STANDARDIZATION AND EVALUATION OF TWO MARKETED POLYHERBAL FORMULATION (GUTIKAS)

SONIA PALIWAL*

Department of Pharmacy, College of Pharmacy, Graphic Era Hill University, Bhimtal Campus, Nainital- 263 156, Uttarakhanda, India.

Email: soniapaliwal49@gmail.com

Received: 04 May 2020, Revised and Accepted: 20 June 2020

ABSTRACT

Objective: The study was designed as standardization and evaluation of two marketed polyherbal formulation (gutikas) for the treatment of skin disorder and antibacterial.

Methods: Selected marketed polyherbal formulations were containing tulsi (Ocimum sanctum) and neem (Azadirachta indica) as a main ingredient. The standardization of the two polyherbal formulation was carried out as per official guidelines, in which the polyherbal tablet formulation was subjected that physiochemical characterization, phytochemical, and pharmaceutical parameter would serve as the identity of this polyherbal formulation.

Results: Phytochemical test indicates the presence of alkaloid, glycosides, terpenoids, tannins, and steroids in both formulations. Parameters for loss of drying, pH, ash values, and extractive values documented. Pharmaceutical parameters, such as hardness, friability, weight variation, and disintegration, were found to be within acceptable values.

Conclusion: From the result, it was concluded that polyherbal formulation of tulsi and neem tablet passes all the standardization and evaluation parameters and developed quality standard which can be used as a quality standard for polyherbal formulation.

Keywords: Ayurvedic formulation, Marketed Gutikas, Standardization.

INTRODUCTION

The word Ayurveda (Sanskrit word) is the form in the combination of “Ayur” means life and “Veda” means knowledge or science which means “the science of life,” and based on the theory of Tridosha. According to the WHO report, approximately 70% of population using ancient medicinal system in India and the demand for this system is gradually amplified day by day [1]. Pharmaceutical formulation containing a natural product like herbs as an active constituent is known as herbal medicinal system. The efficiency of the active constituent on the right time and atmospheric condition for the collection and processing [2].

According to a recent current issue in many journals, most of the researchers have an enormous curiosity in a herbal medicinal system in India and the demand for this system is gradually amplified day by day [1]. Pharmaceutical formulation containing a natural product like herbs as an active constituent is known as herbal medicinal system. The efficiency of the active constituent on the right time and atmospheric condition for the collection and processing [2].

In present research, work is to standardization and evaluation of two Patanjali marketed polyherbal formulation (tulsi and neem gutikas). Tulsi (Ocimum sanctum) gutika (tablet) is used as antibacterial, spasmolytic, and immune-modulatory agent and neem (Azadirachta indica) gutika (tablet) have a spermicidal and antimicrobial activity, hence used in skin disorder. According to the WHO guidelines for standardization and evaluation of herbal formulation chemical, biological, quantitative, and qualitative, measures are required. Hence, to prove the composition and quality of polyherbal marketed formulation, adequate analytical methods are used for evaluation.

METHODS

Collection of sample

The sample of tulsi ghanvati 40 g and nimb ghanvati 40 g was purchased from the registered Divya pharmacy store (Uttarakhand).

Phytochemical analysis

The presence of alkaloid, carbohydrates, glycosides, proteins, steroids, tannins, and terpenoids in gutikas was evaluated by the standard test [4].

Physiochemical evaluation

Ash value (Table 1).

Determination of extractive value

Determination of alcohol-soluble extractive value: In a conical flask, 5 g of the drug was macerated with 100 ml alcohol for 1 day, shaking after every 6 h and filtered. Evaporated 25 ml of filtrate in Petri dish at 105°C and weighed the solid matter.

Determination of water-soluble extractive value: In a conical flask, 5 g of the drug was macerated with 100 ml water for 1 day, shaking after every 6 h and filtered. Evaporated 25 ml of filtrate in Petri dish at 105°C and weighed the solid matter.

Loss on drying

Taken 1–2 g of the powdered drug in Petri dish and spread it evenly. Kept the dish in the oven at a temperature between 100 and 105°C for 2 h. Cooled the sample in desiccator, weighed the sample, and calculated % of loss on drying.

pH

In a beaker, 5 g of the sample was dissolved with water and covered it with aluminum foil. Allow to withstand in room temperature for 24 h. After 24 h, decanted the supernatant liquid and determined the pH using pH meter [5–9].

