ESTABLISHMENT OF QUALITY CONTROL PARAMETERS OF VAISHVANARA CHURNA.

Himanshu Parate, Kirti Pawar, Bhupesh Nemade,
Sonali Patil , Shruti Shah

Department of Bioanalytical Sciences

B. K. Birla College of Arts, Commerce and Sciences(Autonomous), Kalyan.

ABSTRACT

Standardization of herbal formulation is essential to confirm its identity, quality and purity. The present study aims to characterize the Ayurvedic formulation: Vaishvanara Churna which is comprising of four types of herbal powder and rock salt. Vaishvanara Churna is prescribed for the treatment of constipation, abdominal pain & arthritis. The standardization was carried out on the basis of organoleptic, pharmacognostic, physicochemical, phytochemical, microbiological, spectroscopic & chromatographic parameters. The fingerprinting was performed using modern analytical technique like HPTLC to check presence of main phytoconstituent i.e gallic acid in raw materials as well as formulation. The parameters were found to be comparable and will be useful in establishing pharmacopeial standards for formulation.

Indexterms:- Ayurvedic, Vaishvanara churna, Formulation, Standardization.

I. Introduction

Vaishvanara means Fire in Sanskrit. This ayurvedic medicine is meant to correct digestive fire(Agni) in body.*(Vijaya Bhogale, 2020)*. Vaishvanara Churna is an Ayurvedic medicine available in herbal powder form. Vaishvanara churna is one of the most effective formulations used in the treatment of arthritis, constipation, abdominal pain and for improvement of digestion and strengthen immunity. Vaishvanara Churna is a mixture of 4 types of herbal powder and rock salt. It pacifies the vata and kapha doshas. It is composed of Ajwain (Carminative), Ajamoda (carminative, stimulant, cardiac tonic), Dry Ginger (Anti-inflammatory,Antinauseant) and Haritaki (Detoxificant, Purgative) and Rock salt . Therapeutic uses of Vaishvanara churna as mentioned in Ayurvedic literatures are in treatment of Amavata (Rheumatoid arthritis), Gulma (lump in abdomen), Hradroga (heart diseases), Sula (pain), Pleeha (spleenic disorder), Granthi (cyst), Vibandha (constipation), Vataroga. It was also recommended for use as Dipana (appetizer), Pachana (digestive), Vadanasamana (analgesic), Shotaprasamana (anti-inflammatory) and Vatanulomana.*(Patil Usha, 2016).*

Various quality control parameters including physicochemical, phytochemical analysis; analysis using modern analytical techniques like UV spectrophotometry, TLC, HPLC and HPTLC; Microbiological test and qualitative determination of heavy metals were carried out for raw materials as well as for finished formulation. (*Pattanayak , 2010).*

स्वस्थस्य स्वास्थ्य रक्षणं, आतुरस्य विकार प्रशमनं। (चरक संहित सूत्र ३०।२६)

Ayurveda Shastra aims at keeping a healthy person healthy and managing or curing diseases (mind, body or both) that manifest in a person.(Charak Samhita Sutra 30/26).

II. Materials and Methods

2.1 Raw Materials

Completely dried raw plant materials were collected from the local ayurvedic mart. The authenticity of the individual ingredients was confirmed by comparison of their power characteristics with those given in the literature.

2.2 Preparation of Churna

The Churna was prepared by mixing the ingredients in appropriate proportions (Table 1) as per guidelines set by Ayurvedic Formulary of India. All the laboratory analysis of the samples were done in the Department of Bioanalytical Sciences, B. K. Birla College (Autonomous), Kalyan(Patil Usha, 2016).

Sr. No	Ayurvedic Name	Scientific Name	Weight (in gms)
1.	Haritaki	*Terminalia chebula*	174.9
2.	Ginger	*Zingiber officinale*	72.91
3.	Sendha Namak	Rock salt	29.16
4.	Ajmoda	*Apium graveolens*	43.74
5.	Ajwain	*Trachyspermum ammi*	29.16

Table 1. Ingredients of Vaishvanara Churna

2.3 Quality Evaluation of Sitopaladi Churna

2.3.1 Organoleptic Evaluation

Organoleptic evaluation refers to evaluation of formulation by color, odor, taste, texture etc. The organoleptic characters of the samples were carried out based on the method described (Siddique *et al*., 1995).

2.3.2 Preliminary Phytochemical and Biochemical Evaluation

Phytochemical screening of some major secondary metabolites (Flavonoids, Tannins, Alkaloides, Glycosides, Terpenoids, Steroids, Phenolic Compounds and Saponins). (Indian Pharmacopoeia, 1996).

2.3.4 Physicochemical Evaluation

The prepared formulation was subjected for physicochemical tests like Bulk density, Tap Density, Compressibility Index, Housner Ratio and Ash Value (Priyabrata Pattanayak, 2010).

