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Formulation And Evaluation Of Avaleha From Anacyclus Pyrethrum Linn. For Tongue Paralysis And Tooth Ache

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ABSTRACT

This study focuses on the formulation and evaluation of a paediatric dosage form Avaleha (semisolid herbal preparation) using *Anacyclus pyrethrum* Linn., commonly known as Akkarkara, aimed at managing tongue paralysis and toothache in children. Rooted in classical Ayurvedic knowledge and supported by modern pharmacological insights, this project addresses the critical need for a safe, effective, and palatable herbal alternative for paediatric patients, particularly for conditions affecting speech and oral health.

Akkarkara is known for its nervine, analgesic, anti-inflammatory, and antimicrobial properties. It has been traditionally used in conditions like facial paralysis, speech disorders, and dental ailments. In this study, a herbal Avaleha was developed using a combination of *Akkarkara* flower bud powder along with Amla, dates, jaggery, ghee, sesame oil, and a blend of aromatic and therapeutic spices. The formulation was modified into a lollipop form for improved acceptability and administration in children, ensuring prolonged mucosal contact and enhanced effectiveness.

The formulation was evaluated for organoleptic properties (colour, taste, odour, texture), pH, moisture content (LOD), ash value, and microbial load. The Avaleha exhibited a pH of 5.3–5.7, suitable for oral administration, with acceptable levels of moisture (3.68%) and ash content (9.5%). Phytochemical analysis revealed the presence of alkaloids, terpenoids, flavonoids, saponins, tannins, and glycosides. Microbial tests demonstrated antibacterial activity, with a zone of inhibition against *E. coli* measuring 16–18 mm and a 66.2% reduction in colony-forming units.

The study concludes that the developed Avaleha offers a child-friendly, natural, and therapeutically potent alternative for treating paediatric tongue paralysis and toothache. This innovative herbal formulation not only aligns with Ayurvedic principles but also meets modern safety and efficacy standards, warranting further pharmacological and clinical exploration.

***Keywords*:** Avaleha, *Anacyclus pyrethrum*, paediatric formulation, tongue paralysis, toothache.

INTRODUCTION

Ayurveda, the ancient Indian system of medicine, continues to offer valuable insights into holistic health management, especially in the realm of herbal remedies. Among the many potent herbs in the Ayurvedic pharmacopeia, *Anacyclus pyrethrum*, commonly known as Akkarkara, holds a distinguished place due to its wide range of therapeutic properties. Traditionally utilized for its stimulating, rejuvenating, and neuroprotective effects, Akkarkara has been documented for its efficacy in conditions such as facial paralysis, toothache, speech disorders, and nervous system ailments. This thesis explores the formulation and evaluation of a palatable paediatric dosage form—*Avaleha*—incorporating Akkarkara as the primary active ingredient, with a focus on treating tongue paralysis and toothache in children, while simultaneously considering its other medicinal benefits.

Biological Source:

***Anacyclus pyrethrum* Linn.** is the **dried roots and flower buds** obtained from the plant ***Anacyclus pyrethrum* Linn.**, which belongs to the family **Asteraceae**.

Taxonomical Classification:

Kingdom: Plantae
Division: Angiospermae
Class: Dicotyledonae
Order: Asterales
Family: Asteraceae
Genus: Anacyclus
Species: *Anacyclus pyrethrum* Linn.

Traditional Ayurvedic Perspective:

Classical Ayurvedic texts such as *Charaka Samhita*, *Sushruta Samhita*, and *Bhavaprakasha Nighantu* have frequently referenced Akkarkara for its potent action on the nervous and sensory systems. It is described as an herb that stimulates *Agni* (digestive fire), sharpens intellect, strengthens nerves, and rejuvenates tissues.

Monograph Details (Pharmacognosy and Phytochemistry):

Macroscopic Characteristics:

- **Shape:** The flower buds are typically small, globular, and slightly flattened.
- **Size:** They are usually around 3-5 mm in diameter.
- **Colour:** The buds are often greenish-yellow or pale yellow, sometimes with a hint of pink or purple.
- **Texture:** The buds are often slightly hairy or pubescent.

Microscopic Characteristics:

- **Trichomes:** The buds have glandular trichomes (hairs) on the surface, which are usually unicellular or multicellular.
- **Epidermal cells:** The epidermal cells are polygonal or irregular in shape, with straight or slightly curved anticlinal walls.
- **Stomata:** The stomata are anomocytic (irregularly shaped) and are present on both the adaxial and abaxial surfaces.

Major Phytochemicals:

- Alkyl amides (e.g., pellitorine)
- Pyrethrins (Pyrethrin I & II, Cinerin I & II, Famoline I & II)
- Flavonoids
- Sterols
- Sesquiterpenes
- Essential oils

Pharmacological Activities:

- Analgesic
- Anti-inflammatory
- Neuroprotective
- Antimicrobial
- Antioxidant
- Aphrodisiac
- Immunomodulatory

Therapeutic Uses of Akkarkara 1. Neurological Disorders: ○ Used in facial and tongue paralysis (lingual palsy) ○ Stimulates cranial and peripheral nerves ○ Enhances cognitive function and memory **2. Oral Disorders:**
Acts as an analgesic in toothache ○ Antiseptic and antimicrobial for oral ulcers and gum infections **3. Speech Disorders:** ○ Used in cases of stammering, slurred speech, and aphasia ○ Improves vocal clarity and stimulates vocal cords **4. Aphrodisiac and Rejuvenator:**
Increases vitality and semen quality ○ Used in infertility and erectile dysfunction **5. Digestive Health:**
Stimulates appetite ○ Relieves flatulence and indigestion **6. Immunostimulant:**
Modulates immune response ○ Protects against infections **7. Anti-inflammatory Effects:**
Reduces inflammation in joints and soft tissues

Traditional Avaleha Formulations

Avaleha is a semisolid Ayurvedic dosage form prepared by boiling herbal decoctions with jaggery/sugar and ghee or oil, to which fine powders of other herbs are added. It is preferred in paediatric and geriatric practice for its ease of ingestion and prolonged shelf life.

