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A Review on Formulation and Evaluation of *Tridax procumbens* Leaves-Based Thermosensitive In-Situ Nasal Gel for Asthma Therapy

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ABSTRACT

Asthma is a common, non-infectious, and multifaceted illness marked by persistent airway inflammation, bronchial tube sensitivity, immune cell presence, increased airway reactivity (also referred to as airway hyperresponsiveness), and structural changes in the airways. It affects over 300 million individuals globally, or about 7% of the total population. The smooth muscles in the airways constrict during an asthma attack, causing swelling and irritation that makes breathing difficult. At normal room temperatures, which are between 20 and 25 degrees Celsius, a thermosensitive liquid stays liquid; but, when it comes into contact with bodily fluids, which are normally between 35 and 37 degrees Celsius, it turns into a gel. This study examines the phytochemical composition and pharmacological significance of various plant-based compounds used in asthma treatment. It covers their formulation properties in addition to findings from in vitro and in vivo assessments. The primary challenges, limitations, and opportunities for the creation of nasal formulations based on phytomedicines for respiratory disorders are also identified in the study. One possible technique for effective in situ gel formation is the use of thermosensitive biomaterials, which remain liquid at ambient temperature but gel when subjected to higher temperatures.

Keywords Tridax procumbens, thermosensitive nasal gel, in-situ gelation, asthma therapy, phytomedicine, nasal drug delivery.

1. INTRODUCTION

Asthma is a long-term inflammatory illness that impacts the airways. The continuous inflammation causes the airways to become overly sensitive, resulting in recurring symptoms like wheezing, breathing difficulties, a sensation of tightness in the chest, and coughing, particularly at night or in the early morning.[1] These symptoms are caused by substances released during allergic reactions and inflammation in the lungs' air passages.[2] These substances include histamine, leukotrienes, bradykinine, prostaglandins, nitric oxide, platelet activation factor, chemokines, and endothelin.In-situ gel is a new method of delivering medication that has recently been used for nasal drug delivery. The ideal temperature for the gel to form is between 26 and 34 degrees Celsius.[3] In 1753, the Tridax species was introduced by Linnaeus.[5] Tridax procumbens is traditionally known for its ability to promote wound healing, fight microbes, and reduce inflammation. It may also be helpful in treating respiratory conditions like the recent increase in cases of the coronavirus, COVID-19.[4] This plant contains several chemical compounds, such as flavonoids, essential oils, saponins, and terpenoids, which are secondary metabolites.[5] These compounds may assist in regulating inflammatory mediators linked to asthma, such as IL-4, IL-5, and TNF-α.[7]

FIG NO .1 Tridax procumbens

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2. PLANT DESCRIPTION[20]

