



Vijaya (Cannabis sativa): Medicinal facts, myths,-regulatory and molecular aspects

The plant Vijaya (*Cannabis sativa*) has a long history of medical use in the treatment of pain and spasms, insomnia, and the suppression of nausea and vomiting. Therapeutic use of Vijaya and its formulations have been mentioned in Ayurveda granthas as Bhavprakash nighantu, Shodhal nighantu. However, in the 19th century, Cannabis was classified as a narcotic drug and medicines made out cannabis came to be strictly regulated in countries all over the world. In India, the use of cannabis is regulated by The Drugs and Cosmetics Act, 1940 (DCA).

Cannabis as a plant, and its flowers and buds (popularly known as 'Ganja') are regulated as a "narcotic drug" under The Narcotic Drugs and Psychotropic Substances Act, 1985 (NDPS Act), but its leaves (popularly known as 'Bhang') and seeds when separated from the plant, or when separated from the flower and buds (Ganja), are not regulated as a 'narcotic drug' under NDPS Act. Therefore, ayurvedic medicines that contain Bhang or Vijaya seeds as an ingredient are not regulated as a narcotic drug under NDPS Act.

However, there is a widespread and popular misconception that medicines made from Bhang or Vijaya seeds are narcotic drugs and therefore will require special license for sale, even by practitioners of Ayurveda. To remove this misconception, and to repose confidence of ayurvedic practitioners in the medicinal benefits of Vijaya which have been ignored for so long, this document reviews the literature and therapeutic potential of Cannabis based Ayurvedic Proprietary Medicines in India.

As the existing laws in India stand, there are absolutely no restrictions or limitations to legally utilizing the fibre, seed & leaf of the Hemp plant to develop & commercially distribute products, particularly so since the NDPS Act recognizes the fibre, seed & leaf (Bhang) from the definition of Cannabis in the NDPS Act.

From a cultivation perspective;

As per Section 14 of the NDPS Act, notwithstanding anything contained in section 8, Government may, by general or special order and subject to such conditions as may be specified in such order, allow cultivation & utilization of any cannabis plant for industrial purposes only of obtaining fibre or seed or for horticultural purposes.

Within the state of Uttarakhand, several developments have taken place on this front :-

- The state government has issued a letter to Excise Commissioner through [letter no. 639/XXX111/2016/04\(02\)201 dated 05 December 2016](#) for the cultivation Industrial Hemp within the limits of 0.3 THC.
- Government of Uttarakhand has authorized through [letter number 581/XXIII/2018/04\(11\)/2012 dated 29 May 2018](#), Centre for Aromatic Plants, Selaqui, Dehradun, and National Botanical Research Institute, Lucknow as a technical testing lab of testing crop sample for delta-9-tetrahydrocannabinol concentration in Industrial Hemp as described in the state government order to Excise Commissioner on 05 Dec 2016.
- The government has issued a [letter no. 348 dated 18 April 2018](#) to Excise Commissioner on Medical and Scientific use of cannabis plants by the R&D institutions.

- Centre for Aromatic Plants, Selaqui, Dehradun is nominated as a nodal agency for the cultivation of Industrial Hemp through [Government order number 984/XVI-2/19/19\(23\)/2019 dated 30 December 2019](#).

This follows in the footsteps of positive policy & regulatory developments in countries such as U.S.A where The Agriculture Improvement Act of 2018 (2018 Farm Bill) authorized the production of hemp and removed hemp and hemp seeds from the Drug Enforcement Administration's (DEA) schedule of Controlled Substances. It also directed the U.S. Department of Agriculture (USDA) to issue regulations and guidance to implement a program to create a consistent regulatory framework around production of hemp throughout the United States. The establishment of hemp as a regulated commodity also paves the way for U.S. hemp farmers to participate in other USDA farm programs.

Furthermore, Section 8 and Section 10 of the NDPS Act allow state governments to permit the cultivation & utilization of cannabis exclusively for horticultural, industrial, medical, and scientific purposes.

State Governments of Himachal Pradesh, Uttarakhand and Manipur are presently finalizing policies & laws to allow for the legal & licensed cultivation of Cannabis for medical & scientific purposes.

References :-

1. <https://bit.ly/3di1W2R>
2. <https://bit.ly/3DjiaDI>

From a licensed manufacturing use perspective:

Bhang is not regulated by NDPS Act

The Cannabis Sativa leaf (Bhang) falls under Schedule E(1) of D&C Rule 1945 as a potentially poisonous substance of vegetable origin under the AYUSH Systems of medicine.

Other herbs classified in the same category (vegetable origin) under Schedule E(1) of D&C Rules 1945 as Cannabis leaf include Wild Castor(Danti), Rosary Pea(Gunja), Purging Croton (Jayphala), Indian Oleander (Karavira), Climbing Lily (Langli), Black Henbane (Parasika Yavani), Common Milk Hedge (Snuhi) amongst others.

As per Rule 161(2) of the Drugs and Cosmetic Rules, 1945 AYUSH medicines containing a Schedule E(1) ingredient can legally be taken are taken under medical supervision. As per legal provisions, manufacturers require to ensure caution is to be printed on the label of the container of such medicines.

No restriction on sale of Schedule E(I) substance to own patient by AYUSH practitioner

The Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982 do not restrict sale of ayurvedic medicines containing Schedule E (1) substances by a registered ayurvedic practitioner himself or herself, provided such medicine is sold to his or her own patients and not to public at large.

Hemp as FSSAI approved ingredient

With respect to Hemp seeds, in 2021 under Gazette notification CG-DL-E-20112021-231259: Extraordinary: Part III, Section 4, Sub-section 2.16 The hemp seed, hemp seed oil and hemp seed flour shall be sold as food or used as an ingredient in a food for sale subject to conforming to certain technical standards.

The regulation passed by FSSAI is a positive step towards the development of Hemp in the category of Foods, Dietary supplement, and Nutraceuticals in India. This gives all the FBOs (Food Business Operators) to manufacture, distribute and market products derived from the Hemp seeds as an ingredient under FSSAI.

BOHECO's Forward Statement:

BOHECO's approach to business is unlike in the North American markets where recreational Cannabis is being hyped & propagated from a commercial + regulatory lens (Example – Recent Federal developments in Canada to legalize recreational Cannabis + developments in USA to amend Controlled Substances Act to exclude Cannabis), we in India are steering away from any potential misuse or abuse of the Bhang plant. Instead, we are offering a range of pain alleviating & anxiolytic products/formulations through the ancient & holistic science form – Ayurveda while developing modern clinical safety & efficacy data through human grade clinical studies around the same.

We work towards improving the quality of life of our consumer and patient groups through clinically validated state-of-the-art hemp & cannabis-based products. Therefore, our vision is to be a vertically integrated (lab-farm-factory-market) direct-to-consumer brand that is environmentally sound, socially inclusive and economically equitable.