MSN SCIENTIFIC SPARKLES

MSN
Research for Better Medicines

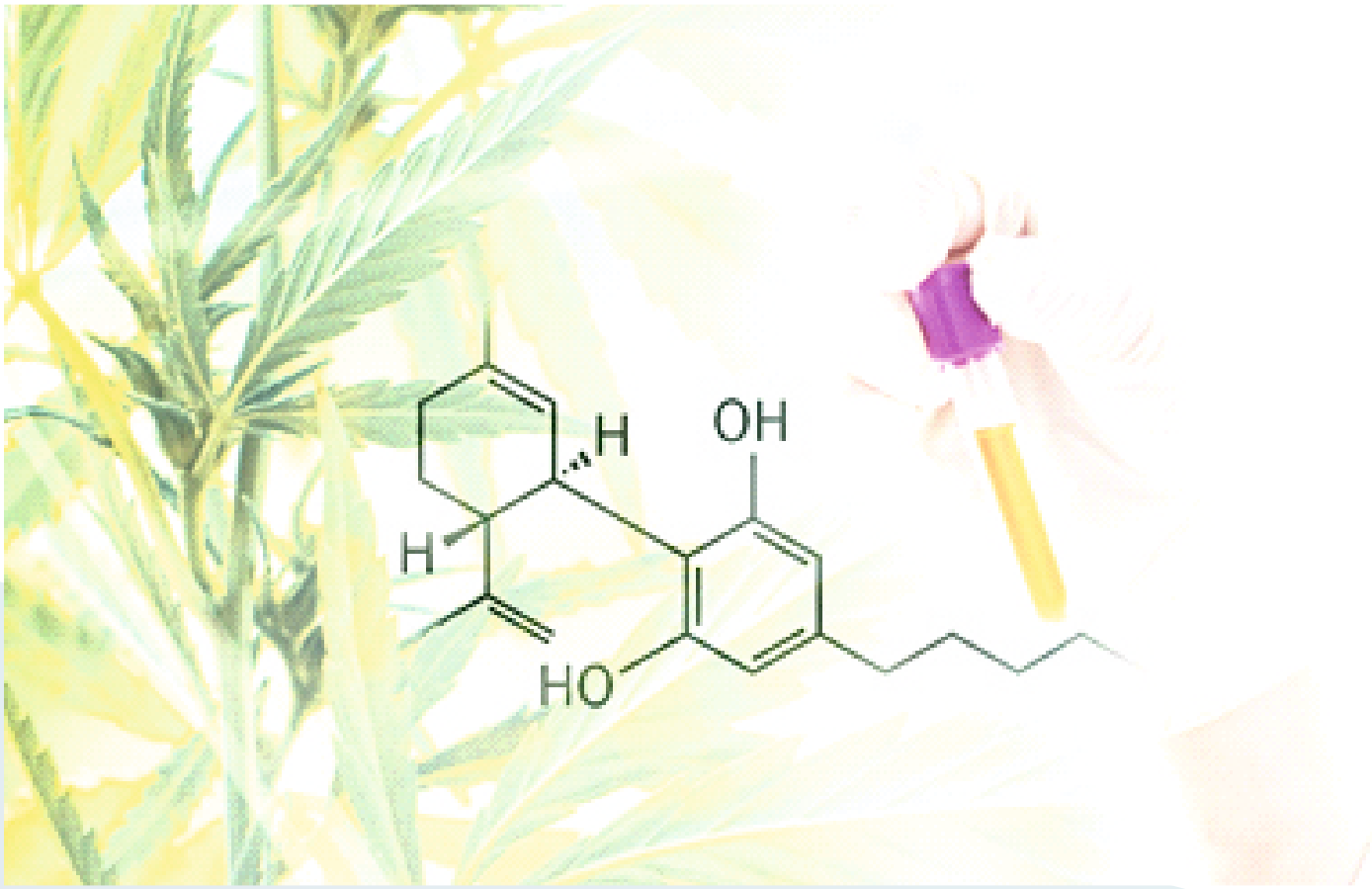
MSN CANNABIDIOL

MSNSS No: 00010
Published on 29-Mar-2025

Reliable delivery of high pure cannabidiol from chemical synthesis

PRODUCT PROFILE

Cannabidiol (CBD) is a naturally occurring compound found in the plant species Cannabis; Cannabis sativa, Cannabis indica, particularly in hemp. CBD is non-toxic and non-psychoactive, unlike other popular cannabinoids. CBD is known for its potential therapeutic properties, such as anti-inflammatory, analgesic, anti-anxiety, and neuroprotective effects. It is commonly available in various forms, including oils, capsules, edibles, and topical applications. However, it was approved only for certain rare seizure disorders associated with Dravet syndrome, Lennox–Gastaut syndrome, or tuberous sclerosis complex in people one year of age and older by USFDA/EMA under the brand name Epidiolex/Epidyolex respectively. It is the first prescription formulation of plant-derived cannabidiol approved by regulatory bodies in the US and Europe.



Structure of Cannabidiol

MSN development motto for Cannabidiol

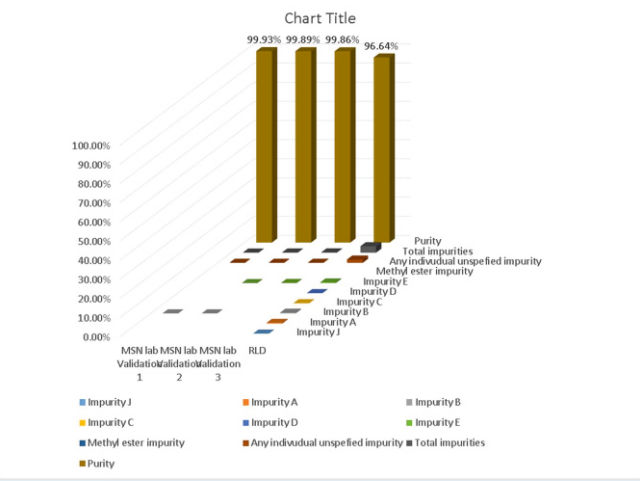
