

PHARMACEUTICAL FORMULATION AND EVALUATION OF VIDANGADI ARKA (HYDROSOL) AND ITS CONVERSION INTO A GEL BASED ROLL-ON DOSAGE FORM FOR MANAGEMENT OF ARDHAVABHEDAKA (MIGRAINE)

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ABSTRACT

Migraine is a neurological disorder characterized by recurrent moderate to severe headaches, often accompanied by nausea, photophobia, and phonophobia. The word Ardhavabhedaka comprises of two components viz. Ardha and Avabhedaka. Ardha means half or half side, Ava suggests bad prognosis and Bhedaka means breaking, perforating or bursting out type of pain. Thus, literal meaning of Ardhavabhedaka is perforating or bursting out like pain in one half of the head either right or left. Conventional treatments are effective but may have side effects, limiting long-term use. Ayurveda offers safer alternative approaches using herbal formulations. Arka Kalpana is an essential Ayurvedic formulation technique involving the distillation of herbs to extract their volatile and water-soluble active principles. This process has gained prominence due to its ability to preserve the medicinal properties of herbs while enhancing their therapeutic efficacy. Traditional Arka is a thin,

volatile liquid that evaporates quickly and runs off the skin, limiting the penetration of its active medicinal compounds. Converting it into gel based roll-on improves topical retention, enhances delivery of active constituents, and provides more effective and convenient pain relief. The portability and convenience of roll-on devices make them suitable for on-demand

use during acute migraine episodes. ensuring ease of application, improved patient compliance, and precision. This study focused on developing an Ayurvedic roll-on using Arka (hydrosol) with analgesic, cooling, and neuro-calming properties. The formulation was prepared with suitable excipients and evaluated for pH, viscosity, stability, and skin compatibility.

Results showed that the formulation was stable with suitable physicochemical and sensory properties for topical use. The study indicates that Arka-based roll-ons may be a promising non-invasive option for migraine relief, supporting further clinical evaluation.

KEYWORDS: Arka, Roll-On, Gel, Ardhavabhedak, Migraine, Vidanga, Krishna tila.

INTRODUCTION

Migraines are common neurological disorders affecting over 10% of the population. The pain is primarily associated with the meninges and cranial blood vessels, especially the dural arteries. While earlier theories linked migraine to vascular dilation, current evidence highlights neurogenic inflammation mediated by the trigeminal nerve and involvement of 5-HT_{1B/1D} receptors. Vasoactive neuropeptides such as serotonin, calcitonin gene-related peptide (CGRP), pituitary adenylate cyclase-activating peptide, and histamine play key roles in this process. Additionally, the brainstem, hypothalamus, and cerebral cortex contribute to pain modulation and aura. Cortical spreading depression, a wave of altered neuronal activity across the cortex, is considered a major mechanism underlying migraine onset.

Limitations of conventional treatments

Conventional migraine treatments such as NSAIDs, triptans, and preventive drugs are widely used but have limitations. Overuse of acute medications may lead to medication-overuse headaches, and triptans are contraindicated in cardiovascular patients. Preventive therapies often require long-term use and may cause side effects, reducing adherence. Variable response and incomplete relief further highlight the need for safer, more patient-friendly options like topical formulations.

Ayurvedic perspective on migraine (i.e. *Ardhavabhedaka*)

The term *Ardhavabhedaka* is composed of two words: *Ardha* meaning half, and *Avabhedaka*, which refers to a breaking or piercing type of pain. Thus, it denotes a severe, piercing or splitting pain affecting one side of the head (*Ardha Mastaka Vedana*). It is described as a

recurrent unilateral headache often associated with symptoms such as giddiness and stabbing sensations occurring at regular intervals such as every 3, 5, 10, 15, or 30 days, commonly attributed to the vitiation of Vata, Vata-Kapha, or all three doshas (Tridosha).

Concept of Arka (hydrosol) in Ayurveda

Arka Prakasha describes *Kalka* (paste), *Churna* (powder), *Rasa* (juice), *Taila* (oil) and *Arka* (distillate) as Panchavidha Kashaya Kalpana (primary preparations). Among these, Arka is said to be the most potent.

