

**Product:** Full Spectrum Extract THC:CBD 10:10 (10 mg/mL | 10 mg/mL) Oral Solution, 10 mL

**Commercial name:** Adven 10/10 Lösung, 10 ml (PZN: 17877256)

**Analysis No.:** PFC-0246/24

**Certificate Version:** 00

**Manufacture Date:** March 2024

**Analysis Date:** March 2024

**Lot No.:** B11/02/24-10

**Expiry date:** March 2025

**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 and CBD peaks comply with those of reference standard | Complies   |
| Identification B (HPLC)                                | PA/ECDP/03 (in house)                          | UV spectrum of THC and CBD peaks comply with those of reference standard    | Complies   |
| Identification C (TLC)                                 | DAB Cannabis extract<br><i>Ph. Eur. 2.2.27</i> | Complies with the reference standard  | Complies   |
| Relative density                                       | <i>Ph. Eur. 2.2.5</i>                          | Informative   | 0.946  |
| Assay (HPLC, on as-is basis)                           | PA/ECDP/03 <sup>(1)</sup> (in house)           | THC 90–110 % of the labelled content (9 – 11 mg/mL)                         | 100 %<br>10 mg/mL  |
|  |  | CBD 90–110 % of the labelled content (9 – 11 mg/mL)                         | 100 %<br>10 mg/mL  |
| Cannabinoid profile (HPLC)                             |  | Informative<br>THC, THCA,<br>CBD and CBDA in %w/w                           | THC: 1.05 %<br>THCA: < 0.05 %<br>CBD: 1.06 %<br>CBDA: < 0.05 % |
| Related substances (HPLC)                              |  | CBN ≤ 0.2 % w/v   | < 0.05 %   |
| Water content (KF titration)                           | DAB Cannabis extract<br><i>Ph. Eur. 2.5.12</i> | ≤ 0.5 %   | 0.02 %   |
| Residual solvents <sup>(2)</sup> (HS-GC)               | PA/ECDP/07 (in house)                          | Ethanol < 0.5 %<br>( <i>Ph. Eur. 5.4</i> )                                  | < 0.5 %  |
| Microbial limits<br>( <i>Ph. Eur. 5.1.8, Table B</i> ) | <i>Ph. Eur. 2.6.12</i>                         | Total Aerobic Microbial Count<br>TAMC ≤ 10 <sup>4</sup> CFU/mL              | < 10 CFU/mL  |
|  |  | Total Yeast and Mould Count<br>TYMC ≤ 10 <sup>2</sup> CFU/mL                | 20 CFU/mL  |
|  | <i>Ph. Eur. 2.6.31</i>                         | Bile-tolerant gram-negative bacteria<br>≤ 10 <sup>2</sup> 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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(stability studies in progress)

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### Certificate of Analysis

| Parameter                               | Method                                      | Specification   | Result     |
|---|---|---|------------|
| Aflatoxins <sup>(3)</sup><br>(HPLC)     | PA/ECDP/09<br>(in house)<br>Ph. Eur. 2.8.18 | Aflatoxin B <sub>1</sub> ≤ 2 µg/kg  | < 2 µg/kg  |
|   |   | Sum of Aflatoxin B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> and G <sub>2</sub><br>≤ 4 µg/kg | < 4 µg/kg  |
| Ochratoxin A <sup>(3)</sup><br>(HPLC)   | PA/ECDP/09<br>(in house)<br>Ph. Eur. 2.8.22 | Ochratoxin A ≤ 20 µg/kg   | < 20 µg/kg |
| Heavy metals <sup>(3)</sup><br>(ICP-MS) | Ph. Eur. 2.4.27                             | 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 <sup>(3)</sup>    | Ph. Eur. 2.8.13                             | Complies  | Complies   |
| Filling volume                          | PA/ECDP/05<br>(in house)                    | ≥ 100% of labelled content  | Complies   |

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

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

<sup>3</sup> 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:<br><br>Paula Infantes<br>26/04/2024 | Revised by:<br><br>Ana Amorós<br>06/05/2024 | Released by:     |
| Paula Infantes<br>Quality Control                | Ana Amorós<br>Quality Assurance             | Qualified person |