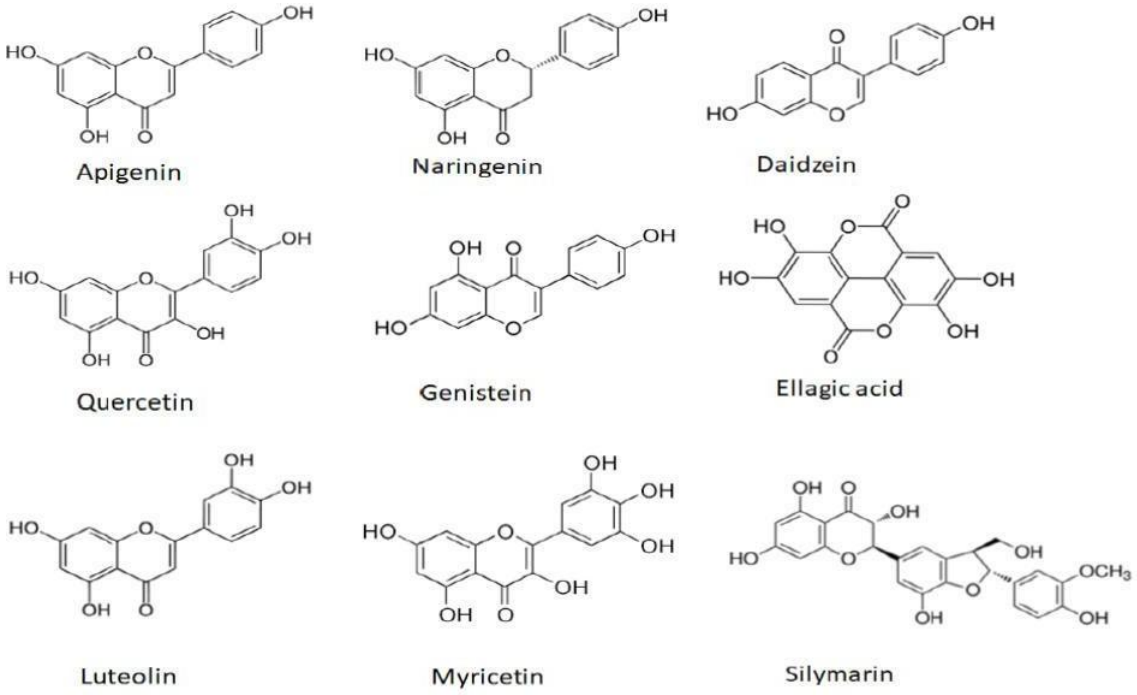
Table No.1 Plant Discription

Classification	Scientific Name	Biological Name
Kingdom	Plantae	Plants
Sub kingdom	Tracheobionta	Vascular plant
Division	Spermatophyta	-
Subdivision	Magnoliophyta	Flowering plants
Class	Magnoliopsida	Dicotyledons
Subclass	Asteridae	-
Order	Asterales	-
Family	Asteraceae	Aster family
Genus	Tridax L	Tridax

3. TRIDAX PROCUMBENS : PHYTOCHEMISTRY AND PHARMACOLOGICAL PROFILE

Coat button is common name that many speak for Tridax Procumbens, which is a medicinal herb. The phytochemistry together with an pharmacological aspects for T. procumbens have been researched in detailed. This plant contains alkaloids and there are saponins flavonoids with steroids carbohydrates and tannins, some essential oils terpenoids the carotenoids, along with extra chemicals.[5]

3.1 Phytochemical Constituents The leaves of T. procumbens contain a wide array of bioactive phytoconstituents, including .[6]



3.2 Pharmacological Activities

Extensive pharmacological studies demonstrate that T. procumbens exhibits.

Anti-inflammatory

Reduced inflammation Anti-inflammatory effects COX-1 and COX-2, bergenin and centaurein, flavonoids, and other polyphenols extracted ethyl acetate.[4]

Wound Healing

The biological process of wound healing is intricate, and plant-based natural treatments have long been utilized and extensively researched to support successful wound healing.

Hepatoprotective Activity

The Tridax procumbens aerial parts show hepatoprotective activity. In rats, it was investigated for its efficacy in treating hepatitis induced by both d-Galactosamine and Lipopolysaccharide (d- GalN/LPS).

Antioxidant activity

Antioxidant activity Numerous illnesses are linked to free radical stress, and oxidative stress- related conditions are treated using flavonoids and polyphenols.

Antimicrobial Activity

Because of their antibacterial properties, Tridax procumbens extracts were the primary focus of the study. They were shown to be effective against a range of fungal diseases and bacteria.

Immunomodulatory activities

The ability of bioactive chemicals to alter immunoresponse and treat certain illnesses was a reflection of the cellular and humoral immunoresponses controlled by them, whether through biology or pharmacology.[6]

4. Asthma: Pathophysiology and Therapeutic Targets

Chronic airway inflammation, increased bronchial reactivity, immune cell infiltration, airway hyperresponsiveness (AHR), and airway remodeling are the hallmarks of asthma, a widespread non-communicable, diverse disease. Among other things, cytokines released during inflammatory processes—most notably IL-2, IL-6, IFN-γ, and TNF-α—induce respiratory airway sensitization, which causes inflammatory pain and discomfort and ultimately releases prostaglandins indirectly.[7]

5. Rationale for Herbal-based Nasal Formulation

The nasal route ensures faster absorption and greater bioavailability by avoiding hepatic metabolism. Herbal extracts can produce regulated release and prolonged mucosal retention when combined with thermosensitive polymers like Poloxamer 407 and 188. Therefore, a thermosensitive nasal gel based on Tridax procumbens may provide a novel and secure treatment method for managing asthma.[8]

6. Thermosensitive in Situ Nasal Gel Technology

Thickness of such an thermosensitive in-situ gels is able to be turned back and forth when temperature goes up or down. When the temperature is increasing polymer liquid types will turnto an gel form according to what is reported in source.[3] to an gel form according to what is reported in source.[2]

