

DOSSIER RELEASE
(PROJECT ONNISHAAKATHAKAADHI KASHAYAM)

Ayurveda, being an age-old classical system of healthcare, had remained a less-controversial Indian system of medicine within the country through centuries. As regulatory mechanism was less stringent, research on formulations and manufacturing processes were limited to random studies. This being the situation, ayurveda never came to the forefront of modern scientific research.

Thenon-insistenceonin-depth scientific studies on the therapeutic actions and adverse effects of products has led to thriving of spurious products and quacks in Ayurveda. Many have developed fear for Ayurveda preparations because of the ill effects reported on unscientific formulations. This situation calls for controlled studies that conclusively demonstrate efficacy and safety. Adequate preclinical as well as clinical safety and efficacy data is also an essential regulatory requirement in many countries, lackof which limits the export potential of Ayurveda to a few neutraceutical formulations.

It was in this context that the National Innovation Council (NInC),chaired by the Prime Minister's Scientific Advisor Sri. Sam Pitroda, helped and supported us conduct a study on *Nishaakathakaadhikashayam*(NKK), a widely prescribed ayurvedic formulationfor diabetes.The study was conducted at CARE KERALAM Ltd, a Common Facility Centerestablished with support of the AYUSH department, Govt. of India. It was a comprehensive multidisciplinary study on the eight raw materials,and the Ayurvedic product formulated from them, demonstrating its efficacy and toxicity on rats.

The project outcome is adossier (drug master file) which is first of its kind in Ayurveda. The dossier contains quality control parameters of ingredients, product profile, manufacturing process, toxicity studies, and anti-diabetic activity in rats with streptzocin induced diabetes. In addition, the dossier also contains formats for regulatory submission, drug licencing and GMP certification.

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Benefit to industry: (i) The scientific findings on NKK is a value addition for the product already marketed by different companies, (ii) The dossier can be used for preparing drug master files for registering *Nishaakathakaadhikashayamin* other countries as an anti-diabetic drug, and this will improve market penetration and sales.

Benefit to Ayurveda: (i) Further investigations of the compounds identified from the formulations and its targeted site could lead to new information leading to patent registration (ii) The present study throws light on the need and usefulness of conducting similar studies on all classical herbal formulations (iii) Similar studies on other products will fetch a fair space for Ayurveda in modern science.

Benefit to the cluster (CARE KERALAM): The NIC initiative helped establishment of technical collaborations between CARE KERALAM and CSIR, and this has strengthened the scientific capability of the cluster.