

Internal Code	NAME	Batch no.		
FIN000246	Balancial 18/1 PT-S1 250g	2500381		
Manufacture Date	Expiry date	Analysis Date	Analytical Protocol	Specification
12/03/2025	09/2025	27/03/2025	PRT-0000515-1.0	SPE-0001171-ver.1.0

Tests	Methods	Specification	Results
<b>1. Identification</b>			
1.1. Method A: Macroscopy Examination	EP monograph 07/2024:3028	Complies with requirements of monograph	Complies
1.2. Method B: Microscopy Examination	EP monograph 07/2024:3028; Ph.Eur.2.8.23	Complies with requirements of monograph	Complies
1.3. Method C: HPTLC	EP monograph 07/2024:3028; Ph.Eur.2.8.25	Complies with requirements of monograph	Complies
<b>2. Foreign Matter</b>			
	EP monograph 07/2024:3028; Ph.Eur.2.8.2	≤ 2% w/w Cannabis flower does not contain any seeds and the whole herbal drug does not contain any leaves more than 1.0 cm in length	0% Cannabis flower does not contain any seeds and the whole herbal drug does not contain any leaves more than 1.0 cm in length
<b>3. Loss on Drying<sup>a)</sup></b>	EP monograph 07/2024:3028; Ph.Eur.2.2.32	≤ 12.0% w/w	8.3%
<b>4. Assay<sup>a)</sup></b>			
4.1. Total THC	EP monograph 07/2024:3028; Ph.Eur.2.2.29	16.2% - 19.8% w/w	17.4% (17.40%)
4.2. Total CBD		≤ 1.0% w/w	<LOQ (0.2%)
<b>5. Total CBN<sup>a)</sup></b>	EP monograph 07/2024:3028; Ph.Eur.2.2.29	≤ 1.0% w/w	0.1% (0.10%)
<b>6. Heavy Metals<sup>b)</sup></b>			
6.1. Cd		≤ 0.3 ppm	< LOQ (0.005 ppm)
6.2. Pb	EP monograph 07/2024:3028; Ph.Eur.2.4.27	≤ 0.5 ppm	< LOQ (0.020 ppm)
6.3. Hg		≤ 0.1 ppm	< LOQ (0.050 ppm)
6.4. As		≤ 0.2 ppm	< LOQ (0.020 ppm)

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Tests	Methods	Specification	Results	
<b>7. Microbiology</b>				
7.1. Total Aerobic Microbial Count (TAMC)	Ph.Eur. (5.1.8C, 2.6.12)	$\leq 10^5$ CFU/g (max: 500 000 CFU/g)	<100 CFU/g	
7.2. Total Yeast and Mold Count (TYMC)		$\leq 10^4$ CFU/g (max: 50 000 CFU/g)	<100 CFU/g	
7.3. Bile-tolerant gram-negative bacteria		$\leq 10^4$ CFU/g	<10 CFU/g	
7.4. Escherichia coli		Absence in 1 g	Absent/g	
7.5. Salmonella		Ph.Eur. (5.1.8C, 2.6.31)	Absence in 25 g	Absent/25g
7.6. Pseudomonas aeruginosa			Absence in 1 g	Absent/g
7.7. Staphylococcus aureus <sup>c)</sup>			Absence in 1 g	Absent/g
<b>8. Aflatoxins <sup>b)</sup></b>				
8.1. B1	Ph. Eur. 2.8.18	$\leq 2$ µg/kg	< LOD (0.25 µg/kg)	
8.2. B1 + B2 + G1 + G2		$\leq 4$ µg/kg	< LOQ (0.5 µg/kg)	
<b>9. Ochratoxin A <sup>b)</sup></b>	Ph.Eur. 2.8.22	$\leq 20$ µg/kg	< LOD (2 µg/kg)	
<b>10. Pesticides <sup>b)</sup></b>	Ph.Eur. 2.8.13	Must comply with requirements of monograph	Complies	

Remarks:

- a) From Canapac Certificate of Analysis No: 113/2025, dated on 18/02/2025.
- b) From Canapac Certificate of Analysis No: 100/2025 rev 002, dated on 19/02/2025.
- c) From LEF Certificate of Analysis No: 25/2019, dated on 24/03/2025.

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

**Conclusion: Approved - Complies with specification**

Prepared by	Approved by
<u>P. Jessica Tomai</u> Quality Control Manager	<u>Catarina Pereira</u> Qualified Person
<u>04/04/2025</u> Date	<u>04/04/2025</u> Date