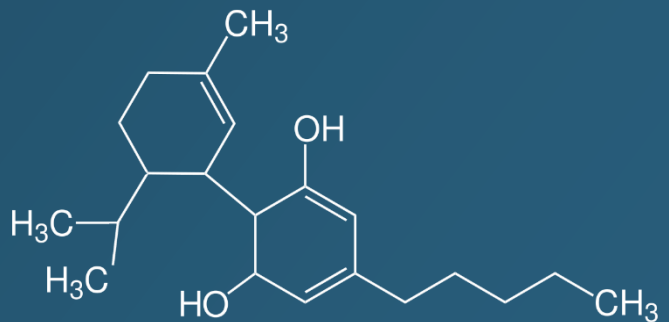


TECHNICAL INSIGHT  
PHARMACEUTICALS



# SUBLINGUAL

Delivery of CBD



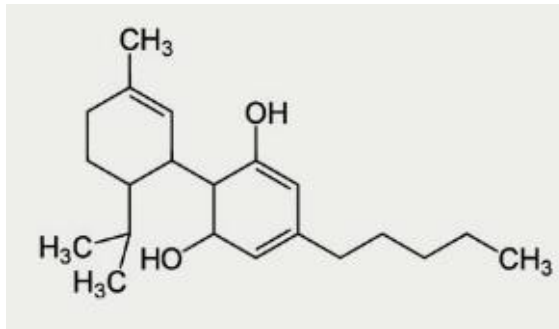
# Introduction

CBD or cannabidiol is a compound which is found in hemp plants. CBD is growing popularity now a days and people are curious about knowing the potential health benefits and risks of using CBD. CBD is one of the most powerful cannabinoids, found primarily in the flowers and leaves of hemp plant. Many research activities are going on regarding supporting body and mind by CBD in various ways. <sup>1</sup>

## Chemical name

IUPAC Name: 2-[(6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol

## Chemical structure



CBD sublingual pill or oil is designed to apply to the skin under the tongue. Pill or oil is placed below tongue, the active ingredients are absorbed in the skin and small blood vessels present there. From here CBD can directly enter the blood stream. Other benefits of sublingual route of administration are the higher bioavailability, ease of use and suitable for patients who have difficulty in swallowing. <sup>2</sup>

<sup>1</sup> <https://q13fox.com/2019/06/12/healthy-living-nutritionist-calls-regulation-of-cbd-infused-products-the-wild-wild-west/>

<sup>2</sup> <https://www.scriphessco.com/shop-by-department/nutritional-supplements/cbd-products/sublingual-oils/>

# Recent studies and clinical trials

Clinical trials are going on for sublingual delivery of cannabidiol for treatment of anxiety. This clinical study is in phase 2, has been started in August 2018 and expected to be completed in August 2019. Sublingual tincture of cannabis whole plant derived CBD is administered three times daily for four weeks in addition to normal treatment regimen. Phase 2 study is a double-blind clinical trial study of this tincture in patients with anxiety.<sup>3</sup>

Rapid dose therapeutics, a Canadian based life science company has developed a new innovative solution **Quick strips™ oral thin strips** for administration of CBD. This delivery system is true sublingual delivery system, and used for administration of CBD, THC and other cannabinoids.<sup>4</sup>

Recently, Chemesis international, a licensee of RDT started commercializing **Quick strips™ oral thin strips** of cannabidiol. Chemesis has begun signing distribution agreements with Rapid Dose Therapeutics (RDT) in United States for Cannabidiol infused QuickStrip products to ensure the company maintains a first mover advantage by forming distribution channels and partnerships that will gain market share. Rapid dose therapeutics Quick strips delivery system is a sublingual delivery device for administration of CBD, THC and other cannabinoids.<sup>5</sup>



Cannova Medical Ltd has developed an alternative solution for consumption of cannabis by using sublingual strips infused with a variety of active cannabis substances such as CBD, THC. Sublingual strips of cannabis more effectively control the dosage quantities. Nabis Holding, a Canadian investment company announced that it will acquire 49% of Cannova Medical.<sup>6</sup>

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<sup>3</sup> <https://clinicaltrials.gov/ct2/show/NCT02548559?term=Cannabidiol&rank=4>

