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STANDARDIZATION OF *KUTAJAGHANA VATI*: AN AYURVEDIC POLYHERBAL FORMULATION

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ABSTRACT

In order to have a good coordination between the quality of raw materials, in process materials and the final products, it has become essential to develop reliable, specific and sensitive quality control methods using a combination of classical and modern instrumental method of analysis. 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. *Kutajaghana vati* is official in Ayurvedic formulary of India and is prescribed for the treatment of diarrhea, Irritable bowel syndrome. It is a polyherbal preparation containing two ingredients. In this research paper, an attempt has been made to develop standardization methods of *Kutajaghana vati*. In-house preparation and the marketed drug have been standardized on the basis of macroscopic, microscopic, physic-chemical parameters and Thin Layer Chromatographic study (TLC). The set parameters were found to be sufficient to evaluate the *Vati* and can be used as reference standards for the quality control/quality assurance.

INTRODUCTION: In recent years, there has been great demand for plant derived products in developed countries. These products are increasingly being sought out as medicinal products, nutraceuticals and cosmetics [1].

There are around 6000 herbal manufacturers in India. More than 4000 units are producing Ayurveda medicines. Due to lack of infrastructures, skilled manpower reliable methods and stringent regulatory laws most of these manufacturers produce their product on very tentative basis [2].

In order to have a good coordination between the quality of raw materials, in process materials and the final products, it has become essential to develop reliable, specific and sensitive quality control methods using a combination of classical and modern instrumental method of analysis. Standardization is an essential measurement for ensuring the quality control of the herbal drugs [3].

"Standardization" expression is used to describe all measures, which are taken during the manufacturing process and quality control leading to a reproducible quality. It also encompasses the entire field of study from birth of a plant to its clinical application. It also means adjusting the herbal drug preparation to a defined content of a constituent or a group of substances with known therapeutic activity respectively by adding excipients or by mixing herbal drugs or herbal drug preparations [4]."Evaluation" of a drug means confirmation of its identity and

determination of its quality and purity and detection of its nature of adulteration [5].

Standardization of herbal drugs is not an easy task as numerous factors influence the bio efficacy and reproducible therapeutic effect. In order to obtain quality oriented herbal products, care should be taken right from the proper identification of plants, season and area of collection and their extraction and purification process and rationalizing the combination in case of polyherbal drugs [5].

The herbal formulation in general can be standardize schematically as to formulate the medicament using raw materials collected from different localities and a comparative chemical efficacy of different batches of formulation are to be observed. The preparations with better clinical efficacy are to be selected. After all the routine physical, chemical and pharmacological parameters are to be checked for all the batches to select the final finished product and to validate the whole manufacturing process [6].

The World Health Organization (WHO) has appreciated the importance of medicinal plants for public health care in developing nations and has evolved guidelines to support the member states in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation, safety, and efficacy [7]. *Lasunadi vati* is official in Ayurvedic formulary of India (AFI Part II, 10:4) and is prescribed for the treatment of diarrhea, Irritable bowel syndrome [8]. It contains two drugs i.e. Kutaja (*Holarrhena antidysentrica*) and Ativisa (*Aconitum heterophyllum*). This study reports on the standardization of *Kutajaghana Vati* based on macroscopic, microscopic, physic-chemical parameters and Thin Layer Chromatographic study (TLC).

MATERIALS AND METHODS:

Procurements of Drugs: The crude drugs were purchased from the local crude drug shop, Vaidya store and their identity was confirmed by correlating their morphological and microscopical characters with those given in literature [9].

Prepration of Lasunadi Vati: The ingredients were dried below 60^{o}C, powdered, sieved through 85# and stored in air tight containers. Standard laboratory reference sample of *Kutajaghana Vati* was prepared as per the formula given in Ayurvedic Formulary Part -1I and labeled as KGVL.

Marketed samples: The marketed samples of one brand of *Kutajaghana Vati*, sample 1 (KGVS 1) was standardized based on their macroscopic, microscopic, physic-chemical parameters and Thin Layer Chromatographic study (TLC).

Macroscopic study: It refers to evaluation of the formulation by color, odor, taste, texture, etc. The macroscopic study of the samples was evaluated based on the method described by Siddiqui *et al.,* [10].

Microscopic study: For microscopic study, 5 g of the drug sample was taken, powdered. The powdered material was taken on a 85 mesh sieve and allowed in slow running water for washing away the minerals. The materials were cleared in chloral hydrate, wash with distilled water and mounted in glycerin, then observed characters [11].

Physico-chemical Parameters Study: Physico-chemical parameters such as loss on drying, total ash, acid insoluble ash, water- and alcohol- soluble extractives test were determined according to methods described in the Indian Pharmacopoeia[11].

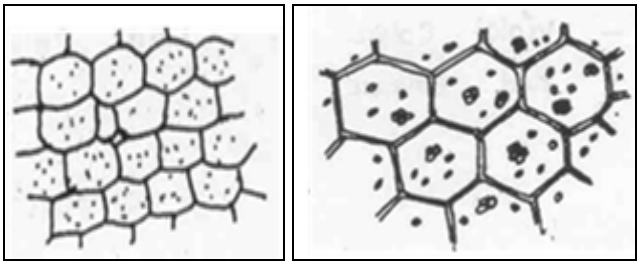
Fluorescence Study: The fluorescence properties were studied under UV light adopting the method described by Kokoshi[12] and Chase & Pratt [13]. The behavior of the samples with different chemical reagents was studied and fluorescence characters were observed on long UV light at day light and UV light 366 nm.

