

## ***Final Report***

### ***Study Title: Phase I study of the possible toxicity of the Ayurvedic preparation, Rasna Sapthakaya in Healthy Volunteers***

*The study was approved by the Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura (Ref: 46/14) and Registered in Clinical Trial Registry, Sri Lanka (Reg.No. SLCTR/ 2015/ 006).*

- Study period 09.03.2015 – 20.04.2015
- Study sites : University of Sri Jayewardenepura and Institute of Indigenous Medicine
- The bulk amount of ingredients of Rasna sapthakaya decoction were purchased from Karunaratna & Company (Main Ayurvedha herbal suppliers), Mulleriyawa and identified and authenticated by Dr. J. M. Dahanayake.
- The ingredients were washed thoroughly and dried and then cut into small pieces and packed hygienically at the Ayurvedha Pharmacy of Institute of Indigenous Medicine, UOC, Rajagiriya.
- During the study period, the decoction was prepared freshly in everyday morning using standard Ayurvedha conventional method at Ayurvedha pharmacy/ IIM. The decoction was distributed in air tight dark glass bottles to the participants.
- Healthy volunteers, aged 18 – 60 of either sex were recruited by advertisements displayed in the notice boards of Department of Biochemistry/FMS/USJP and Institute of Indigenous Medicine / UOC. Written consent was obtained from the participants before initiating the study and the information sheet and diary were distributed to the participants in their own language.
- Thirty healthy volunteers were included to this study and every day, freshly prepared decoction was distributed for 14 days (Dosage 120ml / 60Kg /- bd). Blood was drawn on Day 0, 8 and 15. The blood samples were drawn by qualified Phlebotomists at Family Practice Centre, Dept of Community Medicine / FMS/USJ and Medical Centre / IIM
- The blood samples were immediately transferred to the Department of Biochemistry/FMS for serum separation, and the serum samples were stored at -20°C. The liver and kidney functions tests (ALT, ALP, AST,  $\gamma$ GT, Creatinine and urea) were done using the automated biochemical analyser (Kone) at the Department of biochemistry. The kits were purchased from Analytical Instrument (Pvt) Ltd, Colombo.
- According to the findings of the study in tested parameters, there were no statistically significant ( $p>0.05$ ) changes observed in Day 8 and 15 when compare to the base line values (Day 0).
- Therefore from the findings of this study, it can be concluded that, Rasna sapthakaya decoction is not cause any significant adverse effects in the human body at the human therapeutic dose using in Ayurvedha.