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FORMULATION AND QUALITATIVE STANDARDIZATION SHATYADI SYRUP

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ABSTRACT

Cough management remains a critical concern in respiratory tract infections as it severely impacts quality of life. The classical Ayurvedic formulation *Shatyadi Kashaya* has been traditionally used to manage *Pittaja Kasa*, which is a subtype of cough as described in Ayurveda. Syrup is the most commonly used dosage form to cure cough and cold. Present study focuses on Shatyadi syrup, a modern adaptation of the classical Ayurvedic decoction. The method of formulation of shatyadi syrup at lab scale is discussed in the present studies. Shatyadi syrup was formulated and analyzed for organoleptic, physicochemical, microbial, and phytochemical parameters, along with HPTLC fingerprinting. The findings established the formulation's compliance with quality standards, ensuring safety and efficacy. Overall, studies highlight the potential of integrating traditional Ayurvedic formulations into modern healthcare through standardization and quality control.

KEYWORDS: *Ayurveda*, cough syrup, *Kasa*, Shatyadi Syrup, standardization, HPTLC.

INTRODUCTION

Respiratory tract infections (RTIs) are among the most significant human health issues due to their high incidence and consequent economic costs.[1] The majority of RTIs are caused by viruses, followed by bacterial infections.[2] Cough is a common presenting symptom of both upper and lower respiratory tract infections and leading cause of medical consultant worldwide accounting for approximately 30 million clinical visits annually.[3,4] About 9.6% global population and 5-10% Indians are reported to suffer from cough.[5]

Persistent cough or severe bouts of cough can result in complications like sleep disruption, headache, vomiting, syncope, excessive sweating, rib fracture, urinary incontinence, etc. thus, negatively affecting the quality of life.[4] The available conventional medications in cough management offer only symptomatic relief and have known side effects like constipation, respiratory depression, dependence, drowsiness and death.[6,7,8] Hence, there is an ardent need to explore the potential of safer and efficacious alternative therapies in the management of cough.

Ayurveda, the Indian system of medicine offers a wide range of medicinal formulations beneficial in the management of cough. Cough is described both as an individual disease termed *Kasa* as well as a symptom of other diseases in Ayurveda scriptures. *Kasa* has been classified into five main types, namely *Vataja Kasa*, *Pittaja Kasa*, *Kaphaja Kasa*, *Kshayaja Kasa* and *Kshataja Kasa* based on the etiology.[9] Many classical formulations in different dosage forms are described in the management of *Kasa*. *Shatyadi Kashaya* (decoction) is one such classical *Kwath* or *Kashaya* (decoction) formulation indicated in the management of *Pittaja Kas* type.[10] This classical formulation has limitations in terms of low palatability, lower shelf life, time-consuming and cumbersome preparation and administration. To overcome these limitations, classical decoctions are commonly modified into modern dosage forms like tablets, syrup, etc. In the present scenario, standardization of these Ayurveda formulations by quality control parameters is the need of the hour to establish their quality standards and ensure consistent and non-compromising quality, safety and efficacy. Hence, the primary objective of this study was to formulate and evaluate Shatyadi syrup by various analytical parameters.

MATERIALS AND METHODS

Procurement, authentication and analysis of ingredients of Shatyadi syrup

All the herbal ingredients were procured from the local herb store in Mumbai, India. The botanical identification of herbal ingredients was done using pharmacognostic methods.[11-12] The ingredients (refer Table 1) were validated on the basis of the standard monographs in the Ayurveda Pharmacopoeia of India.[13-14] For the herbal raw materials (Ingredients 1 to 4,Table 1), organoleptic parameters like colour, odour and taste and physicochemical parameters like pH, total ash, acid insoluble ash, water soluble extractive and alcohol soluble extractive and HPTLC were analyzed as per standard procedures.[13-15] The physicochemical parameters for analysis of *Sharkara* included loss on drying at 105°C, total ash, acid

insoluble ash and refractive index.[15] The analysis of potable water included physical parameters like odour, pH, color, density and viscosity.[14]

Table 1: Composition of shatyadi syrup.

