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# Pharmacognostical And Pharmaceutical Analysis OfTrikatuKajjaliTablet– A Herbo-Mineral Formulation For Non - Alcoholic Fatty Liver Disease

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**ABSTRACT: Background**: TrikatuKajjaliVati, a herbo- mineral formulation containing only two compounds Trikatu and Kajjalithat can be used in the treatment ofAma, Ajirna, Gulma, and in the condition of Agnimandya.Non Alcoholic Fatty Liver Disease (NAFLD) is the build-up of extra fat in liver cells. It is normal for the liver to contain some fat. However, if more than 5% - 10% of livers weight is fat then it is called fatty liver. Excess fat deposition in the liver results in a generalized slowing down of the metabolic process, which affects the metabolism of the body, even at the cellular level. TrikatuKajjaliVati can be a promising formulation in the management of NAFLD.**Objectives**: In the present study, for assurance of quality of TrikatuKajjaliVati, pharmacognostical and pharmaceutical analysis have been done and an attempt has been made to develop pharmacognostic and pharmaceutical standards for TrikatuKajjaliVati. **Methods**: TrikatuKajjaliVati was subjected to microscopic evaluation for pharmacognostical study.For physicochemical parameters like analysis like hardness, weight variation, loss on drying, ash value,acid insoluble extract, pH value, water-soluble extract,alcohol soluble extract, and high-performance thin-layer chromatography( HPTLC) were carried out. **Result**:Pharmacognostical study showed the presence of certain identifying characters of all of the ingredients of TrikatuKajjaliVati that is Shunthi, Maricha,Pipalli, and Kajjali. In a pharmaceutical study preliminary physicochemical analysis showed that hardness of Vati was 3.5 Kg/cm$^2$, ash value 12.84%w/w,loss on drying 1.6%w/w,water soluble extract 35.93%w/w,alcohol soluble extract 22.14%w/w. HPTLC analysis showed 11 spots in 265nm and 8 spots in 356nm.**Conclusion**: Present work was carried out to standardize the herbomineral formulation TrikatuKajjaliVati in terms of its identity, quality,and purity.Pharmacognostical and pharmaceutical observations revealed the specific characters of all active constituents in the preparation.

**Keywords**: Non-Alcoholic Fatty Liver Disease, pharmacognosy, pharmaceutics TrikatuKajjaliVati

## I. INTRODUCTION:

Non Alcoholic Fatty Liver Disease (NAFLD)is the build-up of extra fat in liver cells that is not caused by alcohol. NAFLD involves a wide spectrum of liver damage, ranging from simple, uncomplicated steatosis to steatohepatitis, steatosis plus ballooning degeneration, and Non-Alcoholic Steato Hepatitis(NASH), the latter being the most serious form[i]NASH is defined histologically by the presence of steatosis along with necro-inflammatory activity including ballooning degeneration, Mallory's hyaline, lipogranuloma& pericellular fibrosis, mostly of lobular distribution. NAFLD has a benign prognosis, but NASH is associated with fibrosis and progression to cirrhosis. Insulin resistance is the underlying factor between these various disorders & numerous studies have shown that virtually all patients with NASH have insulin resistance. Abnormal ferritin values are seen in ≈ 50% of patients with NASH and an elevated ferritin level may be a marker of insulin resistance in NASH.

The liver is the largest organ of the body, which accounts for 2-3% of the total body weight in adults. Fat accounts for around 5% of the total weight of the normal liver. Fatty liver is defined as a condition of excessive accumulation of fat inside liver cells. When the fat content exceeds 5% of the total weight or more than 30% of liver cells in a liver lobule are with the fat deposit, it is diagnosed

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as fatty liver. Disturbances in lipid metabolism in the liver due to various etiological factors lead to Fatty Liver. Fat accumulating in the liver is mainly in the form of triglycerides and fatty acids, and also is present in small amounts in the form of cholesterol, cholesterol esters, and phospholipids.

Indian population has a higher body fat content and abdominal adiposity: the latter is particularly associated with insulin resistance and thus NAFLD, even if the Body Mass Index is normal. Indians also more often have atherogenic dyslipidemia (combination of hypertriglyceridemia, low HDL-cholesterol, and high LDL-cholesterol) and diabetes. These factors along with urbanization and associated sedentary lifestyle and fat-rich diet may make Indians particularly prone to metabolic syndrome, insulin resistance, NAFLD/NASH.

The more important is to search out safe, effective, and cheaper remedies. Looking into the pathogenesis and complication of NAFLD requires a systemic and radical therapy for which Ayurveda may provide a ray of hope through ShamanaChikitsha or Rasayana.

