

NBRMAP-DB, AN AYURVEDIC PROPRIETARY FORMULATION FOR THE MANAGEMENT OF TYPE-II DIABETES AND ASSOCIATED SYMPTOMS A JOINT PRODUCT OF CSIR-NBRI & CSIR-CIMAP



Prelude: NBRMAP-DB is a formulation based on reverse pharmacological approach combining the aqueous extract of six traditionally used plants of medicinal importance mentioned in the authoritative texts of Ayurveda (Bhavprakash). The selection of these plants primarily is based upon the traditional usage, clinical experience of Ayurvedic practitioners, and the scientific knowledge available on these plants related to their effects on blood sugar metabolism.

Selected Plants: *Trigonella foenum-graecum* L.(मेथी), *Pterocarpus marsupium* Roxb.(त्रिजयसार), *Gymnema sylvestre* Rbr.(गुडमार), *Berberis aritata* DC.(दारुहरिद्रा), *Rubia cordifolia* Linn. (मंजीठ) & *Tinospora cordifolia* Miers.(गिलोय).

Plant processing and Standardization:

- Standardized aqueous extraction (शीतकषाय) of all the six plants prepared separately and characterized physico-chemically.
- Thin Layer Chromatographic (TLC) fingerprinting of each plant has been derived for quality control.
- Final formulation (NBRMAP-DB) assessed through parameters of Ayurvedic Pharmacopoeia of India (API) for batch to batch consistency viz., extractive value, TLC profile and microbial load.
- HPTLC profile of the NBRMAP-DB developed for quality control.

Pre-clinical studies on safety and efficacy:

- Acute oral toxicity studies of individual plant extracts and the final formulation on lipid metabolism (Cholesterol, Triglycerides, HDL and LDL), Liver function (SGOT & SGPT), and kidney function (Creatinine) in mice.
- Effect of individual extracts and the final formulation on bodyweight, blood glucose, systolic & diastolic blood pressure and pulse rate for 14 days in rats.
- Oral glucose tolerance test of individual plant extracts and the final formulation in mice and rats separately.
- Effect of the final formulation on the blood glucose levels in Streptozotocin induced diabetic rats for a period upto 21 days.
- Effect of the final formulation on the liver function, kidney function and lipid profile of diabetic rats.

Clinical studies:

- Conducted by M/S AIMIL Pharmaceutical Pvt. Ltd. at Agarwal Dharmath Society Hospital, Delhi.

Regulatory compliance:

- NBRMAP-DB falls under 'औषध घन' category of Ayurvedic Proprietary Medicine included in the Ayurvedic Siddha and Unani drugs, under the 6th Amendment (2010) of the Drugs and Cosmetic Act, 1940.
- The guidelines apply to the use of aqueous or hydroalcohol extracts from medicinal plants mentioned in the books of the first schedule.
- Under this category, if the ingredients of the proprietary medicine are as per the authoritative texts (भावप्रकाश in case of NBRMAP-DB) and the indications are as per the textual rationale (प्रमेह or मधुमेह), then the safety studies and experience/evidence of effectiveness is not required.

Brief chronology of events:

- Knowhow of the formulation NBRMAP-DB released on 22nd Feb 2014.
- Licensing / transfer of knowhow for NBRMAP-DB to M/S AIMIL Pharmaceuticals on 12th May 2014.
- Launching of commercial product **BGR-34** by M/S AIMIL Pharmaceuticals on 25th October 2015.



Methika



Vijaysar



Gudmar



Daru haridra



Majeeth



Giloy

