JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

FORMULATION AND EVALUATION OF SHATA-DHAUTA GHRITA ANTI-ULCER CREAM

Jargal Shahid[1], Kajal Sahu[2], Panchal Vaishvi[1] [1]Student, B. Pharmacy College Rampura
[2]Assistant Professor, B. Pharmacy College Rampura

ABSTRACT: Herbal formulations for the treatment of oral ulcers represent a promising avenue in the development of alternative therapeutics due to their biocompatibility, minimal side effects, and synergistic action of multiple phytoconstituents. The current study focuses on the design and evaluation of a polyherbal mouth ulcer cream, integrating traditional Ayurvedic ingredients such as ***Psidium guajava* (guava leaves), *Piper betle* (betel leaves), *Ocimum sanctum* (basil), *Glycyrrhiza glabra* (liquorice), *Syzygium cumini* (jamun seed), along with clove oil, neem oil, and pomegranate peel extract**. The base of the formulation comprises a medicated *Shata Dhauta Ghrita*, prepared using therapeutic herbal decoctions in place of water. Extraction processes were optimized using microwave-assisted extraction and conventional decoction methods to retain maximum bioactivity. The final cream was evaluated through a series of physicochemical and microbiological tests including pH, spreadability, stability, antimicrobial activity, and skin irritation studies. Results indicate the formulation's potential as a safe, stable, and efficacious alternative for the management of oral ulcers.

Index terms – Piper betle, Psidium guajava, Ocimum sanctum, Glycyrrhiza glabra, Syzygium cumini, clove oil, Anti-ulcer cream

INTRODUCTION:

The mouth serves as the primary organ for ingestion, speech, and digestion. It consists of multiple structures, including the lips, oral mucosa, tongue, teeth, salivary glands, and soft and hard palate. These structures play a crucial role in maintaining oral health and healing ulcers. The oral cavity is lined with mucous membrane, which contains specialized epithelial cells and blood vessels that facilitate rapid healing. The buccal mucosa, gingiva, and tongue are the most affected areas in cases of oral ulcers, often due to friction, infections, or acidic foods. The mouth is highly vascularized, with blood supply primarily from the facial artery and lingual artery, which aid in tissue repair. The oral mucosa also has a thin epithelium, making it highly permeable to bioactive compounds, such as those found in Shata Dhauta Ghrita. The salivary glands (parotid, submandibular, and sublingual) continuously produce saliva, which contains antimicrobial enzymes and growth factors that help in natural healing. The soft palate, hard palate, and floor of the mouth contribute to proper swallowing and protection against irritants that may worsen ulceration.By leveraging the soothing, anti-inflammatory, and wound-healing properties of Shata Dhauta Ghrita combined with herbal extracts such as liquorice, guava leaves, betel leaves, and pomegranate, this formulation can effectively promote healing and relieve pain associated with oral ulcers.

MOUTH DISORDERS:

- **Ulcers (Canker Sores)** – Small, painful lesions that appear inside the mouth, often caused by stress, injury, or nutritional deficiencies. They are non-contagious and usually heal within 1-2 weeks. Acidic or spicy foods can worsen irritation.
- **Oral Thrush (Candidiasis)** – A fungal infection caused by *Candida albicans*, leading to white, creamy patches on the tongue, inner cheeks, and throat. It is common in immunocompromised individuals, diabetics, or those using antibiotics. Treatment involves antifungal medications.
- **Gingivitis** – A mild form of gum disease caused by plaque buildup, leading to red, swollen, and bleeding gums. Poor oral hygiene is the main cause, but smoking and certain health conditions can increase risk. Reversible with proper brushing, flossing, and professional cleaning.
- **Periodontitis** – An advanced stage of gum disease where infection spreads, damaging the bones supporting the teeth. It can lead to tooth loss and has been linked to heart disease and diabetes. Requires deep cleaning, medication, or surgery in severe cases.
- **Tooth Decay (Cavities)** – Caused by bacteria breaking down sugars into acids that erode tooth enamel. Symptoms include sensitivity, pain, and visible holes in teeth. Prevention includes proper brushing, flossing, fluoride treatments, and reducing sugar intake.
- **Dry Mouth (Xerostomia)** – A condition where the salivary glands produce less saliva, leading to difficulty swallowing, speaking, and an increased risk of cavities. Causes include medications, dehydration, nerve damage, or autoimmune diseases. Drinking water and saliva stimulants can help manage symptoms.
- **Leukoplakia** – White or gray patches on the tongue, gums, or inner cheeks that can't be scraped off. Often linked to tobacco and alcohol use, it may sometimes develop into oral cancer. Regular monitoring and biopsy are recommended for persistent cases.
- **Lichen Planus** – A chronic inflammatory condition that affects the mucous membranes of the mouth, leading to white, lacy patches, redness, and sometimes painful ulcers. The exact cause is unknown, but it may be related to immune system dysfunction. Corticosteroids and oral rinses help in management.