No.	Ingredients	Botanical Name	Plant Part used	Quantity (g) For each batch
1.	*Shati (Kapoorkachari)*	*Hedychium spicatum* Buch.-Ham. ex Sm.	Rhizome	37.5
2.	*Hribera*	*Pavonia odorata* Willd.	Whole plant	37.5
3.	*Bruhati*	*Solanum indicum* L.	Root	37.5
4.	*Shunthi*	*Zingiber officinale* Roscoe	Rhizome	37.5
5.	*Sharkara* (rock sugar)	*Saccharum officinarum* L.	As such	180
6.	Potable water	-	As such	2.4 (l)

Method of preparation of Shatyadi syrup

Step 1. Preparation of *Shatyadi Kashaya*

Initially, *Shatyadi Kashaya* (decoction) was prepared as per the classical method mentioned in the Ayurveda text Yogaratnakar[10] without the addition of *Sharkara*. All the herbal ingredients of pharmacopoeial quality were cleaned manually to remove any physical impurities and later coarsely powdered. All the herbal ingredients (except *Sharkara*) were soaked in potable water in a stainless-steel (SS) container overnight at room temperature. The next morning, the soaked mixture was boiled on a low flame and reduced to 1/4th of the total volume of the mixture. Resultant product was filtered using a clean and dry, double layered white muslin cloth. The filtrate (*Shatyadi Kashaya*) was divided into three parts for the preparation of three batches of Shatyadi syrup and kept in respective three clean and dry SS containers.

Step 2. Preparation of Shatyadi syrup

Standard procedures were used to prepare Shatyadi syrup in three batches. In each batch, 65% of *Sharkara* (rock sugar) was added to *Shatyadi Kashaya*. The mixture was heated on low flame and stirred continuously to avoid sticking of sugar to the container, till the mixture reached a two-thread consistency. The syrup was cooled at room temperature and stored in a dry, airtight, amber-colored bottle.

Analytical parameters for Shatyadi syrup

The following parameters were evaluated for analysis of Shatyadi syrup using standard procedures[13,15]:

A. Organoleptic parameters- colour, odour and taste
B. Physico-chemical parameters- pH, total ash, acid insoluble ash, water soluble extractive and alcohol soluble extractive
C. Microbial contamination - Total bacterial count and total fungal count [15]
D. Test for specific pathogen - *E. coli, Salmonella spp., S.aureus, Pseudomonas aeruginosa*
E. Phytochemical evaluation- Preliminary phytochemical analysis included tests for alkaloids, flavonoids, steroids, glycosides, tannins, carbohydrate, saponin, proteins, phenol and starch.[16]

HPTLC analysis of herbal ingredients and Shatyadi syrup

The HPTLC fingerprinting analysis of herbal ingredients and Shatyadi syrup was conducted using CAMAG make HPTLC instrument, winCATS 1.4.3 software and Linomat 5 as sample applicator. The detection was done at 254nm and 366nm in Densitometry TLC Scanner 3. For sample preparation, the sample was partitioned in a separating funnel with butanol. The butanol soluble portion was evaporated to dryness and dissolved in methanol.[17] Aluminum plate coated with Silica gel 60 F 254 were used as stationary phase for HPTLC analysis. Toluene: Ethyl Acetate: Formic Acid (2.5:02:0.5v/v/v) mixture was used as mobile phase. Anisaldehyde sulphuric reagent was used as derivatising agent. [18]

RESULT

Table 2: Analytical parameters for herbal ingredients of Shatyadi syrup.

Parameters	**Name of the herbal ingredients**			
	Shati	***Hribera***	***Bruhati***	***Shunthi***
A] Organoleptic Parameters				
Colour	Light Brown	Pale brown	Yellowish-brown	Light Brown
Odour	Camphoraceous	No Distinct	No Distinct	Aromatic
Taste	Bitter	Slightly Bitter	No Distinct	Punget
B] Physico-chemical parameters				
Total ash (%)	4.913±0.015	4.666±0.208	5.413±0.015	4.853±0.055
Acid-insoluble ash (%)	0.923±0.0321	1.866±0.152	0.783±0.030	0.816±0.020
Water-soluble extractive (%)	12.253±0.743	4.2±1.597	16.02±0.026	12.253±0.567
Alcohol-soluble extractive (%)	10.59±0.04	2.39±0.08	4.733±0.041	12.376±0.025

Results of physicochemical analysis of *Sharkara* showed that the moisture content was 0.34%w/w, total ash was 0.29%, acid insoluble ash was 0.49%, and the refractive index was 1.365.