For the present study TrikatuKajjaliVati, a herbomineral formulation that containsTrikatu and Kajjali was prepared.The bitter and astringent taste of Trikatu and that too in the powder form is not easily acceptable for the patients. So, discover that form of Trikatu, which is easy to take, effective in low dose, has long shelf life and simple to dispense is need. Kajjali possesses Yogavahiproperty[ii]and is one of the main ingredientsof about 80 formulations mentioned in Ayurveda for examplewith Ricinus communis[iii]for the management of VataRoga. These references indicate the need for research in the dosage form of SukshmaAushadhi Kalpana, which can be applied for Ayurvedic classical drugs. SukshmaAushadhican be effectively used after accessing Hetu, Linga,Nidanaaccording to Ayurveda, as also mentioned in SukshmaAushadhi Kalpana[iv].

In the case of internal administration of herbomineral drug, it should be safe, effective, and free from adulteration, with appropriate quantity and ingredients. It is difficult to identify the herbal drug in dry or powdered form. This condition leads to an increase in adulteration. So, it is a need of time to set proper parameters for the standardization of such drugs. Pharmacognostical studies reveal plant identification and set parameters for standardization which can be done in the case of herbal traditional medicine.Generally, the physiochemical analytical study of drugs helps to interpret the pharmacokinetics and pharmacodynamics involved. With the help of physiochemical analytical studies, it is possible to standardize the drug and differentiate the adulterants. High-performance liquid chromatography (HPLC) and thin-layer chromatography (TLC) are the conventional methods used in the analysis of secondary metabolites originating from plants. It is the necessity of time in the field of Ayurveda to go for quality control of the raw drugs as well as final products using modern parameters which provides credibility to Ayurvedic medicines and also helps in the globalization of Ayurveda.

## II. AIMS AND OBJECTIVES

1. To evaluate the authenticity of TrikatuKajjaliVatithrough various pharmacognostical procedures.
2. To develop the pharmacognostical and phytochemical profile of TrikatuKajjalli

## III. MATERIALS AND METHODS

**Collection, identification and authentication of raw drugs**

The raw materials were collected from the pharmacy of Gujarat Ayurved University, Jamnagar. All the raw drugs were identified and authenticated in the Pharmacogonosy laboratory, Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar.

**Preparation of drug:**

Raw drugs of Shunthi ,Maricha , andPippaliwere converted into fine powder. Then fine powder of Trikatu was trituratеted along with Kajjali. Water was added till the mixture was completely mixed with it and trituration was carried out till the mixture acquired semisolid form and after that it was dried in the oven and granules were made, then these granules were mixed with slight amount of starch and kept in tablet punching machine. Thentablet of 250 mg was prepared and stored in bottles under hygienic condition.

**PHARMACOGNOSTICAL STUDY**

The pharmacognostical study was divided into organoleptic study and microscopic study of the finished product.

**Organoleptic study:**

The genuinity of the herbomineralformulation can be confirmed with organoleptic characters of the given sample.Organoleptic parameters comprise taste, colour, odour and touch of TrikatuKajjaliwhichwas

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scientifically studied as per the standard references.[1]

**Microscopic study:**

TrikatuKajjaliwas powdered and dissolved with water and microscopy of the sample was done without stain and after staining with Phloroglucinol + HCl. Microphotographs of TrikatuKajjaliwere also taken under Corl-zeisstrinocular microscope.[1]

**Physico-Chemical Analysis**

With the help of various standard physico-chemical parameters, TrikatuKajjali was analyzed. The common parameters mentioned for Trikatu in Ayurvedic Pharmacopia of India,[1]and CCRAS[1], guidelines are loss on drying, hardness, total ash value, acid insoluble ash, pH value, water soluble extract, methanol soluble extra total ashand water and alcohol soluble extractives.

**HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY**[1]

High Performance Thin Layer Chromatography (HPTLC) is a powerful analytical method suitable for the separation and quantitative determination of a considerable number of compounds even from complicated matrix. HPTLC is used for identification of active constituents, identification and determination of impurities and quantitative analysis of active constituents. Principle of HPTLC remains the same as of TLC i.e. adsorption. One or more compounds can be spotted in a thin layer of adsorbent coated on a chromatographic plate. The mobile phase solvent flows through because of capillary action against gravitational force. The component with more affinity towards stationary phase travels faster. Thus, the components are separated on a thin layer chromatographic plate based on the affinity of the components towards the stationary phase.

