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Quality Parameters of Polyherbal Formulation of Three Different Marketed Brands of *Vilwadi Gutika*: A Comparative Evaluation Study

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ABSTRACT

Background: Ayurveda is a highly beneficial medical system due to its natural components that effectively eliminate disease causes, restore balance, and prevent further recurrence. Polyherbal formulations are highly popular due to their wide therapeutic range, making them safe at high doses and producing minimal negative effects when taken improperly. The goal of this study was to standardize the efficacy and quality of commercial herbal tablet formulations.

Methods: Three marketed samples of vilwadi Gutika ware used for the study. After authentication of the samples, the phytochemical stander like determination of pH, ash value, acid insoluble ash, water soluble ash, water soluble extractive, alcohol and soluble extractive were determined. In vitro anti-microbial activity was determined using Agar well diffusion method and the anti-inflammatory activity of Vilwadi tablet of different ayurvedic agency was assessed by in- vitro HRBC (Human Red Blood Cells) membrane stabilization method.

Results: The physicochemical properties of polyherbal pills met Pharmacopeial criteria, including pH, ash value, hardness, and friability. Sample 1 was the most acceptable, with a noticeable hardness (0.93) for rapid disintegration. The sample 3 (Vilwadi gutika – Arya Vaidya Pharmacy, Coimbatore) exhibited the highest antimicrobial activity against E. coli, Staphylococcus sp, and Candida sp, while sample 1 showed the highest activity against E. coli and Staphylococcus sp, and less activity against Candida sp. The in vitro anti-inflammatory activity shown that at concentration of 100µg / ml, the test compound inhibited 66.6 % of RBC haemolysis as compared with 54.16 % produced by Indomethacin (positive control) at 100µg / ml.

Conclusion: The investigation reveals that the Viladi gutika herbal formulation can be standardized using a scientific quality control technique, meeting Indian pharmacopoeia requirements for tablet dosage form, with further research needed to analyze other characteristics.

Keywords: Viladi gutika, anti-microbial activity, anti-inflammatory activity.

INTRODUCTION

Ayurveda is one of the most advantageous medical systems because it has several natural components that can be used to eliminate the main causes of disease by restoring balance and preventing further recurrence. Traditional medical systems are the only means of ensuring a long and healthy life.[1] Because the powerful phytochemical components of individual plants are insufficient to produce the desired therapeutic impact, the combination of different herbs (polyherbal) in a certain ratio will produce the desired therapeutic effect.[2,3] The polyherbal formulation combines two or more herbs with various

phytoconstituents that have either comparable or differing therapeutic potential and have been working together to provide positive results when treating human illnesses. [4,5] The popularity of polyherbal formulations is exceptional due to their broad therapeutic range, which makes them safe at high doses while yet producing few negative effects when taken improperly. [6,7]

The World Health Organisation (WHO) had provided a concise procedure for the standardization of herbal medicines. To ensuring that each final product that enters the market is free of adulteration, standardization is highly important.[8] Currently, Ayurvedic formulation has to be standardized for consistent quality.[9] This investigation aimed to standardize a commercial herbal tablet formulations for quality and effectiveness. Herbal formulations should be standardized so that their identification, quality, and purity can be verified.[10] This popularly used herbal tablet namely Vilwadi Gutika of different brands contains 10 herbs.

MATERIALS & METHODS

Procurement of samples and authentication

The following marketed viladi gutika were used in the present study. The authentication was done by the Botany Department, CMPR, Arya Vaidya Sala, Kottakkal. All 3 brands of Vilwadi gutika were procured from the ayurvedic pharmacy of local market.

1. Sample no.1 - vilwadi gutika-arya vaidasala kottakal, kerala (Batch no: 209905)
2. Sample no.2- vilwadi gutika-vaidyaratnam oushadhasala PVT.LTD (Batch no: 21C0564)
3. Sample no.3- vilwadi gutika- the aryavaidya pharmacy (coimabatore). LTD (Batch no: 864-048).

Ingredients in sample

Aegle marmelos- Bael(root), Ocimum sanctum- Holy Basil, Valeriana Wallichi-Indian Valerian (root), Cedrus deodara-Himalayan cedar (bark), Terminalia chebula- Belliric myrobalan fruit rind, Emblica offcinalis- Indian gooseberry fruit, Zingiber offcinalis- Ginger rhizomes, Piper nigram- Black pepper, Curcuma longa-Turmeric (rhizomes), Basta mutra- Goat urine.

