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Research Article

DOSAGE FORM DEVELOPMENT AND PRELIMINARY PHYSICOCHEMICAL CHARACTERIZATION OF *TRIKANTAKADI KVATHA*

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ABSTRACT

Objective: This is aimed to study the development of different dosage form and physicochemical characterization of *Trikantakadi Kvatha* (TK).

Methods: Stability, shelf life, non-convenient, and large dosages administration are the major concern for *Kvatha*. To overcome these problems, an effort has been made to modify the formulation without changing its efficacy into various dosage forms such as tablet, syrup, and tincture. Comparative pharmacognostic, physicochemical, and phytochemical parameters of crude herbs and prepared formulations were investigated. TK was prepared by classical method mentioned in literature and converted into TK syrup, TK *Ghana vati*, and *Trikantakadi* tincture (TT). Precaution should be taken during the processing of formulations. TT placed at a dark place in airtight container.

Results: Physicochemical and phytochemical investigations are not shown any remarkable variations with various prepared dosage forms. The R_f range observed between the 0.08 and 0.80 follows the standard value when compared with the reference of plant drug used for the preparation of dosage form.

Conclusion: The prepared dosages forms were not exhibited any remarkable difference according to thin-layer chromatography studies and physicochemical parameters. However, the developed dosage forms are more stable than *kvatha*.

Keyword: *Trikantakadi kvatha*, *Ghana vati*, Syrup, Tincture.

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INTRODUCTION

Kvatha one of the most popular *Kalpana* among five basic *Kalpanas* widely used therapeutically (to cure the different ailment) as well as pharmaceutically (used to prepare the different dosage forms like *Ghana, vati*, syrup, etc. Although a clear description is not available in *Vedic* literature, a detailed description is present in all *Samhitas* regarding its preparation, amount of water, and reduction in volume of liquid. *Kvatha Kalpana* may be defined as a *Kalpana* in which a specific quantity of *Kvatha Dravya* is taken and specific amount of water is used as menstruum and applying specific quantum of heat, the volume of water is reduced to specific amount and then by filtering *Kvatha* can be obtained [1].

Trikantakadi kvatha (TK) is an aqueous extract hence it is always questioned against its stability period. Hence, that modification in the dosage form was attempted in the present study and modified dosage forms such as TK syrup (TKS), *Trikantakadi* tincture (TT), and TK *Ghana Vati* (TKGV) were prepared. To ensure the stability period of prepared dosage form, the stability study was done and compared the observed value of all the physicochemical properties with the previous data.

Chronicled appraisal

Reference is cited for *Kvatha Dravya* along with nature and various proportion of water taken for the preparation of *kvatha* (aqueous extract) (Table 1a). In *Ayurveda Sara Samgraha* and *Rasatantrasara Va Sidhaprayoga Samgraha* mentioned the use of TK in *Asmari, Mutrakricha, Mutraghat* and to remove the kidney stones outside the body (Table 1b) [7,8].

METHODS

All the raw herbs are collected from the local market of Jalandhar and authentication is carried out by Dr. Satiwinderjeet Kaur, Head, Department of Botanical and Environmental Sciences, Guru Nanak Dev University Amritsar, Punjab, with ref. no. 1088, dated 18.10.2016. Microscopic analysis of raw materials was studied according to the methods of the Quality Standard of Indian Medicinal Plant (Tables 2 – Figs. 1-6 and Table 3 – Figs. 7-12) [9].

Method of preparation

Preparation of TK

TK was prepared according to the procedure mentioned in the *Ayurveda Sar Samgraha* [7].

TKS

500 g of sugar candy powder was added to previously prepared TK (1000 ml). Citric acid (0.1 g), propylparaben (2 g), and methylparaben (2 g) were used as a preservative.

