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Standardization and detailed aspects of Marichadi Gutika

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Abstract
Since ancient times, there has been exponential growth in the field of herbal remedies. Newer guidelines for standardization, manufacture, quality control and scientifically rigorous research are necessary for traditional medicines. Marichadi Gutika is an Ayurvedic formulation described in Ayurvedic pharmacopoeia. Marichadi Gutika (Vati) is an efficient Ayurvedic formulation that is able to maintain the balance of Vata and Kapha Doshas in the body. Gutika was standardized by different parameters like physicochemical parameters include Ash value, extractive value, LOD, Physical parameters like hardness, friability, disintegration and chromatographic examination include HPTLC fingerprinting, quantification of marker. And also evaluated by various parameters like, Hardness, weight variation and disintegration time. All parameters were passed from its standard limits. The set parameters were found to be sufficient to evaluate the gutika and can be used as reference standards for quality control/quality assurance laboratory of Pharmaceutical house.

Keywords: Marichadi gutika, HPTLC fingerprinting, quality control, standardization

Introduction
Herbal medicines are generally available as a mixture of more than one plant constituent. It is important to quantify the maximum possible number of markers in such herbal formulations through which the quality of the formulation may be assessed. Marichadi Gutika (Vati) is known as one of the great Ayurvedic formulation that is prepared from various mixtures of herbs. This is known to treat the problem of respiratory system. Marichadi Gutika (Vati) is an efficient Ayurvedic formulation that is able to maintain the balance of Vata and Kapha Doshas in the body. Marichadi Gutika (Vati) is an efficient Ayurvedic formulation that is able to maintain the balance of Vata and Kapha Doshas in the body. It is very useful to get rid of respiratory conditions. It is an effective Ayurvedic medicine which is helpful in bronchitis, where it improves the immunity and reduces fever and along reduces inflammation in the airways. Helps to expectorate excess of the mucus, and thus reduces chest pain, helps in ease of breathing. It is also much beneficial in controlling asthma; it enhances the immunity to fight the allergy and having bronchodilator effect, provides satisfactory relief, by reducing breathlessness. It is also able to control the cough and relaxing the sufferer as well as provides soothing feeling in cold. It is beneficial in rhinitis too, boosts the immunity, and helps to reduce inflammation of the nose and relieves congestion and promotes easy elimination of mucus from the nose and, imparts relief from sneezing and lessens the irritation in the throat. As it is difficult to estimate each and every ingredient for its chemical constituent, few of the main ingredients of Marichadi gutika have been identified and standardized. The formulation describes the presence of pepper the principal constituents of which are piperine respectively. It was thought worthwhile to evaluate the content of these four ingredients in the formulation.

Marichadi Gutika: मरिचादि गुटिका कासादौ:
मरिचं कर्षमात्रं स्यात्पिप्पली कर्षसंमिता ॥१३॥
अर्धकर्षौ यवक्षार: कर्षयुग्मं च दाडिमम्
एतत् चूर्णीकृतं युञ्ज्यत् अष्टकर्षगुडेन हि ॥१४॥
शाणप्रमाणं गुटिकां कृत्वा वक्त्रे विधारयेत् ।
अस्या: प्रभावात् सर्वेऽपि कासा यान्त्येव संक्षयम् ॥१५॥

Materials and Methods

All the methods used were as per the Patil S. *et al* (2011) [5].

Raw materials, chemicals and reagents

Plant Raw materials used for the preparation of Marichadi Gutika 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.

Preparation of Marichadi gutika

Raw materials complying the pharmacopoeial quality and quantity were subjected to the preparation of Marichadi Gutika as per the composition (Table 1). All the prepared powders viz. Maricha, Pipali, Yavakshara, Dadima and Guda were mixed thoroughly as per the standard protocol and stored in air tight container.

Table 1: Formulation composition

S. No.	Ayurvedic name	Botanical /English name	Part use	Quantity
1	Maricha	*Piper nigrum*	Seed powder	36gm
2	Pippali	*Piper longum*	Fruit Powder	36gm
3	Yavakshara	*Hordeum vulgare*	---	18gm
4	Dadima	*Punica grantum*	Fruit powder	72gm
5	Guda (Jaggery)	---		288gm

Quality evaluation of Thirikadu choornam

All the parameters have been performed as described by Patil Sonali, *et al.,* (2018).

Organoleptic evaluation

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

Preliminary phytochemical evaluation

Phytochemical screening of some major secondary metabolites (Flavonoids, Tannins, Alkaloides, Glycosides, Terpenoids, Steroids, Phlobatannin, Phenolic Compounds and Saponins) 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, Ash Value, Hardness, Friability and disintegration studies.