Key Components of Avaleha:

- **Kashaya (Decoction):** Extracted from selected herbs
- **Madhura Dravya (Sweetening agents):** Jaggery, dates, honey
- **Sneha Dravya (Lipids):** Ghee, sesame oil
- **Kalka (Paste):** Fine powder of herbs

Existing Avaleha Formulations Using Akkarkara:

While not many classical formulations include Akkarkara as a lead ingredient, it is occasionally incorporated in formulations intended for: • Aphrodisiac purpose (*Vajikarana Avaleha*)

- Speech therapy (*Medhya Avaleha*)
- Digestive tonics

However, none of the documented Avalehas are specifically targeted at paediatric tongue paralysis or toothache.

Modern Scientific Research on Anacyclus pyrethrum:

Several modern studies have explored the pharmacological actions of *Anacyclus pyrethrum*:

- **Neuroprotective Activity:** Studies demonstrate improvement in nerve conduction and protection against neurodegeneration in experimental models.
- **Cognitive Enhancement:** Animal studies show improved memory and learning, supporting its Medhya (nootropic) classification.
- **Antibacterial and Antifungal Activity:** Root extracts show significant activity against oral pathogens such as *Streptococcus mutans* and *Candida albicans*.
- **Analgesic and Anti-inflammatory:** Exhibits pain-relieving effects comparable to standard NSAIDs in rat models.
- **Safety Profile:** Acute toxicity studies in rodents suggest a wide margin of safety for aqueous and alcoholic extracts.

Therapeutic Uses of Akkarkara:

Beyond tongue paralysis and toothache, Akkarkara is reputed for a variety of therapeutic uses, many of which have been validated by traditional knowledge as well as emerging scientific studies:

1. **Nervine Stimulant and Tonic:** Akkarkara enhances nerve function and is used in managing conditions like facial paralysis, epilepsy, and speech delays. It acts on the brain and spinal cord, promoting better coordination and reflexes.
2. **Speech Disorders (Mukh Badhirya):** Due to its stimulating action on the tongue and vocal cords, Akkarkara is traditionally used to improve clarity of speech and manage conditions like stammering and aphasia.
3. **Oral Health:** Its antimicrobial activity is effective against oral pathogens responsible for gingivitis, dental caries, and mouth ulcers. It is often included in herbal tooth powders and mouth rinses.
4. **Digestive Aid:** It stimulates appetite, enhances salivation, and improves digestion, making it useful in conditions like anorexia, indigestion, and flatulence.
5. **Reproductive Health:** Akkarkara is a known aphrodisiac and is used in the treatment of male infertility, erectile dysfunction, and low libido due to its strengthening and revitalizing effects.
6. **Anti-inflammatory and Analgesic Effects:** The root of the plant is chewed to relieve pain and swelling in inflammatory conditions.
7. **Immunomodulatory Properties:** Some studies suggest its potential in modulating immune responses and enhancing resistance against infections.

Justification for Paediatric Application:

Paediatric therapeutics requires special consideration of taste, dosage, palatability, and ease of administration. Children are more sensitive to bitterness and often resist taking medicine. *Avaleha* is an Ayurvedic preparation that overcomes this barrier through the incorporation of sweeteners like jaggery or sugar, ghee, and honey, which not only improve taste but also contribute to the therapeutic action by acting as *Yogavahi* (catalytic agents enhancing bioavailability).

By formulating Akkarkara into an *Avaleha*, the aim is to create a child-friendly dosage form that:

- Provides sustained release of the active phytoconstituents
- Masks the pungency and bitterness of Akkarkara • Enhances the acceptability among paediatric patients.

This study directly addresses the critical unmet need for a safe, effective, and highly palatable herbal therapeutic for pediatric tongue paralysis and toothache, conditions currently lacking child-friendly Ayurvedic interventions. By meticulously formulating an *Anacyclus pyrethrum*-based Avaleha into an innovative lollipop form, this research aims to bridge classical Ayurvedic wisdom with modern pharmaceutical standards, thereby demonstrating a novel approach to enhance compliance and efficacy in young patients. Through comprehensive physicochemical, phytochemical, and microbial evaluations, this investigation hypothesizes that the developed Avaleha will serve as a potent, natural, and highly acceptable solution, paving the way for further clinical validation and broader adoption of traditional remedies in pediatric healthcare.

LITERATURE REVIEW

1. **Indian Journal of Drugs and Diseases, A treasure of medicinal herb - Anacyclus pyrethrum A review, R. Annalakshmi, R. Uma, G. Subash chandran, A. Muneeswaran, ISSN: 2278–294x (Print), ISSN: 2278-2958 (Online)**

Anacyclus pyrethrum (Linn) De Candolle, commonly referred to as ‘Akarkara’ is widely recognized in ayurvedic system of Indian medicine as tonic and rejuvenator. It is a hard, compact, fusiform root, about the size of the little finger, with sometimes leaf -remnants at the top, and beset with few or no hair-like rootlets; externally brownish, deeply fissured longitudinally. Various phytochemical and biological evaluations have been reported in the literature for the importance of A.pyrethrum. So, it have been used in ethno medicine to exploit its medicinal properties including antimicrobial effect, local anesthetic effect, insecticidal & mollusidal effect also showing anti-inflammatory activity. This review summarizes the botany, ethnopharmacology query, phytochemistry, biological activity of A. pyrethrum plant.