TKGV

Granules were prepared from 80 g of TKG and mix 80 g of a mixture of herbal drugs (TK) powder for making the tablet 550 mg by adding

Table 1a: *Kvatha Dravya* along with their types of water and proportion of water

Reference book	Nature of drugs/ quantity of drugs	Quantity of water	Reduction up to
Charaka Samhita [2]	4 tola (48 g)	16 times	1/8th
Sushruta Samhita [3]	-	16 times	1/4th
Astanga Samgraha [4]	-	8 times	1/4th
Sharangdhara Samhita [5]	*Madhyam*	16 times	1/8th
Yogatarangini [6]	-	26 times	1/8th

Table 1b: Literature review on TK

Name of drugs	Common name	B. N. and family	Part used	A. S. S.	R. Va S. S.	Quantity
Gokshura	*Gokhru*	*Tribulus terrestris* Linn. Zygophyllaceae	Fruit	+	+	1 Part
Amaltaas ka gudha (pulp)	*Girimaal, Amaltaas*	*Cassia fistula* Linn. Fabaceae	Fruit pulp	+	+	1 Part
Darbhmoola	*Doob*	*Cynodon dactylon* Linn. Poaceae	Root	+	+	1 Part
Damasha/javasha	*Javasa*	*Alhagi camelorum* (Bieb). Desv. Fabaceae	Whole part	+	+	1 Part
Pashan bheda	*Silphara, Pakhanabheda*	*Bergenia ligulata* (Haw.) Sternb. Saxifragaceae	Root	+	+	1 Part
Harar	*Harad, Harre*	*Terminalia chebula* Retz. Combretaceae	Fruit	+	+	1 Part
Kaasmool	*Kasa, Kans*	*Saccharum spontaneum* Linn. Poaceae	Root	+	+	1 Part
Pitpapda	*Dhamgajra*	*Fumaria vaillantii* Lam. Fumaraceae	Whole plant	+	-	1 Part

B.N: Botanical name, R. Va S. S.: *Rasatantrasara Va Sidhaprayoga Sangraha*, A. S. S.: *Ayurveda Sar Sangraha*, TK: *Trikantakadi kvatha*

Table 2: Microscopical characters of Raw materials

Microscopical characters of Raw herbs

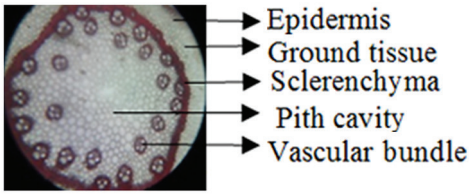


Fig. 1: *Durbha* (Root)

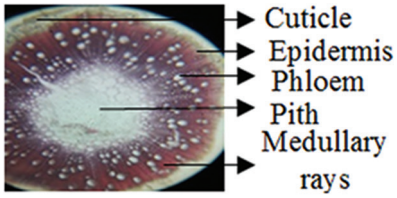


Fig. 2: *Javasha* (Stem part)

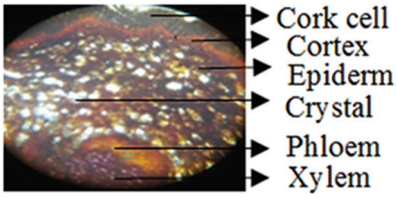


Fig. 3: *Pasahan bheda* (Root)

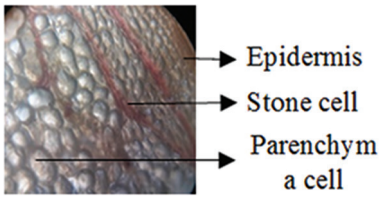


Fig. 4: *Harar* (Fruit pulp)

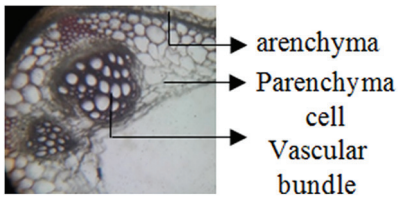


Fig. 5: *Pitpapda* (Stem part)

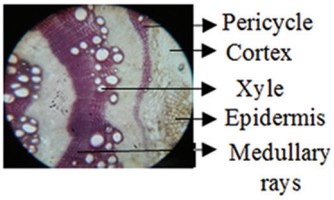


Fig. 6: *Kaas* (Root)