According to the results of the physical analysis of purified water, its appearance was colorless transparent, odorless, with no specific taste, pH was 6.99, density was 0.98g/cm^3 and viscosity was 0.79 cP. From the results, it can be stated that all the ingredients used in the preparation of Shatyadi syrup were of pharmacopoeial quality.

Table 3: Details of preparation of *Shatyadi Kashaya* and Shatyadi Syrup.

Parameters	**Results**
Initial quantity of *Kashaya Choorna* (powder of herbal ingredients)	150 g
Total quantity of water used (L)	2.4 L
Total time for soaking (hours)	15 hrs (Overnight)
Temperature during preparation of *Kwath* (after 1 hour)	80°C-100°C
Total time taken for *Kwath* (hours)	1 hour 20 mins
Total quantity of *Kwath* obtained (L)	0.6 L
Quantity of *Sharkara* powder (g)	180 g
Temperature during syrup preparation (°C)	60°C-90°C
Total time taken for preparation of syrup	30 mins

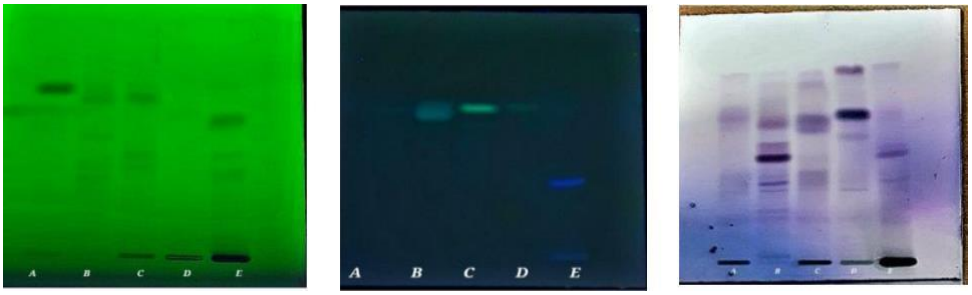
Table 4: Analytical parameters for Shatyadi Syrup.

Parameters	**Results**			
A] Organoleptic Parameters	**Batch 1**	**Batch 2**	**Batch 3**	
Colour	Brown	Brown	Brown	
Odour	No odour	No odour	No odour	
Taste	Slightly Bitter Sweet	Slightly Bitter Sweet	Slightly Bitter Sweet	
B] Physico-chemical parameters	**Batch 1**	**Batch 2**	**Batch 3**	**Mean ±SD**
pH	5.9	5.9	5.9	
Total ash (%)	0.75	0.74	0.74	0.743±0.005
Acid-insoluble ash (%)	0.3	0.32	0.31	0.31±0.01
Water-soluble extractive (%)	63.96	63.3	63.2	63.3±0.1
Alcohol-soluble extractive (%)	0.86	0.85	0.84	0.85±0.01
C] Microbial Contamination	**Batch 1**	**Batch 2**	**Batch 3**	
Total bacterial count (CFU/ml)	<10 CFU/ml	<10 CFU/ml	<10 CFU/ml	
Total fungal count (CFU/ml)	<10 CFU/ml	<10 CFU/ml	<10 CFU/ml	
D] Test for specific pathogen	**Batch 1**	**Batch 2**	**Batch 3**	
E. coli (CFU/ml)	Absent/ml	Absent/ml	Absent/ml	
Salmonella spp. (CFU/ml)	Absent/10 ml	Absent/10 ml	Absent/10 ml	
S. aureus (CFU/ml)	Absent/ml	Absent/ml	Absent/ml	
Pseudomonas aeruginosa (CFU/ml)	Absent/ml	Absent/ml	Absent/ml	

E] Phytochemical evaluation	Batch 1	Batch 2	Batch 3
Alkaloids	+	+	+
Flavonoids	+	+	+
Steroids	-	-	-
Glycosides	+	+	+
Tannins	+	+	+
Carbohydrates	+	+	+
Saponins	+	+	+
Proteins	-	-	-
Phenols	-	-	-
Starch	+	+	+

"+": Present, "-": Absent

HPTLC analysis of herbal ingredients and Shatyadi syrup



At 254 nm **At 366 nm** **After Derivatization**

Fig 1: HPTLC analysis of herbal ingredients and Shatyadi syrup at 254nm, 366nm and after derivatization.