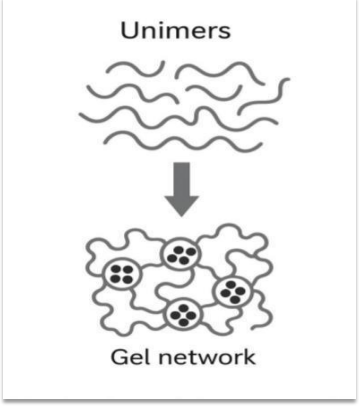


FIG NO.2 Mechanism of action gelling

6.1 Polymers Used in Thermosensitive Nasal Gel Formulation

Based on Poloxamer 407 (P407), Carbopol 974P NF, and Polyoxyl 15 hydroxystearate (Kolliphor HS15, HS15), the hydrogel delivery method was developed. At room temperature, it flowed smoothly; when the temperature went over 33 °C, it quickly formed a hydrogel in the nasal cavity.[19]

6.2 Advantages

1) The drug's prolonged and extended release is repeatable.

2) Patient-friendly and non-invasive medication administration.

3) Steers clear of hepatic first-pass metabolism.

4) Improves drug bioavailability.

5) Minimizes adverse systemic effects.

7. Formulation and Evaluation Parameters

7.1 Formulation design

1. Poloxamer has a longer residence period and a superior thermal setting property. the medication. It has both gelling and solubilizing properties. Colorless results from poloxamer gel that is see- through. Different molecular weights and gelling qualities are possible depending on the ratio and distribution of hydrophilic and hydrophobic chains[10].

2. Carbopol The water adsorption properties of carbopol polymers are outstanding. The two most common gelling agents are carbopol 934 and carbopol 981.[12]

7.2 Preparation Method

1. Extraction of Tridax procumbens Leaves

Powdered leaves that have been shade-dried are extracted for eight hours in a Soxhlet system using 70% ethanol. A rotary evaporator is used to concentrate the extract, and it is then vacuum-dried.[13]

2. Preparation of Thermosensitive Gel Base

The cold approach involves dissolving the necessary amounts of Poloxamer 407 and Poloxamer 188 in chilled distilled water (4 °C) while stirring with a magnetic stirrer. In order to create a transparent solution, polymers are refrigerated throughout the entire night.[14]

3. Incorporation of Extract and Additives

The hydrated polymer base is mixed with a measured extract of Tridax procumbens. Phosphate buffer or triethanolamine to bring the pH down to 5.5–6.5.Preservatives include benzalkonium chloride and sodium benzoate.[15]

4. Final Packaging

Placed in sterile nasal dropper bottles and kept for assessment at 4 °C.[16]

FIG NO.3 Nasal drop

7.3 EVALUATION PARAMETERS

1. Appearance The Appearance of in situ nasal gel is examined visually for clarity in sol and gel form.

2. PH with the help of PH meter PH in situ gel measure.

3. Gelling temperature The sol-gel transition temperature (Tsol-gel) of the prepared in situ gel formulations.

4. Texture Analysis The firmness, consistency and cohesiveness of formulation are assessed using texture analyzer which mainly indicates the syringe ability of sol so the formulation can be easily administered in vivo.

5. Viscosity The viscosity and rheological properties of the polymeric formulations, either in solution or in gel made with artificial tissue fluid and may be determined with different viscometer like Brookfield viscometer, cone and plate viscometer. The viscosity of these formulations should be such that it should be patient compliance.[11]

6. Mucoadhesion As explained above, mucociliary clearance largely reduces the drug residence time, which directly affects the permeation and absorption of drugs. The most effective solution against mucociliary clearance is the use of mucoadhesive gels.[12]

8. Physicochemical and Phytochemical Analysis[22]

8.1 Physicochemical Analysis of Raw Material

Table no.2 Physicochemical Analysis of raw material

Parameter	Observation Range	Pharmaceutical Significance
Organoleptic properties	Greenish powder, characteristic odor	Confirms identity
Moisture content	4–6% w/w	Indicates stability against microbial growth
Total ash	8–10% w/w	Reflects inorganic residue
Acid-insoluble ash	<1%	Confirms minimal siliceous contamination
Water-soluble extractive	18–22%	Indicates hydrophilic phytochemicals
Alcohol-soluble extractive	10–14%	Suggests flavonoid-rich fraction

8.2 Phytochemical Screening of Tridax procumbens Extract

1. Flavonoids – Shinoda Test Fill a test tube with one milliliter of ethanolic extract. Add a little dust of zinc.With extreme caution, add a few drops of the strong HCl solution. So eventually, observe.

