Especificação de Produto
Product Specification

ESP	ESP-157/02
Produto/*Product*	**Oral Solution THC:CBD <1:100 mg/mL MCT 30 mL CR+**
Código/*Code*	**SFP0149**

Apresentação/*Presentation*	30 mL amber glass vials with child resistant closure system

Teste *Test*	**Método** *Method*	**Critério de aceitação** *Acceptance Criteria*
Appearance	MA-008	Yellowish to amber liquid
Identification: TLC	MA-008 DAB	The sequence of zones in the chromatograms of the reference solution and the test solution are similar
Identification: HPLC	MA-008 DAB	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
Relative density	MA-008	Informative value
Water	MA-008	≤ 0.5 %
Deliverable volume	MA-008	Mean volume ≥ 30 mL Individual volume ≥ 28.5 mL
Cannabinoids		
Δ^9-THC	MA-008 DAB	Report value
Δ^9-THCA	MA-008 DAB	Report value
Total THC THC + (THCA x 0.877)	MA-008 DAB	< 1.00 mg/mL
CBD	MA-008 DAB	Report value
CBDA	MA-008 DAB	Report value
Total CBD CBD + (CBDA x 0.877)	MA-008 DAB	90.0 % to 110.0 % of the label claim
CBN	MA-008 DAB	≤ 1.0 %
Other cannabinoid (Together with any corresponding acid)	MA-008 DAB	≤ 2.0 %
Total other cannabinoids	MA-008 DAB	Report value
Mycotoxins		
Aflatoxin B1	MA-008 Ph.Eur.2.8.18	≤ 2 µg/Kg
Aflatoxin (B1+B2+G1+G2)	MA-008 Ph.Eur.2.8.18	≤ 4 µg/Kg
Ochratoxin A	MA-008 Ph.Eur.2.8.22	≤ 20 µg/Kg

Especificação de Produto
Product Specification

ESP	ESP-157/02
Produto/*Product*	**Oral Solution THC:CBD <1:100 mg/mL MCT 30 mL CR+**
Código/*Code*	**SFP0149**

Apresentação/*Presentation*	30 mL amber glass vials with child resistant closure system

Teste *Test*	**Método** *Method*	**Critério de aceitação** *Acceptance Criteria*
Heavy Metals		
Arsenic (As)	MA-008 Ph.Eur.2.4.27	≤ 0.2 ppm
Cadmium (Cd)	MA-008 Ph.Eur.2.4.27	≤ 0.3 ppm
Lead (Pb)	MA-008 Ph.Eur.2.4.27	≤ 0.5 ppm
Mercury (Hg)	MA-008 Ph.Eur.2.4.27	≤ 0.1 ppm
Nickel (Ni)	MA-008 Ph.Eur.2.4.27	Indicative
Zinc (Zn)	MA-008 Ph.Eur.2.4.27	Indicative
Pesticides	MA-008 Ph.Eur.2.8.13	Complies with Ph.Eur.2.8.13
Residual solvents		
Ethanol	MA-008 Ph.Eur.5.4	< 5000 ppm
Microbial Quality		
TAMC Total aerobic microbial count	MA-008 Ph.Eur.2.6.12 & Ph.Eur.5.1.4	≤ 10^3 CFU/mL
TYMC Total combined yeast & mould count	MA-008 Ph.Eur.2.6.12 & Ph.Eur.5.1.4	≤ 10^2 CFU/mL
Bile-tolerant gram-negative bacteria	MA-008 Ph.Eur.2.6.13 & Ph.Eur.5.1.4	≤ 10^2 CFU/mL
Escherichia coli	MA-008 Ph.Eur.2.6.13 & Ph.Eur.5.1.4	Absence in 1 mL
Salmonella	MA-008 Ph.Eur.2.6.13 & Ph.Eur.5.1.4	Absence in 10 mL
Staphylococcus aureus	MA-008 Ph.Eur.2.6.13 & Ph.Eur.5.1.4	Absence in 1 mL
Notas/Notes:		

Especificação de Produto
Product Specification

Quantidade de amostra necessária *Required sample amount*	
1. Ensaios físico-químicos / *Physical-chemical tests*	13 units
2. Qualidade microbiológica / *Microbial quality*	2 units
3. Para amostra de referência / *For reference sample*	15 units
Condições de armazenamento *Storage conditions*	
Tightly sealed, protected from light, between 15 and 25 ºC	
Outras Informações *Other Informations*	
-	