Steps involved in H.P.T.L.C were as follows:

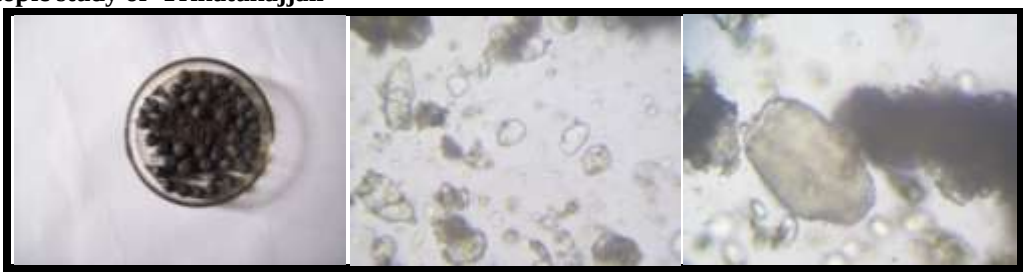
1. Sample and standard preparation
2. Selection of chromatographic layer
3. Layer pre-washing
4. Layer pre-conditioning
5. Application of sample
6. Chromatographic development
7. Detection of spots
8. Scanning and documentation

## IV. RESULTS

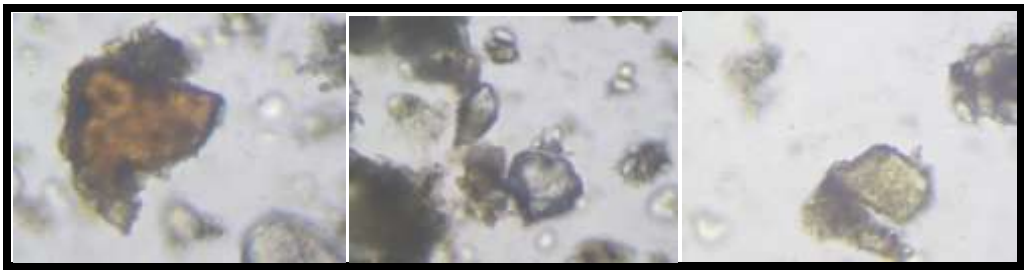
**Organoleptic characters of TrikatuKajjali**

Organoleptic characters contents of TrikatuKajjalilike colour, taste, touch, odor were recorded.The color of TrikatuKajjali was black. TrikatuKajjali hadpungent smell , taste was KatuTiktaand felt hard on touchwhich is shown in Table- 2.

**Microscopic study of Trikatukajjali**



**TrikatuKajjaliVati** **Strach grain of Shunthi** **Black debris of Maricha**



Epicarp cells of Pipalli Crystelline Blackish Material of Kajjali Stone Cells of Maricha

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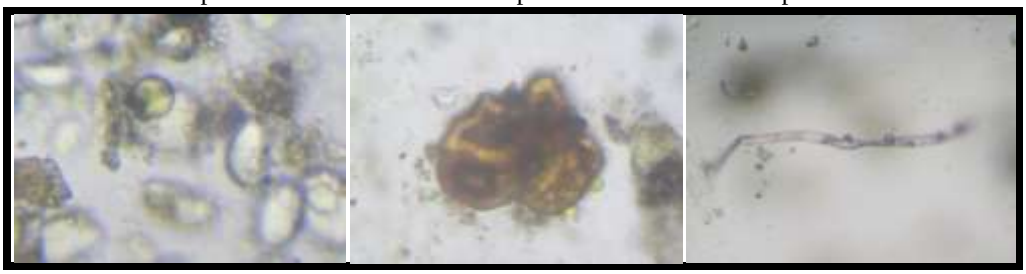
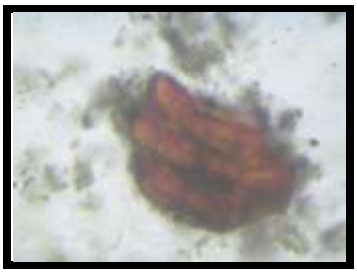
Olioresin content of Pipalli Stone cells of Pipalli Group of stone cells of Maricha



Olioresin content of ShunthiScalleryform vessels of ShunthiLignified stone cells of Maricha along with oil globule

