Int J Pharma Res Health Sci. 2018; 6 (2): 2551-54
DOI:10.21276/ijprhs.2018. 2018. 02.37
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CODEN (USA)-IJPRUR, e-ISSN: 2348-6465

PHS Scientific House
PHARMAHEALTHSCIENCES

International Journal of Pharma Research and Health Sciences

Available online at www.pharmahealthsciences.net

Original Article

Evaluation of *Agatsya Patra Bhavita Gandhakadi Yoga* Tablet w.s.r. to Pharmacognostical, Pharmaceutical, Stability Study used in Thalassemia Major

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ARTICLE INFO

Received: 20 Apr 2018
Accepted: 29 Apr 2018

ABSTRACT

The Thalassemia Syndrome was the first genetic disease to be understood at molecular level. No definite treatment is claimed till date. Aacharyas have mentioned herbal, Animal and mineral products are used to make Ayurvedic formulations. *Gandhakadi yoga* tablet is used in Thalassemia major as an adjuvant therapy. Having contain *shuddha Gandhaka* (sulpher), *Vidanga* (*Embelia robusta* Burm.f.) and *Agatsya patara* (*Sesbania grandiflora* Linn.), used for *Bhavana.* The present work was carried out to standardize the finished product "*Gandhakadi Yoga* Tables" to confirm its identity, quality and Stability study. Pharmacognostical and phytochemical observations revealed the specific characters of all active constituents used in the preparation. The pharmacognostical study reveals the presence of Fibers of *Agatsya,* Olirasine of *Vidanga*, Starch grain of *Vidanga*, Scleroids of *Vidanga* etc. Pharmaceutical analysis showed that Hardnes 1.75, Uniformity of weight aveg. 520mg, Loss on drying 8.1%w/w , Ash value 61.65%w/w, pH 6.5, Alcohol soluble extractive 12.52%w/w and water soluble extractive 13.6%w/w, HPTLC finger printing profile of *Gandhakadi Yoga* revealed 10 spots at 254nm, 6 spots on 366nm. So this study is prove to authenticity and quality of the drugs *Gandhakadi yoga* tablet. Also Carried out Microbiology study as a Stability for *Gandhakadi yoga.*

Keywords: Thalassemia, *Gandhakadi yoga*, pharmacognostical, HPTLC, Microbiology, Stability.

1. INTRODUCTION

Ayurveda is not only the science of therapeutics but it advocates more of promotion of health and prevention of disease than cure. Ayurveda is one of the oldest health care system that originated in india. There is a huge trend in people to turn towards herbal medicine like Ayurveda.

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Though Ayurveda is cost effective with good therapeutic effects, the therapeutic effect depends on the quality of the drug administered. A quality of drug gives best results on disease. *Acharya describe Upatapti* of *Beeja*, *Beejabhaaga* and *Beejabhaagaavayava* and related various diseases. *Beejabhaaga avayava dushti* is found in Thalassemia as mutation or deletion occur in chromosome 11 and 16. Genetic disorders occur more where consanguinity found positive. *Aachaarya Charaka* in *Vimaanasthaana* (*Trividharogavisheshavigyaaneeya Adhyaaya*), Thalassemia may be correlated to *Tridoshajanya Panduroga* and named as *Beejadushtijanya Pandu*, *Kulaja* or *Aanuvanshika Pandu*. According to the World Health Organization(WHO) thalassemias are the most common inherited single-gene disorders in the world. Thalassemias are inherited from a person's parents. characterized by abnormal synthesis of hemoglobin due to defects in the globin chain. This causes early excessive destruction of red blood cells leading to hypochromic, microcytic anemia the characteristic presenting symptom of thalassemia. It can be classified into 3 types, such as Thalassemia Major (TM), Thalassemia Intermedia (TI) and Thalassemia minor (Tm) or traits .the main stay of managing these disease is repeated blood ransfusion. Chronic red cell transfusion therapy leads to progressive iron accumulation in the body. It can be reduce by iron chelation therapy, but iron chelators are coastly and have side effect like growth retardation, visual andauditory toxicity, cataract etc. Due to those complications and incompleteness of modern medical management, there is a need of some adjuvant therapy like Ayurveda, and it should be applied simultaneously with the blood transfusion which help to increase the blood transfusion interval, to enhance the quality of life and life span of the Thalassemic patients, and to minimize the complications.

Gandhakadi Yoga used in treatment of Thalassemia major with good results which was also given in Ayurveda science. *Gandhakadi Yoga* is a modified form of the drug suggested for symptoms produced after intake of improperly prepared *Loha Bhasma* as well as improper digestion of *Loha Bhasma* (*Apakva Loha Sevanajanya Vikara Prashamana* or Iron overload) in text Ayurveda Prakasha[1]**.** *Agatsya patra bhavit Gandhakadi Yoga* used as trial drug Where in *Gandhaka* and *Vidanga* are triturated with *Agastyapatra swarasa*.