Instrumentation

Digital pH meter (Pico, Lab India) was used, Dissolution test apparatus (Electro lab- USP TDT-08L), Disintegration test apparatus (Electro lab ED-2SAPO), Friabilator (Electro lab – USP EF-1W), Monsanto hardness tester (Dolphin), UV-visible spectrophotometer (Double beam) Shimadzu 1650 PC were used.

Physicochemical standards for polyherbal formulation

Determination of pH

One tablet each of three samples (sample no.1, sample no.2, sample no 3) was dissolved in distilled water to prepare 1% and 10% solution and PH was measured by using digital pH meter.[11-14]

Determination of ash value

3 gram of material was correctly weighed in a tarred silica dish at a temperature no higher than 450℃ until it was carbon-free. It was then chilled and weighed. The percentage ash was obtained by subtracting the empty weight of the crucible from the weight of the crucible with complete ash. [11-14]

Determination of Acid insoluble ash

The crucible holding entire ash was covered with a watch glass and heated for 5 minutes with 25 ml of weak hydrochloric acid. The ash-free filter paper was used to capture the insoluble materials, which was then washed with hot water until the filtrate was neutral. The filter paper-containing insoluble substance was transferred to a crucible, dried on a hot plate, and burned to a consistent weight. The acid insoluble ash content was determined as a percentage of the total acid insoluble ash. [11-14]

Determination of Water-soluble ash

Water soluble ash is that part of total ash content which is soluble in water. It is good indicator of either previous extraction of the water-soluble salt in the drug or incorrect preparation. The total boiled for 5 minutes with 25ml of water and insoluble matter was collected on an ash less filter paper washed with hot water and ignited for 15 minutes at a temperature not exceeding 450℃. Subtract the weight of insoluble matter from the weight of total ash gives water soluble ash value and the percentage of water-soluble ash was calculated. [11-14]

Determination of water-soluble extractive

In an enclosed flask, 25 gm of material was pulverized and macerated with 50 ml of water for 24 hours. The flask was shaken often for the first 6 hours and then left to stand for the remaining 18 hours. After 24 hours, filtering was completed quickly. Solvent evaporated at decreased pressure and temperature in a vacuumed evaporator. Water soluble extractives were determined based on the weight of the dried residue. [11-14]

Determination of alcohol-soluble extractive

Weigh accurately about 1g of coarsely powdered drug and macerate it with 100ml of ethanol (95%) in a conical flask for 24 hours. Shake occasionally in a such way that the total shaking period should be not less than 15 minutes, filter it rapidly through filter paper. Discard the first 25 ml of filtrate, collect second 25 ml of filtrate and transfer it to a tared porcelain dish, evaporate it to dryness and calculated the percentage of alcohol soluble extractive value. [12-14]

Quality control test of tablet as per IP (2010)

1. Hardness: 5 tablets of sample were taken to measure hardness. The hardness calculated and compared to IP standard.
2. Friability: 20 tablets of sample were used for test. Friabilator was run for 4 min at 25 rpm and percentage friability was calculated and compared with IP standard.
3. Disintegration Test: Disintegration test was performed using 6 tablets of sample. The media used for this test was distilled water and time required to disintegrate the tablet were recorded.

Weight Variation Test: 20 tablets were weighed individually. Average weight and % weight variation was calculated and compared with IP limit. [12-14]

***In vitro* antimicrobial study**

The antibacterial activity of Vilwadi Gutika (samples 1, 2, and 3) was determined using the Agar well diffusion method. The Muller Hinton agar plates were prepared and the bacterial cultures (*Staphylococcus sp, Escherichia coli*) and the fungal culture (*Candida sp*) were inoculated separately into the MHA plates by swab inoculation method and allowed to dry for 2 minutes. After inoculation, wells of 5mm diameter were bored on agar media equidistantly using a sterile well cutter. Different concentrations (0.1g/ml, 0.5g/ml, and 1g/ml) of each sample (1, 2 and 3) were prepared in sterile distilled water and 200µl of each concentration of appropriate samples were separately added to the wells on the culture inoculated plates using a sterile pipette. After sample diffusion, the bacterial culture plates were incubated at 37℃ for 24 hours and the fungal culture plates were incubated at 27℃ for 48 hours. After incubation, the zone of inhibition around diffused sample wells was observed and the diameter of the zone was measured.[15]

