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Formulation and Evaluation of Polyherbal Spansule for Anti-Ulcer Activity by Using *Piper betle* and *Hibiscus rosa-sinensis* Leaves

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ABSTRACT

The formulation and evaluation of polyherbal spansules containing *Piper betle* and *Hibiscus rosa-sinensis* for anti-ulcer activity. Spansules were developed as a sustained-release dosage form to enhance therapeutic efficacy and patient compliance. The herbal powders were directly incorporated without extraction and formulated using suitable excipients. The prepared spansules were evaluated for various physicochemical parameters. The results showed good mechanical strength, uniformity, and acceptable disintegration characteristics, indicating the suitability of the formulation as a natural sustained-release anti-ulcer dosage form.

Keywords: Polyherbal spansules, Anti-ulcer activity, *Piper betle*, *Hibiscus rosa-sinensis*, Sustained-release dosage form, Herbal drug delivery system, Gastroprotective activity

INTRODUCTION

The importance of herbal medicine as a traditional and modern healthcare system, emphasizing its role in disease prevention and treatment through plant-based bioactive compounds. Medicinal plants contain diverse phytochemicals responsible for multiple pharmacological effects, including antiulcer activity. Due to the side effects and recurrence associated with synthetic antiulcer drugs, there is growing interest in safer herbal alternatives. Peptic ulcer disease is highlighted as a common gastrointestinal disorder caused by factors such as stress, NSAIDs, Helicobacter pylori infection, and lifestyle habits. The article emphasizes the advantages of herbal drug delivery systems, particularly spansules, which provide sustained drug release, improved stability, and enhanced patient compliance. The therapeutic potential of *Piper betle* and *Hibiscus rosa-sinensis* leaves is reviewed, focusing on their gastroprotective and antioxidant properties. The study aims to formulate and evaluate a polyherbal spansule combining both plants to enhance antiulcer efficacy, bioavailability, and therapeutic outcomes.

Figure:1 Image of spansules

Aim

In order to explore its potential anti-ulcer action using suitable pharmacological, phytochemical and analytical techniques, the current study aims to create and completely assess a polyherbal spansule including *Piper betle* and *Hibiscus rosa-sinensis* leaves.

Objectives

The goal is to evaluate the antiulcer efficacy and safety of a stable polyherbal spansule made from *Piper betle* and *Hibiscus rosa sinensis* leaves. The goal of this research is to create an affordable substitute for traditional synthetic medications, which frequently have adverse effects. Assessing antioxidant capacity, calculating the ulcer index in animal models, and figuring out impacts on gastric acidity, volume, and pH are standard evaluation parameters.

Plant profile

Piper betle and Hibiscus rosa Sinensis Plant leaves

1) Profile for piper betle

Figure:2 Piper betle

Botanical Classification

Kingdom	:	Plantae
Division	:	Angiosperms
Class	:	Magnoliopsida
Order	:	Piperales
Family	:	Piperaceae
Genus	:	Piper
Species	:	Piper betel Linn

Traditional use

The leaves are traditionally used as a stimulant, carminative, antiseptic, and digestive agent. They are commonly employed in the treatment of conditions such as cough, sore throat, and constipation. In addition, the leaves are used as a natural mouth freshener and are known to promote wound healing.

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Pharmacological review

Table: 1

Pharmacological Activity	Major Active Constituents	Experimental Model / Evidence	Mechanism of Action	Relevance to Anti-Ulcer Therapy
Anti-microbial activity	Hydroxychavicol, Eugenol	In vitro studies against S. aureus, E. coli, K. pneumoniae, C. albicans, and A. niger	Disruption of microbial cell membranes and inhibition of microbial growth	Prevents secondary gastric infections and supports mucosal health
Anti-oxidant activity	Phenols, Flavonoids	DPPH, FRAP, and superoxide radical scavenging assays	Neutralization of reactive oxygen species and inhibition of lipid peroxidation	Protects gastric mucosa from oxidative stress-induced injury
Anti-inflammatory activity	Polyphenols, Eugenol	Carrageenan-induced paw edema model	Inhibition of prostaglandin synthesis, nitric oxide, and COX-2 enzymes	Reduces gastric inflammation associated with ulcer formation
Analgesic and antipyretic activity	Methanolic extract constituents	Animal models (mice)	Modulation of inflammatory mediators involved in pain and fever	Provides symptomatic relief in ulcer-associated inflammation
Anti-cancer activity	Hydroxychavicol	In vitro human cancer cell line studies	Induction of apoptosis via ROS generation and mitochondrial dysfunction	Indicates chemopreventive potential and cellular protection
Anti-diabetic activity	Phenolic compounds	Alloxan-induced diabetic rat model	Enhancement of insulin secretion and protection of pancreatic β-cells	Supports metabolic regulation in ulcer-prone diabetic patients
Wound healing activity	Flavonoids, Tannins	In vivo wound healing models	Enhanced collagen synthesis, epithelialization, and wound contraction	Accelerates healing of gastric mucosal lesions

Phytochemical review

➢ **Essential oils:** Rich in eugenol, chavicol, chavibetol, terpinene, estragole, safrole, and caryophyllene, providing antioxidant, antimicrobial, antifungal, analgesic, and anti-inflammatory activities.