Heavy metal determination

According to the principles of Ayurvedic medicine, heavy metals may be used because of their reputed therapeutic properties. However, improper manufacturing processes may result in dangerously high levels of heavy metals remaining in the final product. Heavy metals pose a particular health risk because they may accumulate in vital organs. Thus, it is important to check for their presence in the ayurvedic formulations.

Microbiological assay

Total viable count was most widely accepted technique recommended by WHO for total count of microorganisms in plant materials and herbal formulations. All of the various pharmacopoeia the total viable count has range from 10^5-10^7 cfu/g. Total aerobic and anaerobic bacteria count is done by spread plate technique and then incubate at 30-35^{0}C for 24hrs. To count yeast and mould the technique employed spread plate technique in saboraud dextrose agar is used and incubate at 30-35^{0}C for 24 hours. The specification of WHO for total aerobic microorganism is not more than 10^7 cfu/g and for fungi and mould 10^4 cfu/g for plant materials. High counts of fungi are risk because of the possibility to produce mycotoxin such as aflatoxin which are carcinogenic. Based on OSP3 the total microbial count dried or powdered herbal materials and product was not more than 10^5 cfu/g.

High performance thin layer chromatography (HPTLC) fingerprinting

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 whatman filter paper to obtain clear extracts.

10 µl of the filtered solution of formulation extract and standard was applied on the HPTLC plate as per condtions mentioned in table 1a. For authentication of presence for raw material in formulation without any presence of adultrations.

Table 1a: Chromatographic Conditions for HPTLC

Stationary Phase	HPTLC plates silica gel 60 F 254
Plate size	10.0x10.0 cm
Mobile Phase	Hexane: Ethyl Acetate: Glacial Acetic Acid (3:1:0.1)
Saturation Time	20 min.
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	4

Stability testing by HPTLC

Stability Testing by HPTLC was also performed to find out the evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light.

Table 1b: Chromatographic Conditions for HPTLC

Stationary Phase	HPTLC plates silica gel 60 F 254
Plate size	10.0x10.0 cm
Mobile Phase	Hexane : Ethyl Acetate : Glacial Acetic Acid (3:1:0.1)
Saturation Time	20 min.
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	4

Results and Discussion

Marichadi Gutika was prepared in the laboratory as given in standard Ayurvedic literature. The observed results clearly indicates good quality of Marichadi Gutika.

The organoleptic evaluation (Table 2) provides the simplest and quickest means to establish the identity and quality of a particular sample which are useful in judging the material in its entirety and in powder form. Physicochemical evaluation (Table 3) like ash value, Hausner's ratio, compressibility etc was carried out.

Ashing involves an oxidation of the components of the product. The total ash usually consists of carbonates, phosphates, silicates and silica which include both physiological ash and non-physiological ash. Acid insoluble ash particularly indicates contamination with silicious materials, comparisons of this with the total cash value of the same sample will differentiate between contaminating materials and variations of the natural ash of the drug. Bulk characterization is necessary to avoid misleading predictions of stability or solubility which depends on a particulate flow ability of granules or powder. Bulk density and tapped density is useful for determination of packing of powders material. The results indicate that the bulk density and tap density of formulation was found to be comparable and variation was insignificant. Hausner's ratio was related to interparticulate friction and could be used to predict powder flow properties. It showed that powder with low interparticulate friction, such as coarse sphere, had ratio of approximately 1.2 whereas less free flowing powder such as flakes have Hausner's ratio greater than 1.6. The percentage compressibility of a powder that is Carr's index is a direct measure of a potential powder arch or bridge strength and stability. If percentage compressibility is in the range of 28-35 it show fluid cohesive powder, the percentage compressibility of formulations indicates that formulation has fluid cohesive powder. Heaavy metal analysis provides absence of adulteration and its safety (Table 4). The Phytochemical evaluation (Table 5) gives the information about phytoconstituents present in the formulation. Phytochemical evaluation of gutika showed various type of major secondary metabolites which revealed their potent therapeutic activity. Microbiological assay (Table 6) showed the formulation is safe to consume as the cfu/ml is within the permissible limit. 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).

The main ingredient of formulation that is piperine is having same band length and color on TLC plate for day0, day15, and day 30 as in TLC plate for Marichadi Gutika fingerprint. So it can be concluded that formulation is stable for 30 days. Further confirmation of stability studies has to be carried out for longer period.