HERBAL ANTI-ULCER CREAM:

Shata Dhauta Ghrita Mouth Anti-Ulcer Cream is a specially formulated Ayurvedic remedy designed to soothe, heal, and protect against oral ulcers and related discomforts. At the core of this formulation lies *Shata Dhauta Ghrita*—a classical preparation of ghee (clarified butter) that has been washed a hundred times using a traditional Ayurvedic process. This intensive purification and transformation process enhances the cooling, anti-inflammatory, and regenerative properties of ghee, making it exceptionally gentle and effective for sensitive mucosal tissues in the mouth.

The cream is further enriched with potent herbal extracts, each selected for their specific therapeutic benefits.

Together, these ingredients work synergistically to deliver a comprehensive approach to oral care. The cream not only promotes **faster healing of mouth ulcers** but also provides **immediate pain relief**, **reduces irritation**, and **protects oral tissues from further damage**. Its natural base and holistic composition make it suitable for daily use without the risk of harsh chemical exposure.

Ideal for individuals suffering from recurrent aphthous ulcers, denture sores, or minor mouth injuries, **Shata Dhauta Ghrita Mouth Anti-Ulcer cream** offers a time-tested, plant-based solution that supports overall oral health and comfort.

AIM & OBJECTIVES:

Aim: To formulate and evaluate a polyherbal cream for the treatment of oral ulcers using standardized herbal extracts and a medicated Shata Dhauta Ghrita base.

Objectives:

- To select medicinal herbs with proven anti-ulcer, antimicrobial, and wound-healing properties.
- To prepare and optimize extracts using modern and classical extraction methods.
- To formulate a topical oral cream using Shata Dhauta Ghrita as a bioactive base.
- To evaluate the physicochemical, microbiological, and dermatological safety of the formulation.
- To establish the therapeutic efficacy and stability of the cream under different storage conditions.

MATERIALS & METHODOLOGY:

Selection of Herbal Ingredients Medicinal herbs were selected based on ethnopharmacological data and traditional Ayurvedic literature for their efficacy in wound healing, antimicrobial action, and mucosal protection.

No.	Ingredient	Botanical Name	Pharmacological Role
1	Guava leaves	Psidium guajava	Antibacterial, anti-inflammatory, astringent
2	Betel leaves	Piper betle	Analgesic, antifungal
3	Basil (Tulsi)	Ocimum sanctum	Antimicrobial, antioxidant,
4	Liquorice powder	Glycyrrhiza glabra	Mucoprotective, anti-inflammatory, demulcent
5	Jamun seed powder	Syzygium cumini	Antioxidant, wound healing, antimicrobial
6	Clove oil	Syzygium aromaticum	Local anesthetic, antimicrobial
7	Neem oil	Azadirachta indica	healing promoter
8	Pomegranate peel	Punica granatum	promotes epithelialization
9	Strawberry extract	Fragaria ananassa	improves flavor
10	Shata Dhauta Ghrita	-	Cooling, penetration enhancer, healing base

Extraction methods for different ingredients:

Steam distillation method by Clevenger apparatus:

Clove seed essential oil was obtained via hydro-distillation using a Clevenger-type apparatus. Dried clove seeds (100–200 g) were coarsely ground and transferred to a 1–2 L round-bottom flask containing 500–1000 mL of distilled water. The apparatus was assembled with a water-cooled condenser to ensure continuous condensation. The mixture was subjected to gentle boiling for 3–4 hours. The volatile oil was carried by steam, condensed, and separated in the Clevenger trap. Upon completion of distillation, the oil layer was collected, dehydrated using anhydrous sodium sulfate, and filtered through Whatman No. 1 filter paper. The purified essential oil was stored in amber glass containers at refrigerated temperature and protected from light to prevent oxidative degradation.

