

CERTIFICATE OF RELEASE

Product Name:	Cannabisblüten Bathera 24/1, 250g
Dosage Form:	Bags of 250g
Strength/ Potency:	24% THC; ≤ 1% CBD
Batch Number:	2400071

Pack Size:	250g
Quantity:	234 un
Manufacturing Date:	01/07/2024
Expiry Date:	01/01/2025
Country of market place:	Germany

API Manufacturer:	Batherafarm Unipessoal Lda. Rua 5 de Outubro, Cassais 85 e 86, Nucho de Pegões Velhos, 2985-155 Santo Isidro de Pegões, Portugal
Finished-Product Manufacturer:	Canapac Lda. Rua 3B, Lote 48, Zona Industrial de Cantanhede, 3060-197 Cantanhede, Portugal
Finished-Product Quality Control:	LEF/ INFOSAÚDE - Instituto de Formação e Inovação em Saúde, S.A. Rua das Ferrarias del Rei, nº6 Urbanização da Fábrica da Pólvora 2730 Barcarena, Portugal Canapac Lda. Rua 3B, Lote 48, Zona Industrial de Cantanhede, 3060-197 Cantanhede, Portugal

Certificate of Analysis number:	030/2024	Issued date:	16/07/2024
Specification:	SPE-0000437-ver.1.0		

Tests	Method	Specification	Results
1. Identification^{a)}			
1.1. Method A:			
Macroscopy Observation	DAB Monograph Cannabis flos	Complies with requirements of monograph	Complies
1.2. Method B:			
Microscopy Observation	DAB Monograph Cannabis flos	Complies with requirements of monograph	Complies
1.3. Method C: TLC	DAB Monograph Cannabis flos	Complies with requirements of monograph	Complies
2. Foreign Matter^{a)}	DAB Monograph Cannabis flos (Ph. Eur. 2.8.2)	≤ 2.0% w/w	0.0%
3. Loss on Drying^{b)}	DAB Monograph Cannabis flos (Ph. Eur. 2.2.32)	≤ 10% w/w	10%
4. Assay^{b)}			
4.1. THC + THCA	DAB Monograph Cannabis flos (Ph. Eur. 2.2.29)	90% - 110% [21.6% - 26.4%]	94% (22.55%)
4.2. CBD + CBDA		≤ 1% w/w	0% (0.06%)

CERTIFICATE OF RELEASE

Tests	Method	Specification	Results
5. Related Substances ^{b)} Cannabinol (CBN)	DAB Monograph Cannabis flos (Ph. Eur. 2.2.29)	≤ 1.0% w/w	0.0% (0.01%)
6. Heavy Metals ^{a)}			
6.1. Cd		≤ 1.0 ppm	< LOQ (0.005ppm)
6.2. Pb		≤ 5.0 ppm	< LOQ (0.020ppm)
6.3. Hg	DAB Monograph Cannabis flos (Ph. Eur. 2.4.27)	≤ 0.1 ppm	< LOQ (0.050ppm)
6.4. As		Optional (Informative)	< LOQ (0.020ppm)
6.5. Zn		Optional (Informative)	34.178 ppm
6.6. Ni		Optional (Informative)	< LOQ (2.000 ppm)
7. Microbiology ^{a)}	Ph.Eur. 5.1.8C		
7.1. Total Aerobic Microbial Count (TAMC)	Ph.Eur. 2.6.12	≤ 10 ⁵ CFU/g (max: 500 000 CFU/g)	5.00 × 10 ¹ CFU/g
7.2. Total Yeast and Mold Count (TYMC)		≤ 10 ⁴ CFU/g (max: 50 000 CFU/g)	1.50 × 10 ² CFU/g
7.3. Bile-tolerant gram-negative bacteria		≤ 10 ⁴ CFU/g	< 10 CFU/g
7.4. Escherichia coli	Ph.Eur. 2.6.31	Absence in 1 g	Absent/g
7.5. Salmonella		Absence in 25 g	Absent/25g
8. Average weight	In-house	250g - 252.5g	250.5g
9. Aflatoxins ^{c)}			
9.1. B1	Ph. Eur. Monograph Herbal drugs (Ph. Eur. 2.8.18)	≤ 2 µg/kg	< LOD (0.25 µg/kg)
9.2. B1 + B2 + G1 + G2		≤ 4 µg/kg	< LOD (0.25 µg/kg)
10. Ochratoxin A ^{c)}	Ph. Eur. Monograph Herbal drugs (Ph. Eur. 2.8.22)	≤ 20 µg/kg	< LOD (2 µg/kg)
11. Pesticides ^{c)}	Ph. Eur. Monograph Herbal drugs (Ph. Eur. 2.8.13)	Must comply with requirements of monograph	Complies
12. Total Ash ^{d)}	DAB Monograph Cannabis flos (Ph. Eur. 2.4.16)	≤ 20% w/w	9%

Remarks:

a) From LEF Certificate of Analysis No: 24/3625, dated on 15/07/2024

b) From LEF Certificate of Analysis No: 24/3009, dated on 18/06/2024

c) From LEF Certificate of Analysis No: 24/2826, dated on 28/06/2024

Legend: LOD - Limit of Detection; LOQ - Limit of Quantitation

I hereby certify that the above information is authentic and accurate. This batch of product has been cultivated in compliance with GACP requirements and manufactured, including packaging and quality control at the above mentioned sites in full compliance with EU-GMP requirements.

 Catarina Paixão
 Qualified Person Name

 Catarina Paixão
 Qualified Person Signature

 16/07/2024
 Date