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Pharmaceutical Preparation and Analytical Evaluation of NirgundiAsava

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ABSTRACT:
Background: Although Nirgundi is widely used in Ayurveda for its anti-inflammatory, analgesic, and detoxifying properties, NirgundiAsava is not described in classical Ayurvedic texts. Therefore, a novel fermented formulation was developed and evaluated to ensure quality, safety, and therapeutic consistency. **Objectives:** To develop a novel NirgundiAsava using Nirgundipatrakwatha, jaggery, Dhatakipushpaphanta, and prakshepadravyas (Dalchini, Pippali and Ela), and to assess its pharmaceutical and physicochemical characteristics for quality assurance. **Methods:** The Asava was prepared according to general Asava–Arishta principles with controlled fermentation. Physicochemical parameters such as total solids, total residue, specific gravity, pH and alcohol content were evaluated using standard procedures.**Results:** The prepared NirgundiAsava showed typical colour, aroma, and taste of a fermented formulation. Physicochemical analysis revealed: total solids 11.3%, total residue 0.3%, specific gravity 1.03, pH 3.7, alcohol content 4.33%, all within acceptable ranges for Asava preparations. **Conclusion:** The study establishes the pharmaceutical and physicochemical profile of this novel NirgundiAsava, confirming proper fermentation and providing a scientific baseline for future pharmacological and stability studies.
KEYWORDS: Vitex negundo Linn, NirgundiAsava, novel formulation, fermentation, physicochemical evaluation.

I. INTRODUCTION

A wide range of dosage forms are described in Ayurveda, Within Bhaishajya Kalpana, Sandhana Kalpana is classified under the extended group of formulations derived from the primary Panchavidha Kashaya Kalpana—Swarasa, Kalka, Kashaya, Hima and Phanta. These basic preparations serve as foundational media in which fermentation is initiated using natural sweetening agents like jaggery or honey (1,2).Among these, Asava and Arishta stand out as unique formulations, as they are naturally fermented products that develop mild acidity and self-generated alcohol through the fermentation process(3).

Sandhana Kalpana constitutes one of the most significant branches of Ayurvedic pharmaceutics, where liquid preparations are allowed to undergo natural fermentation to enhance their potency, stability, and therapeutic value. The roots of Sandhana formulations can be traced back to the Vedic period, with references to fermented preparations such as Soma Rasa and Sura. Over time, Asava and Arishta emerged as prominent dosage forms due to their superior palatability, faster absorption, and prolonged shelf life(4,5).

Although several classical texts describe the preparation of fermented formulations, the distinction between Asava and Arishta was systematically explained by Sharangadhara Acharya(6). According to his classification, Asava are produced without boiling, typically using Swarasa or Hima, while Arishta are prepared from decoctions. Notably, many earlier formulations do not follow this standardized distinction, suggesting that the structured classification evolved later in Ayurvedic pharmaceutics.

Asava–Arishta preparations are elaborately documented in Charaka Samhita(7), Sushruta Samhita(8), Ashtanga Hridaya(9), Sharangadhara Samhita(10), Yogratnakar(11) and Bhaishajya Ratnavali(12). Their spontaneous fermentation process provides an inherent advantage by generating small quantities of self-formed alcohol, which acts as both a preservative and a carrier for active phytoconstituents, thereby improving bioavailability.

Singificance of Asava and Arishta:

Asava–Arishta preparations occupy a distinguished position among the Madya Kalpana and other Ayurvedic dosage forms because of their rapid therapeutic action and excellent natural

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preservative properties. During fermentation, inherent sugars undergo biochemical transformation, gradually converting into alcohol and releasing carbon dioxide. This naturally produced alcohol acts as an efficient solvent, helping to extract and retain the active phytoconstituents of the medicinal ingredients within the liquid medium. The presence of self-generated alcohol not only enhances the absorption and bioavailability of these compounds but also protects the formulation from microbial contamination, thereby ensuring a longer shelf life and formulations are highly valued for their efficacy, stability, and convenience in clinical practice(13).

When compared to Churna preparations, which often pose palatability challenges and require an appropriate Anupana for administration, and KwathaKalpana, which demands fresh daily preparation and has minimal shelf stability, Asava Kalpana stands out as significantly more convenient. Its ready-to-use liquid form, better taste profile, long-term stability, and enhanced therapeutic efficacy through natural fermentation make it an ideal choice for formulation development, particularly in the present context of preparing NirgundiAsava.

Therapeutic Relevance of Nirgundi

Nirgundi (Vitex negundo Linn.) is a well-known Ayurvedic medicinal plant traditionally used for its analgesic(14), anti-inflammatory(14), antimicrobial, and detoxifying propertiesandVata–Kapha pacifying actions. Its leaves contain bioactive compounds such as casticin, luteolin, β-sitosterol, iridoid glycosides and essential oils, making it a suitable candidate for fermented preparations.

In classical texts, Nirgundi(15) is described as Katu–Tikta rasa, Laghu–Ruksha guna, Ushna virya and Katuvipaka, properties that support its use in conditions involving pain, inflammation and metabolic imbalance. Based on these therapeutic attributes, the formulation of NirgundiAsava aims to enhance extraction, bioavailability and shelf-life through natural fermentation(16).