Present study is carried out for standardization of *Gandhakadi Yoga* for in idendity, quality and purity and Long term Stability. This Ayurvedic formulations used in adjuvant therapy of Thalassemia major. To ensure the quality standards of the formulation such as identity, quality, and purity of ingredients and finished product along with preliminary physico-chemical parameters and pharmacognostical characteristics also Microbiology study as stability test, this study was carried out.

2. MATERIALS AND METHODS

Drug materials:

Collection, Identification and authentication of raw drugs : The raw drugs for the study were procured form the Pharmacy of Institute The ingredients were identified and authenticated in the Pharmacognosy Lab of Institute The ingredients and parts used are listed in the table 1.

Table 1: Ingredients of *Gandhakadi Yoga* tablet

No.	Drug Name	English / Latin Name	Part used	Quantity
1.	*Shuddha Gandhaka*	Sulphur	As whole	1 Part
2.	*Vidanga*	*Embelia robusta* Burm.f.	Dried fruits	1 Part
3.	*Agatsya*	*Sesbenia grandiflora* Linn	Green leaves	As sufficient

Method of Preparation of the *Gandhakadi yoga* Tablet: Method of preparation was adopted as standard procedure as given in *Samhitas*. All the raw drugs except *Agatsya patra* were Provided by the raw drug store of Pharmacy, The whole plant of *Agatsya Patra* (*Sesbania grandifolia* linn.) was collected from the Dist. Kodinar. They were authenticated by the experts of Pharmacognosy laboratory, I. P. G. T. & R. A., Jamnagar and then submitted in Pharmacy for making of *Gandhakadi yoga* Tablets. The Finished product of test drug was used for the pharmacognostical and physico-chemical Parameters study at the Pharmacognosy laboratory and the Pharmaceutical chemistry laboratory.

Pharmacognostical evaluation:

Pharmacognostical study comprises Organoleptic study and Microscopic study of finished products. Raw drugs were identified and authenticated by the Pharmacognosy lab, IPGT&RA, Jamnagar. For pharmacognostical evaluation, drugs studied under the Corl zeiss Trinocular microscope attached with camera, with stain and without stain[2]. The microphotographs were also taken under the microscope[3].

Physico-chemical evaluation:

Gandhakadi yoga Tablet was analysed by using standard qualitative and quantitative parameters, HPTLC was carried out after making appropriate solvent system with Methanolic extract of *Gandhakadi yoga* Tablet at the Pharmaceutical Chemistry lab, I.P.G.T. & R.A. Gujarat Ayurved University, Jamnagar. Presence of more moisture content in a sample may create preservation problem. Hence loss on drying [4] was also selected as one of the parameters. Ash value, Water soluble extract[5], Methanol soluble extract[6], pH [7] selected as the parameters. Organoleptical parameters, Physicochemical analysis, investigations were carried out by following standard procedure. High Performance Thin layer chromatography (HPTLC) studies were carried out with acid hydrolysed methanolic extract on pre-coated silica gel GF 254(E.Merck) precoated TLC aluminium plate as 5mm bands, 5mm apart and 1cm from the edge of the plates, by means of a Camag Linomate V sample applicator fitted with a 100 µL Hamilton syringe. The plates were developed in Camag twin trough chamber (20 x 10 cm2) and spots were

detected in short U.V. (254 nm), Long U.V (366nm). Camag Scanner II (Ver. 3.14) and Cats soft ware (Ver. 3.17) were used for documentation.

Microbiological study:

Microbiological study of *Gandhakadi yoga* Tablets was conducted for the different preparations in the microbiology Lab as per standard procedures.

3. OBSERVATIONS AND RESULTS

Pharmacognostical study:

Organoleptic study: Organoleptic features of *Gandhakadi Yoga* Tablets were observed by sensory observations results were mentioned in table no.2. All parameters found as per API standards.

Table 2: Organoleptic characteristics of Sour, *Gandhakadi yoga* Tablets

Sr.No	Parameters	Observations
1.	Colour	Grayish to ash
2.	Odour	Sulphur smell
3.	Taste	Tasteless, Astringent
4.	Touch	Smooth, hard

Microscopical Study:

The purpose of the Microscopic study was to confirm the authenticity of the drugs used in the preparation of *Gandhakadi Yoga* tablets. Observed characters are Fibres of *Agastya*, Olioresine of *Vidanga*, Scleroids of *Vidanga*, Prismatic crystals of *Vidanga*, Starch grains of *Vidanga*, Stone cell of *Vidanga*, Trichome of *Agastya* shows in Plate no.1 .

