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Pharmaceutical Analysis of An Anti-Diabetic Formulation: *Kimshukatvagadi Ghana* Capsule

Research Article

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Abstract

Ayurveda is one of the oldest and holistic science. Herbal medicines have a long therapeutic history; serving many of the health needs of large population of the world. However, the quality control and assurance remains as a challenge due to the high discrepancy of chemical components involved. In *Ayurvedic* texts, several formulations have been mentioned in Prameha (Diabetes Mellitus). *Kimshukatvagadi* is one such formulation mentioned in Sahasrayoga Vati Prakarana adhyaya. It contains *Palash* (*Butea monosperma* Lam.), *Haridra* (*Curcuma longa* L.), *Amalak*i (*Emblica officinalis* L.), *Kataka* (*Strychnos potatorum* L.f.), *Vairi* (*Salacia reticulata* Wight). *Kimshukatvagadi Vati* was converted into Ghana to increase its potency and then it was sealed into Capsule for increasing the shelf life, making it easy to dispense, dose fixation etc. *Kimshukatvagadi Ghana Capsule* was subjected to organoleptic analysis, phytochemical and qualitative analysis to detect the presence of various functional groups, and to high performance thin layer chromatography (HPTLC) examination by optimizing the solvent systems.

Key Words: *Kimshukatvagadi Ghana Capsule*, Anti-Diabetic, HPTLC.

Introduction

Diabetes Mellitus is a metabolic syndrome of multiple etiologies characterized by chronic hyperglycemia with disturbances in carbohydrate, fat and protein metabolism resulting into defects in insulin secretion, insulin action or both(1). It has claimed ~4 million adult deaths in 2017 and India is considered as the "diabetes capital" of the world(2).

Ayurveda emphasizes on maintenance and promotion of health along with a vivid description of diseases and its management. Herbal drugs- singularly and in combinations are used(3). It contains several compounds in complex matrices where a single active constituent is not responsible for its overall efficacy. The Standardization of herbal formulations plays a pivotal role in the assessment of drug quality, its active principles and chemical constituents. Quality of raw materials along with preparation plays an important role in the acceptability and safety of the drug(4). In India, the Department of AYUSH has launched a central scheme to develop standard operating procedures for the manufacturing process for developing the pharmacopoeial standards of Ayurvedic preparations.

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In this study, *Kimshukatvagadi Ghana Capsule* was prepared by following the standard operating procedures in a GMP certified ayurvedic pharmacy. This formulation is used as a Pramehaghna medicine. The pharmaceutical analysis of this formulation has been taken for its therapeutic values and efficacy. Analytical study of *Ghana Capsule* was performed with the following parameters: Organoleptic parameters (Appearance, color, odor, taste), physio-chemical parameters (Loss on drying, Total ash, Acid insoluble ash, Water soluble extract, Alcohol soluble extract, pH, Uniformity of weight, qualitative and HPTLC.

Aims and Objectives

- Identification and authentication of raw drugs used for *Kimshukatvagadi Ghana Capsule.*
- Preparation of *Kimshukatvagadi Ghana Capsule* at GMP certified pharmacy.
- Physicochemical, phytochemical and HPTLC analysis of *Kimshukatvagadi Ghana Capsule*

Materials and methods

Collection Plant Material

Palash (*Butea monosperma* Lam.), *Haridra* (*Curcuma longa* L.), *Amalak*i (*Emblica officinalis* L.), *Kataka* (*Strychnos potatorum* L.f.), *Vairi* (*Salacia reticulata* Wight) were purchased from authenticated resources of Vadodara and Kerala.

Identification and Authentication of Raw Drugs

Identification and authentication of raw drugs were done by the Department of *Dravyaguna,* Parul Institute of Ayurveda, Parul University, Vadodara.

Method of preparation of *Kimshukatvagadi Ghana Capsule*

All the ingredients of Kimshukatvagadi *Ghana Capsule* (Table 1) were taken in equal quantity, converted into coarse powder, stirred thoroughly until a homogenous mixture was obtained. According to *Sharangdhar Samhita* the Kashaya preparation was done and transformed into Ghana(5). Prepared Ghana was kept in a hot oven for 3 days until it was completely dried. The dried Ghana was collected from hot oven, powdered and capsule of 500mg were prepared.