Pharmaceutical analysis

Hardness

The hardness of gutikas was evaluated using hardness tester.
Table 1: Procedure of total ash, acid-soluble ash, and water-soluble ash

| Method          | Total Ash                        | Acid-soluble ash                        | Water-soluble ash                        |
|-----------------|---------------------------------|----------------------------------------|-----------------------------------------|
| Step I          | Incinerate 2–3 g of powdered drug in tared silica crucible at a temp not above 45°C | Boiled the ash with 25 ml of conc. hydrochloric acid for 5 min | In 25 ml water, total ash was boiled for 5 min |
| Step II         | Allow to cool in desiccator and weighted (X) | Filtered it and the solid matter was collected on an ashless filter media | Insoluble matter was filtered and collected on ashless filter media |
| Step III        | Calculate the percentage of ash. Solid matter was washed with hot water and ignited in crucible | | |
| Step IV         | Allowed to cool in desiccator and weighed | | |
| Step V          | Calculate the percentage of acid-insoluble ash | | |
| Step VI         | Acid-insoluble ash = Total ash – solid matter | | |

Friability

Deduct the ten tablets weighed and kept in a curved part of the plastic chamber and closed the lid. Switched on and rotate it with 25 rpm for 100 times. After completion of the cycle, open the lid, remove dust from tablets, and weighed it. Values are compared with the IP standard.

Disintegration test

On USP device, taken six tablets on each tube covered and poured it on 1000 ml beaker. After 28–32 cycle per min at temp 37°C in 1.2 pH buffer, disintegration time was noted and compared the value with the standard.

Weight variation

Weighed 20 tablets and calculated its average weight. Values are compared with the standard [10-12].

RESULTS

Phytochemical analysis

The presence of phytochemical constituents mentioned in Table 2.

Physicochemical parameters

The mean percentage of physiochemical parameters, that is, ash value, extractive value, loss of drying, and pH value of tulsi and neem tablets is shown in Table 3. Marketed formulations are also free from any heavy metals.

Pharmaceutical analysis

In pharmaceutical analysis, hardness (kg/cm²), friability (%), weight variation, dissolution, and disintegration time (min) were determined, all the value under the IP limits and depicted in Table 4.

DISCUSSION

Selected polyherbal tablets are commonly formulation for a skin disorder and antibacterial diseases, but its standardization has not performed yet; hence, the present work has been done.

In phytochemical analysis, it shows the presence of alkaloids, glycosides, tannins, steroids, and terpenoids and due to the presence of terpenoids in tulsi and neem tablets shows the spasmodic and antibacterial activity, respectively. Ash value is a tool to determine drug authenticity and purity. The total ash and water-soluble ash value was found to be high in both polyherbal formulations which indicate that presence of high mineral content and less acid-insoluble ash value indicates presence of less earthy content like nitrogen, argon, helium, carbon.

Extractive value is indicated the nature of chemical constituents and helps to the identification of adulterants. Tulsi tablets show high water extractive value, that is, maximum drug present in water, and the neem tablet shows high alcohol extractive value indicate alcoholic nature of drug.

Loss on drying was found to be 0.16±0.02 g and 0.26±0.003 g for tulsi and neem tablet, respectively. Loss of drying indicates the presence amount of water and volatile substances in a formulation. More moisture level in formulation becomes an ideal medium for the growth of different types of bacteria and fungi affecting the purity, quality, and efficacy of a drug.

The pH of tulsi and neem tablet was found to be 6.5±0.002 and 7.8±0.001, which is slightly acidic and alkaline in nature, respectively.

Hardness and friability of tulsi and neem tablet were found to be 7.7±0.046 and 7.5±0.003 and 0.48±0.010 and 0.16±0.015, respectively. Both are in acceptable limits and indicate tablet strength during processing and transportation. The average weight of both polyherbal tablets was found to be in IP limits (i.e., ±5%).

The disintegration time of tulsi and neem polyherbal tablets was recorded in the acidic buffer at 37°C is 36 and 38 min, respectively.

CONCLUSION

As a part of standardization procedure, both samples (tulsi and neem) were tested for relevant physicochemical parameters. Result for physicochemical parameters such as the water-soluble, acid-soluble extractive values, total

| Parameter                           | Tulsi tablet | Neem tablet |
|-------------------------------------|-------------|-------------|
| Acid-insoluble ash value (%)        | 5.6±0.043   | 1.33±0.040  |
| Water-soluble ash value (%)         | 10.8±0.0219 | 3.6±0.210   |
| Total ash (%)                       | 8.8±0.041   | 5.33±0.033  |
| Alcohol-soluble extractive value (%)| 21.6±0.012  | 62.4±0.058  |
| Water-soluble extractive value (%)  | 42.6±0.031  | 53.6±0.052  |
| Loss of drying (g)                  | 0.16±0.02   | 0.26±0.003  |
| pH value                            | 6.5±0.002   | 7.8±0.001   |