2. Flavonoids – $AlCl_3$ Test Take a milliliter of ethanol extract. Pour in 1 mL of 2% aluminum chloride mixture.After giving it a good stir, give it a minute or two.

3. Alkaloids – Dragendorff's Test Add a tiny amount of extract to diluted HCl and dissolve it. Dragendorff's reagent, 1-2 drops. Gently blend.

4. Tannins – Ferric Chloride Test Take one millilitre of alcoholic or aqueous extract. Add a few drops of ferric chloride solution (5%). Shake a little.

5. Saponins – Foam Test Take a milliliter of an aqueous extract. Add ten milliliters of water that has been distilled. For thirty seconds, give it a good shake. Take a ten-minute rest.

6. Steroids – Liebermann–Burchard Test Mix 1 milliliter of the extract with chloroform. Pour in 1-2 mL of acetic anhydride. Carefully place a few drops of concentrated H2SO4 along the side of the test tube. Stir lightly.

7. Terpenoids – Salkowski Test 2 ml of chloroform extract should be taken. Along the tube's side, gradually add a few drops of concentrated H2SO4. Keep an eye on the interface and don't shake.

8. Phenolics – Folin–Ciocalteu Test Pour 1 mL of extract into 1 mL of diluted Folin- Ciocalteu solution. Pour in 1–2 mL of the 10% sodium carbonate solution and let it stand for 5–10 minutes. times.

9. IN-VITRO AND EX-VIVO TESTING[21,22]

1. Drug Release Dialysis membrane and Franz cell. Medium: at 37°C, SNF pH 6.5 and PB pH

6.8.UV analysis of samples at 320 nm (0.5–8 h). Models: Korsmeyer-Peppas, Higuchi, Zero, and First.

Outcome Higuchi model based on diffusion with >80% release up to 8 hours.

2. Mucoadhesion texture analyzer using the nasal mucosa of sheep and goats. Residence time is Determined by detachment force (dynes/cm^2).

Outcome Longer nasal retention = stronger.

3. Rheology 25°C to 37°C Brookfield viscometer.

Outcome Longer nasal retention is a result of higher strength.

4. Cytotoxicity MTT (570 nm) with Vero/RPMI-2650 cell line.

Outcome 90% viability: biocompatible and nontoxic.

9.1 Ex-Vivo Evaluation

1. Permeation Franz cell with mucosa from goats or sheep. pH of PBS 6.5. Kp and flux (J) are Computed.

Outcome Nasal safety was proven with no necrosis or epithelial damage.

2. Anti-Inflammatory Activity albumin stabilization and protein denaturation. Standard: 100 µg/mL diclofenac sodium.

Outcome strong potential to reduce inflammation (≥80% inhibition).

10. FUTURE PROSPECTIVE

First, nanotechnology can enhance the solubility, retention, and absorption of drugs.within the gel's sensitivity to heat. Two. Tridax procumbens nasal gels can be proven to be helpful through interdisciplinary research. Options in place of corticosteroids.

11. RESULT

Alkaloids, phenolics, and flavonoids were among the main phytoconstituents found in Tridax procumbens' ethanolic extract. The improved thermosensitive nasal gel demonstrated appropriate pH, viscosity, stability, and prolonged drug release for successful asthma treatment. It remained liquid at ambient temperature and gelled at nasal temperature (~33 °C).

12. DISCUSSION

Tridax procumbens contains phytochemicals that help with asthma by having bronchodilatory, anti-inflammatory, and antioxidant properties. A promising herbal formulation for the treatment of asthma, the thermosensitive nasal gel offered regulated drug release, extended nasal retention, and enhanced therapeutic efficacy.

13. CONCLUSION

First-pass metabolism is avoided and quick absorption is made possible by the nasal route. In-situ gels provide controlled release and extend contact times. By inhibiting NF-κB/ERK, Tridax procumbens extract lessens airway inflammation.

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