Table 3: Microscopical characters of TK *churna*

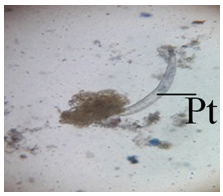


Fig. 7: Pitted tracheid

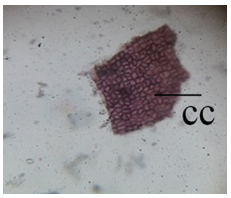


Fig. 8: Cork cell

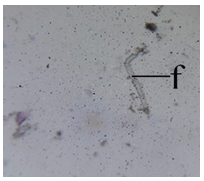


Fig. 9: Fiber

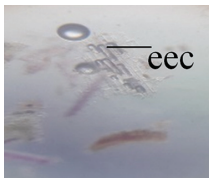


Fig. 10: Elongated cubical cell

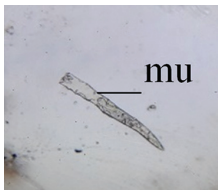


Fig. 11: Multicellular uniseriate

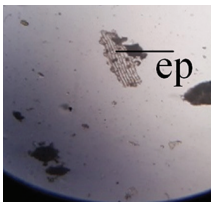


Fig. 12: Epidermal cell

Table 4: Master formula of formulations

Formulations	Quantity								
	Ingredients (g)								Other excipients (%)
	G	A	D	J	P	H	Pa	K	
TK	62.5	62.5	62.5	62.5	62.5	62.5	62.5	62.5	Nil
TKS	62.5	62.5	62.5	62.5	62.5	62.5	62.5	62.5	Preservative (50 S, 0.01 CA, 0.2 PP and MP) (% w/v)
TKGV	20	20	20	20	20	20	20	20	Gum acacia- 4 (% w/w)
TT	25	25	25	25	25	25	25	25	Ethanol- 15 (% v/v)

TK: *Trikantakadi kvatha*, TKS: *Trikantakadi kvatha* syrup, TKGV: *Trikantakadi kvatha Ghana vati*, TT: *Trikantakadi* tincture, G: *Gokshura*, A: *Amaltaas*, D: *Durbhamoola*, J: *Javasa*, P: *Pashanbheda*, H: *Harar*, Pa: *Parpata*, K: *Kaasmoola*, S: Sugar, CA: Citric acid, PP: Propylparaben, MP: Methylparaben

6.4 g of gum acacia as binding agent and were compressed into tablet form [10].

TT

850 ml (water) and 150 ml (ethanol) were taken together, and then, 200 g of TK *Dravya* added. The entire wort was kept for extraction for the time period of 14 days (Table 4) [11].

Characterization of formulation

Determination of organoleptic characteristics such as color, odor, taste, and state of prepared formulations was carried out (Table 5 – Figs. 13-16). All the physicochemical parameters of prepared formulations were carried out, and results of the experiment are asserted in Tables 6 and 7 [12-14]. Phytochemical analysis and thin-layer chromatography (TLC) of formulation were performed

Table 5: Organoleptic characters of formulations

Organoleptic character	TK	TKS	TT	TKGV
Color	Dark brown	Dark brown	Brown	Dull brownish
Odor	Characteristics	Characteristics	Alcoholic fragrance	Characteristics
State	Liquid	Liquid	Liquid	Solid
Taste	*Tikta, kashaya*	*Madhura, tikta*	*Kashaya, tikta*	*Kashaya, tikta*

TK: *Trikantakadi kvatha*, TKS: *Trikantakadi kvatha syrup*, TKGV: *Trikantakadi kvatha Ghana vati*, TT: *Trikantakadi* tincture

