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Preparation, Quality Control and Stability Studies of Avipattikar churna

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ABSTRACT

Throughout world more people are turning to use medicinal plant products in healthcare system. Worldwide need of alternative medicine has resulted in growth of natural product markets and interest in traditional systems of medicine. Proper integration of modern scientific techniques and traditional knowledge is important. There is a growing focus on the importance of traditional health care system (*viz*. Ayurveda, Unani, Homoeopathy, Yoga) in solving health care problems. Systematic approach and well-designed methodologies for the standardization of herbal formulations are developed. In the present study preparation of *Avipattikar Churna* was carried out and then it was subjected to various quality control parameters. The formulation was prepared as per the guidelines mentioned in pharmacopeia & various tests performed were physical properties (such as moisture content) , biochemical test, ash value, HPLC, IR spectroscopy. The above parameters can be used as preliminary standardization for quality control of *Avipattikar Churna* .

Keywords: Standardization, herbal formulation, *Avipattikar Churna*, Physicochemical properties.

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INTRODUCTION

Ayurveda, Siddha, Unani and Homeopathy drugs consist of various kinds of formulations prepared from plants, minerals, metals, animal and marine products as raw material. These formulations are prepared after various kinds of processing with the specific methods prescribed in these systems. These formulations are grouped in various dosage form according to their method of preparation, palatability, bioavailability and therapeutic values accordingly their nomenclature is given in texts mentioned in Drugs and cosmetic Act.

Standardization of drugs means confirmation of its identity, determination of its quality, purity and detection of nature of adulterant by various parameters like morphological, microscopical, physical, chemical and biological evaluations.

The propagation and acceptance of ASU (Ayurveda, Siddha & Unani) particularly Ayurveda, is increasing. *Avipattikar Churna* is an Ayurvedic medication used for treating gastrointestinal complaints. It is beneficial for the management of constipation and gastritis. It contains powerful medicinal herbs, which help in supporting the functions of the digestive tract and relieve the symptoms of these diseases. It can also be used to treat urinary disorders that cause a difficulty in passing urine or painful urination.AvipattikarChurna is an ayurvedic herbal medicine used for hyperacidity, gastritis, burning ache due to excess acid, loss of appetite and indigestion linked with gastritis, piles, urinary problems, difficulty in micturition and kidney stones.

त्रिकटु त्रिफला मुस्तं विडञ्चैव विडङ्गकम् ।
एलापत्रञ्च चूर्णानि समभागानि कारयेत् ।।२४।।
सर्वमेकीकृतं यावल्लवङ्गं तत्समं भवेत् ।
सर्वचूर्णद्विगुणितं त्रिवृच्चूर्णं प्रदापयेत् ।।२५।।
सर्वमेकीकृतं यावत्तावच्छर्करयान्वितम्।
अम्लपित्तं निहन्त्याशु विबन्धं मलमूत्रयोः।।२६।।
अग्निमान्द्यभवान् रोगान् नाशयेदविकल्पतः।
प्रमेहान् विंशतिञ्चैव सर्वदुर्नामनाशनम्।।
अविपत्तिकरं चूर्णमगस्त्यविहितं शुभम्।।२७।।
(भैषज्यरत्नावली, अम्लपित्ताधिकार; २४-२७)

Dose : 3 to 6 g

Important Therapeutic Uses

Agnim¡ndya (Digestive impairment), Malabandha (Constipation), Amlapitta (Dyspepsia), Arsa (Haemorrhoids), M£trabandha (Retention of urine), Prameha (Urinary disorders)

Indications, Benefits & Uses

The health conditions that can be treated using AvipattikarChurna are as follows:

Stomach complaints

Avipattikar Churna is a combination of Ayurvedic herbs, which can help in relieving the symptoms of several gastrointestinal problems. It is used for treating gastritis, and peptic ulcers. It works by balancing the pH levels of the stomach and helps to control hyperacidity. The natural herbs present in this medicine reduce the production of acid in the stomach and protect the stomach mucosa from the damage caused by the acidic secretion.

