

FORMULATION AND EVALUATION OF HERBAL ANTI-ULCER CHURNA ENRICH VITAMIN B9

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ABSTRACT

Peptic ulcer is a common gastrointestinal disorder caused by excessive gastric acid secretion, stress, infection, and prolonged use of non-steroidal anti-inflammatory drugs (NSAIDs). Herbal medicines are widely used for the management of gastric ulcers due to their safety, natural origin, and fewer side effects compared to synthetic drugs. The present study aims to formulate and evaluate a polyherbal antiulcer churna enriched with natural Vitamin B9 using herbal ingredients such as Spinach, Tulsi, Aloe vera, and Glycyrrhiza glabra. Spinach was selected as a natural source of Vitamin B9 (folic acid), which helps in tissue repair and regeneration of gastric mucosa. Tulsi possesses antioxidant and anti-inflammatory properties, while Aloe vera provides soothing and ulcer-healing activity. Glycyrrhiza glabra is well known for its gastroprotective and mucosal protective effects. The prepared churna was evaluated for organoleptic properties, particle size, bulk density, angle of repose, moisture content, and antiulcer activity. The polyherbal formulation is expected to provide effective gastric protection, reduce ulcer symptoms, and promote healing naturally with minimal side effects. This study highlights the potential of herbal churna enriched with natural Vitamin B9 as a safe, economical, and effective approach for the management of peptic ulcer disease.

KEYWORDS: Peptic ulcer, Polyherbal churna, Antiulcer activity, Natural Vitamin B9, Folic acid, Spinach, Tulsi, Aloe vera, Glycyrrhiza glabra, Gastroprotective activity.

1. INTRODUCTION

Peptic ulcer is one of the most common gastrointestinal disorders affecting a large population worldwide. It is characterized by the formation of sores or lesions in the lining of the stomach or upper part of the small intestine due to an imbalance between aggressive factors such as gastric acid, pepsin, stress, alcohol consumption, smoking, *Helicobacter pylori* infection, and prolonged use of non-steroidal anti-inflammatory drugs (NSAIDs), and protective factors like mucus secretion and mucosal defense. Common symptoms of peptic ulcer include abdominal pain, burning sensation, nausea, bloating, indigestion, vomiting, and loss of appetite. If untreated, ulcers may lead to severe complications such as bleeding, perforation, and gastric cancer.

Conventional antiulcer drugs such as proton pump inhibitors, antacids, and H₂ receptor blockers are effective but may produce several side effects during long-term use, including headache, diarrhea, constipation, and nutrient deficiency. Due to these limitations, there is growing interest in herbal medicines because of their natural origin, safety, affordability, and minimal adverse effects. Herbal formulations have been traditionally used in the management of gastric disorders and are considered effective in promoting ulcer healing and protecting gastric mucosa.

Spinach is a rich natural source of Vitamin B₉ (folic acid), iron, antioxidants, and essential nutrients. Vitamin B₉ plays an important role in cell growth, tissue repair, and regeneration of damaged gastric mucosa, thereby supporting ulcer healing. Tulsi contains bioactive compounds such as eugenol and flavonoids which help reduce gastric acid secretion and oxidative stress. Aloe vera possesses soothing, anti-inflammatory, and wound-healing properties that protect the gastric lining and enhance tissue regeneration. Glycyrrhiza glabra is widely known for its mucoprotective activity, which increases mucus production and reduces irritation in the stomach lining.

Churna is one of the oldest and most widely used Ayurvedic dosage forms prepared by mixing finely powdered herbal ingredients. It offers advantages such as ease of preparation, better patient compliance, faster absorption, cost-effectiveness, and improved therapeutic action due to the synergistic effect of multiple herbs. The incorporation of natural Vitamin B₉-rich ingredients into the churna may further enhance the healing process and nutritional support in peptic ulcer pati

2. PEPTIC ULCER: ETIOLOGY AND PATHOPHYSIOLOGY

2.1 Etiology

The etiology of peptic ulcer is multifactorial:

- *Helicobacter pylori* infection: Present in ~70–80% of duodenal ulcer cases and ~50–60% of gastric ulcer cases; promotes inflammation via urease, cytotoxin-associated gene A (CagA), and vacuolating cytotoxin A (VacA).
- NSAID use: Inhibit cyclooxygenase (COX) enzymes, reducing protective prostaglandin synthesis; direct mucosal damage also occurs.
- Acid hypersecretion: Conditions such as Zollinger-Ellison syndrome; excess gastrin-driven acid secretion.
- Lifestyle factors: Smoking, alcohol consumption, psychological stress, and poor dietary habits.
- Nutritional deficiencies: Vitamin B₉, vitamin C, and zinc deficiency impair mucosal healing and immune defence.

