



Certificate of Analysis

Specification	ESP-144/01
Product	Oral Solution THC:CBD 0:100 mg/mL 30 mL CR+ UK IPS
Code	FDF0021
Batch no.	C0086
Date of Analysis	26/04/2024

CoA no.	2401923
Manufacturing date	27/02/2024
Expiry date	27/02/2025
Presentation	30 mL amber glass vials with child resistant closure system
Bulk batch no.	C0048

TEST	Method	Acceptance Criteria	Results
Appearance	MA-008	Colourless to slightly yellowish liquid	Complies
Deliverable Volume	MA-008	Mean volume $\geq$ 30 mL; Individual volume $\geq$ 28.5 mL	Complies
Identification: HPLC	MA-008	The chromatograms of the sample solution obtained in the assay test must show the main peaks with a retention time similar to the chromatograms of the standard solution	Positive
Identification: TLC	MA-008	The sequence of zones in the chromatograms of the reference solution and the test solution are similar	Positive
Relative density	MA-008	Informative value	0.953
Water	MA-008	$\leq$ 0.5 %	0.04 %
Cannabinoids			
Δ^9 -THC	MA-008 / DAB	$\leq$ 0.01 %	0.002 %
Δ^9 -THCA	MA-008 / DAB	$\leq$ 0.01 %	< 0.0003 (LOD) %
CBD	MA-008 / DAB	90.0 % to 110.0 % of the label claim	99.0 % (98.96 mg/mL)
CBDA	MA-008 / DAB	$\leq$ 0.05 %	< 0.0003 (LOD) %
CBN	MA-008 / DAB	$\leq$ 0.01 %	< 0.0003 (LOD) %
Other cannabinoid	MA-008 / DAB	Report value	0.003 %
Total other cannabinoids	MA-008 / DAB	$\leq$ 0.15 %	0.07 %
Mycotoxins			
Aflatoxin B1	MA-008 / Ph.Eur.2.8.18	$\leq$ 2 μ g/Kg	< 0.25 (LOD) μ g/Kg
Aflatoxins (B1+B2+G1+G2)	MA-008 / Ph.Eur.2.8.18	$\leq$ 4 μ g/Kg	< 0.25 (LOD) μ g/Kg
Ochratoxin A	MA-008 / Ph.Eur.2.8.22	$\leq$ 20 μ g/Kg	< 2 (LOD) μ g/Kg
Heavy Metals			
Arsenic (As) $\diamond$	Test performed by the Manufacturer	$\leq$ 0.2 ppm	< 0.020 (LOQ) ppm
Cadmium (Cd) $\diamond$	Test performed by the Manufacturer	$\leq$ 0.3 ppm	< 0.005 (LOQ) ppm
Lead (Pb) $\diamond$	Test performed by the Manufacturer	$\leq$ 0.5 ppm	< 0.020 (LOQ) ppm
Mercury (Hg) $\diamond$	Test performed by the Manufacturer	$\leq$ 0.1 ppm	< 0.050 (LOQ) ppm
Pesticides			
Pesticides $\diamond$	Test performed by the Manufacturer	Complies with Ph.Eur.2.8.13	Complies
Residual solvents			
Ethanol $\diamond$	Test performed by the Manufacturer	< 5000 ppm	< 2228.5 (LOQ) ppm



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TEST	Method	Acceptance Criteria	Results
Microbial Quality			
<i>Pseudomonas aeruginosa</i>	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 1 mL	Absence/mL
TAMC - Total aerobic microbial count	MA-008 / Ph.Eur.2.6.12. & Ph.Eur.5.1.4.	$\leq 10^2$ CFU/mL	< 10 CFU/mL
TYMC - Total combined yeast & mould count	MA-008 / Ph.Eur.2.6.12. & Ph.Eur.5.1.4.	$\leq 10^1$ CFU/mL	< 10 CFU/mL
Bile-tolerant gram-negative bacteria	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	$\leq 10^2$ CFU/mL	< 10 CFU/mL
<i>Escherichia coli</i>	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 1 mL	Absence/mL
<i>Salmonella</i>	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 10 mL	Absence/10mL
<i>Staphylococcus aureus</i>	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 1 mL	Absence/mL

Comments

Results in compliance with the specification.

Heavy Metals, Pesticides and Ethanol were performed on the API batch.

(◊)Result reported from Clever Leaves (CoA Batch: CD23060470)

Status:

Approved

Signed by:

Iva Vinhas

Quality Control Director

Application of electronic signature