2. **Anacyclus pyrethrum (L): Chemical Composition,Analgesic, Anti-Inflammatory, and Wound Healing Properties, Fatima Zahra Jawhari, Abdelfattah El Moussaoui, Mohammed Bourhia, Hamada Imtara, Hamza Mechchate, Imane Es-Safi, Molecules 2020, 25, 5469**

Background: Anacyclus pyrethrum (A. pyrethrum) is a wild species belonging to the family Asteraceae, which is used in traditional medicines. Aim of the study: This work was undertaken to study the chemical composition, analgesic, anti-inflammatory, and wound healing properties of hydroalcoholic extracts of different parts (roots, seeds, leaves, and capitula) of A. pyrethrum. Material and Methods: The phytochemical analysis of the studied extracts was conducted by GC-MS. The analgesic activity was evaluated in mice using acetic acid and formaldehyde methods. The anti-inflammatory activity was tested using the inhibitory method of edema induced in rats. The healing activity of the hydroethanolic extracts was explored by excision and incision wound healing models in rats. Results: The phytochemical analysis of the studied plant extracts affirmed the presence of interesting compounds, including some newly detected elements, such as sarcosine, N-(trifluoroacetyl)-butyl ester, levulinic acid, malonic acid, palmitic acid, morphinan-6-One, 4,5.alpha.-epoxy-3-hydroxy-17-methyl, 2,4-undecadiene-8,10-diyne-N-tyramide, and isovaleric acid. Theextractsofdifferentparts (roots, seeds, leaves, andcapitula) exhibitedpromisingantiinflammatory, analgesic, and wound healing effects, with percentages of inhibition up to 98%, 94%, and 100%, respectively. Conclusion: This study might contribute towards the well-being of society as it provides evidence on the potential analgesic, anti-inflammatory, and wound healing properties of A. pyrethrum.

3. **Journal of Applied Pharmaceutical Science Vol. 6 (03), pp. 144-150, March, 2016, ISSN 2231-3354, Pharmacognostic and phytopharmacology study of Anacyclus pyrethrum: An insight, Afreen Usmani, Mohd Khushtar, Muhammad Arif, Mohd. Aftab Siddiqui, Satya Prakash Sing, Md Mujahid**

Anacyclus pyrethrum an amazing medicinal plant is one of the most widely growing species of the family Asteraceae. The present review endow with significant information about its phytochemical investigations, pharmacological activities and medicinal properties as a folk medicine to treat several disease like antirheumatic, analgesic, antibacterial, antiviral, carminative, anti-catarrh, improve digestion, emmenagogue, febrifuge, nervine, vermifuge, and sialagogue. The plant has been reported several pharmacological actions such as antidiabetic, immunostimulating effect, inhibitory effects, antidepressant activity, anticonvulsant activity, memory-enhancing activity, aphrodisiacs, antimicrobial activity, antioxidant, local anesthetic effect, insecticidal effect, action on COX and LOX, interactions with testosterone, interaction with libido, and it interaction with testicles. Mainly the root portion has beneficial properties that can serve the mankind. The entire plant can be extensively studied for further future prospective.

4. **The antibacterial activity of methanolic Anacyclus pyrethrum and Pistacia lentiscus L. extract on Escherichia coli, Noushin Jalayer-Naderi, Mohammad Niakan , Elham Khodadadi , Maryam Mohamadi-Motlagh Iran Journal of Microbiology 2016 Dec;8(6):372-376**

Background and objectives: Antibiotic therapy is the main choice in treatment of Escherichia coli induced infections. Using herbal medication is an alternative choice in treatment of diseases. The aim of this study was to determine the antibacterial activity of two traditionally used herbs in Iranian medicine, Anacyclus pyrethrum and Pistacia lentiscus L., on Escherichia coli.

Materials and methods: The antibacterial effect of methanolic extract of Anacyclus pyrethrum and Pistacia lentiscus L. were examined in disk diffusion and skipped wells methods by measuring the diameter of inhibition zones around wells containing different concentrations of extracts from (10-1000 mg/ml) using standard broth macrodilution, method the MIC and MBC were defined.

Results: The methanolic extract of Anacyclus pyrethrum from 300 to 1000 mg/ml and the methanolic extract of Pistacia lentiscus L. from 30 to 1000 mg/ml showed antibacterial activity on Escherichia coli. The MIC of Anacyclus pyrethrum and Pistacia lentiscus L. methanolic based extract were 800 and 1000 mg/ml, respectively. The MBC was achieved at 800 mg/ml for methanolic extract of Anacyclus pyrethrum and Pistacia lentiscus L.

Conclusion: The methanolic extract of Anacyclus pyrethrum and Pistacia lentiscus L. have antibacterial effect on Escherichia coli bacteria. This activity is dose-dependent.

5. International Journal of Pharmacognosy and Clinical Research, Online ISSN: 2664-7648; Print ISSN: 2664-763X; Volume 2; Issue 1; 2020; Page No. 20-23, Anacyculus pyrethrum (Akarkara) Anjali Bargal, Jasvanti Patil, Aishwarya Shinde, Deepak Musmade

Anacyculus pyrethrum also called as Akarkara, is a perinnial herb that grows in the Himalayan. Anacyculus Pyrethrum root have unique ayurvedic value. The other parts of this herb possess insecticidal property.
Anacyclus Pyrethrum is used in South Asia to treat toothache, facial neuroglia and chronic catarrh. Basically, Anacyculus Pyrethrum (Akarkara) is described in unani system of medicine as a great drug used in various purposes. In Akarkara medicinal part is root, It have pungent taste and are slightly aromatic. Which has considered as tonic used in remady since ancient times, to aid the nervous system. The main contribution of this work is to study herbal application and biological study of Anacyculus Pyrethrum. This review will help us to understand multidimensional uses of Akarkara and helps to future study.