2.3.5 Heavy Metals Determation

Heavy Metal analysis was done to check if any heavy metals are present in the formulation (Agarwal Princy, 2018).

2.3.6 Microbial Screening

Vaishvanara Churna formulations were evaluated for their microbial load.Media such as Nutrient Agar and Saboraud Dextrose Agar were used for the identification of aerobic and anaerobic as well as fungi respectively. Total aerobic and anaerobic bacteria count is done by spread plate technique and then incubate at 30-35^{o} C for 24hrs. To count yeast and mould the technique employed spread plate technique in saboraud dextrose agar is used and incubate at RT for 24 hours (Bhogale Vijaya Prakash, 2020).

2.3.7 UV-Visible Spectrometer

The methanolic extract of formulation was analysed under UV Spectrometer ranging on various wavelength from 200nm up to 700nm. (Nitin V. Kokare,2014).

2.3.8 Chromatographic Evaluation Preparation of Standard

Gallic acid standard was prepared in methanol with initial concentration of 1000 ppm. Further dilution of 10 ppm was prepared using mobile phases (Patil Usha, 2016).

2.3.9 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(Alok K. Hazar, 2017).

2.3.10 High Perfiormance Thin Layer Chromatography(HPTLC)

Filtered solution of formulation extract and standard was applied on the TLC plate as per condtions.

Conditions were maintained as per below given (Table 2).

Stationary Phase	HPTLC plates silica gel
Plate Size	10.0 x 10.0 cm
Mobile Phase	Toluene: Ethyl acetate: Formic acid (3:6:1)
Saturation Time	20 mins

Standard Used	10 ppm Gallic acid
Spot Volume	10 µl
Band Length	8.0 mm
Solvent Front	80mm
Wavelenth and Lamp	Ultra Violet Lamp at 336nm
Sample Applicator	CAMAG Linomat 5
Sample Detection	CAMAG Visualizer : 200480
Number of Tracks	6

Table 2. HPTLC conditions for Vaishvanara Churna

III. Result And Discussion

Herbal medicines are not simple task as many factors influence its biological efficacy and therapeutic effect .The. Standardization of herbal formulation is essential to confirm its identity, quality and purity As part of Standardization the prepared formulation of Vaishvanara Churna was qualitatively evaluated using physical and chemical parameters. Vaishvanara churna was prepared as per the guidelines set by Ayurvedic Formulary of India .Microscopic evaluation of raw material as well as formulation were studied ,no contamination was observed so the raw materials were pure and hence used for preparation of formulation.

Organoleptic evaluation: Vaishvanara churna was studied for organoleptic characteristics showed in (Table 3).

Color	Brown
Odour	Characteristic
Texture	Smooth powder
Taste	Bitter

Table 3. Organoleptic Characterstics of Vaishvanara Churna

Physicochemical Characteristics: Physicochemical parameters of Vaishvanara Churna such as Bulk density, Tap Density, Compressibility Index, Housner Ratio and Ash Value were tested to determine the physical properties and solubility of formulation and the values are presented in (Table 4).

Sr No.	Paramaters	Vaishvanara Churna
1	Loss on drying	2.25%
2	Total Ash value	15.65%
3	Alcohol soluble extraction	27.92%
4	Water soluble extraction	24.55%
5	Bulk density	0.4579 g/ml
6	Tapped density	0.6372 g/ml.
7	Powder compressibility	28%
8	Hausner ratio	1.39

Table 4. Physiochemical Characterstics of Vaishvanara Churna

Phytochemical Characteristics : Qualitative tests for Phytochemical evaluation found the presence of Tannins, Glycoside, Alkaloid, Sterol, Carbohydrate (Table 5) which indicates, Vaishvanara Churna is a mixture of all the constituents.

SR. NO	TEST	HARITAKI	GINGER	AJMODA	AJWAIN	FORMULATION
1	Tannins	+	+	+	+	+
2	Glycoside	+	+	+	+	+
3	Terpenoid	+	-	+	+	-
4	Alkaloid	+	+	-	+	+
5	Flavanoid	+	-	+	-	+
6	Steroids	-	+	-	+	+
7	Saponin	-	+	-	+	+
8	Phenol	-	-	-	-	-
9	Sterol	+	-	+	-	+
10	Anthrocyanin	-	-	-	-	-
11	Carbohydrate	-	+	+	+	+
12	Starch	-	-	-	-	-

Key :- Absent(-),Present (+)

Table 5. Phytochemical Characterstics of Vaishvanara Churna

Heavy metal evaluation: Heavy Metals Determination was done for the sample to check the presence of heavy metals, as there was no heavy metals resulted (Table 6), formulation was free from contamination and is safe.

TEST	RESULT
Lead	-
Chromium	-
Copper	-
Nickel	-
Zinc	-
Cobalt	-

Key :- Absent (-), Present (+)

Table 6. Heavy Metal Evaluation of Vaishvanara Churna

Total Viable Count (Microbiological Testing) : Total viable count was performed in order to determine microbiological quality of formulation ,microbial load in Vaishvanara churna formulation was found to be within the limits lead down in Pharmacopeia for the aerobic microorganisms. No growth were obtained on anerobic and fungi which means it is of good qualityy (Table 7). and was found to be complying with pharmacopeial standards.

