

Lot Number: 20-1002

Date of Manufacture: APR-2020

SKU: 1MGCBD100 Page 1 of 1

# Certificate of Analysis

# Product: Brēz CBD Inhaler (100 Actuations)

Test Description	Test Method Number	Analyst	Specification	Results	Pass/ Fail
Cannabidiol Total Content LM-ET001-001 E0 Assay		ECP	90-110% of target (0.136g) for average and individual units	Mean: 96% Min: 95% Max: 97%	Pass
Dose Content Uniformity (DCU)	LM-ET001-001 LM-ET001-003	ECP	The amount of active ingredient per determination is not outside of 80-120 percent of label claim for more than one of ten containers, none of the determinations is outside of 75-125 percent of the label claim, and the mean is not outside of 85-115 percent of the label claim.  Label Claim: 1mg/actuation	Spray 1         Spray 1           Mean: 1.06mg         Mean: 106%           Min: 0.97mg         Min: 97%           Max: 1.13mg         Max: 113%           Spray 2         Spray 2           Mean: 1.06mg         Mean: 106%           Min: 1.03mg         Min: 103%           Max: 1.11mg         Max: 111%	Pass
DCU through Container Life	LM-ET001- <mark>0</mark> 01 LM-ET001- <mark>00</mark> 3	ECP	The amount of active ingredient per determination is not outside of 80-120 percent of label claim for more than one of nine determinations from three containers, none of the determinations is outside of 75-125 percent of the label claim, and means for each of the beginning, middle, and end determinations are not outside of 85-115 percent of the label claim.  Label Claim: 1mg/actuation	Beginning         Beginning           Mean: 1.03mg         Mean: 103%           Min: 1.00mg         Min: 100%           Max: 1.07mg         Max: 107%           Middle         Mean: 103%           Min: 0.96mg         Min: 96%           Max: 1.08mg         Max: 108%           End         End           Mean: 97%         Min: 89%           Max: 1.01mg         Max: 101%	Pass
THC Content	3 <sup>rd</sup> Party Labo	oratory	Total THC Content: Below detectable limit	None Detected Cert ID: 80789	Pass

Authorization:			
EManuele Piras Print Name	Signature	Date 05JUNDO	
Approval:	3		
Kristen Bobroniecki	Kuster Bol	ici 05 Jun 2020	
Print Name	Signature	Date	

**END OF REPORT** 



Certificate ID: **80793** Received: **4/16/20** 

Client Sample ID: Brez CBD Inhaler - Release

Lot Number: 20-1002

Matrix: Personal Care - De-pressurized pMDI



**Entourage Therapeutics** 

PO Box 9669

Fall River, MA 02720

Attn: Kristen Bobrowiecki

Authorization:

Signature:

Chris Hudalla, Chief Science Officer



Date:

4/22/2020







PJLA Testing
Accreditation
# 80585

The data contained within this report was collected in accordance with the requirements of ISO/IEC17025:2017. I attest that the information contained within the report has been reviewed for accuracy and checked against the quality control requirements for each method. These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety.

### HM: Heavy Metal Analysis [WI-10-13]

Analyst: CJS

Use Limits 2 (ug/kg)

*Test Date: 4/21/2020* 

This test method was performed in accordance with the requirements of ISO/IEC 17025. These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety.

#### 80793-HM

Symbol	Metal	Conc. 1 (µg/kg)	RL	All	Ingestion	Status
As	Arsenic	ND	50	200	1500	PASS
Cd	Cadmium	ND	50	200	500	PASS
Hg	Mercury	ND	50	100	1500	PASS
Pb	Lead	ND	50	500	1000	PASS

- 1) ND = None detected to Lowest Limits of Detection (LLD)
- 2) MA Dept. of Public Health: Protocol for MMJ and MIPS, Exhibit 4(a) for all products.
- 3)USP exposure limits based on daily oral dosing of 1g of concentrate for a 110 lb person.

#### MB1: Microbiological Contaminants [WI-10-09]

Analyst: MM

Test Date: 4/17/2020

This test method was performed in accordance with the requirements of ISO/IEC 17025. These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety.

#### 80793-MB1

Symbol	Analysis	Results	Units	Limits*	Status
AC	Total Aerobic Bacterial Count	<100	CFU/g	100,000 CFU/g	PASS
CC	Total Coliform Bacterial Count	<100	CFU/g	1,000 CFU/g	PASS
EB	Total Bile Tolerant Gram Negative Count	<100	CFU/g	1,000 CFU/g	PASS
YM	Total Yeast & Mold	<100	CFU/g	10,000 CFU/g	PASS

Recommended limits established by the American Herbal Pharmacopoeia (AHP) monograph for Cannabis Inflorescence [2013], for consumable botanical products, including processed and unprocessed cannabis materials, and solvent-based extracts. Note: All recorded Microbiological tests are within the established limits.

# MB2: Pathogenic Bacterial Contaminants [WI-10-10]

Analyst: LabAdmin

*Test Date: 4/18/2020* 

This test method was performed in accordance with the requirements of ISO/IEC 17025. These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety.

80793-MB2

Test ID	Analysis	Results	Units	Limits*	Status
80793-ECPT	E. coli (O157)	Negative	NA	Non Detected	PASS
80793-SPT	Salmonella	Negative	NA	Non Detected	PASS

Note: All recorded pathogenic bacteria tests passed.

## PST: Pesticide Analysis [WI-10-11]

Analyst: CJR

*Test Date: 4/22/2020* 

The client sample was anlayzed for pesticides using Liquid Chromatography with Mass Spectrometric detection (LC/MS/MS). The method used for sample prep was based on the European method for pesticide analysis (EN 15662).

#### 80793-PST

Analyte	CAS	Result	Units	LLD	Limits (ppb)	Status
Abamectin	71751-41-2	ND	ppb	0.2	300	PASS
Azoxystrobin	131860-33-8	ND	ppb	0.10	40000	PASS
Bifenazate	149877-41-8	ND	ppb	0.10	5000	PASS
Bifenthrin	82657-04-3	ND	ppb	0.20	500	PASS
Cyfluthrin	68359-37-5	ND	ppb	0.50	1000	PASS
Daminozide	1596-84-5	ND	ppb	10.00	10	*
Etoxazole	153233-91-1	ND	ppb	0.10	1500	PASS
Fenoxycarb	72490-01-8	ND	ppb	0.10	10	PASS
Imazalil	35554-44-0	ND	ppb	0.10	10	PASS
Imidacloprid	138261-41-3	ND	ppb	0.10	3000	PASS
Myclobutanil	88671-89-0	ND	ppb	0.10	9000	PASS
Paclobutrazol	76738-62-0	ND	ppb	0.10	10	PASS
Piperonyl butoxide	51-03-6	ND	ppb	0.10	8000	PASS
Pyrethrin	8003-34-7	ND	ppb	0.1	1000	PASS
Spinosad	168316-95-8	ND	ppb	0.1	3000	PASS
Spiromesifen	283594-90-1	ND	ppb	0.10	12000	PASS
Spirotetramat	203313-25-1	ND	ppb	0.10	13000	PASS
Trifloxystrobin	141517-21-7	ND	ppb	0.10	30000	PASS

<sup>\*</sup> Testing limits for ingestion established by the State of California: CCR, Title 16, Division 42, Chapter 5, Section 5313. ND indicates "none detected" above the lower limit of detection (LLD). Analytes marked with (\*) indicate analytes for which no recovery was observed for a pre-spiked matrix sample.

# **END OF REPORT**