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PHARMACEUTICAL AND ANALYTICAL STANDARDIZATION OF KIRATATIKTADI GHANA VATI: A GMP PERSPECTIVE

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ABSTRACT

Introduction: This study aims to standardize and validate Medopachak Yoga, focusing on its Ghana Vati (tablet) form. Medopachak Yoga comprises Kiratatikta (Swertia chiraita), Guduchi (Tinospora cordifolia), Raktachandana (Santalum album), and Shunthi (Zinziber officinalis), traditionally used in treating "Vishamjwara" (fever) as described in the Jwara Chikitsa Adhyaya. The necessity for high-quality Ayurvedic products in response to the global demand for herbal treatments, emphasizing the importance of consistent dosage forms, is addressed. **Methods:** The pharmaceutical procedure involved decocting the ingredients, creating a fine powder, and forming tablets of 500 mg each. The physico-chemical analysis included tests for parameters such as color, odor, taste, loss on drying, total ash, water-soluble ash, and others. Microbiological tests were conducted to ensure the absence of harmful microorganisms. **Results:** The analysis confirmed the quality and consistency of the tablets. Tests showed the following results: color (buff), odor (characteristic), taste (bitter), loss on drying (0.24%), total ash (4.73%), water-soluble ash (3.12%), acid-insoluble ash (0.27%), water extractive value (15.77%), alcohol-soluble extractive (9.31%), pH (4.6), disintegration time (3.2 min),

hardness (3.2 kg/cm²), friability (0.5%), and absence of total viable count, Enterobacteriaceae, total fungus count, E. coli, Salmonella, Staphylococcus aureus, and Pseudomonas aeruginosa. **Discussion:** Tablets offer advantages such as precise dosing, ease of administration, and convenience. The successful validation of Kiratatiktadi Ghana Vati, adhering to GMP norms, ensures the medicine's safety, efficacy, and consistency. The processing sequence adhered strictly to GMP norms, with changes documented at every stage from raw material pulverization to the final packaging of the product. **Conclusion:** The standardization of Kiratatiktadi Ghana Vati has been confirmed through validation using both Ayurvedic and modern physico-chemical parameters. This validated method ensures optimal efficacy of the finished product during its preparation. Across all three batches prepared, no significant variations were observed, demonstrating consistency in meeting quality parameters. This study provides a reliable reference for future research on this Ayurvedic formulation.

KEYWORDS: GMP (Good manufacturing practice), Pachak Yoga, Kiratatiktadi Ghana Vati, Pharmaceutical standard.

INTRODUCTION

Five Pachak Yoga is described in Jwara Chikitsa Adhyaya's Treatment of "Vishamjwara".[1] They are Asthimajja Pachak, Mansa Pachak, Medo Pachak, Rakta Pachak, and Rasa Pachak.

The causes of Medovah Strotodushti include inactivity, sleeping throughout the day, consuming an excessive amount of junk food that is greasy and oily, and drinking too much alcohol.[2]

According to the WHO, 80% of people get their main medical treatment from herbs and other traditional remedies. The Ayurvedic sector has been tasked with providing high-quality products in conventional dose forms in response to the growing global demand for herbal treatments. The specific action and the effectiveness of a drug on the human body are significantly influenced by the dosage form. Tablets are the most often used dose form, along with syrup, powder, and injectables. Tablets are more pleasant, easier to travel, easier to give, and come in convenient packaging. Thus, Medopachak Yoga is made on to a tablet (form of Ghana Vati).

In order to prevent batch-to-batch differences in the manufacture of Ayurvedic preparations, the Indian government's AYUSH is now developing S.O.P. This may be accomplished by standardising the process of evaluating and analysing herbal products both during and after the creation of the final product, utilising Ayurvedic and contemporary approaches.

The Vati (Tablet) version of Medopachak Yoga/Kalp is not mentioned in the original reference. Here, the kalpa is regulated in Ghana Vati[3] (Tablet) form to provide appropriate dose administration and prevent its bitter taste.

The lack of distinct pharmacological and analytical validation for herbal medications and their formulations is one of the biggest issues facing Ayurvedic physicians.

Standardising Medopachak Yog in its Ghana vati[4] (tablet) form is a crucial step in the current study. Pharmaceutical and analytical validation of "given" herbal medication is carried out for the purpose of establishing physiochemical profile.

Table 1: Overview of Drug (Kiratatiktadi Ghana Vati).

	Kiratatikta[5]	**Guduchi**[6]	**Raktachandana**[7]	**Shunthi**[8]
Botanical name	Swertia chiraita	Tinospora cordifolia	Santalum album	Zinziber officinalis
Family name	Gentiniaceae	menispermaceae	santelaceae	Zinziberaceae
Rasa	Tikta	Tikta, katu, Kashaya	Tikta, katu	Katu
Virya	Sheeta	Ushna	Sheeta	Ushna
Vipaka	Katu	Madhura	Katu	Madhur
Guna	Laghu,ruksha	Laghu, ruksha, mridu	Laghu, ruksha	Laghu,snigdha
Karma	It should be used as jvarghana, being bitter (tikta). It digests ama, eliminates digested doshas, and alleviates thirst (trishna), dizziness(bhrama), and burning sensations(daha). Therefore, it is useful in treating trityaka jvara.	Its primary action in treating fever (jvara) is due to its bitter taste (tikta rasa).	It digests ama and the kapha-pitta associated with meda dhatu, making it effective in treating trityaka jvara.	Shunthi digests rasagata ama and alleviates cold conditions due to its warm nature (ushna); therefore, it should be used in jvara with a cold onset (sheeta purva jvara).

