TruEase® Soft Gel Capsule

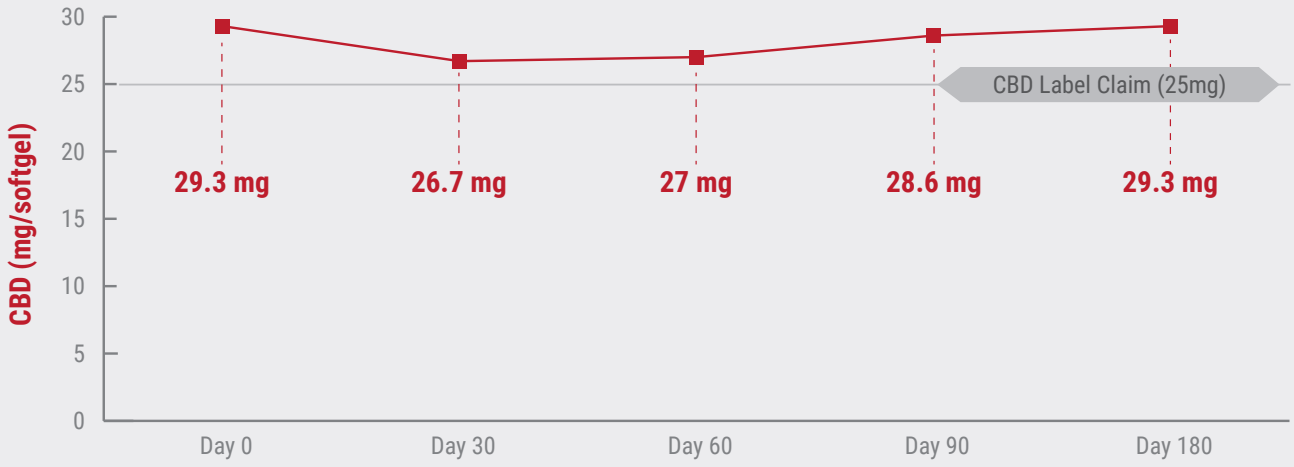
Overview

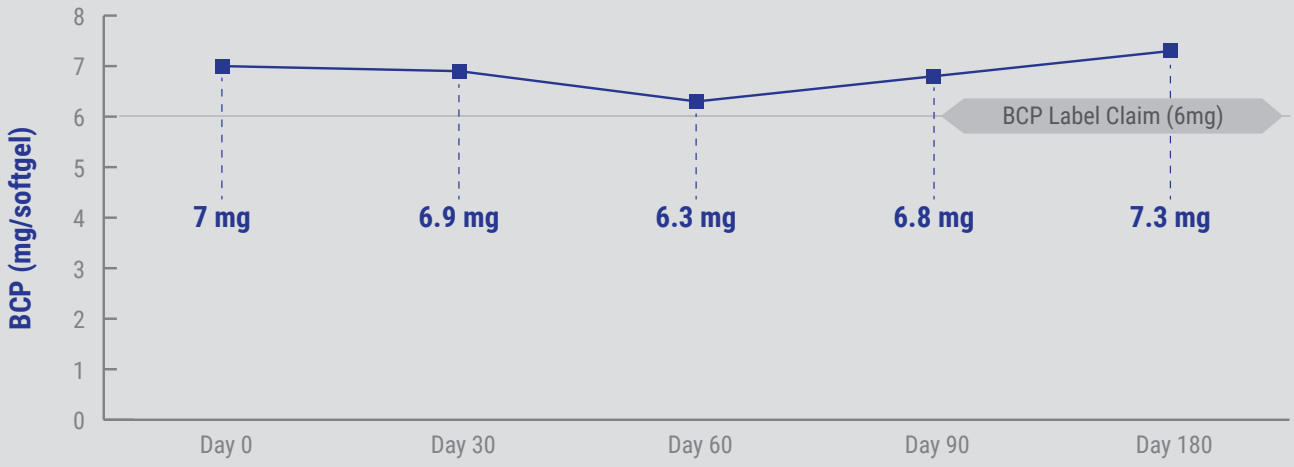
An accelerated stability study was conducted under the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The study used sealed, high-density polyethylene (HDPE) containers stored at 40°C and 75% relative humidity, and tested at the 0, 1, 2, 3 and 6 month time points. The following were subject to testing: Cannabidiol (CBD) Label Claims, Beta-caryophyllene (BCP) Label Claims, Soft Gel Integrity, and Microbiological Contamination.

Conclusion

At the end of 6 months, the product met (and exceeded) label claims for both Cannabidiol (CBD) and Beta-caryophyllene (BCP). Both compounds were proven to be "very stable" over the six-month period in accelerated conditions, equating to a 24-month real time shelf life stability (according to recognized pharmaceutical standards). Furthermore, there were no issues with soft gel integrity, and microbiological contamination was not observed.







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TruGen3®

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TruEase® Formula# 5008

Certificate of Analysis

General Information

Lot Number:	0131-6170
Manufacture Date:	December, 2016
Expiration Date:	December, 2018
Storage:	Room temperature, away from light

	Specification	Result	Method
Product Characteristics			
Appearance:	7.5 oval soft gelatin capsule	Conforms	Visual
Odor:	Characteristic	Conforms	Olfactory
Color	Brown soft gel containing reddish-brown liquid	Conforms	Visual
Disintegration:	< 30 minutes	< 9 minutes	USP
Total Weight:	554mg ± 10%	561 mg	
Contents and Composition			
Hemp Oil Extract	334 mg	Conforms	By Input
Cannabidiol (CBD)	25-31.25 mg	27.2 mg	HPLC
beta-caryophyllene	6-7.5 mg	6.7 mg	GC
Cannabigerol (CBG)	0-1 mg	Not detected	HPLC
d-Limonene	0-1 mg	0.004 mg	GC
Tetrahydrocannabinol (THC)	Not detected*	Not detected	HPLC
Tetrahydrocannabinolic (THC-A)	Not detected	Not detected	HPLC

*Limit of Detection = 10ppm

OTHER INGREDIENTS: VESIsorb® Colloidal Delivery System (medium chain triglycerides, VEDD (Vitamin E Dimer Derivative), mono and diglycerides, fatty acids, natural flavors), capsule shell (bovine gelatin, glycerin, carob, water).

Heavy Metals

Pb (Lead):	NMT 0.5 µg	0.071	ICP-MS
As (Arsenic):	NMT 0.7 µg	0.032	ICP-MS
Hg (Mercury):	NMT 0.4 µg	Not detected	ICP-MS
Cd (Cadmium):	NMT 0.07 µg	0.006	ICP-MS

Microbiology

Total Aerobic Plate Count:	NMT 3,000 cfu/g	30 cfu/gm	Current USP <2021>
Total Yeast & Mold:	NMT 300 cfu/g	< 10 cfu/gm	Current USP <2021>
Salmonella:	Absent/10 g	Absent	Current USP <2021>
Staphylococcus aureus:	Absent/10 g	Absent	Current USP <2021>
Pseudomonas aeruginosa:	Absent/10 g	Absent	Current USP <2021>