Microbiological study of selected herbal preparations widely used in Indigenous system of medicine in Sri Lanka with a view to defining Microbial quality standards relevant to Good Manufacturing Practice.

By

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Abstract

Plant materials contain an inherent microbial flora and may be contaminated during processing. Therefore World Health Assembly (WHA) has given the following limitations for herbal preparations, Aerobic bacteria $1x10^5$/g for internal use and $1x10^7$/g for topical dosage forms. Fungi $1x10^4$/g,E-coli-$1x\ 10^2$ /g, and Salmonellae- None in internal and external dosage forms.

The present study was carried out to asses the general microbial load, identify the specific micro-organisms, define an acceptable microbiological quality standards, and finally to suggest ways to prevent contamination in compound preparations and to study the anti microbial effects of some compound preparations. Various formulations Choorna, Kalka, Vatika, Arista & Asawa , Thaila and Lepa were subjected to the study.

According to statistical analysis microbial counts of all the powder preparations exceeded the limitations given in WHA. Only Buddharaja Kalka, was found falls within the WHA limitations. Chandra Kalka, and Desadun Kalka preparations were within the acceptable limits for Bacterial counts. The microbial load on tested Oil samples, Jeewananda vati, Suranvidura Vati and Samples of Dashamoola Arista, Aravinda Asawa, Pippalyadiyasawa were also within the WHA limits. Except Dashanga lepa other two lepa preparations were within the acceptable limitations.

Isolated pure stock cutlers of bacteria and Fungi were identified through biochemical tests and slide culture techniques. Most of the bacterial stock cultures belong to the genus Bacillus . The isolated fungi were identified as Penicillium Sp, Aspergillus Sp, Mucor Sp, Rhizopus Sp, Fusarium Sp.

Three Thalisadi Choorna and two Chandra Kalka preparations gave positive results for *salmonellae*. None of the preparations tested were positive for *E -Coli* accept four Dashanga lepa preparations.

Antimicrobial activity was tested using ATCC cultures. Hinguastaka Choorna and Manibadra Choorna showed anti microbial effect on *Salmonellae typhi.* Thriphaladi Choorna showed anti microbial effect on *Pseudomonas aeruginosa.* Sarvavisadee Oil was active against *Pseudomonas aeruginosa, Staphylococcus aureas Sp, Salmonellae typhi, and klebsiella.* Buddharaja Kalka was active against *Pseudomonas aeruginosa, Staphyloccous aureas Sp and Bacillus cereus.*

Hazard Analysis and Critical Control Point (HACCP) analysis was done on the manufacturing process of Thalisadi Choorna. The results reveal that the implementation of Good Manufacturing Practice (GMP) and HACCP principals could contribute to microbiologically safe end products. Simultaneously methods to control the microbial load and the effect of the pre treatment methods on the drugs were also studied. The steam treatment method was found to be and effective method to reduce the microbial load. The volatile oil content and the Thin Layer Chromatographic (T.L.C) pattern of the stream treated and untreated samples of Thalisadi Choorna were tested. The T.L.C. patterns and the volatile oil content of both samples were comparatively same, indicating that this treatment method had no effect on the drug.

This study reveals that the microbial load on Choorna preparations were above the acceptable limits and some of the preparations were contaminated. Implementation of the GMP and HACCP principles can reduce the microbial load and exclude the contaminations. Studies on the antimicrobial activity highlighted the justification of use of these compound preparations in common infective conditions.