➢ **Alkaloids:** Piperine and piperidine exhibit carminative, stimulant, and antioxidant properties and enhance the bioavailability of other drugs.

➢ **Phenolic compounds:** Catechol, hydroxychavicol, and eugenol show strong antioxidant, anti-ulcer, and antimicrobial effects by scavenging free radicals.

➢ **Flavonoids:** Quercetin, apigenin, and kaempferol contribute to anti-inflammatory and anticancer activities and protect against oxidative damage.

➢ **Tannins and saponins:** Tannins promote astringent and wound-healing effects, while saponins support immune function and cholesterol reduction.

➢ **Terpenes and steroids:** β-sitosterol and stigmast-4-en-3-one possess anti-inflammatory, lipid-lowering, antimicrobial, and anti-ulcer properties.

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2) Profile for hibiscus

Figure:3 Hibiscus rosa sinensis

Botanical Classification

Kingdom	:	Plantae
Division	:	Angiosperms
Class	:	Magnoliopsida
Order	:	Malvales
Family	:	Malvaceae
Genus	:	Hibiscus
Species	:	Hibiscus rosa - sinensis Linn

Traditional use

Promotes hair growth, reduces dandruff, and helps prevent hair fall. Used in wound healing and skin care due to its antimicrobial and healing properties. Aids in improving digestion and acts as a mild laxative.

Pharmacological Review

Table: 2

Pharmacological Activity	Major Active Constituents	Experimental Model / Evidence	Mechanism of Action	Relevance to Anti-Ulcer Therapy
Anti-inflammatory activity	Anti-inflammatory activity	Carrageenan-induced inflammation models	Inhibition of prostaglandins and nitric oxide	Reduces gastric inflammation and ulcer progression
Antioxidant activity	Anthocyanins, Phenolics	DPPH and lipid peroxidation assays	Scavenging of free radicals and reduction of oxidative stress	Protects gastric mucosa from oxidative damage
Antimicrobial activity	Flavonoids, Tannins	In vitro studies against E. coli, S. aureus, C. albicans	Inhibition of microbial growth and cell wall disruption	Prevents secondary infections at ulcer sites
Wound healing activity	Flavonoids, Mucilage	In vivo wound healing models	Enhanced collagen synthesis and epithelialization	Promotes repair of gastric mucosal lesions
Antidiabetic activity	Polyphenols	Alloxan-induced diabetic rat models	Improved insulin secretion and glucose utilization	Supports ulcer healing in diabetic conditions
Analgesic activity	Phenolic compounds	Animal pain models	Modulation of inflammatory mediators	Relieves pain associated with ulcer inflammation
Anticancer activity	Anthocyanins, Polyphenols	In vitro cancer cell line studies	Induction of apoptosis and inhibition of cell proliferation	Indicates cytoprotective and chemopreventive potential

Phytochemical review

➢ **Flavonoids:** Cyanidin, hibiscetin, kaempferol, and quercetin exhibit antioxidant, anti-inflammatory, antidiabetic, and anti-ulcer activities by reducing oxidative stress.

➢ **Anthocyanins:** Cyanidin-3-sophoroside, cyanidin-3-glucoside, and delphinidin derivatives are responsible for the red color and provide antioxidant, hepatoprotective, and cardioprotective effects.

➢ **Alkaloids**: Hibiscine and hibiscanine present in roots and leaves show antibacterial, antipyretic, and analgesic properties.

➢ **Saponins:** Possess immune-stimulating, cholesterol-lowering, anti-inflammatory, and wound-healing activities.

➢ **Tannins & Phenolics:** Gallic, caffeic, and chlorogenic acids contribute to antibacterial, antioxidant, anti-ulcer, and astringent effects.

➢ **Terpenoids & Steroids:** β-sitosterol and lupeol demonstrate lipid-lowering and anti-inflammatory properties.

➢ **Amino acids & Mucilage:** Mucilage provides soothing, emollient, wound-healing, and anti-ulcer benefits, while amino acids enhance nutritional and healing potential.