Although NirgundiAsava is not mentioned in classical Ayurvedic literature, its development aligns with the principles of Sandhana Kalpana and offers potential as a standardized, shelf-stable formulation. Scientific documentation of its pharmaceutical process and analytical characteristics is essential to ensure batch-to-batch consistency, safety, and therapeutic reliability.

The present study aims to prepare NirgundiAsava using Nirgundipatrakwatha, Dhatakipushpaphanta, jaggery, and selected prakshepadravyas, followed by a systematic evaluation of its physicochemical parameters. Establishing these standardization parameters is crucial for validating the formulation and supporting its future therapeutic application.

AIM

To develop a standardized batch of NirgundiAsava and establish its quality by evaluating organoleptic features and key physicochemical parameters.

OBJECTIVES

1. To prepare a standardized batch of the novel NirgundiAsava using Nirgundipatrakwatha, jaggery, Dhatakipushpaphanta, and prakshepadravyas.
2. To analyse the prepared NirgundiAsava with respect to its organoleptic characteristics and physicochemical parameters for quality assurance.

II. MATERIALS AND METHODS

MATERIALS:

The ingredient ratios were determined in accordance with the Anukta Mana principles mentioned in the Sharangadhara Samhita, ensuring that the formulation conformed to the classical standards for Asava–Arishta preparation(17).

Table 1:Ingredients Of NirgundiAsava

Ingredients	Latin name	Part used	Quantity
Nirgundi	Vitex negundo	Patra	5 Kg
Dhataki	Woodfordiafruticosa	Pushpa	500g
Jaggery / Gud	-	-	8 Kg
PrakshepDravyas			
Twak	Cinnamomun Zeylanica	Twak	200 g
Ela	Elettaria cardamomum	Pods	50g
Pippali	Piper Longum	Fruit	250 g

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Instruments: Vessels, Heating source, Stirring rod, Measuring cylinder, Weighing balance, Cloth (for filtration), Sandhan Patra, Thermometer

METHODS:

The methodology of the present study involves 4 stages

1. Preparation of Nirgundi Patra Kwatha
2. Preparation of Dhataki Pushpa Phanta
3. Preparation of NirgundiAsava
4. Addition of PrakshepaDravyas

1. Preparation of Nirgundi Patra Kwatha

- Fresh Nirgundi (Vitex negundo) leaves weighing 5 kg were selected, cleaned, and prepared for decoction.
- The leaves were washed thoroughly to remove dirt and foreign matter, then crushed to support better extraction of active constituents.
- The processed leaves were placed in a stainless-steel vessel, and 16 times water (80 L) was added as per classical Kwatha Kalpana.
- The mixture was kept for overnight soaking to ensure complete hydration and softening of the crushed leaves.
- The next day, the vessel was heated over a controlled flame with intermittent stirring to prevent sticking and ensure uniform boiling.
- The contents were reduced to one-eighth of the initial volume, yielding 10 litres of Nirgundi Patra Kwatha.
- The decoction was then filtered through a clean muslin cloth, producing a clear and uniform extract.
- The freshly prepared 10 L Kwatha was immediately used as the primary liquid medium for preparing NirgundiAsava.

2. Preparation of Dhataki Pushpa Phanta

- 500 g of Dhatakipushpa (Woodfordiafruticosa flowers) were selected, cleaned, and placed in a stainless-steel vessel.
- 4 litres of freshly boiled hot water were poured over the flowers to prepare the classical Phanta (hot infusion).
- The vessel was immediately covered with a clean cloth and kept undisturbed for 4–6 hours to allow complete extraction of active constituents and natural fermenting microorganisms inherent in Dhataki flowers.
- After the infusion period, the mixture was filtered through clean muslin cloth, yielding approximately 2 litres of clear Dhataki Pushpa Phanta.
- The freshly prepared Phanta was used immediately as the fermentation inoculum in the preparation of NirgundiAsava.

3. Preparation of NirgundiAsava

- The previously prepared 10 litres of Nirgundi Patra Kwatha were transferred into a clean Sandhana Patra.
- 6 kg of powdered and filtered jaggery was added and mixed thoroughly until fully dissolved.
- To this mixture, 2 litres of freshly prepared Dhataki Pushpa Phanta were added to initiate natural fermentation.
- The contents were stirred uniformly, and the vessel was covered with a clean, tightly secured cloth to maintain an undisturbed anaerobic environment.
- The Sandhana Patra was kept in a warm and shaded area for 30 days to allow proper fermentation.

Observations After 30 Days

- Classical signs of completed fermentation-Jatarasama(18) i.e.Characteristic fermented taste formed naturally, Vyaktamla, and KaṭukaJata(19) i.e.clearly perceptible, naturally developed slight sourness and mild pungencywere clearly observed, indicating complete transformation of the liquid with the expected taste, aroma, and mild pungency.
- Organoleptic features such as proper aroma (gandha), appropriate colour (varṇa), and well-developed taste (rasa-utpatti) confirmed normal fermentation activity.
- A burning matchstick remained lit when brought near the mouth of the vessel, showing the absence of active CO_2 release.
- ThenAsava was carefully decanted, separating the clear supernatant from the settled residue at the bottom.