MATERIAL AND METHODS

The four elements of Medopachak Yoga are Kirattikta, Amruta, Chandan, and Vishwabhshajam. All these medicines were decocted to make Bhavana, which increased the drug's potency.

The parts and quantities utilised are listed in Table No. 1 below.

All of the components for this kalpa were gathered from the authentic local market, and using the resources of Mahatma Gandhi Ayurveda College Hospital and Research Center Salod Wardha, Maharashtra, the ingredients were recognised and validated in the quality control laboratory. Each of these herbal components fulfilled the quality standards outlined in API.[9]

Table No. 2: Content and part use of the drug.

Sr. No.	Ingredients	Botanical Name	Part Use	Quantity for batch size 1kg
1	*Kiratatikta*[10]	*Swartia chiraita*	*Root*	250gm
2	*Guduchi*[11]	*Tinospora cardifolia*	*Stem*	250gm
3	*Rakta Chandana* [12]	*Pterocarpus Santalinus*	*Heart wood*	250gm
4	*Shunthi*[13]	*Zinziber officinalis*	*Rhiozme*	250gm

Pharmaceutical Procedure: All the ingredients listed in the table above were combined in equal amounts of 250 grams each. Subsequently, they were processed in a mass pulverizer and sifted using an 80-mesh sieve to achieve a fine powder. The resulting mixture was thoroughly blended in a mass mixer and ground in an end runner for three prahar (approximately 9 hours) with a decoction prepared from the identical ingredients mentioned earlier. After triturating, the substance was dried in an electric dryer at a temperature not exceeding 60°C. Following this, excipients were added to the dried mass as follows: 30 grams of microcrystalline cellulose (MCC), 250 grams of starch, and 50 grams of another component (not specified in the original text). Next, the mixture was processed through a multimill using a No. 2 sieve to produce granules. These granules were subsequently used for tableting with a tableting machine, each tablet being 500 mg in size.

OBSERVATION AND RESULT

The physico-chemical analysis was conducted at the quality control laboratory utilizing the facilities available at Mahatma Gandhi ayurveda college hospital and research center Wardha, Maharashtra.

Table 3: Showing physico- chemical study of *Kiratatiktadi Ghana vati.*

Organoleptic parameter

Sr.No.	Test Name	Parameters
1.	Color	Buff color
2.	Odor	Characteristic
3.	Taste	Bitter

Physicochemical parameter

4.	Loss of drying at 105□ c	0.24%
5.	Total Ash	4.73%
6.	Water Soluble Ash	3.12%
7.	Acid Insoluble Ash	0.27%
8.	Water Extractive value	15.77%
9.	Alcohol soluble extractive	9.31%
10.	pH	4.6
11.	Disintegration test	3.2 min/sec
12.	Hardness test	3.2 kg/cm^2
13.	Friability test	0.5%

Microbiological parameter

14.	Total viable count	Absent
15.	Enterobacteriaceae	Absent
16.	Total fungus count	Absent
17.	E - coli	Absent
18.	Salmonella	Absent
19.	Staphylococcus aureus	Absent
20.	Pseudomonas aueruginosa	Absent

DISCUSSION

Tablets are a highly favored form of medication due to their precise dosing capability, ease of administration, pleasant taste, convenience for transportation, and packaging advantages. As a result, tablets offer numerous benefits compared to other types of dosage forms.

The successful validation of Kiratatiktadi Ghana Vati for pharmaceutical and analytical purposes was achieved through meticulous adherence to each procedural step and employing advanced physico-chemical analysis of the final product.

To enhance the efficacy Kiratatiktadi Ghana Vati, the ingredients mentioned in Charak Samhita were utilized, and during the manufacturing process, they were infused with a decoction (kwath) of the same ingredients.

The processing sequence adhered strictly to GMP norms, with changes documented at every stage from raw material pulverization to the final packaging of the product. Both classical and modern parameters were utilized to assess the finished product for variations and consistency.

Overall, this process highlights a commitment to quality assurance throughout the manufacturing process, from raw materials to the final packaged product, ensuring medicine meets the required standards for safety, efficacy, and consistency.

CONCLUSION

The standardization of the Ayurvedic formulation Kiratatiktadi Ghana Vati has been confirmed through validation using both Ayurvedic and modern physiochemical parameters. This validated method ensures optimal efficacy of the finished product during its preparation. Across all three batches prepared, no significant variations were observed, demonstrating consistency in meeting quality parameters. Since there is no existing standard data available for this formulation, comparisons are not feasible; however, the findings from this study can serve as a reference for future research on Kiratatiktadi Ghana Vati.

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