It is a wonderful remedy for treating heartburn. It soothes the lining of the stomach and the esophagus and gives quick relief from sour eructation. This action of Avipattikar Churna is beneficial in the management of GERD or Gastroesophageal Reflux Disorder that occurs due to the backward flow of acid from the stomach into the esophagus. It reduces the damage caused by the acidic reflux into the esophageal mucosa thus preventing the development of esophageal ulcers and cancer.

It also acts as an appetizer and hence, is commonly given to the patients having loss of appetite due to a range of disorders like depression, peptic ulcers, and any choric debilitating disorder.

Intestinal disorders

Avipattikar Churna also helps in the digestion of the food and prevents bloating and flatulence. It supports the growth of healthy microbial flora, which helps in boosting digestive functions.

Avipattikar Churna helps in treating other digestive ailments like constipation, diarrhea, and indigestion. The main ingredient of this medicine, Amla, is believed to be beneficial in treating intestinal complaints. It is an excellent antioxidant, which fights against the unwanted free radicals and toxins in the gut and thus, ensures proper functioning of the digestive organs. It also activates the action of digestive juices. AvipattikarChurnastimulates the functions of the liver and improves the metabolism of food. It can also be used in the treatment of piles.

Urinary complaints

Avipattikar Churna can be used in the treatment of urinary disorders like renal stone and urinary infections. It is a strong antibacterial agent. It ensures destruction and elimination of the bacteria in the urinary tract, and thus, helps in treating urinary infections.

The Pharmacopeial standards in Ayurvedic, Siddha and Unani are not adequate enough to ensure the quality of formulations. Analysis of marker compounds is necessary to maintain the quality and identity of the formulations. In order to assess the quality of inhouse formulation,it was prepared at laboratory scale as per pharmacopoeial standards and it was subjected to various quality control tests.

MATERIALS AND METHODS

1. Raw Materials,Chemicals and Reagents

Plant Raw materials used for the preparation of *Avipattikar Churna* were procured Ayurvedic Proprietory Medicines Shop (Mumbai) with the knowledge of Ayurvedic physician. The materials were dried in an oven preset at 45°C, powdered, sieved through an 85-mesh (BSS) sieve and stored in air tight containers.

The Gallic Acid standard was procured from Himedia and Assigned purity: 98%.

2. Preparation of *Avipattikar Churna*:

Raw materials complying the pharmacopoeial quality and quantity were subjected to the preparation of Avipattikar Churna as per the composition [Table 1] . All the prepared powders amlaki , haritaki and bibhitaki were mixed thoroughly as per the standard protocol and stored in air tight container.

Table 1: Formulation composition

Sr. No.	Ayurvedic name	Botanical /English name	Quantity
1	Sunthi	*Zingiber officinale (Rz.)*	1 parts
2	Marica	*Piper nigrum (Fr.)*	1 parts
3	Pippali	*Piper longum (Fr.)*	1 parts
4	Haritaki	*Terminalia chebula (P.)*	1 parts
5	Bibhitaki	*Terminalia bellirica (P.).*	1 parts
6	Amlaki	*Phyllanthus emblica (P.)*	1 parts
7	Musta	*Cyperus rotundus (Rz*	1 parts
8	Vidanga	*Embelia ribes (Fr.)*	1 parts
9	Elaichi	*Cardamom (Sd.)*	1 parts
10	Patra	*Cinnamomum tamala (Lf.)*	1 parts
11	Lavanga	*Syzygium aromaticum (Fl. Bd*	1 parts
12	Trivrt	*Operculina turpethum (Rt.)*	1 parts
13	Vida	*VidaLavana*	1 parts
14	Sarkara	*Saccharum officinarum*	1 parts

3. Quality Evaluation of *Avipattikar Churna*

Organoleptic evaluation :

The formulation was studied for its preliminary characters like colour,texture,odour and taste.