2.2 Pathophysiology

Gastric mucosal integrity is maintained by pre-epithelial (mucus-bicarbonate layer), epithelial (tight junctions, prostaglandins), and post-epithelial (mucosal blood flow) defense mechanisms. Disruption of any of these barriers —

by *H. pylori* virulence factors, NSAIDs, oxidative stress, or nutrient deficiencies — leads to mucosal erosion, ulcer formation, and impaired healing. Free radical-mediated oxidative damage, lipid peroxidation, and inflammatory cytokine cascade (IL-1 β , TNF- α , IL-6) further perpetuate the ulceration process.

3. VITAMIN B9 (FOLIC ACID): ROLE IN GASTRIC MUCOSAL PROTECTION

Vitamin B9 exists primarily as folate (natural food form) and folic acid (synthetic, used in fortification and supplements). It is essential for:

- One-carbon metabolism: Required for purine and pyrimidine synthesis, critical for rapidly proliferating mucosal epithelial cells.
- DNA repair: Prevents strand breaks and reduces risk of mucosal atrophy and malignant transformation.
- Homocysteine regulation: Elevated homocysteine damages vascular endothelium and mucosal microcirculation; folate converts homocysteine to methionine via methionine synthase.
- Anti-inflammatory activity: Folate deficiency is associated with elevated CRP and pro-inflammatory cytokines; supplementation attenuates NF- κ B-mediated inflammation.
- Antioxidant support: Indirectly enhances glutathione synthesis and reduces oxidative mucosal damage.

Clinical and experimental studies confirm that folate-deficient subjects exhibit higher susceptibility to gastric mucosal injury and *H. pylori*-associated gastritis. Folic acid supplementation (400–800 μ g/day) has demonstrated accelerated mucosal healing in animal ulcer models and beneficial effects in human gastric atrophy studies. Incorporating Vitamin B9 into churna offers an innovative strategy to address both pathological ulcer mechanisms and nutritional deficiency simultaneously.

4. HERBAL INGREDIENTS AND THEIR ANTIULCER RATIONALE

4.1 Glycyrrhiza glabra (Licorice Root)

Family: Fabaceae. Part used: Root and rhizome. Active constituents: Glycyrrhizin, glycyrrhetic acid, liquiritin, isoliquiritigenin, flavonoids.



Pharmacological basis: Glycyrrhizin and its metabolite glycyrrhetic acid exhibit significant anti-inflammatory activity by inhibiting phospholipase A2 and reducing prostaglandin metabolism. Carbenoxolone (a synthetic derivative of glycyrrhetic acid) has been a clinical antiulcer agent. Licorice extracts promote mucus secretion, enhance mucosal defense, and inhibit *H. pylori* adhesion. Deglycyrrhizinated licorice (DGL) preparations avoid mineralocorticoid-related side effects while retaining mucosal protective properties. Dose in churna: 200–400 mg/dose gastric carcinogenesis. Ginger reduces gastric acid secretion while enhancing mucin secretion. Antiemetic properties address

nausea associated with peptic ulcer symptoms. Dose in churna: 100–200 mg/dose have demonstrated curcumin's efficacy in PUD treatment. Its poor water solubility is addressed by the churna formulation matrix and ginger co-administration (enhancing bioavailability via piperine-like mechanisms). Dose in churna: 200–400 mg/dose.