***In vitro* anti-inflammatory activity by HRBC method**

The anti – inflammatory activity of Vilwadi tablet of different ayurvedic agency was assessed by in- vitro HRBC (Human Red Blood Cells) membrane stabilization method. Blood was collected from healthy volunteers. The collected blood was mixed with equal volume of Al sever solution and centrifuged with isosaline at 3000 rpm for 10 minutes. To 1ml of HRBC suspension equal volume of test drug in three different concentration 100, 200 and 300 µg / ml was added. All the assay mixture were incubated

at 37 ° c for 30 minutes and centrifuged. The haemoglobin content in the supernatant solution was estimated by using spectrophotometer at 516 nm. The percentage of haemolysis was calculated by the formula, percentage of haemolysis = optical density (OD) of test / optical density of control X 100 and percentage protection = 100 – OD of test / OD of control X 100.[16]

RESULT

Despite the popularity of herbal medicine usage in modern medical systems, herbal medicines are not subject to the same supervision and control as conventional medications since they are seen as natural and hence harmless.[17] The physicochemical properties of the test products clearly meet Pharmacopeial criteria. The polyherbal pills were also evaluated for stability.[18] The physicochemical properties of all three samples were tested, including pH, ash value, hardness, friability, weight fluctuation, and *in vitro* disintegration time (table 1). The samples' hardness was tested in kg/cm^2 using a Monsanto tester. In terms of weight fluctuation and *in vitro* disintegration time, sample number 1 was judged to be the most acceptable of all the samples generated. This sample had a noticeable hardness (0.93), which aided in its rapid disintegration.

Table-1: Physicochemical standards for polyherbal formulation.

Sl no:	Parameters	Sample 1	Sample 2	Sample 3
1	pH at 1% and pH at 10 %	6 and 4	5 and 4	5 and 4
2	Total ash (%w/w)	5	4	13.6
3	Acid insoluble ash (%w/w)	6.33	5	16.6
4	Water- soluble ash (%w/w)	1.79	1.33	1.66
5	Water soluble - extractive value (%)	8	24	8
6	Alcohol soluble - extractive value (%)	16	20	20
7	Hardness (kg/cm2)	0.23	0.93	0.61
8	Friability (%)	5.61	1.99	5.35
9	Disintegration time (min)	12	10	15
10	Weight variation (gm)	0.63 – 0.94	0.54 -0.85	0.62-0.86

The result of antibacterial activity of 3 different samples are shown in figure 1. Among the three samples, sample 3 (Vilwadi gutika – The Arya Vaidya Pharmacy, Coimbatore) is having the highest antimicrobial activity against all three test organisms (*Escherichia. Coli (E. coli)*, *Staphylococcus sp*, and *Candida sp*) when compared to samples 1 and 2. The sample 1 (Vilwadi gutika- Arya Vaidyasala, Kottakkal) is showing the highest activity toward *E. coli* and *Staphylococcus sp* and the least antimicrobial activity against *candida sp*. Finally, sample 2 (Vilwadi gulika Vaidyaratnam) is having the highest activity against *Staphylococcus sp.* and *Candida sp* while less active towards *E. coli* (figure 1).