Beyond the approved indications for Dravet syndrome, Lennox-Gastaut syndrome, and Tuberous Sclerosis Complex (TSC), there are ongoing preclinical and clinical studies exploring the therapeutic potential of Cannabidiol (CBD) for various other pathological conditions like Chronic Pain, Anxiety and Depression, Neurodegenerative Disorders, Sleep Disorders, Skin Conditions etc. These studies are investigating its efficacy, safety, and mechanisms of action. It could become an important part of the treatment regimen for these ailments post successful trials, results and regulatory approvals. Consequently, development of CBD, derivatives or analogues of CBD would further stretch the companies diverse drug portfolio.

MSN's high pure synthetic Cannabidiol

The chemical synthesis of Cannabidiol has yielded high pure material compared to that from natural sources. Subject to its recommended maximum daily dosage ICHQ3A recommends to control any specified and unspecified impurities in Cannabidiol to NMT 0.05%. MSN's Cannabidiol is superior in quality . The quality meets both the ICHQ3A recommendations and Ph. Eur specification.

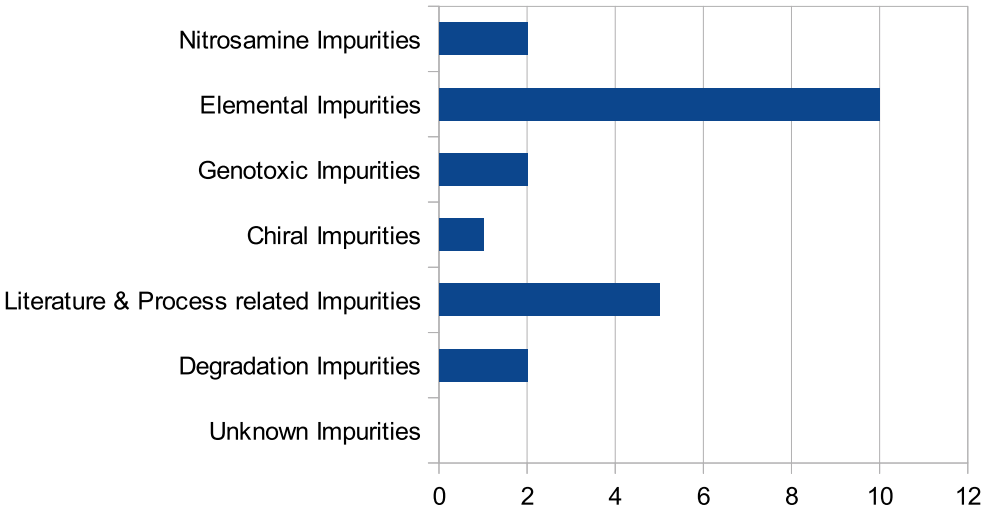
Quality of MSN Cannabidiol

The validated manufacturing process of Cannabidiol has been the result of insightful investigations and innovations with cutting edge technologies. API produced with validated process demonstrated superior quality. The quality comparison between the validation batches of MSN and RLD samples is given below.