6. International Journal of Ayurveda and Pharma Research, ISSN: 2322 - 0902 (P), ISSN: 2322 - 0910 (O), A Critical Review on Avaleha Kalpana Mahesh S, Sheela Karalam B, Aravind S, Neethu S Pillai

Avaleha is the most common secondary Kalpana (dosage form) which has been employed in various disorders and this product is gaining popularity due to its easy administration, palatability and longer shelf life. It is a semisolid preparation of herbal drugs prepared in decoction or extracts of different herbs by adding sweetening agents like jaggery, sugar or sugar candy. The component drugs which are used in the preparation of Avaleha are aqueous medium, substrate, Oushada dravyas, lipid medium, additives etc. By analyzing consistency of various Avaleha varies from freely-flowing, paste-like, semisolid and granular, which depends upon the substrate and Oushada churna ratio. Avaleha can be compared to confections because both contains essential ingredients as sugar and water and optional ingredients as edible oils, honey, flours, starches, edible salts etc. Avaleha are intend to provide better drug absorption through the oral cavity along with absorption through villi. The literature related to Avaleha has been surveyed from various Ayurvedic literatures, journals, Ayurvedic Formulary of India etc. and presented briefly here. Here we have discussed the information regarding Avaleha like ingredients, method of preparation, Avaleha paka lakshana, non-conformances related to Avaleha production, comparison between Avaleha and confections and absorption.

7. Exploring Potential of Kushmanda Avaleha in a Memory Enhancement – A Comprehensive Review, Dr. Divyarani1*, Reeti Rastogi, African Journal of Biomedical Research, Vol. 27 (September 2024); 138- 140

Ayurveda is an ancient Indian medical system, and it is based holistic approach to physical and mental health. Ayurveda has eight major disciplines that are collectively known as Ashtanga Ayurveda. Rasayana Chikitsa is one among the Ashtanga Ayurveda and it is a unique branch of Ayurveda, which comprises a specialized use of herbs, herbal-mineral formulations, food articles, and lifestyle along with self-discipline with social etiquette to achieve the optimum state of tissues and systems of the body. Some of these Rasayanas are having intellect-promoting drugs called Medhya Rasayana. Such Rasayanas act on the brain and helps in the improvement of memory power, retention and grasping power..A large number of drugs like Shankhapushpi, Mandookaparni, Guduchi, Ashwagandha, Kushmanda etc. are mentioned under Medhya Rasayan. Kushmanda Avaleha is a formulation with multi- ingredients mentioned as Smriti Vardhaka drug in the Ayurvedic literature and it is having Medhya effect by its Prabhava. The main ingredient of this herbal formulation is Kushmand (Benincasa Hispida) which is Ash gourd. Thus, this article is emphasized on compiling and exploring various references of Kushmanda formulations and its ingredients which help in the brain functions. All the information has been placed here in comprehensive manner.

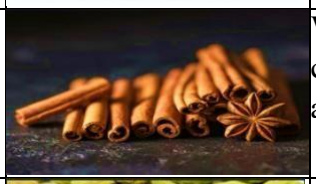
8. Anacyclus pyrethrum var. pyrethrum (L.) and Anacyclus pyrethrum var. depressus (Ball) Maire: Correlation between Total Phenolic and Flavonoid Contents with Antioxidant and Antimicrobial Activities of Chemically Characterized Extracts Fatima Zahra Jawhari, Abdelfattah E. L. Moussaoui, Mohammed Bourhia, Hamada Imtara, Hamza Saghrouchni, Plants 2021, 10, 149.

Bhaishajya Kalpana is a branch of Ayurveda which mainly deals with Medicine preparation in many dosages form in which avaleha is one of the dosages. Avaleha is the Semisolid dosage form which is widely used in different age group. This research delves into the quality assessment of Kalyana Avaleha, a powdered formulation taken by ghrita which is mentioned in Ayurvedic texts for its therapeutic properties in addressing conditions related to Swarabheda. Aims & Objectives:To do Pharmaceutico- Analytical study of Kalyana

Avaleha. Material & Method: The study employs approach encompassing pharmaceutical and analytical evaluations. The pharmaceutical aspect involves the meticulous preparation of Kalyana Avaleha using specified ingredients and an appropriate anupana (Ghrita). The analytical part incorporates flame photometry, Preliminary phytochemicals and Total Tannins and Flavonoids for quantifying essential minerals and metals.Results& Discussion: Notable findings in flame photometry and phytochemical activities. The role of electrolytes in Swarabheda, antibacterial actions and antioxidant effects. The study underscores the potential therapeutic benefits of Kalyana Avaleha, attributing its efficacy to alkaloids, tannins, and flavonoids. Conclusion: Kalyana Avalehais a Semisolid dosage form of Bhaishajya Kalpana, which is mainly indicated for Swarabheda. The results of the pharmaceutical and analytical study can be considered preliminary standards for the preparation of Kalyana Avaleha.

MATERIAL AND METHODOLOGY:

Sr. No.	Name of Ingredients	Quantity	Images	Properties	Uses
1.	Amla (Gooseberry)	1kg		Rich in Vitamin C, antioxidant, rejuvenative	Boosts immunity, supports digestion, anti-inflammatory
2.	Brown Sugar (Jaggery)	1kg		Natural sweetener, iron-rich, detoxifier	Enhances taste, provides energy, aids digestion
3.	Honey (Shahad)	300gm		Antibacterial, demulcent, nutritive	Soothes throat, natural preservative, improves palatability
4.	Dates (Khajoor)	400gm		Nutrient-rich, energizing, laxative	Provides strength, supports digestion, balances Vata
5.	Cow Ghee	50gm		Cooling, unctuous, medhya (brain tonic)	Enhances absorption of herbs, nourishes tissues
6.	Sesame Oil	50gm		Warming, nourishing, antioxidant	Supports nervous system, strengthens gums and teeth
7.	Holy Basil (Tulsi)	50nag		Antimicrobial, adaptogenic, antiinflammatory	Boosts immunity, soothes oral infections