<sup>4</sup> <https://finance.yahoo.com/news/rapid-dose-therapeutics-announces-commercialization-164300242.html>

<sup>5</sup> <https://www.globenewswire.com/news-release/2019/06/13/1868168/0/en/Chemesis-International-Inc-Begins-Commercialization-of-QuickStrip-Oral-Thin-Strips.html>

<sup>6</sup> <https://www.globenewswire.com/news-release/2019/06/03/1862930/0/en/Nabis-Holdings-Announces-Acquisition-of-49-of-Cannova-Medical-A-Creator-of-Innovative-Solutions-for-Cannabis-Consumption.html>

## Available Products



Nutracana CBD is extracted from sustainably cultivated hemp; these tablets are easy to use, and preferred route is sublingual. Dissolvable CBD immediately enters the bloodstream through the tissue under the tongue, bypasses digestive tract and provides vitality for all day from the moment of waking up.<sup>7</sup>



NutriCanna CBD sleep is extracted from hemp and is for sublingual administration. This formulation comprises of CBD and melatonin dissolvable tablets and is easy to use. It is useful for restful and rejuvenating sleep. Dissolvable melatonin and CBD directly enter bloodstream bypassing digestive tract.<sup>8</sup>



Worlds first CBD sublingual pill was introduced by Present naturals and its partner HoneyBee patch in June 2016. These CBD pills are free of THC which helps avail the benefits of dissolvable pill without the physical psychoactive effects of THC. Present naturals CBD sublingual pill comprises of around 98.9% cannabidiol. It dissolves under tongue in less than two minutes and the delivery rates are >99% directly into the blood stream.<sup>9</sup>

<sup>7</sup> <https://nutracannalabs.com/products/cbd-dissolvable-tablets-300mg-daytime>

<sup>8</sup> <https://nutracannalabs.com/collections/cbd-products/products/cbd-dissolvable-tablets-300mg-nighttime-formula>

<sup>9</sup> <https://www.presentnaturals.com/2016/07/19/present-naturals-introduce-worlds-1st-sublingual-cbd-pill/>

# IP analysis

Patenting activities have been observed by many companies in this domain. From Global prospective in terms of patenting activity, maximum IP activity has been observed in between years 2015-2018. United states of America hold maximum number of patent or patent applications followed by European and other countries.

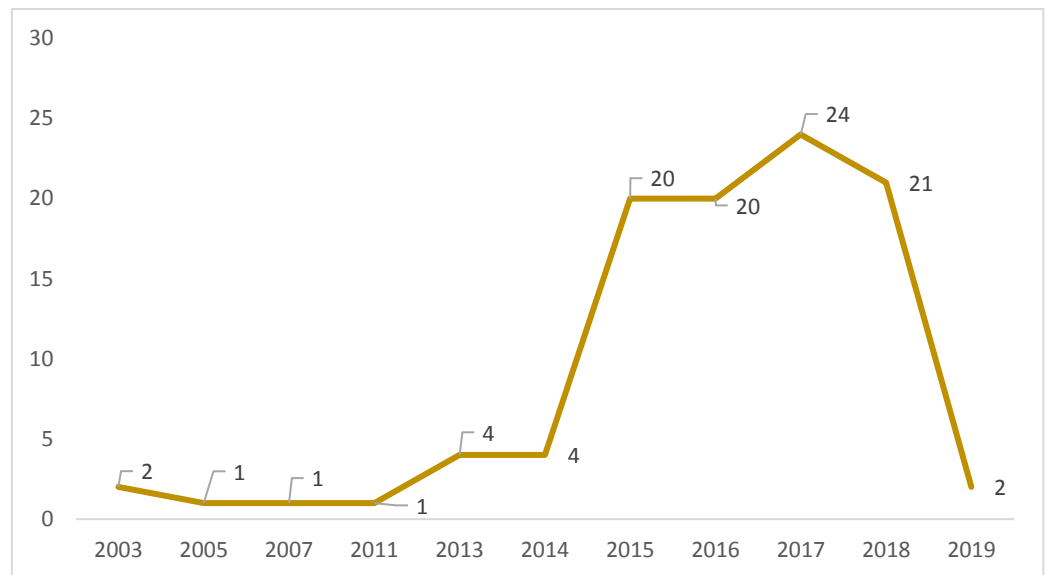


Figure shows filing trend for sublingual CBD. In 2015, 2016, 2017 and 2018 maximum filing has been observed. Though year 2019 has shown less activity till now, it can be speculated that by the year end more patents and patent applications can be shown up as companies are working actively in this domain.

