Assessment on quality control parameters of a newly developed herbal drug from *Coccinia grandis* (Family: Cucurbitaceae)

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Herbal drugs, due to their long historical clinical uses and excellent therapeutic efficacy, have been widely used for the management of chronic diseases as diabetes mellitus in Sri Lanka. The assessment of quality control parameters in newly developed herbal drugs is important before the prospective clinical trials. The new drug will be used in the management of diabetes mellitus particularly in patients with mild hyperglycaemia. The objective of the present study was to assess such parameters of a herbal drug developed from the freeze-dried powder of hot water leaf extraction of *Coccinia grandis* (Linn.) Voigt using *in vitro* protocols. Physicochemical parameters of the herbal drug were determined according to WHO standard methods. Thin layer chromatograms (TLC) were developed using a solvent mixture of dichloromethane, methanol and cyclohexane (3.8:0.1:2.0). The detection of heavy metal (Hg, As, Cd, Pb) contamination was carried out according to Association of Analytical Communities (AOAC) method. The analysis of microbial contamination was carried out using Sri Lanka Standard (SLS) method. Physicochemical analysis revealed that the herbal drug of *C. grandis* contained 42.9±0.1% total ash, 22.4±0.8% water soluble ash, 0.2±0.02% acid insoluble ash and 6.3±0.2% moisture. TLC revealed the presence of several chemical constituents in the herbal drug. Heavy metals were not detected in the drug. Microbes such as *Escherichia coli*, *Salmonella* and total coliforms were not present in the drug. The quality control parameters obtained from the present study satisfy the requirements that the herbal drug of *C. grandis* suitable for further studies in clinical trials.

Keywords:*Coccinia grandis, herbal drug, heavy metal analysis, physicochemical parameters*