8.	Dry/Fresh Ginger (Adrak)	20gm		Digestive, antiemetic, circulatory stimulant	Aids digestion, reduces inflammation, enhances taste
9.	Cinnamon (Dalchini)	2inch		Warming, carminative, antibacterial	Improves circulation, fights microbes, adds flavor
10.	Green Cardamom (Hari Elaichi	20nag		Aromatic, digestive, expectorant	Enhances taste, relieves nausea, freshens breath
11.	Cloves (Laung)	20nag		Analgesic, antiseptic, aromatic	Relieves toothache, treats oral infections
12.	Black Pepper (Kali Mirch)	4tbsp		Pungent, carminative, bioenhancer	Improves bioavailability, supports digestion
13.	Long Pepper (Pipli)	10 sticks		Stimulant, digestive, rejuvenative	Supports respiratory and nervous systems
14.	min Seeds (Jeera)	2tbsp		Carminative, cooling, digestive	Improves digestion, relieves bloating
15.	Mace Flower	2 flowers		Aromatic, antispasmodic, stimulant	Enhances flavor, soothes nerves
16.	Fennel Seeds (Saunf)	4tbsp		Cooling, aromatic, digestive	Reduces acidity, soothes GI tract, freshens breath
17.	Bay Leaf (Tej Patta)	5-6nag		Aromatic, carminative, stimulant	Aids digestion, supports respiratory health
18.	Dried Rose Petals	4tbsp		Cooling, antiinflammatory, aromatic	Improves taste, supports emotional balance

19.	Saffron Threads (Kesar)	10-12 threads		Tonic, antioxidant, mood enhancer	Enhances complexion, improves memory, calms nerves

Table 1 : Ingredients used in formulation **Methodology:**

1. **Collection of Anacyclus pyrethrum Flower Buds:**

For this research, Anacyclus pyrethrum flower buds were collected at their optimal maturity: mature size, closed or just unfurling petals (yellow with red top observed). Harvesting was done by gentle hand-picking under dry morning conditions. Only flower heads were collected, avoiding stalks. Harvested buds were immediately placed in ventilated baskets. Post-harvest, buds were promptly air-dried in a shaded, wellventilated area, turned regularly until brittle. Dried buds were then packaged in breathable cloth bags and stored in a cool, dry, and well-ventilated location until further use. This careful process ensured highquality raw material for subsequent analyses.

2. **Method for preparation of Avaleha formulation using powder of dried flower buds of Anacyclus pyrethrum Linn. :**

First, the ingredients were measured accurately. The amla was boiled in a pressure cooker for 5-8 minutes. After boiling, the seeds were removed. The soft amla was then smashed and ground into a smooth paste. Next, all the spices were put into a mixer and ground into a fine powder. The dates were also ground into a smooth paste after removing their seeds. For cooking, a pan was heated on the stove. Ghee and sesame oil were added to the hot pan. The smooth amla paste was then sautéed in the ghee and oil until it absorbed them completely. Later on, pieces of jaggery were added to the mixture and stirred well. It was cooked for 2 minutes with a cover on, turning it dark brown. Next, all the spices were mixed in thoroughly. Then, the gas was turned off and honey along with powdered dried flower buds of Anaciclus pyrethrum were added. This mixture was stirred well, and saffron sticks were added to the hot Avaleha formulation. Finally, the pan was set aside to cool down, and the Avaleha formulation was ready to serve.

3. **Packaging and Storage:**

Once the Avleha formulation was ready, it was rolled onto wooden sticks to make it easier to use. Then, it was wrapped in plastic to keep it stable. As they were converted into candies this method made it more acceptable for children and helped the medicine stay on the tongue longer, making it work better for toothache and speech disorders in them.Then it was stored in a cool and dry place in a well suitable container.

RESULTS & DISCUSSION:

The Avaleha formulation containing *Anacyclus pyrethrum* root extract was successfully developed using traditional methods, and the prepared formulation was subjected to various physicochemical and organoleptic evaluations.

Procedures :

- **pH:** The formulation exhibited a pH of 5.3-5.7, suitable for oral intake and within the acceptable range for Ayurvedic Avalehas.

- **Moisture Content (LOD):** A quantity of 3 g of the herbal material was measured. The evaporating dish was placed in an oven set at 105 ± 2°C for 5 minutes and subsequently positioned in a desiccator until needed. The evaporating dish was positioned in an oven.This process was repeated 3 to 4 times. The moisture content percentage was determined by using the formula:

  ○ % moisture content = C2-C3/C2-C1×100 ○ where: C1 =weight of the empty evaporating dish C2 = weight of crucible + sample before heating C3 = weight of crucible = sample after heating.

  The loss on drying was found to be 3.68%, indicating acceptable moisture levels that ensure stability and prevent microbial growth.

- **Ash Value:** Ash comprises inorganic elements such as phosphates, carbonates, and silicates, which include sodium, potassium, magnesium, calcium, and others. The 'Total Ash Value' is affected by the concentrations of calcium oxalate, silica, and carbonate present in the raw material. Begin by accurately weighing 2 grams of the air-dried sample in a previously weighed silica crucible and incinerate it at a temperature not exceeding 450ºC until all carbon is eliminated. After cooling, weigh it again. If the ash has carbon in it, wash the burnt material with hot water, collect the leftover particles on a filter paper that has no ash, and incinerate the residue together with the filter paper until the ash turns white or close to white. Return the filtrate to the dish, allow it to evaporate until completely dry, and ignite it again at a maximum temperature of 450ºC. Calculate the percentage of total ash relative to the weight of the dried substance.

Total ash was found to be 9.5%, confirming minimal inorganic residue.