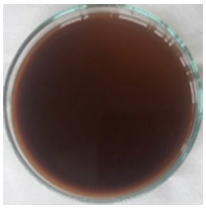


Fig. 13: *Trikantakadi Kvatha*

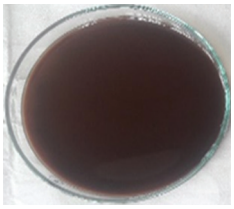


Fig. 14: *Trikantakadi Kvatha* syrup

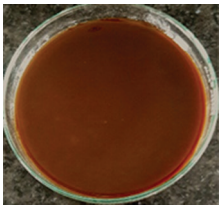


Fig. 15: *Trikantakadi* tincture

Fig. 16: *Trikantakadi Kvatha Ghana Vati*

Table 6: Physicochemical parameters of formulations

Parameters	Batch											
	Kvatha				Syrup				Tincture			
	K1	K2	K3	Avg.	S1	S2	S3	Avg.	T1	T2	T3	Avg.
Total ash (% w/w)	1.5	1	1	1.166	1.82	1.78	1.87	1.82	1.5	1.2	1.2	1.3
Acid insoluble ash(%w/w)	0.3	0.4	0.5	0.4	0.1	0.1	0.2	0.13	0.5	0.5	0.5	0.5
Total solid content (% w/v)	19.32	19.31	19.33	19.32	41.82	43.58	41.98	42.47	3.5	3	3.2	3.24
pH meter	4.77	4.77	4.78	4.77	4.58	4.59	4.59	4.58	4.76	4.75	4.76	4.756
Sp. Gravity at 25°C (g/ml)	1.028	1.029	1.028	1.028	1.208	1.179	1.181	1.189	1.003	1.004	1.004	1.003
Viscosity (millipoise)	1.379	1.350	1.379	1.369	5.65	5.68	5.65	5.65	1.39	1.43	1.39	1.40
Refractive index at room temperature	1.351	1.352	1.352	1.351	1.346	1.347	1.347	1.346	1.35	1.35	1.34	1.34
Alcohol content	NA	NA	NA	NA	NA	NA	NA	NA	3	3	3	3
Total acidity (%v/v)	NA	NA	NA	NA	0.047	0.048	0.047	0.047	0.029	0.027	0.029	0.084
Total sugar (%v/v) titrimetric method	NA	NA	NA	NA	8.46	8.45	8.45	8.45	10.6	10.5	10.4	10.5
Reducing sugar (%v/v) titrimetric method	NA	NA	NA	NA	2.77	2.88	3.15	2.9	2.77	3.01	2.78	2.85
Non- reducing sugar (%v/v) titrimetric method	NA	NA	NA	NA	5.40	5.52	5.80	5.57	7.43	7.88	7.88	7.73

NA: Not applicable

Table 7: Test for tablets

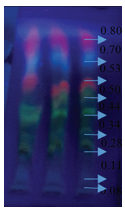
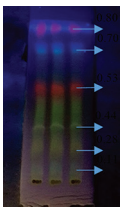
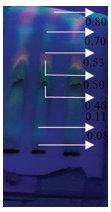
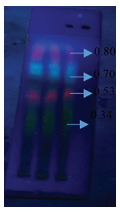
Parameters	Observed result
Appearance	Dull-brownish color, smooth surface
Shape	Round
Hardness	4 kg/inch^2
Thickness and diameter	4 mm, 10.5 mm
Friability	1.001% w/w
Weight variation	1.8% w/w
Disintegration time	14 minutes

Table 8: Phytochemical identification of formulations

Chemical constituents	Test	TK	TKS	TT	TKGV
Alkaloid	Mayer's reagent	+	+	+	+
	Dragendorff's reagent	+	+	+	+
	Wagner's reagent	+	+	+	+
Tannin	Ferric chloride test	+	+	+	+
	Lead acetate test	+	+	+	+
Anthraquinone glycoside	Borntrager's test	+	+	+	+
Sterol/Steroids	Legal test	+	+	+	+
	Keller-killani test	+	+	+	+
	Salkowski test	+	+	+	+
Flavonoids	Shinoda test	+	+	+	+
Test for terpenoids	Libermann-burchard's test	+	+	+	+
	Salkowski test	-	-	-	-
Reducing sugar	Benedict test	NA	-	+	NA
	Fehling test	NA	-	+	NA
Non reducing sugar	Benedict test	NA	+	-	NA
	Fehling test	NA	+	-	NA