- **Preliminary Phytochemical and Biochemical Evaluation**

Phytochemical screening of some major secondary metabolites (Flavonoids, Tannins, Alkaloides,Glycosides ,Terpenoids,Steroids, Phlobatannin, Phenolic Compounds and Saponins) and Biochemical for Carbohydrates ,Proteins and Fats in Avipattikar Churna was carried out by performing preliminary colour based tests.

- **Physicochemical Evaluation :**

The prepared formulation was subjected for physical studies like Bulk density,Tap Density, Compressibility Index, Housner Ratio and Ash Value.

- **Chromatographic Evaluation:**

Preparation of Standard:

Eugenol standard was prepared in methanol with initial concentration of 1000 ppm.Further dilution of 100 ppm was prepared using mobile phases.

Preparation of Sample:

All the raw materials and prepared formulation powders were dissolved in Methanol and kept overnight.Next day al the solutions were filtered through whattman filter paper to obtain clear extracts.

- **High Performance Thin Layer Chromatography (HPTLC) Fingerprinting :**

10 µl of the filtered solution of formulation extract and standard was applied on the HPTLC plate as per condtions mentioned in table 1a followed by development, derivatizing with Vanillinic Acid and scanning at 366 nm.

Table 1a :Chromatographic Conditions for HPTLC:-

Stationary Phase	HPTLC plates silica gel 60 F 254
Plate size	10.0x10.0 cm
Mobile Phase	Toulene:Ethyl Acetate:Glacial Aceatic Acid (9:1:0.1)
Saturation Time	20 min.
Standard Used	100 ppm Eugenol
Spot Volume	10 µl
Band Length	8.0mm
Solvent Front	80mm
Wavelength and Lamp	366nm & Mercury lamp
Sample Applicator	CAMAG Linomat 5
Sample Detection	CAMAG Visualizer : 200480
Number of Tracks	5

- **High Performance Liquid Chromatography (HPLC) evaluation :**

HPLC was also performed to carry out stability studies and to find out the eugenol content in prepared formulation as per conditions mentioned in table 1b.

Table 1b :Chromatographic Conditions for HPLC:-

Mobile phase	Methanol- acetonitrile- water in volume ratio of 10 : 50 : 40
Stationary Phase	C_{18} (4.6 × 250 mm, 5 µm).
Flow rate	1 ml/min
Injection volume	20 µl
Detection	UV at 272nm

RESULTS AND DISCUSSION

Avipattikar churna was prepared in the laboratory as given in standard Ayurvedic literature.The observed results clearly indicates good quality of *Avipattikar churna*. The organoleptic characters (table 2) help to indentify the formulation from its external appearance. Studies on physicochemical constants (table 3) can provide valuable source of information and suitable standards to determine the quality of the formulation. Phytochemical evaluation helped to understand the presence of various therapeutically active constituents in *Avipattikar Churna*. It was found that tannins,Steroides, saponins and phenolic compounds were present (table 4). The presence and absence of these phytoconstituents in particular formulation depends upon raw materials present into it and the procedure used for ots preparation.Biochemical tests were also performed to check presence of nutritives like Carbohydrates ,proteins ,Fats and Starch. The tests were positive for all except Fats(table 5).

These Phytochemical and Biochemical tests are important to obtain preliminary information on the quality. According to Mohan et al. different chemical compounds detected in whole plant extracts could make the plant useful for treating different ailments as having a potential of providing useful drugs of human use.

The prepared formulation was then assesed for its quality by checking the presence of marker compound Gallic acid by hyphenated techniques like HPTLC and HPLC. HPTLC fingerprinting and HPLC both are very useful techniques to check the presence or to confirm raw materials in formulations. For monitoring quality ,one can visualize the presence of various plant chemical constituents in raw materials as well as formulation , out of these a marker compound can serve as a characteristic fingerprint for that formulation (Fig 1 and 2).