Table 2 : Evaluation of Formulated Avaleha

Sr. No.	Evaluation parameter	Observation
1	Colour	Deep brown
2	Odour	Sweet & Aromatic
3	Taste	Herbal & Spicy followed by numbness
4	Texture/Consistency	Sticky, Semi-solid, Granular
5	Mouthfeel	Gritty
6	Spreadability	Not spreadable
7	pH	5.3-5.7
8	Moisture content (LOD)	3.68%
9	Ash value	9.5%,

Phytochemical Screening of *Anacyclus pyrethrum* Extract:

The dried flower bud extract obtained by cold maceration using hydroalcoholic solvent (ethanol:water, 70:30) was subjected to preliminary phytochemical tests. The following results were observed:

- **Terpenes:** *Present.*

1. Salkowski test: Take 2ml of plant extract. Add 2ml of chloroform. Carefully add 2ml of conc. H2SO4 along the sides of the test tube. Observe the colour change.
It yielded a reddish-brown colouration at the interface, confirming the presence of terpenoids in the extract. **2. Libermann-Buchard test:** Take 2ml of extract. Add 2ml of Acetic anhydride. Add few drops of conc. H2SO4 carefully. Observe the colour change.
It yielded red colour showing the presence of terpenoids.
3. Copper acetate: Take 2ml of extract. Add 3-4 drops of copper sulphate solution. Observe the colour change. It resulted in green colouration due to presence of diterpenes. (Note- Copper sulphate was used instead of copper acetate due to its prohibited use.)

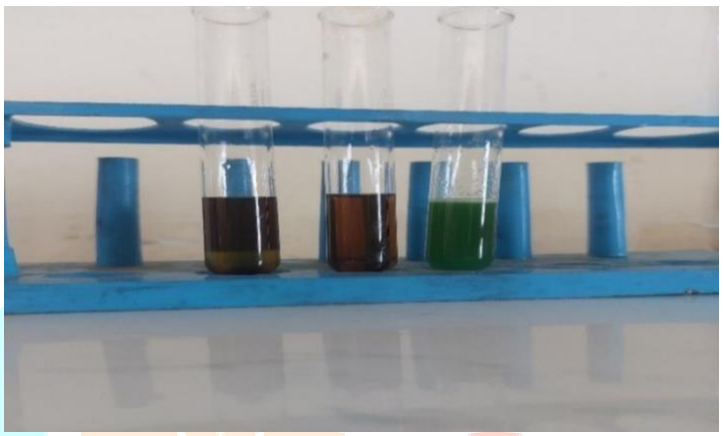


Figure 1 : Results of qualitative test

Sr no.	Tests	Observation	Inference
1.	Salkowski test	Reddish-brown colour	Presence of terpenoids
2.	Libermann-Buchard test	Red colour	Presence of terpenoids
3.	Copper acetate test	Green colour	Presence of diterpenes

- **Alkaloids, Flavonoids, Saponins, Tannins, and Glycosides:** Also detected in the hydroalcoholic extract, indicating a broad spectrum of phytochemicals contributing to the therapeutic effects.

- **Microbial testing:**

1. **Zone of Inhibition:** Zone of Inhibition for Zone A & B was found to be 16mm & 18mm in diameter respectively.

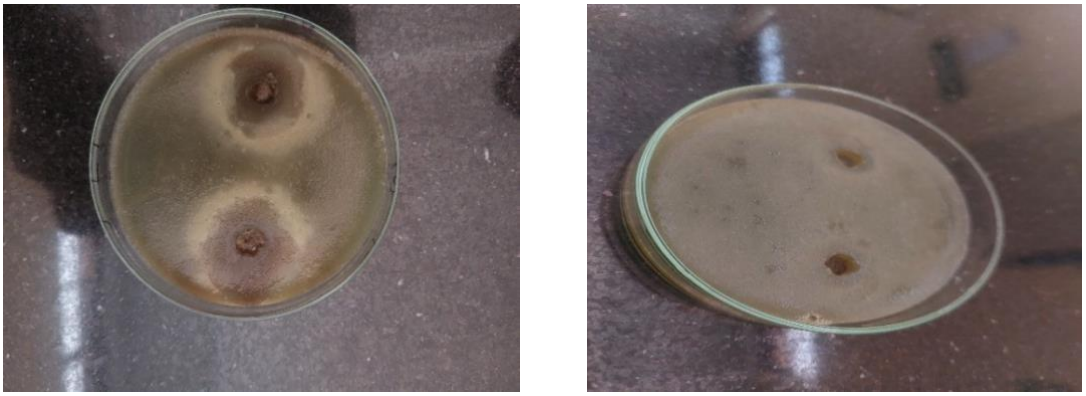


Figure 2 : Zone of Inhibition

2. **Colony counting method:**

In microbiology, percentage inhibition refers to the extent to which a substance (like an antibiotic, plant extract, or chemical compound) reduces the growth or activity of a microorganism, usually compared to a control sample without the substance.

Formula :

% Inhibition = Control-Treatment/Control x100 where,

Control = Growth observed without the inhibitory agent Treatment = Growth observed with the inhibitory agent

Table no. 2 : Comparative Colony counting

CONDITIONS	PLATES (CFU)
Control	287
Treated with Dil. Avaleha	97

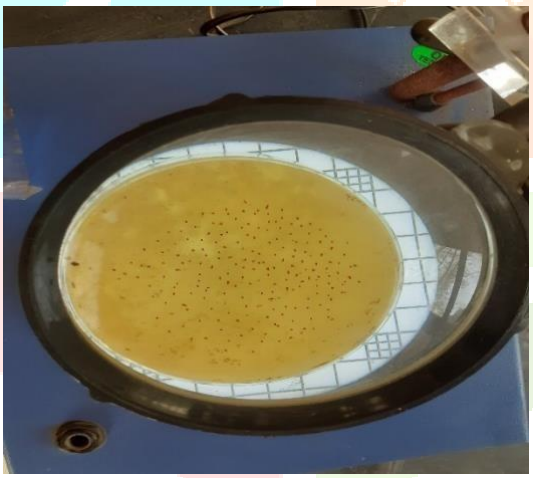


Figure 3.1 : Control e. coli culture

Figure 3.2 : Treatment with dil. Avaleha

Discussion:

The present research successfully formulated an Avaleha, an Ayurvedic semi-solid preparation, specifically designed for pediatric use, incorporating Anacyclus pyrethrum Linn. (Akkarkara). This initiative aimed to address the critical need for a safe, effective, and palatable herbal alternative for managing tongue paralysis and toothache in children, conditions that significantly impact their comfort and speech development. The formulation process meticulously integrated classical Ayurvedic principles with contemporary pharmaceutical insights, ensuring a product grounded in tradition yet validated by modern scientific standards.