++ indicates presence, -- indicates absence

Table 2: Phytochemical analysis of tulsi and neem tablet

| Phytochemical constituents | Tulsi | Neem |
|---------------------------|------|------|
| Alkaloids                  | ++   | ++   |
| Glycosides                | ++   | ++   |
| Tannins                   | ++   | --   |
| Saponin                   | --   | ++   |
| Carbohydrates             | --   | ++   |
| Steroids                  | ++   | ++   |
| Terpenoids                | ++   | ++   |
| Proteins                  | --   | --   |

Table 3: Physiochemical parameters of tulsi and neem tablet

| Parameters                     | Tulsi tablet | Neem tablet |
|--------------------------------|-------------|-------------|
| Acid-insoluble ash value (%)   | 5.6±0.043   | 1.33±0.040  |
| Water-soluble ash value (%)    | 10.8±0.0219 | 3.6±0.210   |
| Total ash (%)                  | 8.8±0.041   | 5.33±0.033  |
| Alcohol-soluble extractive value (%) | 21.6±0.012  | 62.4±0.058  |
| Water-soluble extractive value (%) | 42.6±0.031  | 53.6±0.052  |
| Loss of drying (g)             | 0.16±0.02   | 0.26±0.003  |
| pH value                       | 6.5±0.002   | 7.8±0.001   |

Table 4: Pharmaceutical analysis of tulsi and neem tablet

| Parameters          | Tulsi tablet | Neem tablet |
|---------------------|-------------|-------------|
| Hardness (kg/cm²)   | 7.7±0.046   | 7.5±0.003   |
| Friability (%)      | 0.48±0.010  | 0.16±0.015  |
| Weight variation (%)| ±5%         | ±5%         |
| Disintegration time (min) | 36 min     | 38 min     |
ash value, water-soluble ash, acid-insoluble ash moisture content, pH, and loss on drying and pharmaceutical characteristics such as hardness, friability, weight variation, and disintegration test was calculated and found to be within the acceptable values.

ACKNOWLEDGMENT
The authors are thankful to the Director and Head of the department of Graphic Era Hill University, Uttarakhand, (India), for providing all the essential assistant and motivation to do our research work peacefully.

AUTHORS’ CONTRIBUTIONS
Sonia Paliwal performed all the experimental work and conceptualized all the research outcomes and wrote and edited the manuscript.

CONFLICTS OF INTEREST
There are no conflicts of interest in the publication of the paper.

AUTHORS’ FUNDING
Nil.

REFERENCES
1. World Health Organization. Country cooperation strategy: 2006-2011 India. In: Supplement on Traditional Medicine. New Delhi: World Health Organization; 2006.
2. Kunle A, Folshade O, Egharevba J, Omorogie H, Ochogu P. Standardization of herbal medicine. Int J Biodivers Conserv 2012;4:110-12.
3. National Institutes of Health, U.S. Department of Health and Human Services. Ayurvedic Medicine—an Introduction. United States: National Institutes of Health, U.S. Department of Health and Human Services; 2005.
4. Kokate CK. Text Book of Pharmacognosy. 43rd ed. Pune: Nirali Prakashan; 2009.
5. Khandelwal KR. Practical Pharmacognosy Techniques and experiments. 19th ed. Pune: Nirali Prakashan; 2008.
6. Lala PK. Practical Pharmacognosy. India: Lina Guha Publication; 1981.
7. World Health Organization. Quality Control Methods for Medicinal Plant Materials. Geneva: World Health Organization; 1992.
8. Government of India, Ministry of Health and Family Welfare. Indian Pharmacopoeia. Ghaziabad, New Delhi: Government of India, Ministry of Health and Family Welfare; 1996.
9. Ministry of Health and Social Services for Northern Ireland. British Pharmacopoeia. 2nd ed. Ireland: Ministry of Health and Social Services for Northern Ireland: 1988.
10. Lachman L. The Theory and Practice of Industrial Pharmacy. 4th ed. Mumbai: Varghese Publishing House; 2008.
11. Government of India, Ministry of Health and Family Welfare. Indian Pharmacopoeia. Ghaziabad, New Delhi: Government of India, Ministry of Health and Family Welfare; 2007.
12. Maurya H, Kumar T. Formulation, standardization, and evaluation of polyherbal dispersible tablet. Int J App Pharm 2019;11:158-67.