Material and methods

Fresh plant leaves were collected from a pollution-free area, washed thoroughly, shade-dried at room temperature, and pulverized to obtain a uniform powder. The powdered drugs were stored in airtight containers until use. Required quantities of individual plant powders were accurately weighed and blended to prepare a homogeneous polyherbal formulation, which was mixed with suitable excipients and filled into hard gelatin capsules/spansules. Excipients such as polyvinyl pyrrolidone (binder and film former), lactose monohydrate (diluent and carrier), talc (glidant and anti-adherent), and magnesium stearate (lubricant) were used to enhance flow properties, stability, uniformity, and capsule filling performance.

➢ **Plant processing:** Leaves were washed, shade-dried, powdered, sieved, and stored under controlled conditions.

➢ **Polyherbal formulation:** Individual plant powders were uniformly mixed and filled into capsules/spansules.

➢ **Polyvinyl pyrrolidone (PVP):** Used as a binder, stabilizer, film-forming, and solubilizing agent.

➢ **Lactose monohydrate:** Served as a diluent, carrier, and bulking agent to improve uniformity and palatability.

➢ **Talc & magnesium stearate:** Functioned as glidant, lubricant, and anti-adherent to improve powder flow and capsule filling

FORMULATION OF SPANSULES

Table: 3

INGREDIENTS	CATEGORY	QUANTITY
Betel leaf powder	Active ingredient	150mg
Hibiscus leaf powder	Active ingredient	300mg
Lactose monohydrate	Diluent	30mg
Poly vinyl pyrrolidone	Binder	10mg
Talc	Glident	5mg
Magnesium stearate	Lubricant	5mg

PROCEDURE

SELECTION OF DRUG/HERBAL POWDER:

- Select the active drug or dried herbal leaf powder (Piper betle and Hibiscus rosa sinensis).
- Powder should be fine, dry and free flowing.
- Pass through sieve no. 60 to ensure uniform particle size.

PREPARATION OF GRANULES:

Materials Required:

- Herbal drug
- Lactose monohydrate
- Poly vinyl pyrrolidone
- Talc
- Magnesium stearate

Procedure:

Accurately weigh all ingredients. Mix drugs and diluent uniformly in a mortar or blender. Add binder solution slowly to form a damp mass. Pass the damp mass through sieve no. 16 or 20 to obtain wet granules. Dry the granules in a hot air oven at 40-50 °C until moisture is removed. Pass dried granules through sieve no.22 to obtain uniform size. Store granules in an airtight container.

Capsule filling:

Select appropriate capsule size are filled mixed granules uniformly into hard gelatin capsules. Esure uniform weight and content. Close the capsules properly.

Polishing And Packaging

Clean capsules to remove powder sticking. Pack in airtight containers or blister packs.

Store in a cool, dry place.

Spansule Preparation

Fine, uniform powder is selected and sieved. Powder is converted into granules using binder for better flow. Granules are dried and sieved to obtain uniform size. The mixed granules are filled into hard gelatin capsules. The final spansule provides both immediate and prolonged drug release.

Evaluations

The formulated granules, capsules, and spansules were evaluated through standard quality control tests to ensure uniformity, performance, and patient acceptability. Physical appearance assessment confirmed uniform color, shape, size, and smooth surface without visible defects. Particle size distribution analysis showed uniform granule size, contributing to good flow properties and predictable drug release. Flow behaviour, evaluated using angle of repose, bulk density, and tapped density, indicated satisfactory flowability and packing characteristics, ensuring accurate mixing and uniform capsule filling. Weight variation studies confirmed compliance with pharmacopoeial limits, indicating uniform distribution of the formulation. Disintegration testing demonstrated complete breakdown of the capsules within the specified time at physiological temperature, ensuring effective drug availability.

Dissolution studies revealed consistent and adequate drug release, confirming the bioavailability of the formulation. Hardness and friability tests were performed to evaluate the mechanical strength and durability of the tablets during handling and transport.

- **Physical appearance:** Evaluated color, shape, surface texture, and visible defects.
- **Particle size distribution:** Determined by sieve analysis for uniformity and flow.
- **Flow properties:** Assessed using angle of repose, bulk density, and tapped density.
- **Weight variation:** Ensured uniformity of dosage units.
- **Disintegration test:** Measured time required for complete breakdown of dosage form.

Figure:4 pH and Disintegration test

- **Dissolution test:** Evaluated rate and extent of drug release.

Figure:5 pH and Dissolution test

- **Hardness and friability:** Assessed mechanical strength and resistance to handling damage.