Arka Kalpana is a unique pharmaceutical liquid preparation in Ayurveda obtained by distillation of certain liquids or of drugs soaked in water in which volatile constituents and active principles of drugs are extracted using an *Arka Yantra* or modern distillation apparatus. This process yields a liquid distillate containing water-soluble components along with essential oils. This preparation has specificity in the preparation aspect with increased shelf life and reduced dosage.

It is considered one of the most potent dosage forms due to its rapid onset of action compared to other *Kalpanas*. The final product is a slightly turbid aqueous solution, whose color and aroma depend on the source drug used.

As described in *Arka Prakasha*, *Arka* is characterized as free from impurities (*Dosharahita*) and rich in therapeutic properties (*Gunasangraha Prakasaka*). It has a relatively long shelf life and can be stored without preservatives.

The formulation effectively captures both volatile and active constituents of the drug, which contributes to its therapeutic efficiency. Due to these advantages, *Arka Kalpana* is increasingly gaining attention in contemporary Ayurvedic practice.

Role of selected Arka in migraine relief

Vidangadi Arka prepared from Vidanga and Krishna tila is mentioned in *Arka Prakash* for the management of Ardhavabhedak (Migraine) as Pralepa and Nasya.

External use of Arka as lepa is limited because Arka preparations are highly volatile and fast-acting (*Vyavayi* and *Vikasi*), formulating them into a gel allows the therapeutic components to absorb efficiently into the skin without evaporating instantly.

Converting an Arka distillate into a gel is an excellent formulation strategy to enhance its topical effectiveness. This modification changes the physical delivery vehicle, but the application remains completely non-invasive.

Benefits of a Gel Formulation

- **Prolonged Contact Time and Reduced Evaporation**

1. Volatilization barrier: Gels prevent the volatile distillate from evaporating too quickly from the skin surface.
2. Sustained release: It ensures the medicine stays in contact with the forehead or temples long enough to exert a therapeutic effect.
3. Structural matrix: The gel network traps these volatile molecules within its polymer matrix, significantly slowing down evaporation and slowly releases the active herbal components into the upper skin layers.

- **Enhanced Skin Penetration (Bioavailability)**

1. Better absorption: Hydrated gel bases can soften the stratum corneum (outer skin layer) to improve the penetration of active constituents.
2. Deep absorption: Relaxing the tight lipid barrier due to hydration allows the distilled herbal components to penetrate deeper and reach local nerve endings and blood vessels to soothe the headache.

- **Patient Compliance and Ease of Application**

1. Localized retention: A liquid Arka will drip down the face, potentially running into the eyes and causing severe irritation, whereas gel will be retained after local application.
2. Non-greasy aesthetics: Unlike traditional Ayurvedic oils (*Taila*) or thick pastes (*Lepa*), gels are non-greasy, elegant, easy to spread, and do not stain clothing or hair.

- **Controlled Dosage and Stability**

1. Uniform distribution: A gel ensures that the active distillate is uniformly suspended, providing a consistent dose with every application.
2. Targeted delivery: It allows the user to apply the exact amount needed specifically to the painful trigger points (like the temporal regions) without wasting the medicine.

Herbal Roll-on, a type of semisolid preparation packed in container with an applicator consisting a revolving ball at the top of the dispenser. They are the natural liquid or semisolid preparation containing essential volatile oil and herbal extract used to relief

pain and stress in migraine. Herbal roll on is novel topical dosage form. There is need to develop such dosage form in order to overcome difficulties faced by conventional dosage form like *Pralepa*, tablet and capsule for migraine. Roll on can be applied topically on skin very easily.

AIM

To formulate and evaluate an Ayurvedic Arka (hydrosol) and gel based topical roll-on for the management of Ardhavabhedaka (Migraine).

OBJECTIVES

1. To prepare Vidangadi Arka (hydrosol) using selected medicinal herbs wsr Arka Prakash.
2. To convert Arka into a stable and patient-friendly gel based topical roll-on preparation.
3. To evaluate the physicochemical properties of the Arka and Gel topical roll-on.