Table 2: Organoleptic characters

Sr. No.	Characters	Marichadi Gutika
1.	Colour	Dark Brown
2.	Taste	Spicy Bitter
3.	Texture	Hard solid
4.	Odour	No Specific
5.	Apperence	Sperical

Table 3: Physicochemical and physical evaluation

Sr. No.	Parameters	Marichadi Gutika
1.	Hardness	2.51 kg/m^3
2.	Friability	0.02%
3.	Disintegration	27.22 min
4.	Alcohol soluble extraction	21.11%.
5.	Water soluble extraction	20%.
6.	Ash value	6.59%
7.	Acid insoluble ash	1.47%
8.	Friability	0.02%
9.	Disintegration	27.22 mins.
10.	Hardness	1kg/m2

Table 4: Heavy metal determination

Sr. No.	Test	Result
1.	Lead	-
2.	Chromium	-
3.	Copper	-
4.	Cadmium	-
5.	Nickel	-
6.	Zinc	-
7.	Cobalt	-
8.	Bismuth	-

Table 5: Phytochemical evaluation

Sr. No.	Tests	Observation	Results
1.	Tannin: 1ml Aq. Extract + 0.1% $FeCl_3$ Drop wise	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.	Phlobatanins: 0.5ml aq. Extract+ Boil with 1ml 1% HCl	PPT present	+

7.	Phenolic Compounds: 1ml extract + drop wise $FeCl_3$	Violet colour PPT	-
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	-
10.	Carbohydrate: 1ml extract + 1ml Fehling A + 1ml Fehling B	Blue Colour	+
11.	Proteins:1ml extract + 1ml 4% NaOH + few drops 1% $CuSO_4$	Violet or pink colour	+
12.	Starch: 1ml extract + iodine	Blue colour	-

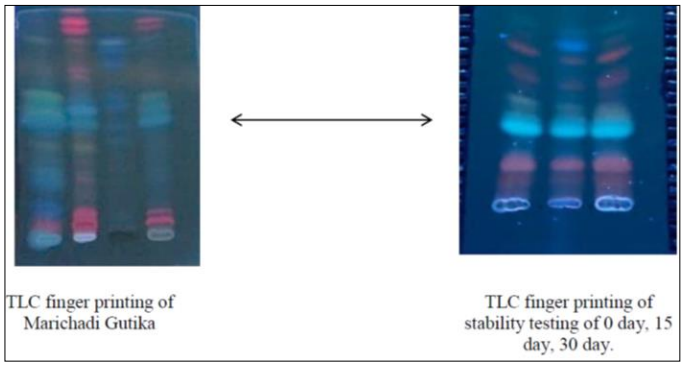
Key: + positive, - Negative

Table 6: Microbiological Assay (Total Viable)

Media	Organism	Dilution	Cfu/0.1ml	Cfu/1ml	Average Cfu/ml
Nutrient Agar	Aerobic	10^{-3}	12 x 10^{-3}	12 x 10^{-4}	3.69 x 10^6
		10^{-4}	11 x 10^{-4}	11 x 10^{-5}	
		10^{-5}	8 x 10^{-5}	8 x 10^{-6}	
Nutrient Agar	Anaerobic	10^{-3}	15 x 10^{-3}	15 x 10^{-4}	1.59 x 10^6
		10^{-4}	9 x 10-4	9 x 10^{-5}	
		10^{-5}	7 x 10^{-5}	7 x 10^{-6}	
Sabourauds Agar	Fungi	10^{-3}	54 x 10^{-3}	54 x 10^{-4}	5.75 x 10^6
		10^{-4}	7 x 10^{-4}	7 x 10^{-5}	
		10^{-5}	3 x 10^{-5}	3 x 10^{-6}	

Key Track: 1 *Piper nigrum*, 2- *Piper longum*, 3- Dadima, 4- Marichadi Gutika

Fig 1: HPTLC fingerprint



Mobile Phase- Hexane: Ethyl acetate: Glacial Acetic Acid (3: 1: 0.1)
Key Track of plate 1: 1- *Piper nigrum*, 2- *Piper longum*, 3- Dadima, 4- Marichadi Gutika
Key Track of plate 2: 1 – day 0 extract, 2 – day 15 extract, 3 – day 30 extract.

Fig 2: HPTLC Analysis

Conclusion

From the present investigation various standardization parameters such as physicochemical standards, HPTLC fingerprinting, physical parameters and stability studies were carried out, it can be concluded that the formulation of Marichadi Gutika was in accordance with the standards laid down for vati. The results obtained were found to be within the permissible limits as per WHO. As the above investigations are not specified in the standard literature such as in pharmacopoeia, the study will be helpful in authentication of Marichadi Gutika. The result of present study can be served as reference monograph in the preparation of drug formulation.

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