4.2 Spinach

Spinach (*Spinacia oleracea*) is a highly nutritious green leafy vegetable known for its rich content of antioxidants, vitamins, minerals, iron, and folic acid (Vitamin B9). Spinach contains bioactive compounds such as flavonoids and carotenoids that possess antioxidant and anti-inflammatory properties, which may help in protecting the gastric mucosa from ulcer formation. The presence of natural antioxidants helps reduce oxidative stress and promotes healing of damaged gastric tissues.



4.3 Tulsi

Tulsi (*Ocimum sanctum*) is widely used in the treatment of peptic ulcer due to its anti-inflammatory, antioxidant, and gastroprotective properties. It helps reduce gastric acid secretion, protects the stomach lining from damage, and decreases inflammation. Tulsi also promotes healing of ulcerated tissue and protects the gastric mucosa from harmful free radicals. Therefore, it is used as an important herbal ingredient in antiulcer formulations.



4.4 Aloe vera

Aloe vera (*Aloe barbadensis Miller*) is widely used in the treatment of peptic ulcer due to its soothing, anti-inflammatory, and healing properties. It helps protect the gastric mucosa, reduces irritation and inflammation in the stomach, and promotes healing of ulcerated tissue. Aloe vera also supports regeneration of damaged cells and provides a cooling effect on the stomach lining. Therefore, it is used as an important herbal ingredient in antiulcer formulations.



5. PROPOSED FORMULATION COMPOSITION

Table 1 presents the optimized composition of the herbal antiulcer churna enriched with Vitamin B9 per unit dose (3 g):

Formula Table for Herbal Antiulcer Churna (100 g)

Sr. No.	Ingredient	Biological Name	Quantity (g)	Role
1	Tulsi Powder	<i>Ocimum sanctum</i>	25 g	Anti-inflammatory and antioxidant activity
2	Aloe vera Powder	<i>Aloe barbadensis Miller</i>	25 g	Soothing and healing effect on gastric mucosa
3	Spinach Powder	<i>Spinacia oleracea</i>	25 g	Natural source of Vitamin B9 for tissue repair
4	Yashtimadhu Powder	<i>Glycyrrhiza glabra</i>	25 g	Antiulcer and gastroprotective activity

6. PREPARATION METHODOLOGY

6.1 Collection and Authentication

Plant materials are collected from authenticated herbaria or reputed suppliers and botanically identified by a qualified taxonomist. Voucher specimens are deposited in the institution's herbarium. Raw materials are evaluated for identity per API and WHO guidelines for quality of herbal raw materials.

6.2 Processing of Herbal Powders

- Drying: Fresh plant materials are dried at 40–50°C in a hot air oven to moisture content below 8% (as per API specifications) to prevent microbial degradation.
- Size reduction: Dried materials are coarsely crushed, then finely powdered using a multi-mill or ball mill.
- Sieving: Powders are passed through mesh no. 80 (180 µm) to obtain uniform particle size essential for dose uniformity and dissolution.
- Individual powders are stored in airtight, light-protected containers before blending.

6.3 Vitamin B9 Incorporation

Folic acid (pharmaceutical grade, USP/IP compliant) is dissolved in a minimum quantity of purified water or blended with microcrystalline cellulose as a carrier (geometric dilution technique) to ensure uniform distribution at the microgram level within the churna matrix. Geometric dilution involves mixing folic acid with an equal weight of excipient, then doubling the powder mass stepwise until complete incorporation.

6.4 Blending

Individual herbal powders and the folic acid blend are mixed in a double-cone blender (30 min, 20 rpm) to achieve homogeneity. Blending uniformity is confirmed by content assay at multiple sample points. The final churna is sieved through mesh no. 80 post-blending.

6.5 Packaging

The final churna is filled into unit-dose sachets (3 g) or wide-mouth amber glass containers with silica gel desiccant. Packaging material must be moisture-proof given folic acid's hygroscopic sensitivity and photolability.

7. EVALUATION PARAMETERS

7.1 Organoleptic Evaluation

Color, odour, taste, and texture are assessed organoleptically and compared with pharmacopoeial standards. Churna is expected to be characteristic brownish-yellow in color, aromatic, slightly bitter-pungent in taste, and free-flowing in texture.