MATERIALS AND METHODS

1. **PHARMACEUTICAL STUDY:** Pharmaceutical study started from collection of genuine raw materials, followed by its pre-processing, preparation of Arka (hydrosol) and finally conversion to the product- roll-on.
- **Raw Materials** The ingredients of Vidangadi Arka are Vidanga and Krishna Tila, both the ingredients were taken in equal proportion. There are no other references regarding this formulation, except the one seen in Arka Prakasha. However similar Yoga is described as Nasya yoga in texts like Yogratnakar in the context of Ardhavabhedak with almost same ingredients of Vidangadi Arka.
- **Table 1: Ingredients used for Arka preparation.**

Sr no.	Name of Drug	Botanical Name	Family	Part Used	Quantity
1.	Vidanga	<i>Embelia ribes</i> Burm. f.	Primulaceae	Fruit	100gm
2.	Krishna Tila	<i>Sesamum indicum</i> L.	Pedaliaceae	Seeds	100gm



Table 2: Properties of Ingredients of Arka.

CONTENT	VIDANGA	KRISHNA TILA
RASA	Katu, Tikta, Kashaya	Madhura, Tikta
GUNA	Laghu, Ruksha, Tikshna, Sara	Guru, Snigdha
VIRYA	Ushna	Ushna
VIPAKA	Katu	Madhura
DOSHAGHNATA	Tridosahara Primarily Kapha-Vata Shamak	Tridosahara, Best Vatahara
PROPERTIES	Shirorogahara, Vatahara, Artinut, Vibhrantihara, Shirovirechana, Krimighna, Vishagna, Deepana, Shulahara	Balya, Tvacya, Vataghna, Vedanasthapana, Shoolaprashamana, Medhavardhaka, Shirashulahar, Shankhaka
PHYTOCHEMICAL	Embelin, Embelinol, Embeliaribyl Ester, Embeliol, Vilangin, Potassium Embelate, Quercitol and Fatty Ingredients, Alkaloid, Christembine, Resinoid, Tannins and minute quantities of a Volatile Oil.	Unsaturated Fatty Acids- Oleic and Linoleic Acids with Palmitic and Stearic as Minor Saturated Fatty Acids, Lignans-Sesamin, Sesamolin, Sesamol, Tocopherols
PHARMACOLOGICAL ACTIVITIES	Neuroprotective activity like Analgesic, Antioxidant, Antihistaminic, Antianxiety, Anticonvulsant, Antidepressant activity.	Antioxidant, Anti-inflammatory, Neuroprotective & anti-aging.

- **Excipients and base materials** – Water is used as solvent to soak drugs and prepare Arka.

- **METHOD**

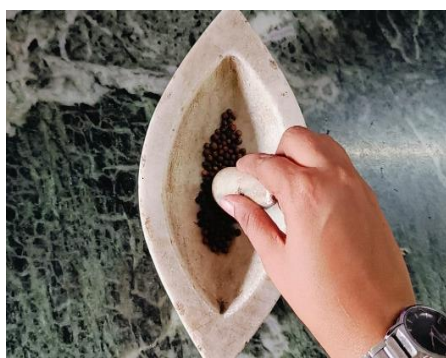
Collection of Raw Drugs: The raw drugs were collected from reliable source in dried form, verified based on macroscopic characteristics. The genuineness of raw drugs was authenticated by Department of Dravyaguna Vigyana and Department of Rasashastra and Bhaishajyakalpana, APM'S Ayurved Mahavidyalaya Sion, Mumbai.

Drug pre-processing: The ingredients of the formulation Vidangadi Arka were cleaned well and made to coarse powder form and weighed.