+: Present, -: Absent, NA: Not applicable. TK: *Trikantakadi kvatha*, TKS: *Trikantakadi kvatha syrup,* TKGV: *Trikantakadi kvatha Ghana vati,* TT: *Trikantakadi* tincture

Table 9: Thin-layer chromatography profile of TK, TKGV, TKS, and TT

Mobile phase- Ethyl acetate: Methanol: Ethanol: Water (81:11:4:8) Stationary phase - silica gel G Extract used for spotting: Methanolic extract				
				
	Fig. 17: *Trikantakadi Kvatha* Observed Rf value under 365 nm: 0.08, 0.11, 0.28, 0.34, 0.44, 0.50, 0.53, 0.70, 0.80	**Fig. 18: *Trikantakadi Kvatha Ghana Vati*** Observed Rf value under 365 nm: 0.11, 0.28, 0.44, 0.53, 0.70, 0.80	**Fig. 19: *Trikantakadi Kvatha syrup*** Observed Rf value under 365 nm: 0.08, 0.11, 0.46, 0.50, 0.53, 0.70, 0.80	**Fig. 20: *Trikantakadi* tincture** Observed Rf value under 365 nm: 0.34, 0.53, 0.70, 0.80

TK*: Trikantakadi kvatha*, TKS: *Trikantakadi kvatha syrup,* TKGV: *Trikantakadi kvatha Ghana vati,* TT: *Trikantakadi* tincture

(Tables 8 and 9 – Figs. 17-20) [9,15]. Stability study of TKS, TT, and TKGV at accelerated temperature conditions was performed (Table 10) [16].

OBSERVATION AND RESULT

Pharmacognostic, physicochemical, phytochemical parameters of all the raw ingredients and formulations were studied, it showed that all the chemical compounds that were present in the *Kwath* (TK) were also present in other prepared dosage form. Stability studies of various prepared dosage forms of *trikantakadi kwath* was done for the time period of three days and during the stability studies of the various physicochemical, phytochemical and Thin Layer Chromatographic studies were done within the specific interval of time. Stability studies showed no significant variation when compared the observed results of accelerated temperature conditions data with the previous data.

Method for stability study

Stability study was performed by keeping the prepared samples at accelerated temperature conditions. Nine samples of each prepared dosage forms were taken and kept it at accelerated temperature of 4°C and room temperature of 47°C. The samples were tested for the physicochemical properties like color, odor, pH, specific gravity, friability, weight variation, hardness, etc. at the interval of 24 hrs, 48 hrs, and 72 hrs to observing the changes in physicochemical properties (Table 10).

DISCUSSION

TK was prepared by classical method mentioned in literature and converted into TKS, TKGV, and TT. Precaution should be taken during the processing of formulations. TT placed at dark place in airtight container. Physicochemical (Tables 6 and 7) and phytochemical investigation (Table 8) not showed remarkable variations with various prepared dosage forms. The R_f range (Table 9 – Figs. 17-20) observed between the 0.08 and 0.80 follow the standard value when compared with the reference of plant drug used for the preparation of dosage form. Result of accelerated stability study (Table 10) of TKS, TT, and TKGV was not showed any remarkable changes in physicochemical properties when compared with the previous data (Tables 6-8). Hence, these results may make some improvement in stability and shelf life degradation studies.

CONCLUSION

TK is a polyherbal formulation used for treating the *Ashmari, Mutraghat*, and *Mutrakricha.* Using stander TK as base, various conventional dosage forms can be prepared. Physicochemical, phytochemical parameters, and TLC showed all chemical compounds that present in the *Kvatha* are also present in other prepared dosage form. Stability studies showed no remarkable variation with physicochemical properties when comparing the observed values, which done in the interval of 24 hrs, 48 hrs, and

Table 10: Stability studies through Physicochemical parameters of TKS, TT, and TKGV