Thin Layer Chromatographic Study [14]: TLC studies of the alcoholic extract was carried out on aluminium plates pre-coated with silica gel 60 F_{254} of 0.2 mm thickness using n-hexane: ethyl acetate: formic acid (8:2: 0.06) as mobile phase and observed under visible light after derivatization with anisaldehyde sulphuric acid (5%) followed by heating the plate at 110°C. The color and R_f values of the resolved spots were noted.

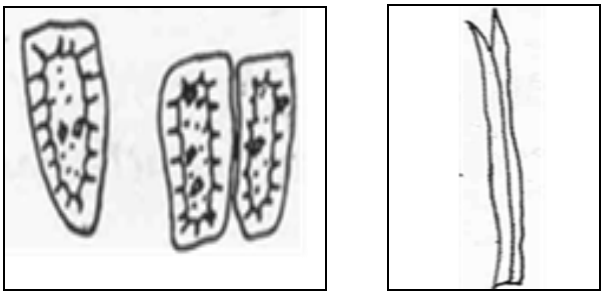
RESULTS AND DISCUSSION:

Macroscopic Characters: All samples were black in color, agreeable in odor and slightly bitter in taste.

Microscopic Characters: Microscopic analysis of all the samples shows the presence of identifying diagnostic characters. It showed the characters in the mount like stone cells rectangular to oval, few containing calcium oxalate crystals; cork consisting of polygonal to iso-diameteric cells having brown pigments (*Holarrhena antidysentrica*); a few fragments of parenchyma, the cells being filled with starch grains; fibers with bifurcate tips from (*Aconitum heterophyllum*) (**Figure 1**).



CORK CELLS (***Holarrhena antidysentrica***) **PARENCHYMA CELLS** (***Aconitum heterophyllum***)



STONE CELLS (***Holarrhena antidysentrica***) **FIBER** (***Aconitum heterophyllum***)

FIG. 1: MICROSCOPIC STRUCTURES OF *KUTAJAGHANA VATI*

Physico-chemical Parameters Study: Physicochemical parameters of *Kutajaghana Vatis* are tabulated in **Table 1**. The physic-chemical parameters of *Kutajaghana Vatis* (KGVL, KGVS 1) were determined as per the standard protocol. The results of loss on drying, total ash, acid insoluble ash, alcohol soluble extractive and water soluble extractive values of KGVL showed higher value in compared with KGVS 1.

TABLE 1: PHYSICO-CHEMICAL PARAMETERS OF *KUTAJAGHANA VATI*

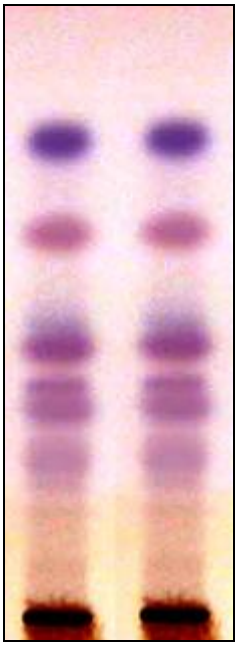
Parameters studied	KGVL (% w/w)	KGVS 1 (% w/w)
Loss on drying at 110^0C	14.52	13.96
Total ash	11.02	9.68
Acid insoluble ash	1.23	1.03
Alcohol soluble extractive	13.35	12.31
Water soluble extractive	21.64	19.81

Fluorescence Study: The powders are treated with various chemicals exhibited various colors in the UV light and the results are depicted in **Table 2**.

TABLE 2: FLUORESCENCE STUDY OF *KUTAJAGHANA VATI*

Fluorescence study of KGVL & KGVS 1	Day light	UV light (366 nm)
Drug powder	Black	Black
Drug powder + Conc. H_2SO_4	Brown	Brownish green
Drug powder + Aqueous NaOH	Brownish pink	Dark green
Drug powder + Conc. HCL	Pale brown	Dark green
Drug powder + Alcoholic NaOH	Light brown	Green

Thin Layer Chromatographic Study: Thin Layer Chromatogram of the alcoholic extract after derivatization with anisaldehyde sulphuric acid reagent showed five major spots at R_f 0.86 (violet), 0.67 (pale orange), 0.52 (purple), 0.45 (purple) and 0.30 (purple) (**Figure 2**).



T1 **T2**

FIGURE 2: TLC CHROMATOGRAM OF *KUTAJAGHANA VATI* T_1- KGVL, T_2- KGVS 1

CONCLUSIONS: After analysis of samples of *Kutajaghana Vati* by different parameters such as loss on drying, total ash, acid insoluble ash, water- and alcohol- soluble extractives and TLC chromatogram shows good co-relation between them. The study of microscopic characters of different samples shows the presence of diagnostic identifying characters for presence of each ingredient. So it can be concluded that these parameters can be used for the evaluation of *Kutajaghana vati*. Purity and potency of the

materials and formulations following the procedure given could be performed in QC/QA laboratory of pharmaceutical house.

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