



## CERTIFICATE OF RELEASE

|                             |              |
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| Certificate number_version: | 2025_006_V00 |
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|                                  |                                                                                                                                                                                                                                                                                                                            |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name                     | CANNABISBLÜTEN Bathera 23/1                                                                                                                                                                                                                                                                                                |
| Strength/Potency                 | 23 THC / ≤ 1 CBD                                                                                                                                                                                                                                                                                                           |
| Dosage Form                      | Herbal drug                                                                                                                                                                                                                                                                                                                |
| Batch Number                     | PRM2404P1YC                                                                                                                                                                                                                                                                                                                |
| Manufacturing date               | 21/02/2025                                                                                                                                                                                                                                                                                                                 |
| Expiry Date                      | 21/08/2025                                                                                                                                                                                                                                                                                                                 |
| API Manufacturer                 | Batherafarm Unipessoal, Lda<br>Rua 5 de Outubro, Casais 85 e 86,<br>Nucho de Pegões Velhos                                                                                                                                                                                                                                 |
| Finished Product Manufacturer    | 2985-155 Santo Isidro de Pegões, Portugal                                                                                                                                                                                                                                                                                  |
| Finished Product Quality Control | INFOSAÚDE, Instituto de Formação e Inovação em Saúde,<br>S.A. (LEF)<br>Rua das Ferrarias del Rei, nº6, Urbanização da Fábrica da<br>Pólvora<br>2730-269 Barcarena, Portugal<br><br>Batherafarm Unipessoal, Lda<br>Rua 5 de Outubro, Casais 85 e 86,<br>Nucho de Pegões Velhos<br>2985-155 Santo Isidro de Pegões, Portugal |
| Country of marketplace           | Germany                                                                                                                                                                                                                                                                                                                    |
| Pack Size (g) / Type             | 250 / Bag                                                                                                                                                                                                                                                                                                                  |
| Quantity (un)                    | 335                                                                                                                                                                                                                                                                                                                        |
| Certificate of Analysis number   | See remarks                                                                                                                                                                                                                                                                                                                |
| Specification                    | ES_QA_Finish product 001_DE_rev1                                                                                                                                                                                                                                                                                           |