Fig.1: Clove oil extraction

Microwave assisted extraction method:

Dried leaves of *Psidium guajava* and *Ocimum sanctum* were powdered and subjected to microwave-assisted extraction. Ten grams of each powder was mixed with 100 mL of a sesame oil:water mixture (70:30 v/v) in a 250 mL glass beaker. The mixture was irradiated in a microwave oven at 300–600 W for 5–10 minutes with intermittent cooling and stirring to avoid thermal degradation. After cooling, the extract was filtered using Whatman No. 1 filter paper and stored in amber glass bottles at 4°C until further use.

METHODOLOGY

Preparation of Multi-Herbal Aqueous Phase Objective:
To formulate a therapeutic aqueous extract rich in tannins, polyphenols, flavonoids, and other phytoconstituents with mucosal healing, antimicrobial, antioxidant, and anti-inflammatory properties.

Materials:

- *Punica granatum* (pomegranate peel: 5–10 g, seeds: 1 cup)
- *Glycyrrhiza glabra* (liquorice powder: 1 tsp)
- *Syzygium cumini* (jamun seed powder: 1 tsp)
- *Piper betle* (fresh betel leaves: 3–5 leaves)
- Purified water: ~400 mL

Method:

1. **Decoction Preparation:**
   Pomegranate peel (5–10 g) was boiled in 250 mL of purified water for 5 minutes. Pomegranate seeds (1 cup) were added and simmered for another 5 minutes.
2. **Incorporation of Powders:**
   Liquorice and jamun seed powders (1 tsp each) were added along with 100 mL additional water. The mixture was simmered for 5–7 minutes with occasional stirring.
3. **Betel Leaf Extraction:**
   Betel leaves (3–5) were washed, shredded, and gently boiled in 50 mL of water for 5 minutes. The extract was cooled, macerated, and filtered through muslin cloth.
4. **Final Integration:**
   The filtered betel leaf extract was added to the main decoction. The combined extract was allowed to macerate for 15–20 minutes, filtered, and cooled to room temperature. This constituted the multi-herbal aqueous phase used in the cream base.

Fig.2: Pomegranate water

Fig.3: Decoction process

PREPARATION OF BASE USING SHATA DHAUTA GHRITA TECHNIQUE

Objective:
To develop a bio-enhanced emollient base using the Ayurvedic method of 100-times-washed ghee (*Shata Dhauta Ghrita*, SDG), integrating medicinal oils and the prepared herbal aqueous phase.

Materials:

- Cow's ghee: 1 tbsp
- Guava leaf oil (*Psidium guajava*): 5 drops
- Tulsi oil (*Ocimum sanctum*): 5 drops
- Clove oil (*Syzygium aromaticum*): 2–3 drops
- Herbal aqueous phase (from Section 5.2.1): ~100 mL
- Fresh strawberry pulp: ½ tsp
- Copper plate and blunt spatula

Method:

1. **Initial Oil Blend:**
   Cow's ghee (1 tbsp) was placed on a clean copper plate and mixed with guava leaf oil, tulsi oil (5 drops each), and clove oil (2–3 drops) to form a uniform oily phase.
2. **Shata Dhauta Process:**
   Approximately 5–10 mL of the herbal aqueous phase was added to the oil blend. The mixture was triturated in circular motions using a blunt spatula until the liquid phase was absorbed. This washing process was repeated with fresh portions of the aqueous phase for 100 cycles. The formulation gradually converted into a smooth, water-soluble emulsion.
3. **Final Enhancement:**
   Upon completion of 100 washings, ½ teaspoon of fresh strawberry pulp was added as a natural coloring and flavoring agent. Also 5ml of rose oil is incorporating for pleasant fragrance. The mixture was gently blended to achieve a uniform pink-colored, pleasantly scented base suitable for mucosal application.

Fig. 4: Procedure for preparation of cream




EVALUATION PARAMETERS FOR HERBAL ANTI-ULCER CREAM:

1. Physical Evaluation

- Color**:** Assessed visually.
- Consistency: Evaluated by applying cream to the skin**.**
- Odor**:** Determined by mixing the cream with water and sniffing.

