Short Communication

ADVANTAGES OF USING BASIC LABORATORY METHODS FOR DRUG STANDARDIZATION IN AYURVEDIC PHARMACY :TULSI (OCIMUM SANCTUM) - A CASE IN EXAMPLE

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Abstract

According to WHO 80% of world's population still relies on traditional system of medicines for primary healthcare. Standardization of ISM formulations includes--quality of herbal medicine, storage, minimizing batch to batch variation and elimination of adulteration and substitution. In the present study the plant *Tulsi* (Ocimum sanctum) studied pharmacognostically, and its two formulations i.e *Tulsi Vati* (tablet) and *Tulsi Arka* (distillate) were assessed pharmaceutically and analytically at laboratory of IPGT & RA, Jamnagar by basic methods of standardization. There are many latest methods of standardization available but in the present study it is shown that how the basic laboratory facilities available at Ayurvedic colleges and other setups can help standardization of Ayurvedic preparations to the workable needs.

Key words- Standardization, *Tulsi* , Herbal Tablet, Herbal *arka*

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Introduction

Safety and efficacy of phytopharmaceuticals is based on their reproducible quality. Therefore, if phytopharmaceuticals are to be recognized as rational drugs, they need to be standardized and pharmaceutical quality must be approved.[1] WHO, in number of its resolutions has emphasized the need of ensuring quality control of herbal products by using modern techniques and applying suitable standards.[2] In the present study, pharmacognostic and analytical study of the plant *Tulsi* (Ocimum sanctum) was done using basic laboratory methods at Institute of Post Graduate Training and Research in Ayurveda, Jamnagar. The type of *Tulsi* taken for the study was *Shri Tulsi* (green leaved).

Materials and Methods

Pharmacognostic study- *Tulsi* leaf, stem and root were collected from Jamnagar and were preserved in a solution of Formalin Aceto Alcohol (FAA) .Macroscopic and microscopic characters of the plant were studied systematically by taking transverse section. The Macroscopic characters and microscopic features of Tulsi (Ocimum sanctum) were found according to available standards and references.[3]

Pharmaceutical study-

Preparation of *Tulsi* powder [4]

Results

Total duration required for preparation of *Tulsi p*owder - 30 min.

Final weight	- 9990 gm
Total loss of weight	- 1510 gm
Percentage of loss of weight	- 15.11 %

Preparation of *Tulsi* tablet

(By wet granulation method as per the reference of The theory and Practice of industrial Pharmacy, Leon-Lachman)

Tulsi tablet was made using the following ingredients- 1st batch -*Tulsi* panchang-9990 gm with gum acacia-499.5 gm, 2nd batch- *Tulsi* panchang-1000 gm with gum acacia-50 gm

Results

Table 1. Observations upon *Tulsi* tablet

Batch no	Time taken for preparation of *Tulsi* tablet	Total weight of tablets obtained	Loss of weight	% of weight loss
1st batch	10 hrs	7622 g	2368 g	31.06
2nd batch	6 hrs	768 g	232 g	30.20
3rd batch	6 hrs	762 g	238 g	31.23

It can be seen that percentage of weight loss was 30.20% approximately. (Table 1)
Preparing the *Tulsi Arka* (as per the reference of Arka Prakash)

Results

Table 2. Showing the observation and result of *Tulsi* arka preparation

Batch No	Fresh Tulsi in gm.	Water	Starting Temp.(^{0}c)	Room Temp.(^{0}c)	Temperature during process(^{0}c)	Total duration of process(hrs)	Obtained Arka
1	300	3 Ltr	100	37	50	3.50	300 ml
2	300	3 Ltr	100	37	50	4.00	300 ml
3	200	2 Ltr	98	36	48	3.55	200 ml
4	170	1700 ml	96	37.5	45	3.45	170 ml
5	100	1 Ltr	98	37	48	3.45	100 ml

The *arka* was prepared in 05 batches and it was seen that approximately 50 degree centigrade temperature was required for preparation of *arka* (Table 2)

Analytical study

Tulsi panchang: The volatile oil content was approximately 1%, 0.9% and 1% in batch I, batch II and batch III respectively.

Tulsi* powder*: On analyzing the physcio- chemical parameters of *Tulsi* powder, it was found that loss on drying was 6.10% w/w , Ash value was 8.74% w/w, Water soluble extract was 12.93% w/w and Methanol soluble extract was 5.83% w/w respectively.

***Tulsi* tablet:** *Tulsi* tablet was made in three batches and it was found that the tablet was brown in colour, *kashaya* (astringent) in taste, round in appearance and it had typical smell of *tulsi.*

Weight of *Tulsi* tablets:

Table 3. Showing the weight, hardness and disintegration time of *Tulsi* tablets

Sr. No.	Batch I	Batch II	Batch III
Weight (Average)	548mg	575mg	565mg
Hardness	7.86 *kg/cm^2*	6.1 *kg/cm^2*	6.45 *kg/cm^2*
Disintegration time	4 min	2.5 min	3 min

Results of *Tulsi Arka* analysis: *Tulsi arka* was made in three batches and it was found that the *arka* was transparent in colour with typical smell of *tul*si . It was *Tikta, kashaya* in taste with watery consistency.

Physico chemical analysis: It was found that the pH of the *arka* was 6.45, 6.25 and 6.19 in 3 batches respectively. The specific gravity of *arka* in batch I, II and III was 1.0002, 1.0015 and 1.0009 respectively.

Discussion

Standardization is an essential measurement for ensuring the quality control of the herbal drugs. "Standardization" expression is used to describe all measures, which are taken during the manufacturing process and quality control leading to a reproducible quality.[1] The plant *Tulsi* was pharmacognostically evaluated both macroscopically and microscopically. The parameters found were upto the standard level. In pharmaceutical study,*Tulsi* tablet was prepared in three batches from *Tulsi* churna. 5% gum acacia was added as binding agent. Initially *Tulsi churna* was prepared then it was converted into tablet. In present study three batches of *Tulsi* tablet were prepared to maintain the standard operative procedure. Average 30.01% loss was observed during the process. *Tulsi arka* was prepared in 5 batches as per classical method and maintained the temperature pattern. Arka was collected unto $^{1}/_{10th}$ part of water.

Further analysis of the finished product was subdivided into following sections-

Raw material analysis: In this section raw material of *Tulsi panchang* was analysis to see the volatile oil content. The average volatile oil was found 1 % v/w in *Tulsi panchang*.

Intermediate product analysis: In intermediate product analysis, *Tulsi churna* was carried out its organoleptic test an physico chemical test like loss on drying at 110°C, ash value, water soluble extract and alcohol (methanol) soluble extract was carried out i.e. 6.10%w/w, 8.74%w/w,12.93w/w, 5.83 w/w respectively.

Final product analysis:. To maintain the uniformity of tablet following parameters were done like lowest weight, highest weight, average weight i.e.480 mg, 628 mg and 562 mg respectively. The average disintegration and hardness test was carried out of *Tulsi* tablet i.e. 3.16 min and 6.80 kg/cm^{-2}respectively. The pH and specific gravity of *Tulsi arka* was carried out i.e. average 6.29 and 1.00086 respectively.

Conclusions

The subject of herbal drug standardization is massively wide and deep. There are various factors necessary for standardization of herbal drugs .Here, the drug *Tulsi* was analyzed by basic standardization techniques which are easily available at all Ayurvedic setups. It is basic step towards standardization of herbal drugs which should be essentially done at all Ayurveda setups. The results found can be taken as criteria for standardization. An HPTLC is suggested for further evaluation and standardization of Tulsi. An estimation of marker compounds especially for its volatile oil is also suggested.

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