Media	Organism	Dilution	Cfu/0.1 ml	Cfu/1ml	Average cfu/ml
Nutrient Agar	Aerobic	10^{-3}	73 x 10^{3}	0.73 x 10^{5}	54.866 × 10^{5}
		10^{-4}	37 x 10^{4}	3.7 x 10^{5}	
		10^{-5}	12 x 10^{5}	12 x 10^{5}	
Nutrient Agar	Anaerobic	10^{-3}	-	-	-
		10^{-4}	-	-	
		10^{-5}	-	-	
Sabourauds Agar	Fungi	10^{-3}	-	-	-
		10^{-4}	-	-	
		10^{-5}	-	-	

Table 7 : Total Viable Count of Vaishvanara Churna

UV Spectra : The methanolic extract of formulation was analysed under UV Spectrometer ranging on various wavelength from 200nm up to 700nm UV visible spectrophotometry shows that at wavelength 300nm maximun absorbance 1.65 was observed (Table 8) & (Fig 1).

Wavelength	Absorbance
200	0.342
250	1.524
300	1.65
350	1.576
400	0.962
450	0.185
500	0.102
550	0.061
600	0.054
650	0.092
700	0.086

Table 8: UV Spectra of Vaishvanara Churna

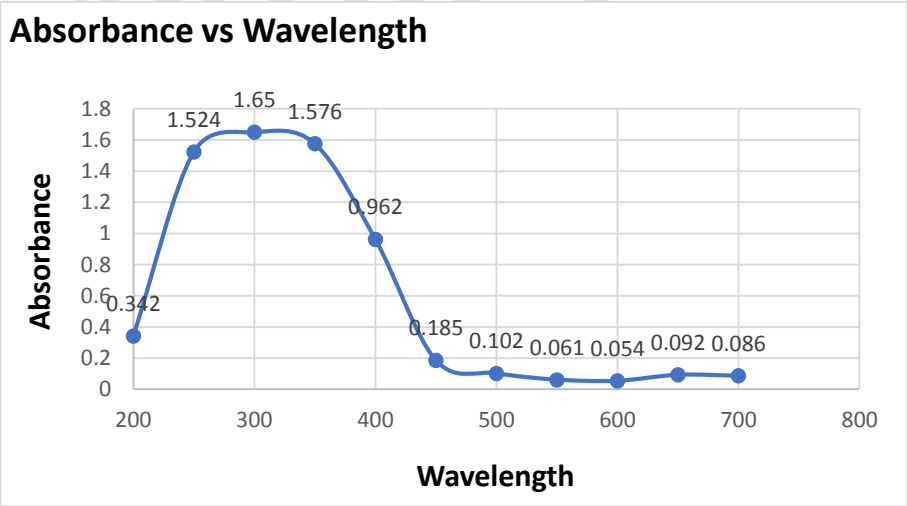
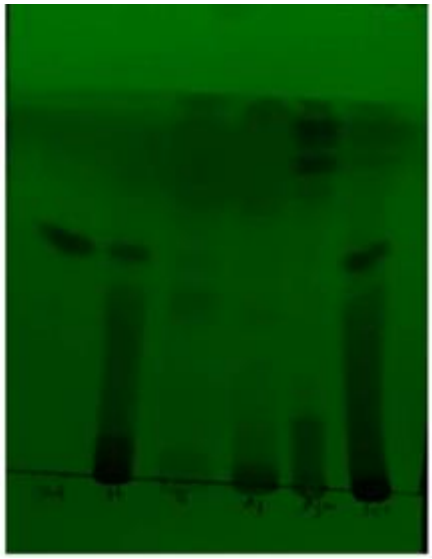


Fig . 1 (200nm to 700nm)

HPTLC Fingerprinting : Quality assessment of formulation was performed in order to check presence of marker compound gallic acid by HPTLCIn HPTLC, the comparison of finished product with raw materials was observed under UV light which distinct characteristic patterns (Fig 2). . HPTLC, UV spectrophotometry is very useful technique to confirm the presence of raw material in formulation .

HPTLC Fingerprinting of Vaishvanara Churna :



Track 1	Standard
Track 2	*Terminalia chebulla*
Track 3	*Zingiber officinalis*
Track 4	*Trachyspermum ammi*
Track 5	*Apium graveolens*
Track 6	Formulation.

Fig. 2 HPTLC

IV. Conclusion

Ayurvedic medicine Vaishvanara Churna has been standardized by intervention of modern scientific quality control measures in the traditional preparation described in classical texts. Pharmacognostic characters established for the raw materials could be employed as Q.C. standards for evaluating its identity and can be used for routine analysis. 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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