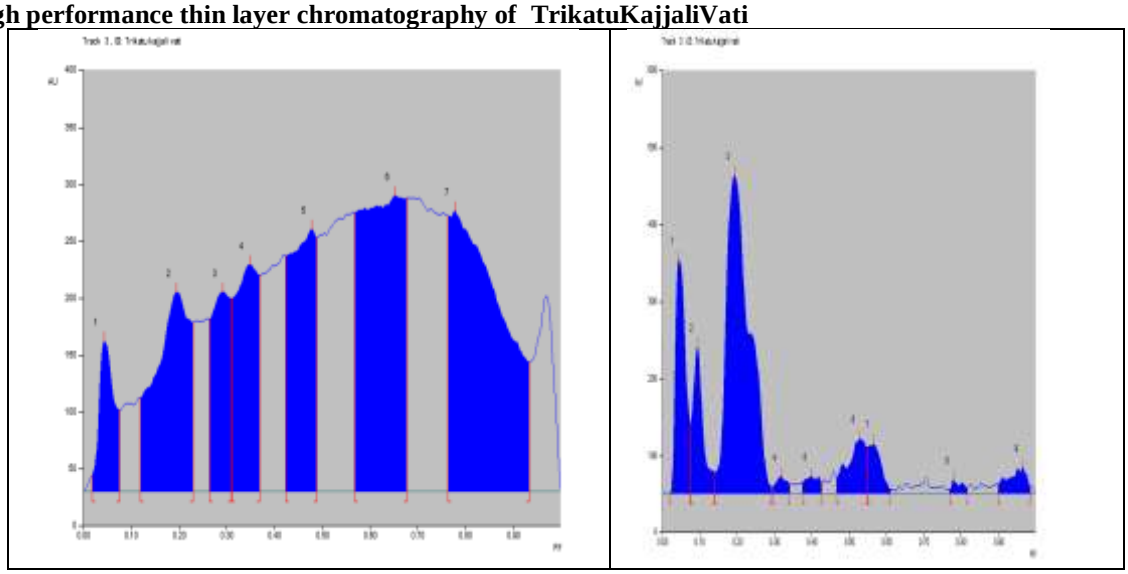


**Fiber of Shunthi**

**Physico-chemical analysis of TrikatuKajjali**

Physico-chemical analysis of **TrikatuKajjali** revealed the hardness of 4.05 $Kg/cm^2$ the ash value was 12.84%w/w, acid insoluble ash value 1.56%w/w, loss on drying 1.6%w/w, water soluble extract 35.93%w/w, alcohol soluble extract 22.14%w/w and pH value was 6.5, which are shown in Table –3.

**High performance thin layer chromatography of TrikatuKajjaliVati**



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| HPTLC at 254nm | HPTLC at 356 nm |
|---|---|

## V. DISCUSSION

Study on TrikatuKajjali Tablet was a step towards pharmacognostical and pharmaceutical standardization of the drug. The pharmacognostical study revealed the presence of the diagnostic characters of TrikatuKajjali Tablet like epicarp cells of Pippali ,stone cells of Maricha ,scullery form cells of Shunthi ,lignified stone cells of Maricha , epidermal cells of Pipalli , olioresin content of Pipalli. This confirm the presence of all ingredients of raw drugs in the final product and there is no major change in the microscopic structure of raw drug during the pharmaceutical process of preparation of tablet , this showed the genuinity of the final product. The Physicochemical parameters showed that the ash values are the criteria to identify the impurity of drugs. TrikatuKajjali Tablet contained 4.02%w/w total ash. The result revealed that TrikatuKajjali Tablet is free from unwanted organic compound and production site was good enough keeping sample free from dust and other solid matters. The 5.07%w/w of water soluble extractives and 25.06% w/w methanol soluble extractive were present in TrikatuKajjali Tablet indicates that drug is having good solubility in water and methanol. In HPTLC study 7 spots at 254nm and 7 spots at 356nm were obtained , indicating its possible components of matrix which may possess its therapeutic effect.

## VI. CONCLUSION

The pharmacognostical and Physico chemical analysis of TrikatuKajjali Tablet confirmed the purity and genuinity of the drug . As no standard fingerprint is available for this formulation , an attempt has been made to evolve pharmacognostical and physico chemical profiles of TrikatuKajjali Tablet. Information acquired from this study may be beneficial for further research work and can be used as a reference standard for quality control researches.

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Conflict of interest : None declared
Ethical approval : The study was approved by the Institutional Ethics Committee

**Table 1: Ingredient of Trikatukajjali**

| Sl No: | Drug | Latin Name | Part Used | Ratio | Form |
|---|---|---|---|---|---|
| 1. | Shunthi | Zingiber officinaleRosc. | Rhizome | 1 part | Powder |
| 2. | Maricha | Piper nigrum Linn. | Fruit | 1 part | Powder |
| 3. | Pippali | Piper longum Linn. | Fruit | 1 part | Powder |
| 4 | Kajjali | Sulphide of mercury | Powder | $1/8^{th}$ part | Powder |

**Table 2: Organoleptic characters of TrikatuKajjali**

| Drug | Colour | Odour | Taste | Consistency |
|---|---|---|---|---|
| **Trikatukajjali** | Black | Aromatic | Pungent | Hard,Tablet |

**Table 3: Physico-chemical parameters of Trikatukajjali**

| Name of the Analysis | Value of Trikatukajjali |
|---|---|
| Loss on drying percentage | 1.6% w/w |
| Acid insoluble Ash | 1.56%w/w |
| Ash value percentage | 12.84% w/w |
| pH value (5% aqueous) | 6.5 |
| Water soluble extract percentage | 35.93% w/w |
| Alcohol soluble extract percentage | 22.14% w/w |
| Weight variation of vati | Average wt. 250 gm<br>Highest wt. 270 gm<br>Lowest wt. 180 gm |

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