

Product: Full Spectrum Extract THC 20 mg/mL Oral Solution, 30 mL

Commercial name: Adven 20/0 Lösung, 30 ml (PZN: 16751553)

Analysis No.: PFC-0340/24

Certificate Version: 00

Manufacture Date: April 2024

Analysis Date: April 2024

Lot No.: ET2/03/24-30

Expiry date: April 2026
(stability studies in progress)

Storage: Protected from light, below 25 °C

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Certificate of Analysis

Parameter	Method	Specification	Result
Appearance (visual)	DAB Cannabis extract	Greenish or yellow to brown liquid	Complies
Identification A (HPLC)	PA/ECDP/03 (in house)	Retention time of THC peak complies with the reference standard	Complies
Identification B (HPLC)	PA/ECDP/03 (in house)	UV Spectrum of THC peak complies with the reference standard	Complies
Identification C (TLC)	DAB Cannabis extract <i>Ph. Eur. 2.2.27</i>	Complies with the reference standard	Complies
Relative density	<i>Ph. Eur. 2.2.5</i>	Informative	0.948
Assay (HPLC, on as-is basis)	PA/ECDP/03 ⁽¹⁾ (in house)	THC 90–110 % of the labelled content (18 – 22 mg/mL)	101 % 20.3 mg/mL
Cannabinoid profile (HPLC)		Informative THC, THCA, CBD and CBDA in %w/w	THC: 2.14 % THCA: <0.05 % CBD: <0.05 % CBDA: <0.05 %
Related substances (HPLC)		CBD ≤ 0.1 % w/v CBN ≤ 0.1 % w/v	<0.05 % <0.05 %
Water content (KF titration)	DAB Cannabis extract <i>Ph. Eur. 2.5.12</i>	≤ 0.5 %	0.05 %
Residual solvents ⁽²⁾ (HS-GC)	PA/ECDP/07 (in house)	Ethanol < 0.5 % (<i>Ph. Eur. 5.4</i>)	< 0.5 %
Microbial limits (<i>Ph. Eur. 5.1.8,</i> <i>Table B</i>)	<i>Ph. Eur. 2.6.12</i>	Total Aerobic Microbial Count TAMC ≤ 10 ⁴ CFU/mL	<10 CFU/mL
		Total Yeast and Mould Count TYMC ≤ 10 ² CFU/mL	<10 CFU/mL
	<i>Ph. Eur. 2.6.31</i>	Bile-tolerant gram-negative bacteria ≤ 10 ² CFU/mL	<10 CFU/mL
		<i>Escherichia coli</i> absent in 1 mL	Absent in 1 mL
		<i>Salmonella</i> absent in 25 mL	Absent in 25 mL

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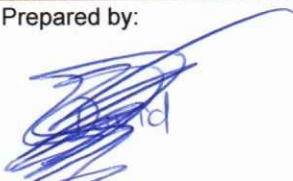
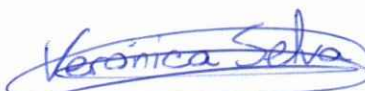
Parameter	Method	Specification	Result
Aflatoxins ⁽³⁾ (HPLC)	PA/ECDP/09 (in house) <i>Ph. Eur. 2.8.18</i>	Aflatoxin B ₁ ≤ 2 µg/kg	< 2 µg/kg
		Sum of Aflatoxin B ₁ , B ₂ , G ₁ and G ₂ ≤ 4 µg/kg	< 4 µg/kg
Ochratoxin A ⁽³⁾ (HPLC)	PA/ECDP/09 (in house) <i>Ph. Eur. 2.8.22</i>	Ochratoxin A ≤ 20 µg/kg	< 20 µg/kg
Heavy metals ⁽³⁾ (ICP-MS)	<i>Ph. Eur. 2.4.27</i>	Cd ≤ 1.0 ppm	< 1.0 ppm
		Pb ≤ 5.0 ppm	< 5.0 ppm
		Hg ≤ 0.1 ppm	< 0.1 ppm
		As ≤ 3.0 ppm	< 3.0 ppm
Absence of pesticides ⁽³⁾	<i>Ph. Eur. 2.8.13</i>	Complies	Complies
Filling volume	PA/ECDP/05 (in house)	≥ 100% of labelled content	Complies

¹ Validated method with the same system suitability parameters than the DAB 2020 monograph "Cannabis extractum normatum".

² Analytical testing performed on every batch of API and absence in final product confirmed by process validation.

³ Analytical testing performed on every batch of flower and absence in final product confirmed by process validation.

The medicinal product has been manufactured, tested, and released in Spain. Country of origin of the flowers is Portugal. The product complies with DAB monograph "Cannabis extract".

Prepared by: 	Revised by:  06-05-2024	Released by:
David Lledó 29/04/2024	Verónica Selva	
Quality Control	Quality Assurance	Qualified person