ORIGINAL RESEARCH PAPER

Ayurveda

STANDARDIZATION AND QUALITY CONTROL PARAMETERS OF PRADARAHARA KASHAYA GHAN GRANULES FOR INSTANT USE: A POLYHERBAL AYURVEDIC FORMULATION

KEY WORDS: Kwath ghan granules, Pradarahara Kashaya, Asrigdara, HPTLC fingerprinting.

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ABSTRACT

Kwath (decoction) preparations are one of the most widely used ayurvedic dosage forms, which are highly effective but they are to be used only in fresh state due to short shelf life (i.e ½ - 1 day). This is the major drawback of the kwath for the large-scale production. Considering this, Pradarahara Kashaya, a polyherbal ayurvedic formulation mentioned in sahasrayogam for the treatment of Asrigdara (Excessive uterine bleeding) is converted into Pradarahara Kashaya ghan granules form for instant use. The present study mainly deals with the preparation and standardization of Pradarahara Kashaya ghan granules based on organoleptic characteristics, physiochemical parameters and HPTLC fingerprinting.

INTRODUCTION

Ayurveda has given utmost importance to maturity of plant, season, time of collection and its mode of usage in logical manner. Standardization of ayurvedic formulation means confirmation of its identity, quality, and purity throughout all phases of its cycle i.e shelf-life, storage, distribution and use by various parameters.

Kwath/Kashaya Kalpana (decoction preparations) is mentioned among the five basic Kalpanas mentioned in charak samhita [1]. Currently, there are various Kashaya preparations available in the market in liquid form which contain sugar, alcohol, or preservatives. These liquid preparations are very difficult to carry and have a strong chance of leakage, spoilage, and breakage. Additionally, in fast moving generation, the lack of time for Kashaya preparation has been losing its utility. Owing to certain drawbacks in fresh Kashaya preparation, there is need to develop different dosage forms which could be accepted by pharmaceutical companies. Pradarahara kashaya is mentioned in Sahasrayogam Kashaya Prakaran in the context of Asrigdara [2]. The ingredients are Khadira (Acacia catechu Willd), Chandan (Santalum album L.), Bala (Sida cordifolia Linn.), Asana (Pterocarpus marsupium Roxb.), Sariva (Hemidesmus indicus R. Br), vasa (Adhatoda vasica Nees.), Japa (Hibiscus rosa-sinensis L.), Musta (Cyperus rotundus Linn.), Shalmali (Salmalia malabarica Schott. and Endl.), Amalaki (Emblica officinalis Gaertn.) and Sitakhanda (sugar candy) (Table 1). Therefore, to overcome these disadvantages of Kashaya preparations, an attempt has been made to formulate the dosage form of Pradarahara Kashaya into more concentrated instant use Ghana granules form.

AIMS AND OBJECTIVES

To develop standard manufacturing procedure (SMP) and to evaluate quality control parameters for preparation of Pradarahara Kashaya Ghana granules for instant use.

MATERIALS AND METHODS

Collection, Identification And Authentication Of Raw Drugs

The raw material used in this study was procured in crude form from local market of Vadodara, Gujrat, India. Identification and authentication of the raw drugs was done at Dravya guna department of Parul Institute of Ayurved, Vadodara, Gujrat. Finally, drug was prepared in the G.M.P certified pharmacy of same institute.

Method Of Preparation Of Pradarahara Kashaya Ghana Granules

Preparation Of Pradarahara Kashaya

Coarse drugs were mixed with 16 times of water in a stainless-steel vessel and kept aside overnight for soaking (12 hours). Next morning it was subjected to mild heat with continuous stirring process and reduction was done until the quantity was reduced to pada-shesha i.e $1/4^{th}$ of the initial quantity (Fig. 1a). During heating process, continuous stirring was done to fasten the evaporation process and to prevent any deterioration due to burning of materials. When desired quality and quantity achieved, the Kashaya was filtered through four folded clean cotton cloth and collected as Pradarahara Kashaya into separate vessel [3].

Preparation of Pradarahara Kashaya Ghan Granules (PKGG)

Freshly prepared decoction was taken and subjected to mild heat for further boiling. Reduction was done with continuous stirring upto semisolid stage without covering the mouth of vessel. When desired consistency was achieved vessel was taken out from the heat source. Small boluses were prepared from this ghan and placed on the tray and left to dry in hot air oven. After complete drying, fine powder was prepared from these boluses. Sugar syrup was prepared and boiled until appearance of Avaleha siddha lakshanas. Finally, the powder was added with thorough stirring to get a homogeneous blend. The blended mass was passed through #10 sieve to obtain granules. The dried granules were placed in airtight container (Fig 1).

