

CBD Oil Chewable Tablets – Direct Compression with PROSOLV[®] 730

4282-074

Aim of the Study

Due to the physico-chemical properties of cannabidiol (CBD), the vast majority of the marketed products containing CBD are oils. To provide greater convenience in dosing, the goal of this experiment was to make directly compressible 25 mg CBD oil tablets as well as 25 mg CBD oil chewable tablets with minimal effort.



CBD Oil

Cannabidiol (CBD) is a non-psychoactive compound found in the cannabis plant. Its anti-inflammatory, anti-anxiety, anti-spasmodic, and anti-nausea properties make CBD an increasingly popular natural remedy used for relieving uncomfortable symptoms of many common diseases. Further pharmacological effects are being researched, making CBD an appealing option for new therapies.^[1,2]

The CBD oil used in this study was a thick dark green to black tar like substance (Figure 1) which would have been difficult – if not impossible – to work with, using conventional tableting excipients.



Fig. 1 CBD Oil (raw material)

Formulations

Two different solid dose formulations were made, combining the CBD oil with the high functionality adsorbent binder PROSOLV[®] 730 and other JRS excipients depending on the formulation as described in the table below. All formulations produced 25 mg CBD oil tablets.

	Formulation 1 (Standard)		Formulation 2 (Chewable)	
	mg per tablet	%	mg per tablet	%
CBD Oil	25.0	19.5	25.0	5.0
PROSOLV[®] 730	100.0	78.0	100.0	20.0
EMDEX[®] Dextrates			372.5	74.5
EXPLOTAB[®] * Sodium Starch Glycolate	2.6	2.0		
PRUV[®] ** Sodium Stearyl Fumarate	0.6	0.5	2.5	0.5
Total	128.2	100.0	500.0	100.0

* Can be substituted by VIVASOL[®] croscarmellose sodium, if required by local food regulations.

** Can be substituted by LUBRI-PREZ magnesium stearate, if required by local food regulations.

The CBD oil was obtained from HempMeds.

Excipients Used

PROSOLV[®] 730 is a high functionality excipient that was specifically designed for the direct compression or encapsulation of oily active ingredients or lipophilic actives dissolved in oil.

Combining PROSOLV[®] 730 with CBD oil and additional excipients, such as EXPLOTAB[®] sodium starch glycolate as disintegrant, and PRUV[®] sodium stearyl fumarate or LUBRI-PREZ magnesium stearate as lubricant, conveniently enables direct compression of standard, immediate-release tablets.

Chewable tablets can be produced by direct compression in an equally straightforward way by combining CBD-loaded PROSOLV[®] 730 with EMDEX[®] dextrates as a naturally sweet and highly soluble binder. Due to its neutral taste, PRUV[®] sodium stearyl fumarate is the preferred lubricant for chewable formulations. If required due to local food regulations, LUBRI-PREZ magnesium stearate can be a suitable alternative.

Procedure

Blending

The CBD oil was added to PROSOLV® 730 via high shear mixing for 10 minutes. The oil-loaded PROSOLV® 730 was then transferred to a low shear mixing vessel and blended for 10 minutes with the remaining excipients, except for the lubricant. PRUV® sodium stearyl fumarate was sieved through a 20 mesh screen and subsequently added to the low shear mixer and blended for an additional 5 minutes. This blend was then immediately used for direct compression tableting.

The CBD oil can first be heated to 50 °C in a water bath for 10 minutes to reduce the viscosity of the material if necessary. The formulations presented here were made with and without heating the CBD oil, with no difference in results.

Equipment

High Shear Mixer	Braun Multiquick 3 Mixer
Low Shear Mixer	Glen Mills Turbula
Tablet Press	Piccola Rotary Instrumented Tablet Press
Hardness Tester	Sotax Model HT10 Hardness Tester
Disintegration Tester	Dr. Schleuniger Pharmatron DISI-2 Disintegration Apparatus

Tablet Characteristics at 15 kN Compaction Force

	Formulation 1 (Standard)	Formulation 2 (Chewable)
Tablet Weight	128 mg	500 mg
Tablet Diameter	6.4 mm	11.2 mm
Tablet Height	3.9 mm	4.9 mm
Disintegration Time	40 s	-



Fig. 2 CBD Oil Tablets-Formulation 1 Standard Oral Dosage (Left), and Formulation 2 Chewable Tablet (Right)

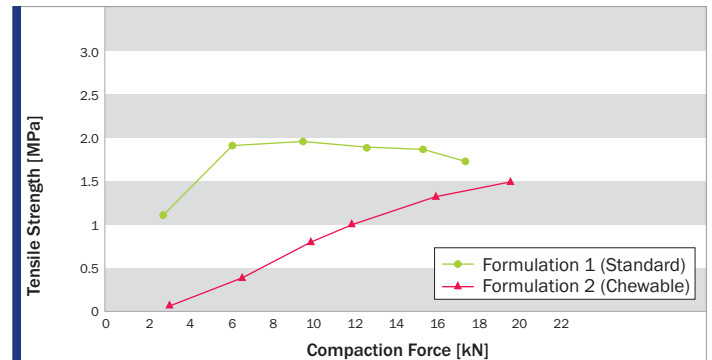


Fig. 3 Tensile Strength vs. Compaction Force of CBD Oil Tablets made with PROSOLV® 730

Conclusion

PROSOLV® 730 was found to be perfectly suited for the production of CBD oil tablets by direct compression. Both dosage forms showed good overall tableability. The standard orally ingestible tablets (Formulation 1) had the highest tensile strength, lowest ejection forces, and fast disintegration times. The chewable tablets (Formulation 2) exhibited the physical properties, desirable for this type of tablet.

PROSOLV® 730 enables simple, direct compression formulation of CBD Oil, thus offering the possibility of producing different solid dosage forms.

References

- [1] P. Nagarkatti et. al., Future Med Chem. 2009 Oct; 1(7): 1333-1349.
- [2] A.W. Zuardi et. al., Braz J Med Biol Res 2006 Apr; 39 (4).

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https://www.jrspharma.com/pharma_en/products-services/prosolv-730.php

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