Table 5: Rf values of herbal ingredients and Shatyadi syrup at different wavelengths.

	Raw Materials				Finished Formulation
	Track A	Track B	Track C	Track D	Track E
	Shati	Shunthi	Hribera	Bruhati	Shatyadi Syrup
At 254 nm	0.474	0.423	0.487	0.777	0.465
	0.532	0.485	0.550	0.947	0.563
	0.787	0.645	0.869	-	0.758
	0.913	0.853	-	-	0.969
At 366nm	0.910	0.426	0.487	-	0.456
	-	0.677	-	-	-
	-	0.860	-	-	-
After Derivatizing	0.212	0.187	0.187	0.112	0.185
	0.2	0.312	0.4	0.2	0.201
	0.337	0.65	0.65	0.325	0.344
	0.375	0.87	-	0.587	0.87
	-	-	-	0.875	-

DISCUSSION

The use of herbal medicine is the earliest form of the healthcare known and has been

practiced across all culture throughout the human civilization. The need for herbal standardization arises from the increasing global reliance on herbal products for medicinal, cosmetic, and nutraceutical purposes. According to WHO (1996a and b, 1992), standardization and quality control of herbals involve the physicochemical evaluation of the crude drug materials. Standardization ensures the quality, safety, efficacy, and consistency of these products [19] Our study successfully achieved the development of an Ayurvedic cough syrup by modifying a classical Ayurvedic dosage form using herbs such as Shati, Shunthi, Hribera and Bruhati The herbs used in the formulation have well-documented pharmacological significance. Sunthi (*Zingiber officinale*), with its potent (6)-shogaol content, provides antitussive, anti- inflammatory, and antimicrobial effects, particularly for dry coughs.[20] Shati (*Hedychium spicatum*), mentioned in Charak Samhita as a respiratory remedy, treats coughs, respiratory issues, and ulcers, with studies confirming its anti-inflammatory and bronchospasm-protective properties for asthma management.[21] Pavonia odorata contains bioactive compounds with anti-inflammatory, antimicrobial, and antioxidant effects, traditionally used as an expectorant to relieve coughs and congestion[22] Bruhati (*Solanum indicum*) offers analgesic, antipyretic, and anti-inflammatory effects, alleviating throat pain, reducing fever, and easing night-time coughs for better rest.[23] *Sharkara* known as Khadi Shakkar (Rock sugar) used within formulation is unrefined form of sugar that helps soothe the throat, reduces irritation, balances *Pitta dosha*, and enhances the therapeutic effects and taste of the formulation.

The process begins with the preparation of *Kashaya* (decoction), where Clean Overnight soaked herbs are boiled in water for a duration of 2 hours to extract their bioactive compounds. The decoction is then filtered to remove residual plant material. It was bitter in taste and converted into a syrup by adding rock sugar, which acts as preservatives while improving taste making it more palatable and boosting the shelf life of the syrup. The final syrup undergoes standardization to ensure the desired concentration of active compounds.

The standardization of syrup involves determining and maintaining specific values of quality indices such as macro and microscopic examination, extractive values, qualitative phytochemical analysis and chromatographic examination. These parameters are crucial for ensuring the product's stability, efficacy, and patient safety.

The pH value of 5.9 indicates a slightly acidic nature, which is optimal for the stability of the active ingredients and ensures compatibility with the body’s physiological conditions. This pH

is particularly beneficial for preventing microbial growth, enhancing the product's shelf life, and reducing the risk of irritation to the gastrointestinal mucosa.

The acid-insoluble ash value of 0.31% indicates a minimal presence of non-digestible inorganic matter like silicates. Such a low value reflects the careful selection and processing of raw materials, ensuring the absence of adulterants and contaminants.