Phytochemical And Analytic Study

Organoleptic characters, physico-chemical parameters, qualitative test, TLC was done at pharmacy of Parul institute of Ayurveda and HPTLC study was done at Vasu Research Centre, GIDC, Makar Pura, Vadodara (sample ID – AD/22/021, Dated – 21/04/2021). Pradarahara Kashaya Fresh (PKF) and Pradarahara Kashaya Instant (PKI) was analysed by employing various organoleptic character like colour, odour, taste & appearance. Physico-chemical parameters like Loss on Drying, Total Ash Value, Acid Insoluble Ash, Water & Alcohol Soluble Extract, pH Value, Mesh Analysis, Bulk density and Angle of Repose was carried out for PKGG and physio-chemical parameters like pH, Total solid content, Specific gravity, Viscosity and Refractive index were investigated for PKF and PKI. Microbial overload was also inspected for PKGG.

HPTLC Finger Printing

Accurately weighed 2.5 gm of sample was taken in iodine flask and 50 ml methanol was added to it. Vortex the iodine flask for 1 hour to dissolve the sample. Filter the solution with whatman filter paper no. 1 which further filtered with syringe filter. The filtrate thus obtained was used for HPTLC finger printing. The solvent system used was Toluene:Ethyl Acetate:Acetic Acid (7:2:1 v/v/v). 10.0 µL of sample solution was applied on pre-coated silica gel 60 F 254 TLC plate (MERCK) on aluminum sheets to a band width of 10 mm using CAMAG Linomat 5-Applicator. After derivation in CAMAG-

Dip tank for about 1 min with Anisaldehyde sulphuric acid reagent, the plate was visualized under short and long UV radiation and density of the separated spots was recorded using scanner III. The Rf value and Peak display densitogram of all the track at 254 nm, 366 nm and 540 nm were recorded and presented respectively. Chromatographic conditions for HPTLC profile are discussed in table no.2.

RESULTS

Organoleptic characters of Pradarahara Kashaya Fresh (PKF) and Pradarahara Kashaya Instant (PKI) were compared which shows no major differences in color, smell, appearance and taste (Table 3). Observation on physiochemical parameters of PKF and PKI also show so much similarity which is tabulated in table no.4. In PKGG Loss on drying, Total Ash Value, Water Soluble Extract, Alcohol Soluble Extract, Ph Value, Bulk Density, Angle of Repose were obtained as 8.57 % w/w, 7.42 % w/w, 50.89 % w/w, 28.29 % w/w, 5.5, 0.72 and 0.56 respectively (Table 5). Qualitative test between PKF and PKI are almost similar (Table 6). Total microbial count of finished product i.e Pradarahara Kashaya Ghan Granules (PKGG) was found within the prescribed limits given by WHO (Table 7).

HPTLC finger printing was done to find out the active Phyto-constituent present in PKGG. Rf value and colour of spots in chromatogram developed in Toluene:Ethyl Acetate:Acetic Acid (7:2:1 v/v/v) was recorded. Study revealed that at 254 nm got 6 spots with Rf value 0.21, 0.30, 0.37, 0.51, 0.59 and 0.66 and densitometric scan at 254 nm shows 6 peaks. At 366 nm study revealed 2 spots with Rf value 0.21 and 0.71 and densitometric scan shows 2 peaks. At 540 nm study revealed 5 spots with Rf value 0.21,0.59,0.66,0.71,0.75 and densitometric scan shows 5 peaks.