The initial evaluation of the Avaleha focused on its **organoleptic properties**, which are crucial for ensuring pediatric compliance. The formulation presented as a deep brown, sweet, and aromatic semisolid with a characteristic herbal and spicy taste, followed by a noticeable numbness, indicative of Akkarkara's unique constituents. While exhibiting a sticky, granular consistency and limited spreadability, these attributes are inherent to Avalehas and contribute to prolonged oral mucosal contact, essential for localized therapeutic

action, particularly in toothache. This careful sensory balance effectively masked any inherent bitterness, enhancing palatability for children.

Physicochemical parameters were rigorously assessed to confirm the Avaleha's quality and stability. The pH, ranging from 5.3 to 5.7, proved ideal for oral intake and consistent with Ayurvedic standards. A low moisture content of 3.68% (Loss on Drying) was observed, indicating excellent stability and effectively deterring microbial growth, thereby enhancing shelf life. Furthermore, a total ash value of 9.5% confirmed minimal inorganic impurities, attesting to the purity of the raw materials and the integrity of the preparation process. These parameters collectively affirm the robust quality and stability of the developed Avaleha.

Phytochemical screening of the hydroalcoholic extract of Anacyclus pyrethrum flower buds, obtained via cold maceration to preserve heat-sensitive compounds, revealed a rich array of bioactive constituents. The presence of terpenoids was unequivocally confirmed through specific qualitative tests. Additionally, the extract tested positive for alkaloids, flavonoids, tannins, saponins, and glycosides. This comprehensive phytochemical profile suggests a synergistic therapeutic action, where these diverse compounds collectively contribute to the Avaleha's anti-inflammatory, analgesic, neurostimulant, and antimicrobial properties, directly supporting its traditional uses and its targeted application for neurological and oral health conditions.

Crucially, **microbial testing** provided compelling evidence of the Avaleha's safety and inherent antimicrobial potential. Both the Zone of Inhibition assay and the Colony Counting Method demonstrated significant antibacterial activity, particularly against Escherichia coli. Zone of Inhibition diameters ranged from 16mm to 18mm, indicating clear inhibitory effects. Quantitatively, the treated E. coli culture showed a remarkable reduction in colony-forming units (CFU) from 287 (control) to 97, translating to approximately **66.55% inhibition**. This significant antimicrobial action is vital for an oral preparation, ensuring safety by inhibiting microbial contamination and offering direct therapeutic benefits against bacterial infections commonly associated with toothache.

In conclusion, the successful formulation and comprehensive evaluation of this Anacyclus pyrethrumbased Avaleha underscore its immense potential as a child-friendly, natural therapeutic agent for managing tongue paralysis and toothache. The research successfully validated the formulation's quality, stability, palatability, and antimicrobial efficacy through modern scientific analysis, while remaining rooted in traditional Ayurvedic principles. This work not only bridges classical knowledge with contemporary pharmaceutical standards but also opens promising avenues for further rigorous pharmacological studies and comprehensive clinical evaluations. Such future investigations are essential to fully delineate its therapeutic scope, establish optimal dosages, and pave the way for its integration into mainstream pediatric healthcare, offering a valuable addition to the natural medicine landscape.

Future Scope of Akkarkara incorporated in Avaleha are as follows:

The future scope for the Avaleha formulation derived from Anacyclus pyrethrum (Akkarkara) is multifaceted, encompassing further pharmacological investigation, clinical validation, and the development of standardized pediatric formulations.

The study concludes that the developed Avaleha offers a child-friendly, natural, and therapeutically potent alternative for treating pediatric tongue paralysis and toothache. The findings from this research warrant further exploration.

The future scope of this research includes:

Clinical and Pharmacological Studies

Further Pharmacological and Clinical Exploration: The study explicitly states that the findings warrant further pharmacological and clinical exploration. The formulation demonstrates promise for further pharmacological studies and clinical evaluation.

Safety and Efficacy Standards: The research highlights that the innovative herbal formulation aligns with Ayurvedic principles and meets modern safety and efficacy standards. Future work should build upon this foundation to confirm these standards through additional studies.

Specific Effects on Neuromuscular and Oral Health: The objectives include preliminary pharmacological evaluation of the formulation's effects on neuromuscular and oral health. This area requires continued investigation to confirm the observed therapeutic benefits, especially concerning tongue paralysis (lingual palsy) and dental pain.

Standardization and Formulation Development

Development of Holistic, Child-Appropriate Alternatives: The findings of this study may contribute to the development of holistic, child-appropriate alternatives in integrative and herbal medicine. The research successfully addressed key challenges in pediatric therapeutics such as palatability, ease of administration, and safety by formulating the Avaleha into a palatable dosage form and converting it into lollipop-like forms.

Bridging Traditional and Modern Practices: The study aims to bridge the gap between traditional Ayurvedic wisdom and modern pharmaceutical practices by standardizing a formulation that is safe, palatable, and effective for pediatric use. Future work should focus on the standardization processes necessary for clinical application.

The successful formulation and evaluation of this Avaleha serve as a foundation for further clinical investigations and the development of herbal pediatric formulations.

SUMMARY & CONCLUSION:

Summary:

The present research successfully culminates in the formulation and comprehensive evaluation of a novel pediatric-friendly Avaleha, strategically incorporating the esteemed medicinal herb Anacyclus pyrethrum Linn., commonly known as Akkarkara. This innovative therapeutic preparation is specifically designed to address prevalent issues of tongue paralysis and toothache in children, offering a gentle yet effective intervention. The development of this formulation is deeply rooted in the foundational principles of classical Ayurveda, which has long recognized the efficacy of such herbal preparations, while concurrently being rigorously supported and validated by contemporary scientific analytical methodologies. This dual approach ensures that the Avaleha not only aligns with traditional wisdom but also meets modern pharmaceutical standards for quality, safety, and efficacy. A significant driving force behind this research was to overcome the inherent challenges often encountered in pediatric therapeutics, particularly concerning drug palatability, ease of administration, and the paramount importance of safety, thereby enhancing patient compliance and therapeutic outcomes in young individuals.

