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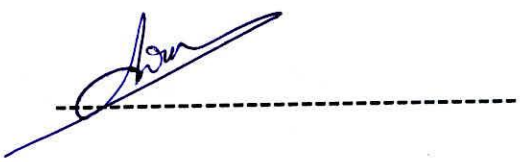
Quality Assessment and Standardization of "Seetharama Watee" and "Maha Wanthikava Watee"

in

Tissa Hewavithana

Thesis Submitted to University of Sri Jayewardenepura for the award of the Degree of Doctor of Philosophy in Food Science and Technology on 2012

The work described in this thesis was carried out by me under the Supervision of Prof. K.K.D.S. Ranaweera Prof. M.H.A. Tissera and Prof. P.A.J. Yapa and a report on this has not been submitted in whole in part to any university or other institution for another Degree/Diploma.



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We certify that the above statement made by the candidate is true and that this thesis is suitable for submission to the University for the purpose of evaluation.

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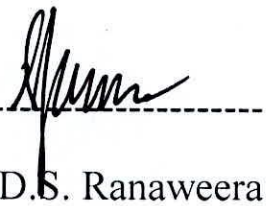

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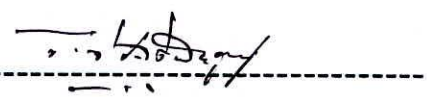

Prof. P.A.J. Yapa

AFFECTIONATELY DEDICATED

TO

My Late Mother and Father

Table of Contents

Chapter 3

Materials and Methods:

Chapter 4

Results and Discussion:

Chapter 5

Conclusion:

Chapter 6

References:

Chapter 7

Appendices:

List of Tables

List of Figures and plates

Abbreviations

SW-Seetharama Watee **VW**-Maha Varthikava Watee

$1S_0$ authentically prepared Seetharama sample 1

$2S_0$ authentically prepared Seetharama sample 2

$3S_0$ authentically prepared Seetharama sample 3

S_1 Commercial Seetharama sample 1

S_2 Commercial Seetharama sample 2

S_3 Commercial Seetharama sample 3

S_4 Commercial Seetharama sample 4

S_5 Commercial Seetharama sample 5

$1V_0$ authentically prepared Maha Varthikava sample 1

$2V_0$ authentically prepared Maha Varthikava sample 2

$3V_0$ authentically prepared Maha Varthikava sample 3

V_1 Commercial Maha Varthikava sample 1

V_2 Commercial Maha Varthikava sample 2

V_3 Commercial Maha Varthikava sample 3

V_4 Commercial Maha Varthikava sample 4

V_5 Commercial Maha Varthikava sample 5

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ABSTRACT

In present context, standardization of herbal drugs is a crucial issue in herbal drug industry as there are unauthentic counterparts found in the market. **Seetharama Watee (SW)** and **Maha Varthikava Watee (MV)** are two effective herbo mineral and poly herbal drugs, recorded in Sri Lankan ancient text **Watika Prakaranaya** published in 1879. **SW** contains 28 herbs and 9 minerals and mainly effective on febrile illnesses while the **MV** contains 29 herbs, and very effective in curing digestive tract disorders. As commercially available products may have not been prepared according to the authentic formulas, their efficacy would not be the same as that of the authentic formulas. This work aimed at generating physico-chemical, spectrophotometric and chromatographic fingerprints for the standardization of these two drugs to confirm their authenticity. Following the authentic formulas, the pills of two drugs **SW** and **MV** have been prepared. In the preparation of **SW**, the powdered herbs and minerals were mixed thoroughly and ground for 7 days using 5 herbal juice extracts and 2 oils. In the preparation of **MV,** all herbals were purified and finely powdered and mixed thoroughly and ground using 3 juice extracts and bee's honey. These pills were made to the size of a green gram grain and dried under shade. Three batches of the two formulations were prepared to account for seasonal changes and were compared with five commercial samples. The quality test for purity and test for the identity were considered as tools for the standardization. One way ANOVA followed by the Dunnett t- test was used in the analysis of data at 0.05 significant level. The SPSS statistical package was used for this data analysis. When considering the variation of the weight of prepared pills, the mean

weight of **SW** and **MV** 10 pills were 1.3±0.04 g and 1.2±0.06 g respectively. pH of the 10% aqueous solutions of two preparations were 5.4±0.15 and 4.6±0.07 respectively, the mean specific gravity of the mean values were 1.2±0.01 and1.2±0.03, the mean values of weight loss on drying were 9.3±0.97 g and 12.3±0.48 g respectively. In ash content, the mean values were 10.1±0.59 g and 6.8±0.17 g respectively. The mean values of acid insoluble ash of the two formulations were 0.49±0.03 g and 0.09±0.07 g. When considering the crude fiber the mean values were 7.9±1.01 g and 8.4±1.8 g. Mean values of the disintegration time, friability and hardness of **SW** were 21.7±3.61 min, 0.77± 0.1%, and 1.3±0.08 kg/cm^2 while for **MV** they were 30.5±2.8 min, 1.1±0.08% and 0.78±0.12 kg/cm^2. Mean weight of the drug extract (residues) of hexane, dichloromethane, ethyl acetate and methanol of **SW** were 26.5±1.4% w/w, 2.4±0.03% w/w, 1.5±0.18% w/w, 8.4±1.5% w/w and 6.1±0.84% w/w, 1.7±0.2% w/w, 2.2±0.52% w/w, 15.3±4.4% w/w for **MV** respectively. When comparing the authentically prepared samples with the commercial counterparts using the above mentioned parameters, some samples were significantly different whereas others were not at the level of 0.05 In the IMVIC test, the microbial content of both preparations were less than the WHO recommended level. The TLC fingerprints of some raw materials were interconnected with these formulations. Aflatoxins were not present in any of the two preparations. Hg and As were present in standard levels and Pb and Cd levels were under the levels WHO recommendation limits in **SW**. In **MV,** all heavy metal contents were under the WHO recommendations. The λ_{max} of uv/vis spectrum of **SW** was 287 nm; 287 nm and 345 nm for **MV**. Five peaks in the **SW** and seven peaks in the **MV** were identified in the HPLC fingerprints of the authentic samples. Hence, **SW** and **MV** can be standardized using the above mentioned measurements.