DISCUSSION

Pradarahara Kashaya Ghan Granules contain Khadira (Acacia catechu Willd), Chandan (Santalum album L), Bala (Sida cordifolia Linn.), Asana (Pterocarpus marsupium Roxb), Sariva (Hemidesmus indicus R.Br), Vasa (Adhatoda vasica Nees.), Japa (Hibiscus rosa-sinensis L.), musta (Cyperus rotundus Linn.), Shalmali (Salmalia malabarica Schott. and Endl.) and Amalaki (Emblica officinalis Gaertn). Commonly these drugs are having anti-inflammatory, antioxidant and anti-haemorrhagic action. So, these drugs help in healing the wounds and ulcers in vaginal mucosa. Tannins present in the drug is having anti-haemorrhagic property [3]. Alpha-santalol present in Santalum album [4] and Ephedrine and pseudoephedrine present in Sida cordifolia [5] have a proven action on neurological symptoms like anxiety, stress and depression. So, they can work on disturbed HPO axis and can regulate the menstrual pattern also. Methanol extract of Pterocarpus marsupium showed potential effect of reverting the reproductive cycle towards normal in PCOS rats. So, it may help in correcting the disruptive ovarian function in D.U.B. Sections of ovaries from PCOS rat treated with Pterocarpus marsupium methanol extract 200mg/kg and 400mg/kg b.w showing the presence of normal developing follicles and normal corpus luteum with intact granulosa layer [6]. Ethanol extract of Hemidesmus indicus root is used in estrogen deficiency induced osteoporosis and to prevent or treat female hormonal disturbance related disorders and assuaging symptoms of menopausal conditions in ovariectomised rats [7]. Vasicine present in Adhatoda vasica has shown uterotonic activity in different species including human beings and the effect was influenced by the degree of priming of the uterus by estrogens. In both pregnant and non-pregnant human uteri vasicine initiate rhythmic contractions of myometrial strips and trial suggests its effect comparable to oxytocin and methergin. It is used in various bleeding disorders, due to its styptic action [8]. The benzene extract of Hibiscus rosa sinensis flowers showed estrogenic activity in immature mice by early opening of the vagina, premature cornification of the vaginal epithelium and an increase in uterine weight [9]. The n-butanol present in Amalaki has a proven effect on the female reproductive system by assessing its estrogenic and gonadotropic activities (follicle-stimulating hormone-like [FSH] activity & luteinizing hormone-like [LH] activity) [10].

CONCLUSION

Asrigdara (AUB) is a significant clinical entity affecting 14-25% women of reproductive age group now a days. Due to this women's physical, social, emotional, and material quality of life gets disturbed. Hence there is an urgent need of some ayurvedic formulations that can reverse the pathogenesis of Asrigdara without any side effects. Pradarahara Kashaya ghan granules have been tested by different quality control parameters which shows no major difference between freshly prepared Kashaya and instantly prepared Kashaya from granules. HPTLC testing done in present study can be considered as a preliminary tool for the authenticity of Pradarahara Kashaya ghan granules for instant use. The method developed by present study can be adopted for future utilization in pharmaceutical companies.

Table 1: Raw Drugs Used In Pradarahara Kashaya Ghan Granules

S. NO.	DRUGS	BOTANICAL NAME	PART USED	Ratio
1	Khadira	Acacia catechu Willd	Bark	1 part
2	Chandan	Santalum album L.	Bark	1 part
3	Bala	Sida cordifolia Linn.	Roots	1 part
4	Asana	Pterocarpus marsupium Roxb.	Heartwood	1 part
5	Sariva	Hemidesmus indicus R. Br	Root	1 part
6	vasa	Adhatoda vasica Nees.	Leaves	1 part
7	Japa	Hibiscus rosa-sinensis L.	Flowers	1 part
8	Musta	Cyperus rotundus Linn.	Tuber	1 part
9	Shalmali	Salmalia malabarica Schott. and Endl.	Stem bark	1 part
10	Amalaki	Emblica officinalis Gaertn.	Fruits	1 part

Table 2: Chromatographic Conditions For HPTLC Profile

Application mode	CAMAG Linomat 5 – Applicator
Filtering system	Whatman filter paper no. 1
Stationary phase	MERCK – TLC/HPTLC Silica gel 60 F 254 on aluminum sheets
Application (Y axis) start position	10 mm
Development end position	80 mm from plate base
Sample application volume	10.0 µL
Development mode	CAMAG TLC Twin trough chamber
Chamber saturation time	30 minutes
Mobile phase (MP)	Toluene: Ethyl acetate: Acetic acid (7:2:1 v/v/v)
Visualization	@ 254 nm, @ 366nm, @540 nm (after derivatization)
Spray reagent	Anisaldehyde sulphuric acid reagent
Derivatization mode	CAMAG – Dip tank for about 1 minute
Drying mode, Temp. & Time	TLC plate heater preheated at 100 degree C for 3 minutes

Table 3: Organoleptic Characters Of PKF and PKGGI

Parameters	Pradarahara Kashaya fresh (PKF)	Pradarahara Kashaya instant (PKI)
Colour	Brown	Brown
Odour	Characteristic	Characteristic
Taste	Astringent	Astringent
Appearance	Dark	Dark

Table 4: Physiochemical Parameters Of PKF and PKI

Parameters	PKF	PKI
Ph	5.20	5.50
Total solid content (% w/w)	9.45	8.89
Viscosity (millipoise)	8.79	7.68
Specific gravity	1.08	1.12
Refractive index	1.47	1.16

Table 5: Physiochemical Parameters Of Pradarahara Kashaya Ghan Granules (PKGG)

Parameters	PKGG
Loss on drying at 110 degree C (% w/w)	8.57
Total Ash value (% w/w)	7.42
Acid insoluble ash (% w/w)	39.23
Water soluble extract (% w/w)	50.89
Alcohol soluble extract (% w/w)	28.29
Ph value (10 % aqueous)	5.5
Mesh analysis	10-20 = 47 20-40 = 25 40-60 = 14 60-80 = 0 80-120 = 0
Bulk density	0.715
Angle of repose	0.562