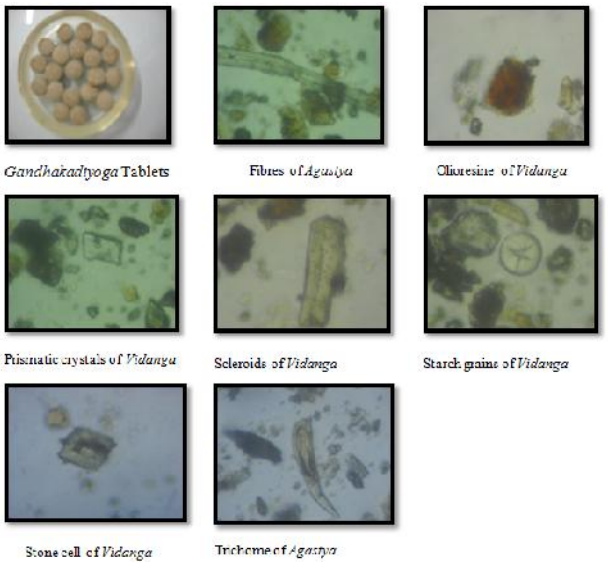

Plate 1: Microphotographs of Gandhakadi Yoga Tablet

Physico- chemical Parameters: Physical analysis of Tablet Shape, Hardness and uniformity of weight., also Physico-chemical Parameters of the *Gandhakadi yoga* Tablet like loss on drying, water soluble extract etc. were examined and found as per (Table 3). All these parameters need evaluation in different size of batches. Also need validation for batch to batch variation.

Table 3: Physical analysis of *Gandhakadi Yoga*

Sr. No.	Parameters		Results
1.	Shape		Round
2.	Hardness		1.75 kg/cm^3
3.	Uniformity of weight	Max. (mg) wt.	674 mg
		Min. (mg) wt.	415 mg
		Avg. (mg) wt.	520 mg

Table 4: Physico-Chemical Parameters of *Gandhakadi yoga* Tablet

Sr No.	Parameters	Results
1.	Loss on drying at 110◦C	8.1 % w/w
2.	Ash Value	61.65% w/w
3.	Alcohol soluble extract	12.52 % w/w
4.	Water soluble extract	13.6% w/w
5.	pH Value	6.5

HPTLC study results: On performing HPTLC, visual observation under UV light showed few spots but on analysing under densitometer much more was observed (Table 4, Plate 2)

Table 5: Max R_f value observed In HPTLC study.

Wave lengths	254nm	366nm
No of Spots	10	6
Max.Rf Value	0.03,0.07,0.10,0.17,0.28,0.39,O.61,0.66,0.69,094	0.03,0.10,0.18,0.39,0.66,0.98

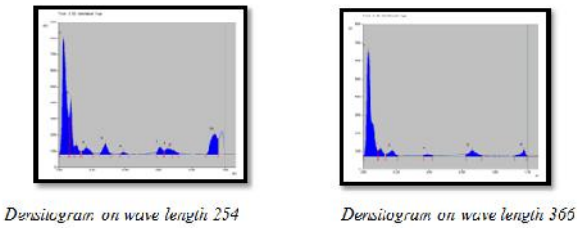

Plate 2: Results of HPTLC

Microbiology of *Gandhakadi Yoga* Tablet

Microbiological study of *Gandhakadi yoga* Tablets was conducted for the different preparations up to 377 days, results are depicted in the table 5.

Table 6: Showing observations of sample preserved at room temperature

S. No.	Days of investigations After preparation of the sample at	Date of Sample given	Observations of sample			
			Gram's Stain	Aerobic culture	Wet mount/ 10% KOH Preparation	Fungal culture
1.	23 Days	22th Feb 2017	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen Isolated
2.	53 Days	23th March 2017	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen Isolated
3.	77 Days	24th April 2017	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen Isolated
4.	106 Days	22th May 2017	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen

						Isolated
5.	137 Days	23th June 2017	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen Isolated
6.	167 Days	24th July 2017	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen Isolated
7.	203 Days	29th August 2017	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen Isolated
8.	230 Days	25th Sep 2017	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen Isolated
9.	261 Days	26th Oct 2017	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen Isolated
10.	288 Days	23st Nov 2017	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen Isolated
11.	316 Days	21th Dec 2017	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen Isolated
12.	377 Days	30rd Jan 2018	Microorganisms Not Seen	No organisms isolated	Fungal filaments not seen.	No Fungal Pathogen Isolated

4. DISCUSSION

The significant effect of the drug on the particular Diseases is shows quality of particular drug. There should be present all ingredients in drug formulation for the good outcomes. Under the microscope *Gandhakadi yoga* shows all pharmacognostical characteristics in it. All pharmaceutical parameter reveals the drug is forms under slandered method of preparations and pharmaceutical parameters all are in standard range. Microbial study of tablet like Gram's stain, Wet mount/ 10% KOH Preparation, Aerobic and Fungal culture at room temperature shows negative result.

5. CONCLUSION

Gandhakadi Yoga Tablet is a potent medicine in the management of disease Thalassemia. Preliminary Pharmacognostical organoleptic and microscopy of results *Gandhakadi yoga* showed all ingredients used were genuine and no adulterants found. Microbial study reveals no any contamination found till 1 year. Hence quality of *Gandhakadi yoga* tablets is established in the given parameters. This study outcome may be considered as reference standard in future scientific studies.

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Conflict of Interest: None

Source of Funding: Nil