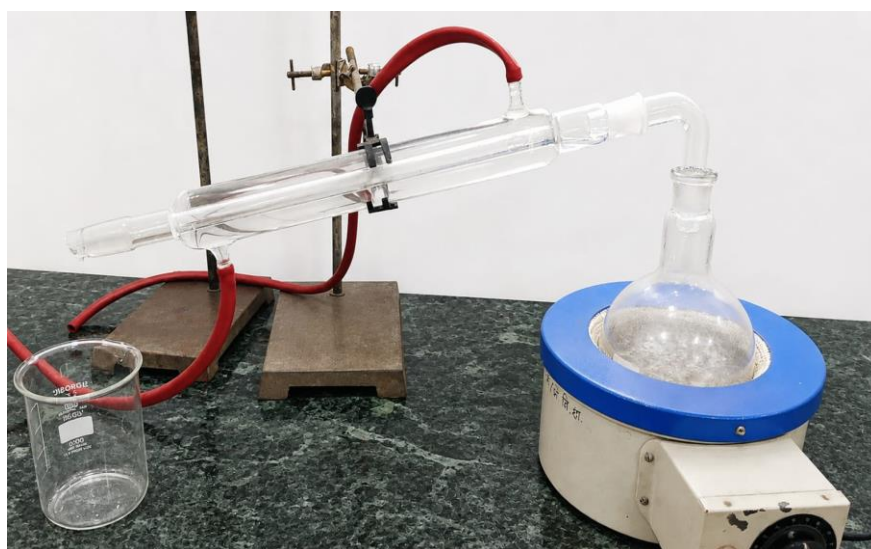
- I. PREPARATION OF VIDANGADI ARKA:** As per the method of preparation of Arka described in Arka Prakash one part of drug was soaked in two times of water. It was kept for twenty-four hours and distilled using distillation apparatus. Madhyagni (moderate fire) must be maintained during the procedure and only two third of the poured liquid must be collected.

Method (Distillation process)

1. The required quantity of water is added to the drugs for soaking and kept for 24 hours.
2. The next day morning it is poured into the Arka yantra (distillation apparatus) and the remaining water was added and boiled.
3. Condensed and collected vapors are cooled and turns back into liquid as Arka.



Vidanga and Krishna Tila made into Coarse Powder Coarse Powder soaked in Water



DISTILLATION PROCESS

II. FORMULATION OF ROLL-ON

• Table. 3: Ingredients used for formulation.

SR NO.	MATERIAL	ACTIVITY	QUANTITY
1.	Vidanga-Krishna Tila Arka (Hydrosol)	Active constituent	10 ml
2.	Xanthum Gum	Swelling agent	0.1 gm
4.	Glycerin	Humectant	0.3 ml
3.	Propylene Glycol	Humectant	0.2 ml
5.	Sodium Benzoate	Preservative	0.01gm

Method of preparation for herbal roll-on

1. In a beaker take 10 ml of Vidanga-Krishna Tila Arka (Hydrosol), dissolve 0.01gm of Sodium Benzoate in it.
2. Add 0.1gm of Xanthum Gum in it and dissolve completely, stir it for a while and keep it aside for approximately 1 hr. to swell in hydrosol to form a thick consistency.
3. Then add dropwise each 0.2 ml of propylene glycol and 0.3 ml of glycerin in the above solution gradually stir it.
4. The prepared mixture is now transferred inside the ambered colored bottle roll-on.



Xanthum gum dissolved to swell



Final Product - GEL

2. ANALYTICAL STUDY

- **Organoleptic evaluation of Ayurvedic roll on:** Organoleptic evaluation test standard for Ayurvedic-roll on typically evaluating the product sensory characteristics such as appearance, color, odor and texture. It also provides valuable information about sensory characteristics of product helping ensure quality standards, user satisfaction, and suitable use in pharmaceutical application.
- **Homogeneity test:** Homogeneity Test ensures that the active ingredient and excipient are uniformly distributed throughout the product. Product is uniform in composition which is

essential for maintaining quality, efficacy and safety. Homogeneity test plays crucial role in ensuring the integrity and reliability of Ayurvedic roll on.

- **After feel test of Ayurvedic roll on:** After feel test of Ayurvedic-roll on involved evaluating how the product feels on the skin after application. Ayurvedic roll on absorb into skin and any initial sensation to subside. After Ayurvedic roll on product has been absorbed, assess the after feel sensation in the skin.
- **Stability test of Ayurvedic roll on:** Stability test of Ayurvedic-roll on is crucial to ensure their quality, efficacy and safety. Stability studies based on different storage conditions that affect the factor such as Temperature, humidity and light. Temperature range such as room temperature (25-30°C). Hot temperature (45°C) and freezing temperatures (-1 to -5°C). Stability study maintains a balanced or steady state in the face of external disturbance.
- **pH test:** Conduct the pH test of the Ayurvedic-roll on product and compare it to human skin pH (5.4- 5.9). The main aim of this test is desired pH level to ensure product stability and safety and that Ayurvedic roll-on does not cause any irritation, allergic reaction on skin. The samples are properly labelled and stored.