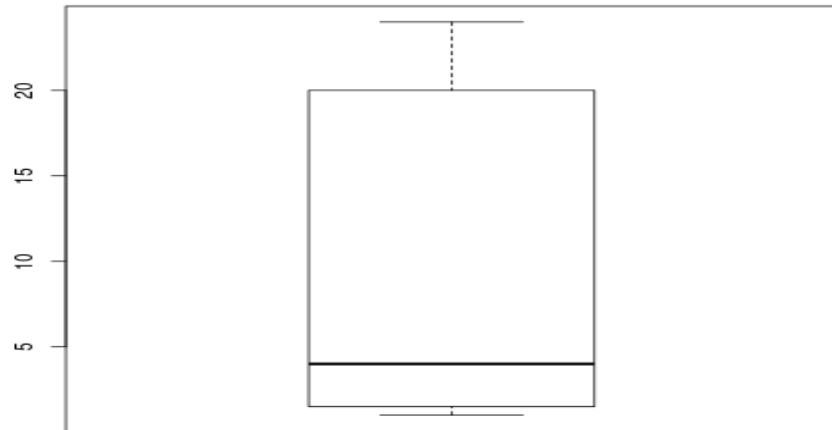
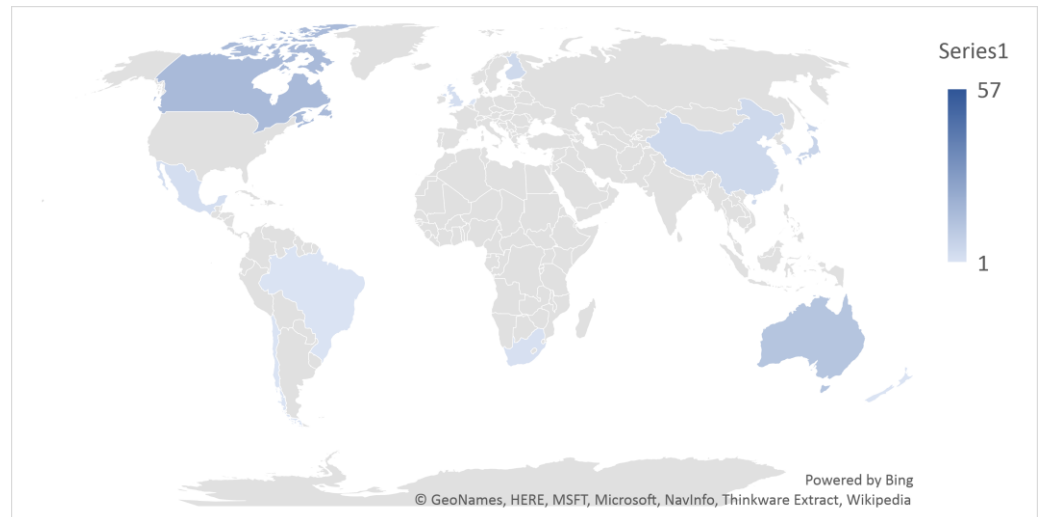


Figure shows the boxplot for filing trend sublingual delivery of CBD. It shows the **median** value for patent and patent application filing which is close to 4.



This figure shows geographical distribution of patents and patent applications worldwide. Among all the family members, United States of America hold maximum number of patents & patent applications followed by European countries, Canada and Australia.