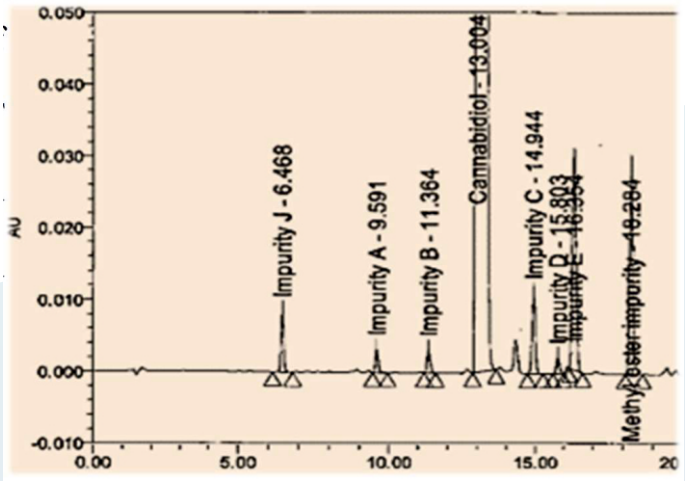
Defining quality of Cannabidiol by Impurity control

Nearly 25 impurities were identified, synthesised, characterized and confirmed its control or absence at different steps of Cannabidiol manufacturing process. The impurities belong to different classes such as process related, degradation, genotoxic and nitrosamine. Genotoxic and nitrosamine impurities are having well control. Below picture gives a glance of the MSN scientific team efforts and efficiency to nail down the unspecified impurities to zero hailing the make of Cannabidiol as one of the classic example in the MSN regulatory compliant landscape.



Analysis of MSN Cannabidiol

A precise HPLC method was developed and validated to quantify process related impurities and degradation impurities of Cannabidiol. The following HPLC SST chromatogram demonstrates the method capability for identification of all degradation and process related impurities.



The drug substance is characterized using orthogonal analytical techniques based on its physico-chemical properties such as intact mass, 1D and 2D NMR, IR, UV, PXRD, DSC, TGA, SOR etc.

Why to choose MSN Cannabidiol:

- API production through synthetic route.
- High quality API (Purity > 99.50 %) with the unspecified impurities below 0.05% as per ICH Q3A. Complies with Ph. Eur specification.
- Stable crystalline polymorph at controlled room temperature.
- Stability study data and Polymorph stress study data are available.
- MSN produced API is free from Genotoxic & Nitrosamine impurities.
- Elemental impurities are in compliance with ICH Q3D.
- Identified, synthesised and characterised nearly 25 impurities of different classes to ensure their control/absence and delivery of high pure Cannabidiol.
- Precise and validated HPLC methods are at hand to ensure high quality Cannabidiol.
- State of the art FDA approved manufacturing facility to manufacture Cannabidiol at multi kilo level to cater the global demand.
- MSN has pool of scientists with an expertise in process development, scale up and analytical method development with integrated understanding of IP, Regulatory affairs of different regions.

INNOVATIVE AND CREATIVE SYNTHETIC TECHNOLOGIES AND ARTISTIC APPROACHES WILL BE CONTINUED FROM MSN SCIENTIFIC EXPERT TEAM TO INSPIRE PHARMA COMMUNITY AND DELIVER HIGH QUALITY DRUG SUBSTANCES TO THE NEEDY.

Disclaimer : *This 'MSN SCIENTIFIC SPARKLES' is meant only to showcase MSN's capabilities. Products under patent protection would be offered and supplied by MSN only for development, testing and regulatory submission related activities which are covered under Bolar Exemption or Experimental use exception available in respective countries and as provided under Section 107A of the Indian Patents Act, 2005.*