Sample code	Time duration (in hour)	Temperature (°C)	Physicochemical parameters												
			C	O	Ts	pH	Sp.	R	V	Tu	H	Ha	F	W	D.T.
SA1	24 hrs	4°C	NC	NC	NC	4.58	1.18	1.346	5.6	X	Y	NA	NA	NA	NA
TA1			NC	NC	NC	4.76	1.00	1.342	1.3	X	Y	NA	NA	NA	NA
TaA1			NC	NC	NC	NA	NA	NA	NA	NA	NA	4	1.001	1.8	14
SA2		Room temperature	NC	NC	NC	4.58	1.18	1.346	5.6	X	Y	NA	NA	NA	NA
TA2			NC	NC	NC	4.76	1.00	1.342	1.3	X	Y	NA	NA	NA	NA
TaA2			NC	NC	NC	NA	NA	NA	NA	NA	NA	4	1.001	1.8	14
SA3		47°C	NC	NC	NC	4.58	1.17	1.346	5.6	X	Y	NA	NA	NA	NA
TA3			NC	NC	NC	4.76	1.00	1.342	1.3	X	Y	NA	NA	NA	NA
TaA3			NC	NC	NC	NA	NA	NA	NA	NA	NA	4	1.001	1.8	14
SB1	48 hrs	4°C	NC	NC	NC	4.58	1.17	1.346	5.6	X	Y	NA	NA	NA	NA
TB1			NC	NC	NC	4.76	1.00	1.342	1.3	X	Y	NA	NA	NA	NA
TaB1			NC	NC	NC	NA	NA	NA	NA	NA	NA	4	1.001	1.8	14
SB2		Room temperature	NC	NC	NC	4.58	1.17	1.346	5.6	X	Y	NA	NA	NA	NA
TB2			NC	NC	NC	4.76	1.00	1.342	1.3	X	Y	NA	NA	NA	NA
TaB2			NC	NC	NC	NA	NA	NA	NA	NA	NA	4	1.001	1.8	14
SB3		47°C	NC	NC	NC	4.58	1.18	1.346	5.6	X	Y	NA	NA	NA	NA
TB3			NC	NC	NC	4.76	1.00	1.342	1.3	X	Y	NA	NA	NA	NA
TaB3			NC	NC	NC	NA	NA	NA	NA	NA	NA	4	1.001	1.8	14
SC1	72 hrs	4°C	NC	NC	NC	4.58	1.17	1.346	5.6	X	Y	NA	NA	NA	NA
TC1			NC	NC	NC	4.76	1.00	1.342	1.3	X	Y	NA	NA	NA	NA
TaC1			NC	NC	NC	NA	NA	NA	NA	NA	NA	4	1.001	1.8	14
SC2		Room temperature	NC	NC	NC	4.58	1.17	1.346	5.6	X	Y	NA	NA	NA	NA
TC2			NC	NC	NC	4.76	1.00	1.342	1.3	X	Y	NA	NA	NA	NA
TaC2			NC	NC	NC	NA	NA	NA	NA	NA	NA	4	1.001	1.8	14
SC3		47°C	NC	NC	NC	4.58	1.18	1.346	5.6	X	Y	NA	NA	NA	NA
TC3			NC	NC	NC	4.76	1.00	1.342	1.3	X	Y	NA	NA	NA	NA
TaC3			NC	NC	NC	NA	NA	NA	NA	NA	NA	4	1.001	1.8	14

C: Color, O: Odor, Ts: Taste, Sp.: Specific gravity at room temperature (g/ml), R: Refractive index at room temperature, V: Viscosity (millipoise), Tu: Turbidity, H: Homogeneity, Ha: Hardness (Kg/inch square), F: Friability (%w/w), W: Weight variation (%w/w), D.T.: Disintegration time (minute), S: Syrup, T: Tincture, Ta: Tablet, NC: No change, X: No, Y: Yes, NA: Not applicable. TKS: *Trikantakadi kvatha* syrup, TKGV: *Trikantakadi kvatha Ghana vati,* TT: *Trikantakadi* tincture

72 hrs. Hence, shelf life and all other related issue of *Kvatha* may be solve by converting *Kvatha* into most convenient dosage formed as per requirement.

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