7.2 Physicochemical Parameters

- Loss on drying (LOD): Should not exceed 8.0% w/w (API limit) — critical for stability and prevention of mold growth.
- Ash values: Total ash ($\leq 5\%$), acid-insoluble ash ($\leq 1\%$), water-soluble ash — indicators of inorganic impurities and adulterants.
- Extractive values: Water-soluble and alcohol-soluble extractives quantify active constituent yield.
- Bulk density and tapped density: Important for dose uniformity; Carr's index and Hausner ratio assess powder flowability (Carr's index $\leq 15\%$ indicates excellent flow).
- pH: Aqueous suspension pH should be 5.0–6.5 — acidic enough not to interfere with gastric environment.
- Particle size analysis: $D_{50} \leq 180 \mu\text{m}$ (mesh no. 80 specification).
- Swelling index: Relevant for mucilaginous ingredients; higher swelling indicates better mucosal coating potential.

7.3 Phytochemical Screening

Qualitative tests for alkaloids (Dragendorff's, Mayer's), flavonoids (Shinoda test), tannins (ferric chloride), saponins (foam test), glycosides (Keller-Killiani), terpenoids (Salkowski), and phenolic compounds are conducted on aqueous and ethanolic extracts of the churna.

7.4 Chromatographic Standardization

- TLC (Thin Layer Chromatography): Fingerprint profile using reference standards (glycyrrhizin, curcumin, gallic acid) as markers on silica gel 60 F254 plates with suitable mobile phases. R_f values documented under UV (254, 366 nm) and after derivatization.
- HPLC (High Performance Liquid Chromatography): Quantitative estimation of marker compounds — glycyrrhizin (210 nm), curcumin (425 nm), gallic acid (272 nm), and folic acid (280 nm) using validated reverse-phase C18 methods (ICH Q2(R1) validation).
- HPTLC: Densitometric fingerprinting for quality control.

7.5 Vitamin B9 (Folic Acid) Assay

Folic acid content is estimated by RP-HPLC (C18 column, mobile phase: methanol: 0.1% phosphoric acid 30:70, detection at 280 nm). Microbiological assay using *Lactobacillus rhamnosus* ATCC 7469 as per USP is also validated. Content uniformity across batches must meet 90–110% of label claim.

7.6 Antimicrobial Activity

Agar well diffusion and broth microdilution (MIC determination) methods are used to evaluate *H. pylori* inhibitory activity of the churna extract. Reference standard: Clarithromycin. Minimum inhibitory concentration (MIC) is reported in µg/mL.

7.7 In vitro Antioxidant Activity

- DPPH (2,2-diphenyl-1-picrylhydrazyl) radical scavenging assay: IC₅₀ values calculated and compared with standard ascorbic acid.
- ABTS (2,2'-azino-bis-3-ethylbenzothiazoline-6-sulfonic acid) assay: Trolox equivalent antioxidant capacity (TEAC).
- FRAP (Ferric Reducing Antioxidant Power): Measures reducing capacity.
- Hydrogen peroxide scavenging assay.

7.8 In vivo Antiulcer Evaluation

Animal models used for in vivo antiulcer activity of churna suspension (aqueous):

- Pylorus ligation model (Shay ulcer model): Gastric volume, total acidity, free acidity, pH, and pepsin activity measured; ulcer index calculated.
- Ethanol-induced ulcer model: Oral ethanol administration; churna pre-treatment evaluated for gastroprotective effect; histopathological examination of gastric mucosa.
- Aspirin/NSAID-induced ulcer model: Relevant for NSAID gastropathy simulation.
- Acetic acid-induced chronic ulcer model: Assessment of healing rate and mucosal integrity.
- Cold-restraint stress model: Evaluates stress-ulcerogenic mechanisms.

Parameters evaluated: Ulcer index, percentage ulcer inhibition, gastric pH, mucin content, PGE₂ levels, oxidative stress markers (MDA, SOD, CAT, GSH), histopathology (H&E staining), and inflammatory cytokines (ELISA).

7.9 Safety and Toxicity Studies

- Acute oral toxicity: OECD guideline 423 (fixed dose method); LD₅₀ determination in Wistar rats.
- Sub-acute (28-day) toxicity: Hematological, biochemical (liver function, renal function), and histopathological assessment.
- Genotoxicity: Ames test and in vitro chromosomal aberration assay.