OBSERVATION AND RESULT

1. Tabulated data for organoleptic and homogeneity evaluation parameters

After performing all evaluation tests results in acceptable range as shown in table given below.

Table 4: VIDANGADI ARKA.

TEST	RESULT
APPEARANCE	Clear liquid
COLOUR	Colorless
ODOUR	Aromatic
TASTE	Slight Aromatic
DENSITY	0.991 gm/ml
TOTAL SOLID CONTENTS	Nil
RESIDUE ON DRYING	0.36 %
pH	5.6
REFRACTIVE INDEX	1.34
VISCOCITY	1.19

Table 5: Vidangadi Gel.

TEST	RESULT
APPEARANCE	Soft Gel
COLOUR	Clear Transparent
ODOUR	Faint
TASTE	Bland
DENSITY	0.921 gm/ml
pH	5.9
UNIFORMITY OF CONTENT	Complies
SPREADABILITY	Uniformly Spreadable
MOISTURE CONTENT	8.45 %
LOSS ON DRYING AT 105 °C	7.65 %
TEXTURE	Smooth, non-gritty
HOMOGENEITY	Uniformly distributed, no phase separation observed
AFTER FEEL TEST	Cooling effect and non-greasy
STABILITY TEST	More stable at room temp (25 ⁰ -30 ⁰ c).
REMOVAL	Easily removed
IRRITANCY TEST	No any irritation

2. pH test: The skin pH is 4.5-6.5, the pH of the formulated roll on is 5.9 and is in range near about skin pH, hence it is more acceptable.

3. Table 6: Observations from stability studies.

STABILITY TEST	RESULT
Freezing Temp -1 to -5 °C	Freezes slightly
Room Temp 25-30°C	More stable
Hot Temp 45°C	Stable

DISCUSSION

Vidanga is kaphavatahara, ushna virya and Krishna tila is tridosha shamaka, ushna virya. Arka is the essence of the drug; and possesses laghu, ushna, kaphavatahara properties, increased potency, more shelf life, easy absorption and acts quickly in the management of Ardhavabhedaka.

After the formulation of gel-based roll on, evaluation of its organoleptic and physicochemical properties exhibits acceptable values.

The primary need for converting an Arka (distillate/hydrosol) into a gel for headaches is to overcome its rapid evaporation and lack of skin retention because traditional Arka is a thin,

watery liquid containing highly volatile essential oils, it runs off the skin immediately and evaporates into the air before the active medicinal compounds can penetrate the skin barrier to relieve pain. Transforming it into a gel creates a stable topical delivery system that solves these physical limitations through several distinct pharmacological advantages.

A topical roll-on formulation is selected for migraine management due to its ability to provide rapid, targeted, and non-invasive delivery of therapeutic agents. Transdermal application allows localized action, particularly in regions such as the temples and forehead, which are commonly associated with migraine pain.

Additionally, the cooling and soothing effect of topical Ayurvedic preparations may contribute to symptomatic relief through sensory modulation and relaxation. The portability and convenience of roll-on devices make them suitable for on-demand use during acute migraine episodes.

Advantages of roll-on delivery system: The roll-on system ensures ease of application, improved patient compliance, and precise dosing without the need for oral administration. It also minimizes systemic exposure and thereby reduces the risk of systemic side effects commonly associated with conventional anti-migraine medications.

CONCLUSION

The roll-on offers a natural and effective solution for addressing a variety of common ailments such as muscle pain, headaches, and stress. With its active plant-based ingredients, it provides targeted relief through its convenient roll-on application.

Potential applications: This topical Ayurvedic roll-on represents a promising approach for the on-demand management of migraine symptoms, offering a convenient and patient-compliant therapeutic option.

• SCOPE FOR FUTURE RESEARCH

1. Advanced Testing: The prepared Arka and formulated roll on can be tested for Phytochemical analysis, FTIR Spectroscopy, GC-MS.
2. Clinical Trials: Further clinical trials may be undertaken to validate its therapeutic potential.

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