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Result and Discussion

Preliminary Phytochemical Screening Results

Table: 4

S. No	Phytochemical test	Piper betle leaves	Hibiscus rosa-sinensis leaves
1.	Alkaloids	-	+
2.	Flavonoids	+	+
3.	Phenols	+	+
4.	Tannins	+	+
5.	Polysaccharides	+	-
6.	Terpenoids	+	+
7.	Anthraquinones	-	+

Key : (+) Present (-) Absent

Figure:6 Chemical test for piper betle & Hibiscus rosa sinensis

The phytochemical screening indicated that both plants contain significant bioactive constituents such as flavonoids, phenols, tannins, and terpenoids, which are well recognized for their antioxidant, anti-inflammatory, and gastroprotective effects, justifying the anti-ulcer potential of the polyherbal formulation.

Evaluation of Polyherbal Spansules

If the compliance with pharmacopoeial specifications across all evaluated parameters clearly demonstrates the adequate physicochemical stability, uniformity, and batch-to-batch consistency of the developed polyherbal formulation. These results confirm that the formulation possesses acceptable quality attributes and is capable of maintaining its integrity during handling, storage, and use. Moreover, the sustained drug release profile observed in dissolution studies indicates controlled and prolonged availability of the active constituents, which is advantageous for reducing dosing frequency and enhancing patient compliance. Collectively, these findings support the suitability of the developed polyherbal spansules for effective long-term therapeutic application in the treatment and management of ulcer conditions.

Table: 5

S. No	Parameter	Inference	Result
1.	Physical appearance	Acceptable formulation quality	Uniform, free from defects
2.	Particle size distribution	Ensures consistent drug release	Uniform granules
3.	Angle of repose (°)	Indicates good flow properties	Within limits
4.	Bulk density (g/cm³)	Proper packing of granules	Acceptable
5.	Tapped density (g/cm³)	Uniform particle arrangement	Acceptable
6.	Weight variation	Confirms dose uniformity	Within limits
7.	Disintegration time	Enables controlled drug release	Satisfactory
8.	In-vitro dissolution	Suitable for prolonged anti-ulcer action	Sustained release observed
9.	Hardness	Withstands handling stress	Adequate
10.	Friability (%)	Good mechanical stability	< 1%

DPPH TEST

Percentage of Drug Release

Table: 6

Trial	Drug release %
5	69.6
10	74.8
15	76
30	76.2
45	80
60	85

Graph For Dissolution

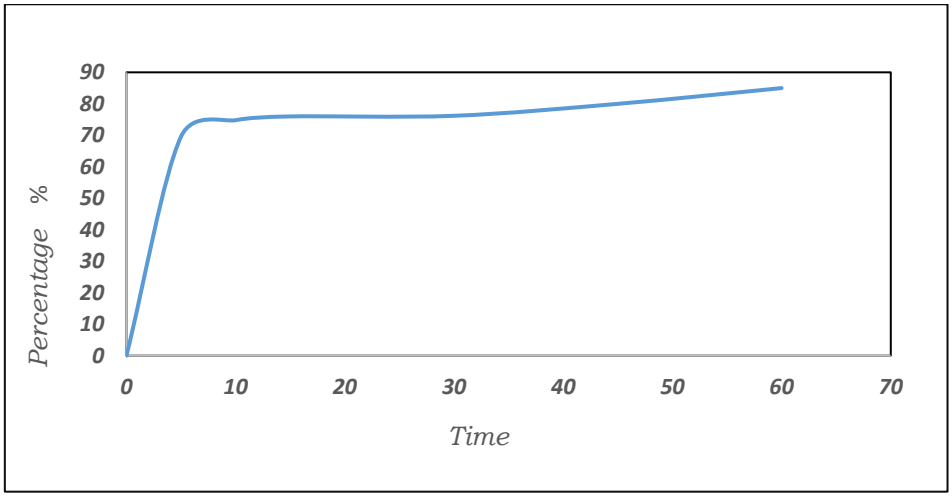

Figure:7 Value of Dissolution

Conclusion

The study demonstrates the successful formulation of sustained-release anti-ulcer spansules using Piper betel and Hibiscus rosa-sinensis leaf powders. Direct incorporation of the powdered leaves offered a simple, economical method while preserving natural phytoconstituents. The prepared spansules exhibited satisfactory physical and quality parameters, indicating good formulation stability and uniformity. Preliminary evaluations suggested controlled drug release, which may enhance therapeutic efficacy and patient compliance. Overall, the findings support the feasibility of using these herbal materials directly, without prior extraction, as a safe, natural, and cost-effective option for long-term ulcer therapy.

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