

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.	Cumple Complies	Cumple Complies
	Microscópica: Ph. Eur. monografía flor de cannabis 3028, ed. vigente Microscopic: Ph. Eur. Cannabis Flower monograph 3028, current ed.	Cumple Complies	Cumple Complies
	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	Contiene THC Contains THC	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 <sup>4</sup> (≤ 50.000) UFC/g ≤ 5.0 x 10 <sup>4</sup> (≤ 50,000) CFU/g	< 10 <sup>3</sup> UFC/g

*Certificado de Análisis de Cannabis Flor var. IBT03.4  
HK 20/1*  
**Certificate Of Analysis of Cannabis Flower str. IBT03.4  
HK 20/1**

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

Microorganism	Reference	Limit	Result
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	$\leq 5,0 \times 10^2 (\leq 500)$ UFC/g $\leq 5.0 \times 10^2 (\leq 500)$ CFU/g	< 10 UFC/g
Enterobacterias Bile-tolerant Gram (-) bacteria		$\leq 1,0 \times 10^2 (\leq 100)$ UFC/g $\leq 1.0 \times 10^2 (\leq 100)$ CFU/g	< 10 UFC/g
Pseudomonas aeruginosa		Ausencia/g Absence/g	Ausencia/g Absence/g
Staphylococcus 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
Prepared by:	Quality Control Technician		
QC Reviewed by:	Quality Control Manager	COMPLIES	
QA Reviewed by:	Quality Assurance Technician	Complies	18/08/25
Approved by:	of Quality and Regulatory Affairs	Complies	