Table 1: Ingredients of *Kimshukatvagadi Ghana Capsule*

Name of Drug	Botonical Name	Family	Part Used
Palash	*Butea monosperma* Lam.	Leguminosae	Stem Bark
Haridra	*Curcuma longa* L.	Zingiberaceae	Rhizome
Amalaki	*Emblica officinalis* L.	Phyllanthaceae	Fruit
Kataka	*Strychnos potatorum* L.f.	Loganiaceae	Seed
Vairi	*Salacia reticulata* Wight	Celastraceae	Root

Methods of evaluation of *Kimshukatvagadi Ghana Capsule*:

Kimshukatvagadi Ghana Capsule was analyzed by using all the standard qualitative and quantitative parameters conducted at Laboratory of G.M.P certified Parul Ayurveda Pharmacy, Vadodara.

Physico-Chemical Analysis

It includes parameters like colour, taste, pH, Loss on Drying(6), total ash value(7), acid insoluble ash(8), alcohol soluble extract(9), water soluble extract and uniformity of weight(10).

Qualitative analysis:

The qualitative analysis(11) of *Kimshukatvagadi Ghana Capsule* was done for Glycoside Sugar, Alkaloids, Tannins, Flavonoids, Gallic acid, Ascorbic Acid, Saponin, Starch.

Chromatography:

High-Performance Thin Layer Chromatography (HPTLC) a refined form of TLC. It works on the same principles as TLC i.e. the principle of adsorption and separation but with a better resolution by separation of components than normal TLC. High performance thin layer chromatography(12) uses chromatographic stationary phases with superior separation efficiency, employs with the state of the art and instrumentation for all steps in the procedure. All the methods and procedures followed for HPTLC of *Kimshukatvagadi Ghana Capsule* have been discussed below.

Results and Discussion

Kimshukatvagadi Ghana Capsule was prepared by following all the standard operating procedures in GMP certified pharmacy and was subjected to qualitative and quantitative analysis. The pharmaceutical analysis results have been discussed below.

Organoleptic evaluation

The organoleptic parameters are one of the basic criteria for the selection of raw ingredients and confirming the quality of the finished formulation. The color was brown, sour and astringent in taste and the smell was slightly aromatic due to the special properties of the ingredients used.

Table 2: Organoleptic Characteristics of *Kimshukatvagadi Ghana Capsule*

Sr. No.	Characters	Observation
1	Color	Brown
2	Odor	Slightly Aromatic
3	Taste	Sour, Astringent

Loss on drying

It is referred to determine the moisture contents of the sample i.e. water and volatile contents. In this sample of *Kimshukatvagadi Ghana Capsule*'s loss of drying was 10 %, i.e. the sample is having a good shelf-life and will not decay when stored for a long period.

Total ash and acid insoluble ash

Total ash value is a method used to quantify the amount of total inorganic compound. Acid insoluble ash test we can know only about silica availability. It is helpful in determining the quality and purity of crude drugs also about contamination, substitution and adulteration. In the given sample, the ash value was 2% and 1.02% acid insoluble ash, which was slightly higher after incineration due to the presence of fibers and sclereids but within normal limits when used internally.

Water and Alcohol soluble extracts

The given sample of *Kimshukatvagadi Ghana Capsule* conatins 80% of Water soluble extract and 3.84% of Alcohol soluble extract. High water solubility indicates that the drug is best suited for extraction with water or water-based preparations.

pH

The pH is expedient to detect the acidity or basicity of the aqueous solution of the drug. It helps to understand the drug absorption and metabolism. In this sample of Kimshukatvagadi Ghana Capsule pH was 6.0% which clearly indicates that the drug tested was acidic in nature.

Uniformity of weight

It helps in the distribution of the medicine and to fix its quantity. The average weight of the present sample of *Kimshukatvagadi Ghana Capsule* was 508 mg. This indicates the uniformity of the weight in relation with the planned weight of each *Capsule* i.e. 500 mg.

Qualitative analysis

Kimshukatvagadi Ghana Capsule was subjected for qualitative analysis, identifying the active principles of the formulation and showing the presence of alkaloids, tannin, saponin, ascorbic acid and glycoside sugar as shown in TABLE 4.

