CERTIFICATE OF RELEASE

Certificate number_version:	2025_033_00

Product Name	CANNABISBLÜTEN BATHERA 35/1
Strength/Potency	35 THC / ≤ 1 CBD
Dosage Form	Herbal drug
Batch Number	PGP2501P1C
Manufacturing date	28/06/2025
Expiry Date	28/12/2025
API Manufacturer	Batherafarm Unipessoal, Lda Rua 5 de Outubro, Casais 85 e 86, Nucho de Pegões Velhos 2985-155 Santo Isidro de Pegões, Portugal
Finished Product Manufacturer	
Finished Product Quality Control	INFOSAÚDE, Instituto de Formação e Inovação em Saúde, S.A. (LEF) Rua das Ferrarias del Rei, nº6, Urbanização da Fábrica da Pólvora 2730-269 Barcarena, Portugal Batherafarm Unipessoal, Lda Rua 5 de Outubro, Casais 85 e 86, Nucho de Pegões Velhos 2985-155 Santo Isidro de Pegões, Portugal
Country of marketplace	Germany
Pack Size (g) / Type	250 / Bag
Quantity (un)	351
Certificate of Analysis number	See remarks
Specification	ES_QA_Finish product 001_DE_rev4

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Parameter		Monograph/ Guideline Reference	Method	Specification	Results
Identification	**Method A** Macroscopy examination	- Ph. Eur. Monograph (3028) *Cannabis flos*	Ph. Eur. Monograph (3028) *Cannabis flos*	Complies with requirements of monograph	Complies [b]
	Method B Microscopy examination				Complies [b]
	Method C HPTLC				Complies [b]
Foreign Matter		- Ph. Eur. Monograph (3028) *Cannabis flos*	Ph. Eur. 2.8.2	Maximum 2%	0.0 % [b]
Loss on Drying		- Ph. Eur. Monograph (3028) *Cannabis flos*	Ph. Eur. 2.2.32	Maximum 12.0%	9.8 % [b]
Total CBN		- Ph. Eur. Monograph (3028) *Cannabis flos*	Ph. Eur. 2.2.29	Maximum 1.0%	0.06 % [b]
Assay	THC + THCA	- Ph. Eur. Monograph (3028) *Cannabis flos*	Ph. Eur. 2.2.29	31.5% - 38.5%	36.4 % [b]
	CBD + CDBA	- Ph. Eur. Monograph (3028) *Cannabis flos*	Ph. Eur. 2.2.29	≤ 1%	0.1 % [b]
Total Ash		- Ph. Eur. Monograph (1433) Herbal drugs	Ph. Eur. 2.4.16	Maximum 20.0%	8.0 % [b]
Aflatoxins	B1	- Ph. Eur. Monograph (1433) Herbal drugs	Ph. Eur. 2.8.18	Not more than 2 µg/kg	<0.25 µg/kg (LOD) [b]
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) [b]
Ochratoxin A		- Ph. Eur. Monograph (1433) Herbal drugs	Ph. Eur. 2.8.22	Not more than 20 µg/kg	<2 µg/kg (LOD) [b]
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 [a]
Heavy Metals	Cadmium (Cd)	- Ph. Eur. Monograph (3028) *Cannabis flos*	Ph. Eur. 2.4.27	Maximum 0.3 ppm	<0.005 ppm (LOQ) [a]
	Lead (Pb)	- Ph. Eur. Monograph (3028) *Cannabis flos*	Ph. Eur. 2.4.27	Maximum 0.5 ppm	<0.020 ppm (LOQ) [a]
	Mercury (Hg)	- Ph. Eur. Monograph (3028) *Cannabis flos*	Ph. Eur. 2.4.27	Maximum 0.1 ppm	<0.050 ppm (LOQ) [a]
	Arsenic (As)	- Ph. Eur. Monograph (3028) *Cannabis flos*	Ph. Eur. 2.4.27	Maximum 0.2 ppm	<0.020 ppm (LOQ) [a]
Microbiological Tests	Total aerobic microbial count (TAMC)	- Ph. Eur. Monograph (5.1.8 C) Microbiological quality of herbal medicinal products and extracts	Ph. Eur. 2.6.12	≤ 10^5 CFU/g (max.: 500 000 CFU/g)	1.00 X 10^4 CFU/g [b]
	Total combined yeasts/moulds count (TYMC)			≤ 10^4 CFU/g (max: 50 000 CFU/g)	1.00 X 10^4 CFU/g [b]
	Bile-tolerant gram (-) bacteria		Ph. Eur. 2.6.31	≤ 10^4 CFU/g	<10 CFU/g [b]
	Escherichia coli			Absence / 1 g	Absent/g [b]
	Salmonella spp			Absence / 25 g	Absent/25g [b]
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

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Remarks:

[a] From LEF CoA nº 25/4727, issued date 04/07/2025
[b] From LEF CoA nº 25/4806, issued date 11/07/2025

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: 15/07/2025