Anacyclus pyrethrum was meticulously selected as the principal active pharmaceutical ingredient due to its extensively documented pharmacological profile. Both ancient traditional texts and modern phytochemical and pharmacological studies consistently corroborate its potent nervine, analgesic, anti-inflammatory, and antimicrobial properties. Its historical use in various conditions, particularly those affecting the nervous system and oral cavity, provides a strong empirical basis for its inclusion. This selection underscores the research's commitment to harnessing naturally occurring compounds with proven therapeutic potential for sensitive pediatric populations.

The Avaleha preparation involved a synergistic blend of potent herbal components and carefully chosen pharmaceutical adjuvants, including amla (Indian gooseberry), dates, jaggery, honey, ghee (clarified butter), and sesame oil. This unique combination was not merely for enhancing the therapeutic value of the formulation but was also critical in making it exceptionally organoleptically acceptable for children.The natural sweetness and rich texture conferred by these adjuvants effectively masked any inherent bitterness from Anacyclus pyrethrum, thereby promoting voluntary intake. A groundbreaking aspect of this formulation's design was its creative conversion into lollipop-like forms. This innovative delivery system was conceived to significantly increase patient compliance among children by transforming medication into a more appealing format. Furthermore, the lollipop design inherently prolongs the mucosal contact time of the active ingredients within the oral cavity, which is crucial for localized effects in conditions like toothache and potentially for systemic absorption or neurological benefits in tongue paralysis. This extended contact enhances the efficacy of the therapeutic compounds, making the treatment more potent and patient-friendly. The prepared Avaleha

underwent a rigorous series of physicochemical and biological evaluations to ascertain its quality, stability, and potential therapeutic attributes. Organoleptic assessment consistently revealed a deep brown, distinctly aromatic, and palatable semisolid product, confirming its successful masking of undesirable tastes and its overall aesthetic appeal. Crucially, the formulation's pH (ranging between 5.3 and 5.7), its controlled moisture content (3.68%), and its ash value (9.5%) were found to be well within the prescribed limits for Ayurvedic preparations, confirming its chemical suitability and long-term stability in accordance with established traditional norms. Further, comprehensive phytochemical screening of the hydroalcoholic extract derived from Anacyclus pyrethrum unequivocally confirmed the abundant presence of key bioactive secondary metabolites. These included terpenoids, alkaloids, flavonoids, tannins, saponins, and glycosides, each known for their significant contributions to the overall therapeutic efficacy, ranging from anti-inflammatory and antioxidant activities to direct neurological and antimicrobial effects, thus validating the traditional claims with scientific evidence.

Significantly, the microbial analysis conducted on the Avaleha formulation yielded highly promising results, demonstrating a substantial antibacterial activity. This was particularly evident against Escherichia coli (E. coli), a common pathogen, indicated by a notable reduction in colony-forming units (CFUs) and impressive zones of inhibition measuring between 16–18 mm. These compelling findings are vital as they not only strongly affirm the intrinsic safety profile of the Avaleha by demonstrating its ability to inhibit microbial growth, thereby reducing contamination risk, but also underscore its inherent antimicrobial potential. This characteristic is particularly beneficial for oral health issues like toothache, where bacterial infections often play a significant role. The presence of such broad-spectrum antimicrobial activity adds another layer of therapeutic value and reinforces the formulation's protective qualities.

Conclusion:

In conclusion, the culmination of this research project unequivocally demonstrates the successful formulation and comprehensive evaluation of an Anacyclus pyrethrum-based Avaleha that stands out as a highly promising, child-friendly, and entirely natural therapeutic agent. Its efficacy is particularly highlighted in managing challenging pediatric conditions such as tongue paralysis and toothache. Beyond these primary targets, the study suggests that the holistic action of the Avaleha, especially given Akkarkara's traditional uses and confirmed nervine properties, holds significant additional benefits, including the potential for enhancing overall speech development and promoting robust oral health in children. This comprehensive approach addresses multiple facets of pediatric well-being, making the formulation a valuable contribution to herbal medicine.

This pioneering study serves as a critical bridge, meticulously connecting the profound wisdom embedded in traditional Ayurvedic practices with the rigorous and verifiable standards of modern pharmaceutical science. By applying contemporary analytical techniques and quality control measures to an ancient formulation concept, the research not only validates the scientific basis of Ayurvedic principles but also establishes a robust framework for the development of future herbal medicines. This integration ensures that the therapeutic benefits of traditional knowledge can be harnessed and delivered in a manner that is both scientifically sound and acceptable within current healthcare paradigms. The successful outcomes reported here are not merely an academic achievement; they lay a solid foundation for significant advancements in pediatric phytotherapy.

Furthermore, the promising results derived from the physicochemical characterization, organoleptic assessment, phytochemical profiling, and particularly the compelling antimicrobial activity, open broad and exciting avenues for subsequent clinical investigations. These future studies are crucial to thoroughly evaluate the Avaleha’s efficacy, safety, and optimal dosage in actual patient populations under controlled clinical settings. Such trials would provide definitive evidence of its therapeutic benefits for tongue paralysis, toothache, and its potential ancillary effects on speech and oral hygiene. Beyond the immediate scope of this specific formulation, this research paradigm encourages and facilitates the broader development of innovative herbal pediatric formulations. It inspires further exploration into traditional herbal remedies, pushing the boundaries of natural medicine to offer more child-appropriate, palatable, and effective alternatives to conventional pharmaceuticals, ultimately benefiting global public health by integrating validated traditional knowledge into modern therapeutic arsenals. This work contributes significantly to the growing body of evidence supporting the efficacy and safety of herbal interventions, particularly in the sensitive and crucial field of pediatric care.

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