas ni hojas de más de 1,0 cm de longitud ≤ 2% It does not contain any seeds and the whole herbal drug does not contain any leaves more than 1.0 cm in length	0 % Cumple Complies
Pérdida por secado Loss on drying	Ph. Eur. 2.2.32 / Ph. Eur. monografía flor de cannabis 3028, ed. vigente Ph. Eur. 2.2.32 / Ph. Eur. Cannabis Flower monograph 3028, current ed.	≤ 12,0 % m/m ≤ 12.0 % w/w	5.8 %
Contenido Total CBN (%) Total Content CBN (%)	HPLC, Ph. Eur. 2.2.29 / Ph. Eur. monografía flor de cannabis ed. vigente 07/2024:3028 HPLC, Ph. Eur. 2.2.29 / Ph. Eur. Cannabis Flower monograph current ed.	≤ 1,0 % ≤ 1.0 %	< 0.2 %
Contenido Total THC (%) Total Content THC (%)		20,0 % (18,0 – 22,0) % 20.0 % (18.0-22.0) %	20.0 %
Contenido Total CBD (%) Total Content CBD (%)		≤ 1,0 % ≤ 1.0 %	< 0.2 %
Plomo Lead	Ph. Eur. 2.4.27 / Ph. Eur. monografía flor de cannabis 3028, ed. vigente Ph. Eur. 2.4.27 / Ph. Eur. Cannabis Flower monograph 3028, current ed.	≤ 0,5 ppm ≤ 0.5 ppm	< 0.5 ppm
Mercurio Mercury		≤ 0,1 ppm ≤ 0.1 ppm	< 0.1 ppm
Cadmio Cadmium		≤ 0,3 ppm ≤ 0.3 ppm	< 0.3 ppm
Arsénico Arsenic		≤ 0,2 ppm ≤ 0.2 ppm	< 0.2 ppm
Aflatoxinas (B1, B2, G1, G2) Aflatoxins (B1, B2, G1, G2)	Ph. Eur. 2.8.18/In house*	≤ 4,0 ppb ≤ 4.0 ppb	< 4.0 ppb
Aflatoxina B1 Aflatoxin B1		≤ 2,0 ppb ≤ 2.0 ppb	< 1.0 ppb
Ocratoxina Ochratoxin	In house*	≤ 20,0 ppb ≤ 20.0 ppb	< 10.0 ppb
Pesticidas Pesticides	Ph. Eur. 2.8.13/In house*	Cumple Complies	Cumple Complies
TAMC (Aerobios totales) TAMC (Total Aerobic Microbial Count)	Farmacopea Europea 2.6.12, 2.6.13, 2.6.31, 5.1.8 Tabla B	≤ 5,0 x 10^4 (≤ 50.000) UFC/g ≤ 5.0 x 10^4 (≤ 50,000) CFU/g	< 10^2 UFC/g

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TYMC (Hongos y levaduras) TYMC (Total Combined Yeast and Moulds Count)	European Pharmacopoeia 2.6.12, 2.6.13, 2.6.31, 5.1.8 Table B	≤ 5,0 x 10^2 (≤ 500) UFC/g ≤ 5.0 x 10^2 (≤ 500) CFU/g	< 10 UFC/g
Enterobacterias Bile-tolerant Gram (-) bacteria		≤ 1,0 x 10^2 (≤ 100) UFC/g ≤ 1.0 x 10^2 (≤ 100) CFU/g	< 10 UFC/g
Pseudomonas aeruginosa		Ausencia/g Absence/g	Ausencia/g Absence/g
Staphyloccoccus aureus		Ausencia/g Absence/g	Ausencia/g Absence/g
Escherichia coli		Ausencia/g Absence/g	Ausencia/g Absence/g
Salmonella spp.		Ausencia/25g Absence/25g	Ausencia/25g Absence/25g

* Method validated according to ICH Q2 (current version)

BoA´s: 25-FQ-0227-v01; 25-HUM-0238-v01; 25-MI-0615-v02; 25-ID-0348-v01; Anexo II IVA18/19; HA-67/01-002

Function	Name/Position	Conclusion	Signature/Date
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Approved by:	María Ángeles Muñoz Director of Quality and Regulatory Affairs	Complies	linneo health Firmado digitalmente por 73195438P MARÍA ÁNGELES MUÑOZ Fecha: 2025.08.18 11:04:46 +02'00'