Table 6: Qualitative Test

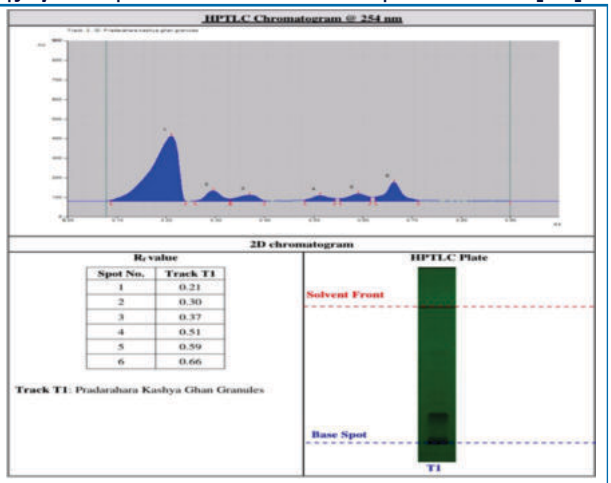
S.NO	SOLVENT	PKF	PKI
1	Sodium	-	-
2	Alkaloid	+	+
3	Tannin	+	+
4	Saponin	+	+
5	Flavonoid	+	+
6	Glycoside	+	+
7	Triterpenoids	+	+
8	Essential oil	+	+
9	Anthraquinones	-	-
10	Ascorbic acid	+	+

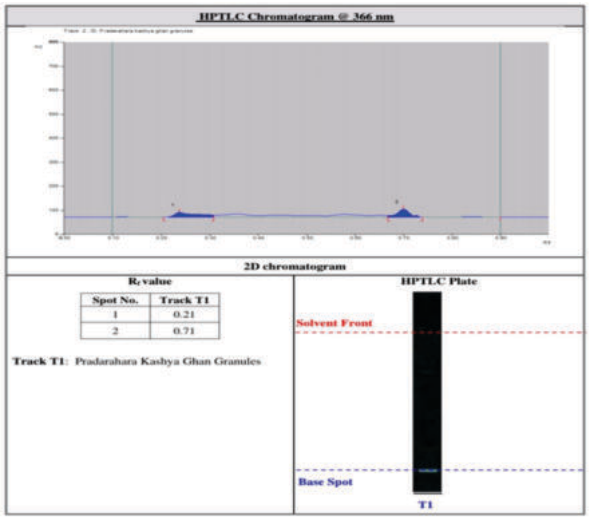
Table 7: Pathogen And Total Microbial Count Of PKGG

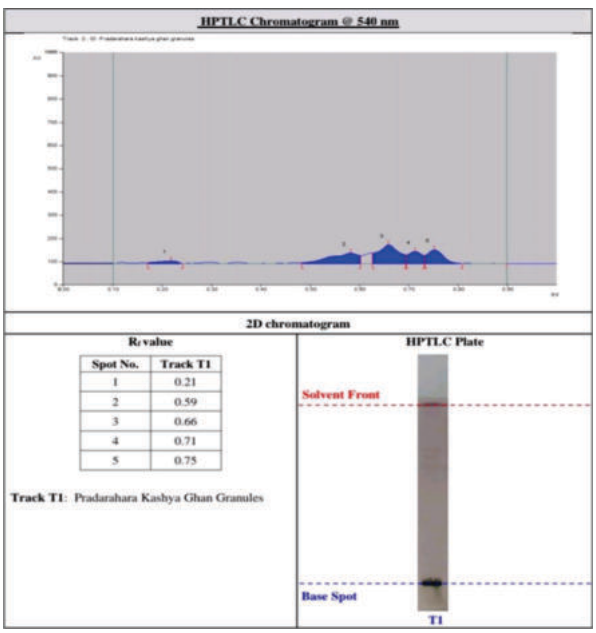
Parameters	Result
Total bacterial count	< 10 CFU/ml
Total yeast & mould	< 10 CFU/ml

Method Of Preparation Of Pradarahara Kashaya Ghan Granules

1. Raw drugs 2. Soaking of raw drugs 3 & 4. Boiling of kwath 5. Filtration of kwath 6. Further boiling of kwath to get semi-solid consistency (ghan) 7. Lumps prepared from ghan & placed in hot air oven 8. Fine power prepared from dried lumps 9. Sugar candy 10. Sugar syrup prepared and powder was added to it 11. Blended mass passed through # 10 sieve 12. Finished product







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