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| Parameter             |                                           | Monograph/ Guideline Reference                                                                      | Method                                         | Specification                                                     | Results                         |
|-----------------------|-------------------------------------------|-----------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------|---------------------------------|
| Identification        | Method A<br>Macroscopy examination        | - Ph. Eur. Monograph (3028) <i>Cannabis flos</i>                                                    | Ph. Eur. Monograph (3028) <i>Cannabis flos</i> | Complies with requirements of monograph                           | Complies <sup>b)</sup>          |
|                       | Method B<br>Microscopy examination        |                                                                                                     |                                                |                                                                   | Complies <sup>b)</sup>          |
|                       | Method C<br>HPTLC                         |                                                                                                     |                                                |                                                                   | Complies <sup>b)</sup>          |
| Foreign Matter        |                                           | - Ph. Eur. Monograph (3028) <i>Cannabis flos</i>                                                    | Ph. Eur. 2.8.2                                 | Maximum 2%                                                        | 0.0 % <sup>b)</sup>             |
| Loss on Drying        |                                           | - Ph. Eur. Monograph (3028) <i>Cannabis flos</i>                                                    | Ph. Eur. 2.2.32                                | Maximum 12.0%                                                     | 9.6 % <sup>b)</sup>             |
| Total CBN             |                                           | - Ph. Eur. Monograph (3028) <i>Cannabis flos</i>                                                    | Ph. Eur. 2.2.29                                | Maximum 1.0%                                                      | 0.31 % <sup>b)</sup>            |
| Assay                 | THC + THCA                                | - Ph. Eur. Monograph (3028) <i>Cannabis flos</i>                                                    | Ph. Eur. 2.2.29                                | 20.7% - 25.3%                                                     | 22.9 % <sup>b)</sup>            |
|                       | CBD + CDBA                                | - Ph. Eur. Monograph (3028) <i>Cannabis flos</i>                                                    | Ph. Eur. 2.2.29                                | ≤ 1%                                                              | 0.11 % <sup>b)</sup>            |
| Total Ash             |                                           | - Ph. Eur. Monograph (1433) Herbal drugs                                                            | Ph. Eur. 2.4.16                                | Maximum 20.0%                                                     | 10.6 % <sup>b)</sup>            |
| Aflatoxins            | B1                                        | - Ph. Eur. Monograph (1433) Herbal drugs                                                            | Ph. Eur. 2.8.18                                | Not more than 2 µg/kg                                             | <0.25 µg/kg (LOD) <sup>b)</sup> |
| Aflatoxins            | Total B1, B2, G1, G2                      | - Ph. Eur. Monograph (1433) Herbal drugs                                                            | Ph. Eur. 2.8.18                                | Not more than 4 µg/kg for the sum of aflatoxins B1, B2, G1 and G2 | <0.25 µg/kg (LOD) <sup>b)</sup> |
| Ochratoxin A          |                                           | - Ph. Eur. Monograph (1433) Herbal drugs                                                            | Ph. Eur. 2.8.22                                | Not more than 20 µg/kg                                            | <2 µg/kg (LOD) <sup>b)</sup>    |
| Pesticides            |                                           | - Ph. Eur. Monograph (1433) Herbal drugs                                                            | Ph. Eur. 2.8.13                                | Not more than the limits specified in Ph. Eur. 2.8.13             | Complies <sup>a)</sup>          |
| Heavy Metals          | Cadmium (Cd)                              | - Ph. Eur. Monograph (3028) <i>Cannabis flos</i>                                                    | Ph. Eur. 2.4.27                                | Maximum 0.3 ppm                                                   | <0.005 ppm (LOQ) <sup>a)</sup>  |
|                       | Lead (Pb)                                 | - Ph. Eur. Monograph (3028) <i>Cannabis flos</i>                                                    | Ph. Eur. 2.4.27                                | Maximum 0.5 ppm                                                   | <0.020 ppm (LOQ) <sup>a)</sup>  |
|                       | Mercury (Hg)                              | - Ph. Eur. Monograph (3028) <i>Cannabis flos</i>                                                    | Ph. Eur. 2.4.27                                | Maximum 0.1 ppm                                                   | <0.050 ppm (LOQ) <sup>a)</sup>  |
|                       | Arsenic (As)                              | - Ph. Eur. Monograph (3028) <i>Cannabis flos</i>                                                    | Ph. Eur. 2.4.27                                | Maximum 0.2 ppm                                                   | <0.020 ppm (LOQ) <sup>a)</sup>  |
| Microbiological Tests | Total aerobic microbial count (TAMC)      | - Ph. Eur. Monograph (5.1.8 C)<br>Microbiological quality of herbal medicinal products and extracts | Ph. Eur. 2.6.12                                | ≤ 10 <sup>5</sup> CFU/g (max.: 500 000 CFU/g)                     | <10 CFU/g <sup>b)</sup>         |
|                       | Total combined yeasts/moulds count (TYMC) |                                                                                                     |                                                | ≤ 10 <sup>4</sup> CFU/g (max.: 50 000 CFU/g)                      | <10 CFU/g <sup>b)</sup>         |
|                       | Bile-tolerant gram (-) bacteria           |                                                                                                     | Ph. Eur. 2.6.31                                | ≤ 10 <sup>4</sup> CFU/g                                           | <10 CFU/g <sup>b)</sup>         |
|                       | <i>Escherichia coli</i>                   |                                                                                                     |                                                | Absence / 1 g                                                     | Absent/g <sup>b)</sup>          |
|                       | <i>Salmonella spp</i>                     |                                                                                                     |                                                | Absence / 25 g                                                    | Absent/25g <sup>b)</sup>        |
| Average weight*       |                                           | - Internal Method                                                                                   | Internal Method                                | 250g – 252,5g                                                     | 250 g                           |

Legend: LOD – Limit of detection; LOQ – Limit of quantification

\*Obtained from packaging batch record

## CERTIFICATE OF RELEASE

**Remarks:**

a) From LEF CoA nº 25/1222, issued date 18/02/2025

b) From LEF CoA nº 25/1747, issued date 11/03/2025

NA: Not applicable

**Major or critical deviations:**

NA

NA: Not applicable

**Certification statement:**

I hereby certify that all stages of cultivation, manufacturing and quality control, of this batch of finished product have been carried out at the mentioned sites, in full compliance with the GACP and cGMP requirements of the EU and the national/regional requirements of the destination country.

**Qualified Person:**

**Name:** Vítor Hugo Ramos Dias

**Signature:**



**Date:** 12/03/2025