Table 2 :Organoleptic Characters

Sr. No.	Characters	Avipattikar Churna
1	Colour	Burdywood
2	Taste	No Specific
3	Texture	powder
4	Odour	No Specific

Table 3 :Physicochemical evaluation

Sr. No.	Parameters	*Avipattikar Churna*
1	Bulk Density	0.542gm/ml
2	Tap Density	0.724gm/ml
3	Hausner Ratio	1.952 gm/ml
4	Compressibility Index	15.8 %
5	Total Ash	0.039

Table 4 : Phytochemical Evaluation

SR NO.	TESTS	OBSERVATION	RESULTS
1	Tannin: 1ml Aq. Extract + 0.1% $FeCl_3$ dropwise	Brownish green or Blue black colour	+
2	Alkaloids: 1ml Alc. Extract + 1ml conc. HCl + Hager's Reagent	Yellow ppt	-
3	Glycosides: 1ml extract + 0.5ml Glacial Acetic acid + few drops of Dil. $FeCl_3$ till colourless + 1ml Dil. H_2SO_4	Brown Ring	-
4	Flavonoids: 1ml extract+ 1ml Dil. ammonia solution + Conc. H_2SO_4	Yellow colour disappear	-
5	Steroids: 1ml extract + 1ml chloroform + Conc H_2SO_4	Red colour after stand	+
6.	Phlobatannin: 0.5ml aq. Extract+ Boil with 1ml 1% HCl	Ppt present	-
7.	Phenolic Compounds: 1ml extract + dropwise $FeCl_3$	Violet colourppt	+
8.	Saponin: 1ml extract + Few drops of olive oil+ Shake vigorously	Froth	+
9.	Terpenoids: 1ml extract +0.5ml $CHCl_3$+ 1ml Conc. H_2SO_4	Yellow colour	-

Key : + positive, - Negative

Table 5 : Biochemical Evaluation

Sr no.	Tests	Observation	Results
1.	Carbohydrate: 1ml extract + 1ml Fehling A + 1ml Fehling B	Blue Colour	+
2.	Proteins: 1ml extract + 1ml 4% NaOH + few drops 1% $CuSO_4$	Violet or pink colour	+
3.	Fats and Fixed oils: 1ml extract + 1ml KOH + 2drops of phenolphthalein + heat for 15mins on water bath	Formation of froth and neutralisation of alkali	-
4	Starch: 1ml extract + iodine	Blue colour	+