The extractive values further demonstrate the formulation's efficiency in capturing bioactive compounds. The high water-soluble extractive value of 63.2% signifies the abundance of Phytochemical compounds which are integral to the syrup's therapeutic effects. In contrast, the lower alcohol-soluble extractive value of 0.84% indicates a minimal presence of lipophilic components, consistent with the aqueous nature of the preparation. This composition aligns with the formulation's focus on water-soluble bioactive, which are more effective in managing respiratory ailments.[24]

The microbial analysis confirmed the absence of contamination and pathogens, ensuring the formulation's safety for consumption. This finding reflects stringent quality control measures during production and underscores the product's compliance with international safety standards.

Qualitative phytochemical analysis was performed to identify the presence of necessary phytochemicals. The Presence of flavonoids, alkaloids, and glycosides were identified, known for their antioxidant, anti-inflammatory, and antiviral properties. They aid in soothing irritated respiratory passages, reducing cough symptoms, and treating respiratory congestion. Saponins, natural surfactants, were also identified. They can help break down mucus and facilitate its removal from the airways, making them beneficial in herbal cough remedies for promoting expectoration. Notably, the absence of steroids, proteins, and phenols ensures the formulation remains focused on compounds directly beneficial for respiratory health without incorporating elements that are unnecessary or potentially counterproductive to its intended use. The combination of these phytochemicals in herbal cough formulations provides a comprehensive approach to managing cough symptoms by targeting inflammation, irritation, mucus clearance, and cough reflex sensitivity.

HPTLC analysis was conducted for both raw materials and finished formulation for a comprehensive assessment of the presence and preservation of active compounds in the

formulations. TLC plates were observed at 254 nm, 366 nm and derivatized by anisaldehyde-sulfuric reagent, and separate bands were observed. Comparing the Shatyadi Syrup with the Raw Materials at 254 nm, Shatyadi Syrup exhibits Rf values that match those of the raw materials. For instance, Rf value 0.465 of Shatyadi Syrup matches with the track A of shati, track B Shunthi, and track C of Hribera. This suggests that the components of these raw materials contribute to the finished formulation. Separated band of Bruhati (track D) was clearly observed after derivatization.

At 366nm, the distinct separation of active components within the raw material and finished formulation has been observed.

HPTLC ensures the identification of raw materials in finished formulation and confirms the authenticity.

CONCLUSION

Ayurvedic Herbal cough syrups are often perceived as safer due to their natural ingredients, reducing the risk of adverse side effects common in some conventional medications. Herbal formulations tend to have a milder impact on the body, making them suitable for individuals with sensitive stomachs or allergies to certain chemicals. Moreover, herbal cough syrups often work in harmony with the body's natural healing processes, providing symptomatic relief while supporting overall respiratory health. *Kasa* is the disease of *Pranavaha Srotas*. It may develop as an independent disease, as a symptom, or as a complication of other diseases. Therefore, a classical formulation, *kashaya*, was prepared by incorporating well-documented herbs like shunthi, bruhati, shati, hribera and modified into a syrup for a more palatable and convenient way to consume these herbs. Future research avenues, such as quantitative analysis of active compounds and comprehensive antimicrobial efficacy testing, will ensure the formulation's safety, efficacy, and quality. Ultimately, this innovative approach to modifying a classical *kashaya* into a more palatable syrup form could significantly enhance respiratory health and overall well-being.

FUTURE ASPECTS

Future aspects outline the potential avenues for further research and development of the Ayurvedic cough syrup formulation. Expand on the initial phytochemical analysis by quantifying active compounds will help further in dose and dosage determination. Exploring methods to isolate bioactive ingredients. Bioactive compounds giving antimicrobial property

in herbal products can be separate and isolate through HPTLC. Developed TLC plate is covered with molten seeded agar medium. After solidification incubate it and staining by using tetrazolium dye inhibition or growth band can be visualized. It is simple and inexpensive tool for simultaneous chemical-biological screening of natural sources. Further one can investigate the antimicrobial efficacy of the formulation against common respiratory pathogens to enhance its therapeutic profile. Investigating the stability of the syrup under different environmental conditions will ensure that its efficacy and safety are maintained throughout its shelf life.

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