

## Certificate of Analysis No. 371/2024

Product:

Cannabis for medical use

Type:

Cannabis Sativa Flos

Strain:

Gelato Pie

Trade name of the product:

Cannabis bava medical 21/1 GELATO PIE

Type of medicinal substance: Package size:

dried flower 10 grams

none

Irradiation: Batch:

K.45.DRB00922

Expiry date:

18.09. 2025

Testing method:

Ph. Eur. Monograph (current edition)

Range of Analyses:

Test	Method	Acceptance limits	Results	Complies
		(Specification)		
Identity 1) 3)			4111	
Odour <sup>1)</sup>	Ph.Eur.3028	Characteristic of	Complies	YES
		cannabis flowers		
Macroscopic		Comply with	Complies	YES
examination	Ph.Eur 3028	monograph		
(appearance) <sup>1)</sup>				
Microscopy <sup>1)</sup>	Ph.Eur. 3028/2.8.23	Comply with monograph	Complies	YES
TLC 3)	Ph.Eur. 3028/2.8.25	Comply with monograph	Complies	YES
Purity 1)	ł	<u> </u>		
Loss on drying <sup>3)</sup>	Ph.Eur. 3028/ 2.2.32	≤ 12%	7,74 %	YES
Foreign matter <sup>1)</sup>	Ph. Eur.3028/ 2.8.2	≤ 2 %	Complies	YES
Pesticides residues <sup>1)</sup>	Ph. Eur. 2.8.13	Below limits in Ph.	Complies	YES
		Eur.		
Assay of cannabinoids c	ontent 1)	A 00000 (*******************************		
Total THC	Ph. Eur. 3028/ 2.2.29	21 ± 10%	21,76 %	YES
(tetrahydrocannabinol)				
Suma CBD	Ph. Eur. 3028/ 2.2.29	≤ 1,0 %	< 1 %	YES
(cannabidiol)				
Related substance	Ph. Eur. 3028/ 2.2.29	≤ 1,0 %	< 1 %	YES
Suma CBN				
(cannabinol)				
Absence of heavy metal	S 1)			
Cadmium	Ph. Eur.3028/ 2.4.27	≤ 0,3 µg/g	≤ 0,3 µg/g	YES
Mercury and its	Ph. Eur. 3028/2.4.27	≤ 0,1 μg/g	≤ 0,1 µg/g	YES
compounds		= 0,1 M8/8	= 0,1 HB/B	. 20
Lead	Ph. Eur. 3028/ 2.4.27	≤ 0,5 µg/g	≤ 0,5 µg/g	YES
Arsen	Ph. Eur.3028/ 2.4.30	≤ 0,2 µg/g	≤ 0,2 µg/g	YES





Mycotoxins purity 1)				
Aflatoxin B1	Ph. Eur. 2.8.18	≤ 2 μg/kg	< 2 μg/kg	YES
Sum of aflatoxins (B1,	Ph. Eur. 2.8.18	≤ 4 μg/kg	< 4 μg/kg	YES
B2, G1, G2)				
Ochratoxin A	Ph. Eur. 2.8.22	≤ 20 µg/kg	< 20 μg/kg	YES
Microbiological purity -	Comply with Ph. Eur.	2.6.12 <sup>2)</sup>		
TAMC	Ph. Eur. 2.6.12,	Max. 500.000	<1000	YES
	limits by 5.1.8 C	CFU/g		
TYMC	Ph. Eur. 2.6.12,	Max. 50.000	<100	YES
	limits by 5.1.8 C	CFU/g		
Bile-tolerant Gram-	Ph. Eur. 2.6.31	≤ 10 <sup>4</sup> CFU/g	Absence/1g	YES
negative bacteria		≥ 10 Cro/g		
Escherichia coli	Ph. Eur. 2.6.31	Absence / 1 g	Absence/1g	YES
Salmonella sp.	Ph. Eur. 2.6.31	Absence / 25 g	Absence/25g	YES
Pseudomonas	Ph. Eur. 2.6.13,	Absonce / 1 a	Absence / 1 g	YES
aeruginosa	5.1.8 C	Absence / 1 g		
Staphylococcus aureus	Ph. Eur. 2.6.13,	Absonso / 1 a	Absence / 1 g	YES
	5.1.8 C	Absence / 1 g		

## **Testing sites:**

<sup>1)</sup>Lagom Pharmatech s.r.o. č.p. 401, 338 21 Osek, CZ

GMP certificate No.: sukls21471/2023

2) ITEST plus s.r.o.

Kladská 1032, 500 03 Hradec Králové, CZ GMP certificate No.: sukls195787/2021

<sup>3)</sup> Zdravotní ústav se sídlem v Ústí nad Labem Zkušební laboratoř Hradec Králové, pracoviště č. 1a HK, Nezvalova 958, 500 03 Hradec Králové GMP certificate No.: sukls119870/2020

## Conclusion of testing:

I hereby confirm that the information provided is true and complete. This batch of product has been analysed to the extent requested by the customer, in full compliance with EU-GMP requirements.

The certificate was

issued by:

Monika Snaiberkova

Controlled by:

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Approved:

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