



## SHORT COMMUNICATION

# Quality and Safety Studies of Metal and Mineral-based Ayurveda Formulations under Golden Triangle Project (GTP) Initiative: A Short Appraisal

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The Golden Triangle Partnership concept emerged in a National Workshop on Ayurveda Research organized at Chitrakoot from 24th to 26th May, 2003 where it was decided to set up an integrated technology mission for the development of Ayurveda and traditional medical knowledge based on synchronized working of modern medicine, traditional medicine and modern science with special budgetary support. Subsequently, in a meeting on 8th July, 2004, Secretary, Department of AYUSH, Director General, CSIR and Director General, ICMR decided to work together to achieve safe, effective and standardized classical Ayurvedic products for the identified disease conditions and to develop new Ayurvedic and herbal products effective in disease conditions of national/global importance. It was also decided to utilize appropriate technologies to develop single, poly-herbal and herbo-mineral products and to develop products which have IPR potentials.

Under this initiative the council has coordinated and executed the quality and safety studies of eight most commonly used Ayurvedic *Rasa kalpa* (herbo-mineral formulations) in clinical practice. *Rasa Kalpa* (herbo-mineral formulations) of Ayurveda contains specified metals or minerals, as composition, along with various herbs which have their beneficial effects on biological systems. Their practices became popular and widely accepted since long, as these *rasa-aushadhi* are having qualities

such as instant effectiveness, requirement in very small dosage and ample therapeutic utility.

Ayurvedic *Rasa aushadhi* has specified different methods of preparation and standard operative procedures (SOPs) right from the collection of raw ingredients, their purification, processing of intermediates, method of use, dosage forms etc. These metals or minerals are transformed into nontoxic forms through these meticulous procedures explained in Ayurveda. Though literature is available on quality aspects of such herbo-mineral formulations; in recent past there has been certain apprehensions on safety aspects of metal based Ayurveda formulations and certain myths are prevailing across the country and globe in this regard.

To take full advantage of the usage of potential sources of traditional healthcare, there is need to draw attention towards a number of issues related to policy on safety, efficacy, quality, accessibility and rational use. Considerable efforts have been put in by the Central Council of Research in Ayurvedic Sciences under Ministry of AYUSH in generating tangible evidence on safety of these interventions.

Through golden triangle partnership Scheme (GTP) coordinated by CCRAS-Ministry of AYUSH, the council has generated evidences on quality standards, chemical characterization and safety of eight such most commonly used metal and mineral based medicines in clinical practice viz. *Rasa Manikya*, *Kajjali*, *Rasa Sindura*, *Vasant Kusumakara Rasa*, *Arogyavardhini vati*, *Maha Yoga-rajya Guggulu*, *Makardhwaja*, *Mahalaxmivilas*, in collaboration with reputed organizations of CSIR viz. Indian Institute of Toxicology Research (CSIR-IITR) Lucknow, Indian Institute of Integrative Medicine (IIIM) Jammu, Central Drug Research Institute (CDRI), Lucknow and Indian Institute of Chemical Technology (IICT), Hyderabad.

In this scheme, these *Rasa kalpa* were prepared as per SOPs/standard guideline mentioned in classical texts and to analyze it chemically which includes organoleptic, physicochemical parameters (following standard methods as per Ayurvedic Pharmacopoeia of India (API) guidelines), assay of elements by ICP-MS, HPTLC, X-ray diffraction (XRD) to ensure the quality of the drug.

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Safety studies of these formulations were also done on animal models. The safety studies were done following Standard methodologies and reference standard as per OECD 408 guidelines (standard protocol decided under GTP project), followed by approval by the Institutional Animal Ethics Committee for each study.

The inferences and the standards laid down in these studies, revealed that the herbo-mineral Ayurveda formulations that are prepared strictly following the SOPs laid down in classical Ayurveda texts, from the beginning, intermediates to final product, are found to be safe in sub chronic toxicity studies, even at 10 times of the therapeutic dose. These results substantiate the safety of these formulations which endorses the use of these drugs without any safety concerns if prepared properly. The Council has brought out the findings of these studies in the form of Research publications<sup>1-4</sup> and technical reports volume 1 and 2.<sup>5,6</sup>

The findings of these studies can certainly be utilized as an important tool for standardization and quality assurance of these herbo-mineral formulations and in pharmaceutical studies and for regulatory authorities.

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