2. Homogeneity

- Method**:** Visual inspection post-packaging to detect presence of aggregates or phase separation.

3. Stability Testing

- Principle**:** Determines shelf life and maintenance of quality over time.
- Conditions: Samples stored at room temperature and 40°C.
- Parameters Evaluated: Color, texture, consistency, and fragrance at regular intervals.

4. pH Measurement

- Principle**:** Uses a combination electrode to detect potential difference due to H^+ ions.
- Procedure:
  - 1g cream mixed with 50 ml distilled water.
  - Mixture kept for 2 hours.
  - pH measured thrice using a pH meter; average value recorded.

5. Spreadability

- Principle**:** Measures ease and uniformity of spreading under applied weight.
- Procedure:
  - Cream placed between glass slides.
  - Standard weight applied for 5 min.
  - Time taken to separate slides measured.
  - Spreadability calculated: $S = (M \times L) / T$**,** where:
    S = Spreadability (g.cm/s), M = weight (g), L = slide length (cm), T = time (s)
  - Result: S = 31.90 g.cm/s

6. Skin Irritation Test

- Principle**:** Evaluates reversible skin irritation without animal use.
- Procedure:
  - Cream patch applied to volunteer's forearm.
  - Observations made for itching, redness, or inflammation after specified time.

7. Evaluation of base:

The base (ghee) was evaluated through the determination of its Acid Value and Saponification Value, which are indicative of the quality and purity of the fat used.

Acid Value

The acid value is defined as the number of milligrams of potassium hydroxide (KOH) required to neutralize the free fatty acids present in 1 gram of the substance. The procedure was carried out as follows:

- **Procedure :** Approximately 10 g of the ghee sample was accurately weighed and transferred into a 250 mL conical flask. Then, 50 mL of neutral alcohol and 1 mL of phenolphthalein indicator were added. The mixture was gently heated in a water bath, if necessary, until the sample completely dissolved. The hot solution was titrated with 0.1 N KOH until a persistent pink endpoint was observed. The volume of KOH consumed was recorded, and the acid value was calculated using the formula:

Acid Value **= (**V x N x 56.1)/ W. Where:
V = volume (mL) of 0.1 N KOH used in titration N = Normality of the standard alkali solution.
W = weight (g) of the sample

Saponification Value

The saponification value is defined as the number of milligrams of KOH required to saponify 1 gram of fat. The determination was performed as follows:

- **Procedure**: A solution of alcoholic potassium hydroxide was prepared by dissolving 40 g of KOH in 20 mL of distilled water and making the volume up to 1000 mL with ethanol. The solution was allowed to stand overnight.

A 4 g sample of ghee was accurately weighed into a 250 mL conical flask, and 25 mL of the alcoholic KOH solution was added. A reflux condenser was attached to the flask, and the mixture was refluxed for one hour on a water bath. A blank was prepared and treated in the same manner using all reagents except the test sample. After refluxing, the flasks were cooled, and 1 mL of phenolphthalein was added to each. The solutions were titrated against 0.5 N hydrochloric acid (HCl) until the pink color disappeared.

The saponification value= (b – a) x 1000/w Where:
a = volume (mL) of 0.5 N HCl used for sample
b = volume (mL) of 0.5 N HCl used for blank W = weight (g) of the sample

Sr. No.	Evaluation Parameter	Inference
1	Color	Light pink
2	Odour	Characteristic Odour
3	Texture	Smooth
4	Viscosity	344.3
4	pH determination	6.5
5	Acid value	1.2
6	Saponification value	25.90
7	Spreadability	294 cm.gm/sec
8	Stability	No change
9	Anti-microbial activity	No microbial growth
10	Homogeneity	Good

RESULT AND

CONCLUSION

The present study successfully formulated and evaluated a medicated herbal anti-ulcer cream with the dual objectives of enhancing therapeutic efficacy and promoting skin regeneration. The formulation incorporated carefully selected botanical ingredients—Cow ghee, clove oil, and tulsi oil—renowned for their antioxidant, anti-inflammatory, and wound-healing properties. Advanced and optimized extraction techniques were utilized to preserve the integrity of their bioactive constituents, ensuring maximum therapeutic benefit.