Table 3: Physico-Chemical Analysis of *Kimshukatvagadi Ghana Capsule*

Sr. No	Parameter	Value
1	Loss on drying at 105⁰ C (%w/w)	10
2	Total Ash Value (%w/w)	2.0
3	Acid Insoluble Ash (%w/w)	1.02
4	Water soluble extractive (%w/w)	80
5	Alcohol soluble extractive (%w/w)	3.84
6	pH (5% Aqueous)	6.0
7	Weight variation	
	Average weight (%w/w)	508
	Highest weight (%w/w)	3.32
	Lowest weight (%w/w)	1.43

Table 4: Showing Qualitative Analysis of *Kimshukatvagadi Ghana Capsule.*

Sr. No.	Solvent	Present (+) / Absent (-)
1	Glycoside Sugar	+
2	Alkaloids	+
3	Tannin	+
4	Saponin	++
5	Ascorbic Acid	+
6	Gallic Acid	+
7	Starch	+
8	Triterpenoid	-

Chromatography

It was done by Vasu Research Centre, Vadodara. HPTLC fingerprinting report was done for the analysis of the finished formulation *Kimshukatvagadi Ghana Capsule.*

High-Performance Thin Layer Chromatographic Study

Sample was prepare by weighing 1g in an iodine flask and applying 20ml of methanol to it. Reflux was done for 30 min in a warm bath. After the timer went off, Whatman filter paper No.1 was used to filter. The test solution was used for HPTLC fingerprinting. Preparation of Spray reagent (Anisaldehyde-Sulphuric acid reagent): A mixture was prepared of 0.5 ml anisaldehyde with 10ml glacial acetic acid followed by 85 ml methanol and 5ml Sulphuric acid (98%).

Table 5: HPTLC chromatographic condition details have been mentioned	
Chromatographic Conditions:	
Application Mode	CAMAG Linomat 5 – Applicator
Filtering System	Whatman filter paper No. 1
Stationary phase	MERCK – TLC / HTPLC Silica gel 60 F_{254} on Aluminium Sheets
Application (Y axis) Starting Position	10 mm
Development End Position	80 mm from plate base
Sample Application Volume	10 µL
Development Mode	CAMAG TLC Twin Trough Chamber
Chamber Saturation Time	30 minutes
Mobile Phase (MP)	Toluene: Ethyl Acetate: Formic Acid (7:3:1 v/v)
Visualization	@ 254nm, @ 366 nm and @ 540 nm (after derivatization)
Spray Reagent	Anisaldehyde Sulphuric Acid reagent
Derivatization mode	CAMAG – Dip tank for about 1 min
Drying Mode, Temp. & Time	TLC Plate Heater Preheated at 100±5⁰C for 3 minutes

HPTLC details at different Rf

After derivatization, plate was examined and different bands at different R_f were found. These following were the findings:

Details of HPTLC of all tracks @ 254 nm**:** Under the 254 nm wavelength-Track -T1 *of Kimshukatvagadi Ghana Capsule*, 9 spots were identified and with respect to retardation factor it is 0.14,0.22,0.32,0.39,0.52,0.59,0.69,0.82 and 0.90.

Details of HPTLC of all tracks @ 366 nm: Under the 366 nm wavelength-Track -T1 of *Kimshukatvagadi Ghana Capsule,* 7 spots were identified and with respect to retardation factor it is 0.14,0.18,0.27,0.43,0.57,0.82 and 0.90.

Details of HPTLC profile of all tracks @540 nm: Under the 540 nm wavelength-Track -T1 of *Kimshukatvagadi Ghana Capsule*, 9 spots were detected and with respect to retardation factor it is 0.22,0.32,0.39,0.43,0.52,0.74,0.77,0.82 and 0.90**.**

HPTLC generated @ 254 nm, @ 366 nm and @ 540 nm after the derivatization, reveals that the presence of 9 spots, 7 spots and 9 spots at each wavelength respectively. Thus, the formulation *Kimshukatvagadi Ghana Capsule* is rich in phytoconstituents.

Conclusion

Any formulation used medicinally requires a detailed study prior to its use. The therapeutic efficacy of the drug depends on the quality of the ingredients used for the preparation of the medicinal product. *Kimshukatvagadi Ghana Capsule* was pharmacologically subjected for physicochemical, qualitative and HPTLC. The ingredients of *Kimshukatvagadi Ghana Capsule* are *Palasha, Haridra, Kataka, Amalaki, Vairi* and it is an herbal formulation. In this study, *Kimshukatvagadi Ghana Capsule* was prepared in according to the classical references and by following standard operative procedures at a GMP certified pharmacy. Raw materials of the drug were identified and authenticated prior to the preparation. The drug was subjected pharmacologically to physicochemical analysis, qualitative and HPTLC analysis. The groundwork for standardization of *Kimshukatvagadi Ghana Capsule* has been attempted in this study.

Conflict of Interest: None

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