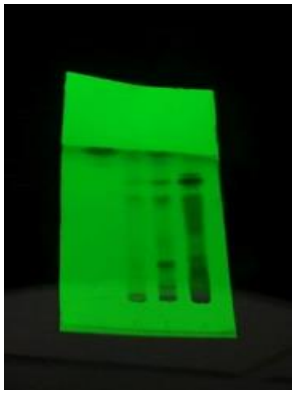

Fig 1 : HPTLC fingerprint

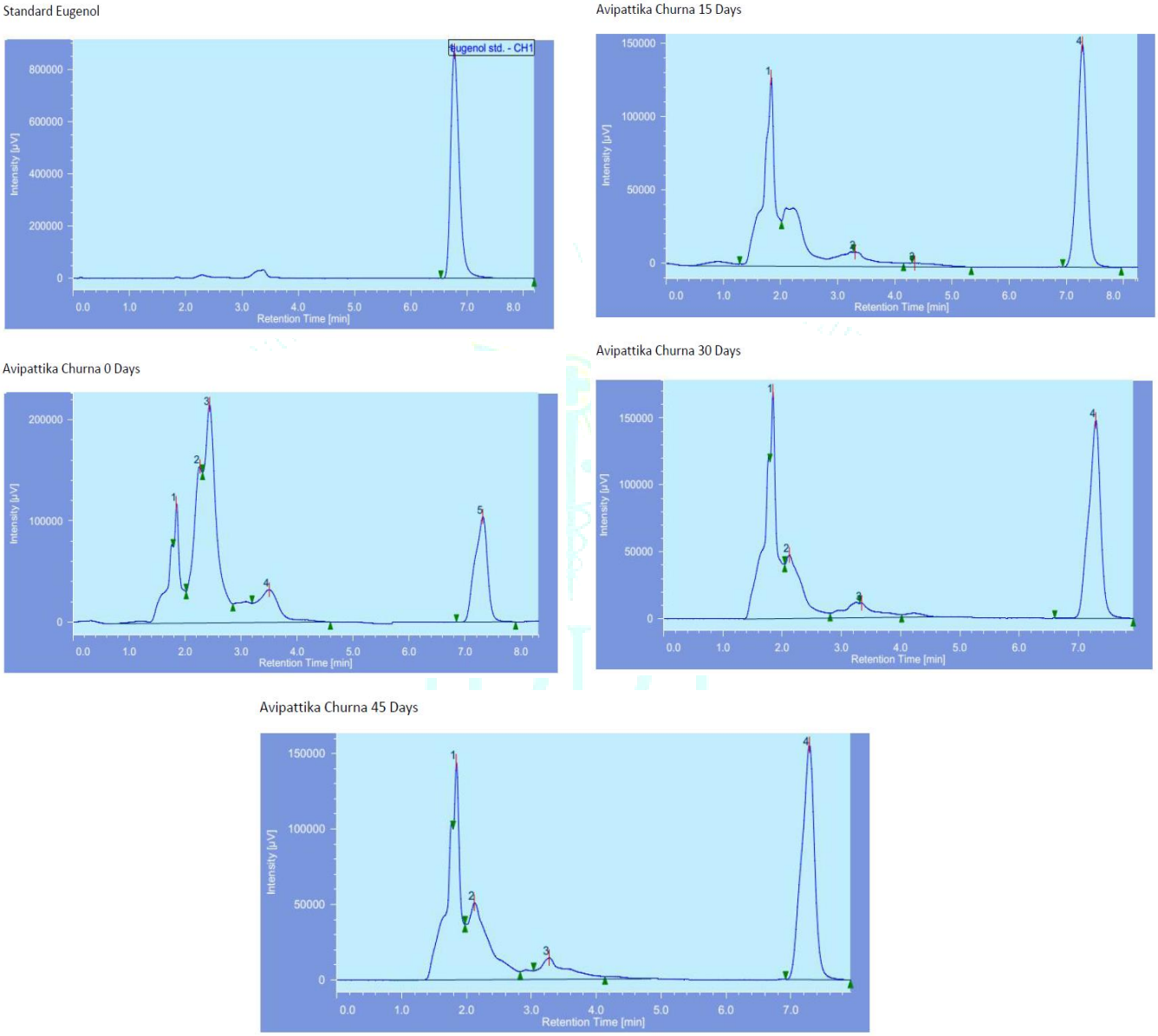

Fig 2 : HPLC Analysis and Stability studies

Sr.No.	Peak Name	CH	tR [min]	Area [µ V sec]
1	Eugenol	1	6.775	9310348
2	0	1	7.317	1617910
3	15	1	7.275	1833863
4	30	1	7.292	2091643
5	45	1	7.283	2162051

CONCLUSION

The main aim of research was to prepare the formulation on the lab scale and did the standardization to study the quality control parameter and shelf life of formulation as per WHO guidelines and API. So different test like physiochemical test, biochemical test, microscopy, microbiological analysis and instrument were used as higher technique in standardization and to study the shelf life. Extracts of the formulations was kept so that further stability studies can be done.

Stability studies of formulations upto 45 days was carried out to confirm whether phytoconstiuents present in the raw materials are same in formulation and to confirm the presence of eugenol after regular interval of time so as to confirm whether product is stable to be consumed or not, even after despite of adding any preservatives.

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