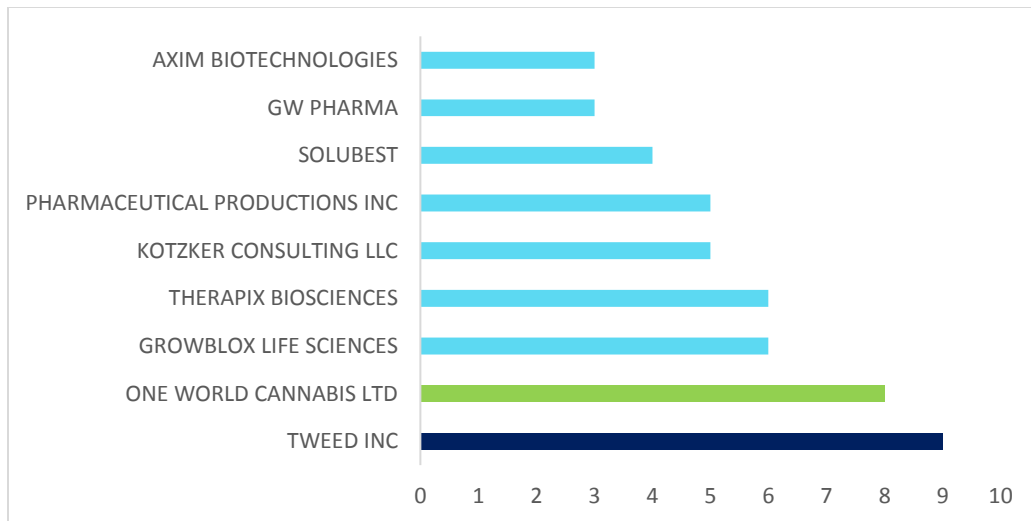
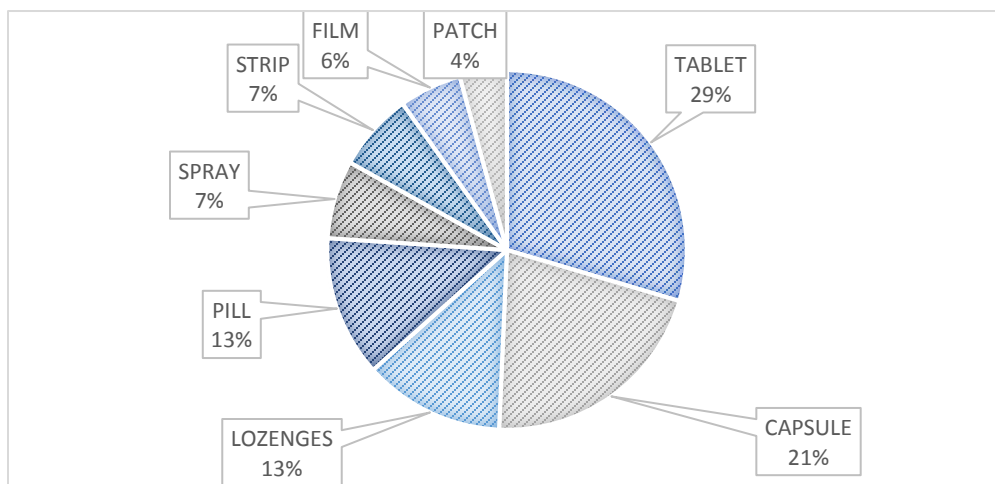


Figure shows top companies having IP rights on sublingual formulation/manufacturing methods of CBD. **Tweed INC** has filed maximum patent application followed by One world cannabis.



Pie chart depicted above shows percentage of commonly used dosage forms for sublingual delivery of CBD. Most commonly used dosage form for CBD delivery is tablet followed by capsule, lozenges and pills. Spray, strip, films and patches are used rarely.

## Conclusion and Future prospective

Sublingual cannabidiol is used for treatment of many diseases and disorders such as pain, inflammation, arthritis, migraine etc. and the focus is to enhance bioavailability and reduce harmful effect of CBD from its higher dose. Companies are performing research activities in the area of sublingual delivery of CBD by changing the doses forms and making it more convenient and suitable for delivery by developing oral strips for sublingual delivery of Cannabidiol. There are undergoing clinical trials (Phase 2) for treatment of anxiety by using sublingual CBD. In recent years, there are collaborations for development and marketing of formulations of CBD. So, it can be concluded that still there is scope of developing new techniques/formulation for administration of CBD as well as there are collaboration opportunities for manufacturing and marketing of CBD formulations.



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