The resulting cream exhibited favorable physicochemical characteristics, including a smooth, homogenous texture, excellent spreadability, and good structural stability—key attributes for ease of application and user satisfaction. The pH of the formulation was maintained within a skin-friendly range to minimize the risk of irritation and support optimal healing conditions.

Microbiological evaluation demonstrated the formulation's effectiveness in inhibiting the growth of common skin pathogens, emphasizing its antimicrobial potential and its role in preventing secondary infections in ulcerated skin. Safety assessments, including dermal irritancy studies, confirmed that the formulation was non-irritant and well-tolerated upon topical application, supporting its suitability for use on compromised or sensitive skin.

Overall, the study highlights the successful integration of traditional herbal remedies with modern formulation science. The medicated herbal anti-ulcer cream offers a natural, safe, and effective alternative to conventional synthetic treatments, aligning with the incr

REFERENCES

1. Georgiana Ioana, Porea Cicalau et al. A review of pomegranate bioactive properties, "*Department of dental medicine, faculty of medicine and pharmacy"* October 2024, 14(5) pg: 2-5.
2. Divyakar K, Patil Mayur D. et al. Phytochemical composition and antibacterial/anti microbial properties of azadirachta indica (Neem)*"International journal of pharmaceutical research and applications*" May 2024 9(3) pg: 283-298.
3. Ms. C.D. Patil, G.G. Sutar et al. Formulation of shata dhuta ghrita as a base in moisturizing cream *"International journal of novel research and development"* August 2023 8(8) pg: 242-244.
4. Pratiksha Vagde, Mayur J. et al. Formulation and evaluation of herbal mouth ulcer gel *"International journal of research in pharmacy and pharmaceutical sciences*" June 2023 8(2) pg: 163-167.
5. Pooja B. Jaiswal Shyam S. et al. Formulation and evaluation of mouth ulcer gel *"IVMS indorani institute of pharmaceutical education and research*" May 2023 8(5) pg: 56-58.
6. Intan nirwana, Moh khalid et al. The use of white pomegranate extract as a bleaching material for roughness and calcium levels in enamel tooth "*World journal of advanced research and reviews (WJARR)"* May 2023, 18(2) pg: 700- 704.
7. Madhuri D., Eknath D., et al. Shatdhuta ghrita: A promising agent in the development of herbal creams "*Department of pharmaceutical, MET institute of pharmacy*" October 2022 13(1) pg: 1332-1340.
8. Vanessa V. Benefits of adding cloves to your diet *"International journal of novel research and development*" July 2022 13(5)

pg: 254-258.
9. Lalita Vishwakarma. Discover jamun, seeds powder benefits for health, skin and diabetes "*IVMS indorani institute of pharmaceutical education and research*" July 2022 16(5) pg: 360-365.
10. Prof. Jagdish S., vilas Mr. tarade A.S. et al. Formulation and evaluation of oral anti ulcer gel from liquorice extract "*Journal of pharmaceutical technologies and innovative research*" June 2022 10(2) pg: 291-310.
11. . Kanchan U., Kirti C. et al. Formulation and evaluation of herbal gel for management of mouth ulcers "*Indian journal of pharmacy and pharmacology (IJPP*)" September 2021 8(3) pg: 263-266
12. Valentina S., Dimitris S. et al. Wound healing properties of pomegranate "*Department of food science and technology, faculty of food science, university"* August 2021 5(3) pg: 263-291.
13. . Pooja R. , Anuja A. , et al. Phytochemical and antimicrobial activties of leaf extract of guava "*international journal of applied research"* April 2020 6(5) pg:106-110
14. Sreevastha S. , Dileep K. et al. Tradition and technology with special respect to dhouta samskara of shata dhuta ghrita "*International journal of ayurvedic medicime"* June 2015 6(2) pg:178-182
15. Vrushali P. , UtkarshaS. Formulation and evaluation of guava leaf extract gel for mouth ulcer mamagment "*Indian journal of pharmacy and pharmacology"* April 2014 9(5) pg:741-745-
16. Supriya D. , Avinash D. Shata dhauta ghrita a case study "*Indian journal traditional knowledge"* July 2009 8(3) pg:387- 391