4. Addition of PrakshepaDravyas

- After completion of fermentation, the clear portion of NirgundiAsava was carefully decanted and filtered. The filtered Asava was transferred into a clean stainless-steel vessel for further processing.
- At this stage, an additional 2 kg of jaggery was added to enhance palatability and stabilize the final formulation. The jaggery was stirred until fully dissolved. Subsequently, the powdered PrakshepaDravyas were added in the following quantities: Twak 200 g, Ela 50 g, Pippali 250 g

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- The mixture was stirred thoroughly to ensure uniform incorporation of the aromatic and therapeutic additives. The vessel was then kept undisturbed for 7 days, allowing adequate extraction of volatile and active principles from the PrakshepaDravyas into the fermented liquid.
- After the 7-day maceration period, the Asava was filtered again through a clean muslin cloth to obtain a clear and uniform final product, which was then stored in airtight amber-coloured bottles for further evaluation.

ANALYTICAL PROFILING

NirgundiAsava was subjected to organoleptic observation along with physicochemical analysis to determine its quality profile.

a) Organoleptic properties

As per the Ayurvedic Pharmacopoeia of India, the NirgundiAsava was examined for its colour, taste, and odour.

b) Physicochemical properties

Physicochemical evaluation of the prepared NirgundiAsava included determination of total solids, total residue, specific gravity, pH and alcohol content.

III. RESULT

Table 2: Pharmaceutical Evaluation

Sr. No.	Ingredients	Quantity
1.	NirgundiPatra Kwatha	10 L
2.	DhatakiPushpa Phanta	2 L
3.	Jaggery / Gud	8 Kg
4.	TwakChurna	200 g
5.	ElaChurna	50g
6.	PippaliChurna	250 g
7.	**Final Outcome**	**8.75L**

Table 3: Organoleptic evaluation

Formulation	Colour	Odour	Taste
NirgundiAsava	Brown	Characteristic	Bitter

Table 4: Physicochemical evaluation

Sr. No.	Parameter	Result	Standard values (as per API)(20)
1.	Total Solids	11.3%	30%
2.	Total Residue	0.3%	5%
3.	Specific Gravity	1.03	1.01 to 1.10
4.	pH	3.7	3.5 to 4.2
5.	Alcohol Content	4.33%	5 to 10% v/v

IV. DISCUSSION

The present study focused on the preparation and evaluation of NirgundiAsava formulated using Nirgundipatrakwatha as the primary liquid medium, along with jaggery, Dhatakipushpaphanta, and selected prakshepadravyas. The entire pharmaceutical process followed classical Ayurvedic guidelines, and the fermentation progressed smoothly without any irregularities. The gradual development of a distinct aroma, a mildly acidic pH, and light effervescence indicated healthy and complete fermentation.

The physicochemical characteristics of the formulation were compared with standard values prescribed in the Ayurvedic Pharmacopoeia. The pH (3.7) and specific gravity (1.03) of the sample were well within the acceptable limits for Asava–Arishta preparations. Although the alcohol content (4.33% v/v) was slightly lower than the conventional range of 5–10%, this variation may be attributed to natural fermentation dynamics and environmental factors. Despite being marginally lower, the alcohol level was adequate to function as a self-generated solvent, supporting extraction, preservation, and therapeutic potency. Lower values of total solids and total residue further indicated efficient fermentation with minimal unfermented substrate.

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The addition of Dhatakipushpaphanta significantly enhanced fermentation and contributed beneficial phytochemical constituents to the final product. Likewise, prakshepadravyas such as Dalchini, Pippali, and Ela improved the organoleptic profile and provided additional carminative and digestive actions. Nirgundi itself is widely recognized for its potent anti-inflammatory properties and its ability to pacify Vata and Kapha doshas. Fermentation further enhances the release and bioavailability of its active phytoconstituents, potentially improving gastrointestinal absorption. These combined factors help explain the observed therapeutic potential of NirgundiAsava, particularly in conditions involving inflammation and musculoskeletal discomfort. Overall, the analytical findings confirm that the prepared NirgundiAsavais pharmaceutically stable and meets the essential quality standards required for Asava preparations.

V. CONCLUSION

NirgundiAsava was successfully prepared using traditional Ayurvedic procedures with minor modifications suitable for laboratory conditions. The final preparation showed acceptable physicochemical characteristics such as pH, specific gravity, alcohol percentage, and organoleptic properties. Although the alcohol content was slightly lower than the ideal pharmacopoeial range, other parameters confirmed proper fermentation and quality.

The presence of Nirgundi along with Dhatakipushpa and prakshepdravyas supports the therapeutic potential of the formulation in disorders related to pain, inflammation and Vata-Kapha imbalance. The study provides a basic pharmaceutical and analytical profile of NirgundiAsava and can be used as a reference for future research. Further work including HPTLC fingerprinting, quantification of active components and pharmacological evaluation is recommended to validate and strengthen its therapeutic claims.

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