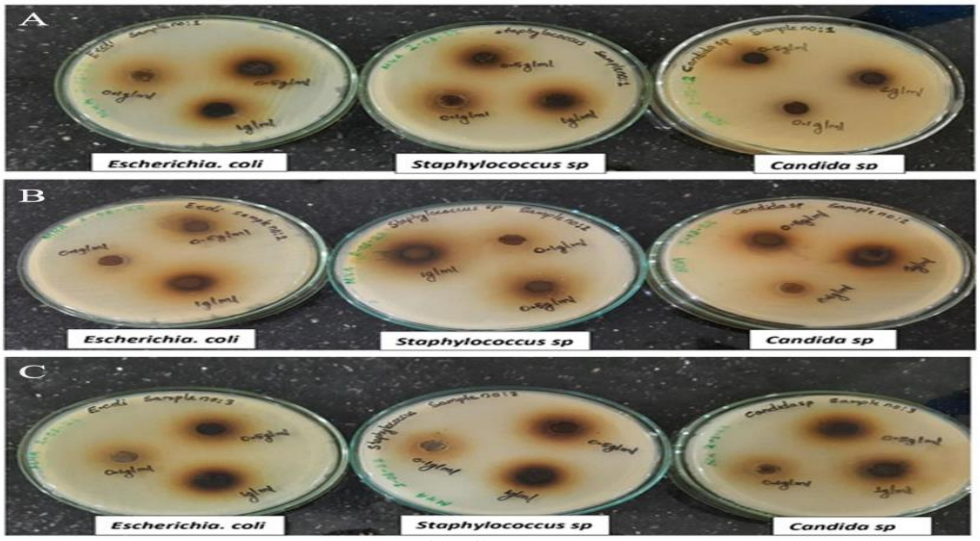

Figure 1. A, B and C represents antimicrobial activity of 3 different samples against *E. coli, Staphylococcus sp* and *candida sp.*

The test compound (Vilwadi tablet – Kottakkal Agency) at concentration range from 100µg / ml to 300µg / ml protects the human erythrocyte membrane against lysis induced by hypotonic solution. At concentration of 100µg / ml, the test compound inhibited 66.6 % of RBC haemolysis as compared with 54.16 % produced by Indomethacin (positive control) at 100µg / ml. The results obtained demonstrated that test compound can significantly and dose dependently inhibits HRBC haemolysis (figure 2).

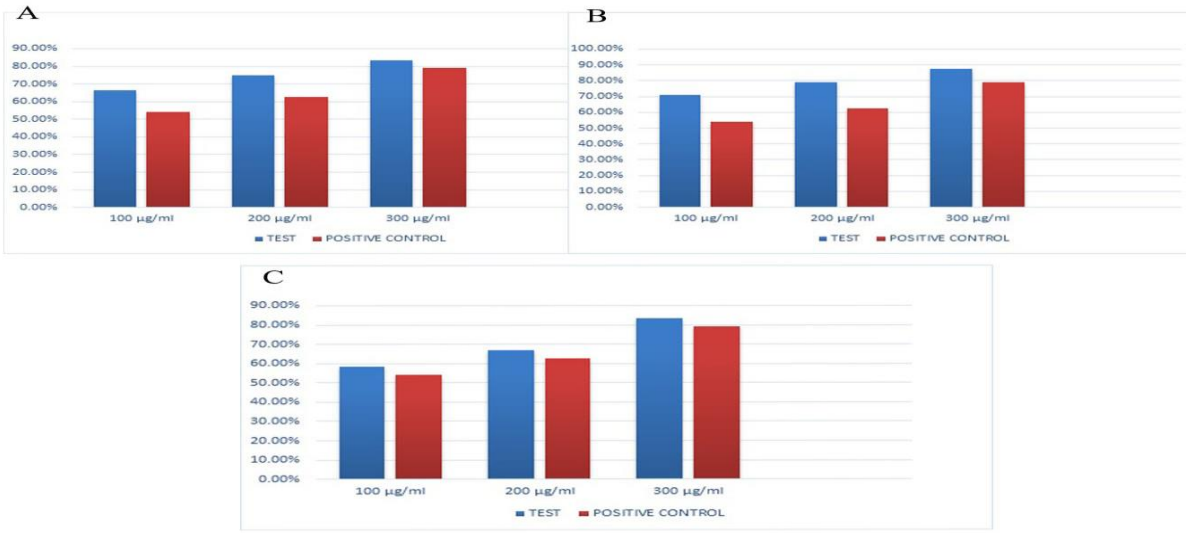

Figure 2. A, B and C represents the effect of each test sample on HRBC membrane stabilisation at different concentrations and compared with positive control indomethacin.

CONCLUSION

Following the investigation, it was determined that the herbal formulation could be standardized using a current scientific quality control technique. This standardization technique is essential for maintaining or repairing the quality standards of herbal formulations. The quality control criteria for this herbal composition fulfilled Indian pharmacopoeia requirements for tablet dosage form. It is possible to infer that the Viladi gutika samples meet the criteria and exhibit antibacterial and anti-inflammatory action. However, further research is necessary to analyse the other qualitative, quantitative, stability and biological characteristics.

Declaration by Authors

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