8. STABILITY STUDIES

Stability is a critical concern for folic acid-enriched churna, as Vitamin B₉ is sensitive to light, heat, humidity, and alkaline conditions. Stability testing is conducted as per ICH Q1A(R2) guidelines:

- Long-term stability: 25°C ± 2°C / 60% RH ± 5% for 24 months.
- Accelerated stability: 40°C ± 2°C / 75% RH ± 5% for 6 months.
- Photostability: ICH Q1B guidelines — fluorescent light and UV exposure.

Stability-indicating HPLC assay monitors folic acid content at 0, 1, 3, 6, 9, 12, 18, and 24 months. Degradation products — pterin-6-carboxaldehyde and p-aminobenzoylglutamate — are monitored. Physicochemical parameters (color, LOD, flow properties) are also evaluated at each time point. Light-opaque packaging (amber containers,

aluminum foil sachets) with antioxidant excipients (sodium ascorbate, 0.1%) is recommended to protect folic acid integrity.

9. SYNERGISTIC INTERACTIONS BETWEEN HERBAL COMPONENTS AND VITAMIN B9

The combination of herbal antiulcer agents with Vitamin B9 is expected to produce synergistic rather than merely additive effects through complementary mechanisms:

- Amla (Vitamin C-rich) + Folic acid: Vitamin C prevents oxidative degradation of folate, enhancing its bioavailability and stability in the formulation and in vivo.
- Curcumin + Folic acid: Both reduce NF- κ B-mediated inflammation; curcumin enhances folate receptor expression and uptake in gastric epithelial cells.
- Licorice + Folic acid: Glycyrrhizin promotes mucosal cell proliferation, which is folic acid-dependent for DNA synthesis and cell division — a natural synergy for mucosal healing.
- Ginger (bioavailability enhancer): 6-Gingerol enhances intestinal absorption of multiple phytonutrients through P-glycoprotein inhibition and membrane fluidity modulation.
- Triphala: Acts as a prebiotic and modulates gut microbiome toward folate-producing bacterial species (*Lactobacillus*, *Bifidobacterium*), potentially enhancing endogenous folate supply.

10. CLINICAL RELEVANCE AND THERAPEUTIC PROSPECTS

The herbal antiulcer churna enriched with Vitamin B9 addresses multiple pathological dimensions of peptic ulcer:

- Antisecretory effect: Licorice and curcumin modulate gastric acid secretion through prostaglandin and histamine pathways.
- Mucosal cytoprotection: Enhanced mucus secretion (licorice, amla), prostaglandin preservation (ginger), and antioxidant defense (amla, turmeric).
- Anti-*H. pylori* activity: *T. chebula*, curcumin, and ginger exhibit documented in vitro and in vivo efficacy.
- Mucosal regeneration: Vitamin B9 + licorice + amla promote epithelial cell proliferation and DNA repair in damaged gastric mucosa.
- Anti-inflammatory cascade inhibition: Multiple herbal components suppress NF- κ B, COX-2, and cytokine-mediated inflammation.

The formulation is particularly suited for patients with nutritional deficiency-associated PUD, NSAID-induced gastropathy, and chronic recurrent ulcers where conventional therapy has limitations. Recommended dose: 3–6 g churna, twice daily, with warm water or honey before meals.

11. REGULATORY AND QUALITY CONSIDERATIONS

The formulation must comply with: Ayurvedic Pharmacopoeia of India (API) monographs for individual herbs, WHO guidelines on quality control methods for herbal medicines, Schedule E1 (list of poisonous plants — to confirm absence), and FSSAI guidelines if marketed as a nutraceutical (food supplement). AYUSH Good Manufacturing Practices (GMP) as per Schedule T (Drugs and Cosmetics Act, 1940) must be adhered to during manufacturing. The folic acid component must meet IP/USP specifications.

12. FUTURE DIRECTIONS

Future research prospects for this formulation include:

- Randomized controlled clinical trials (RCTs) in PUD patients to establish clinical efficacy and safety.
- Bioavailability studies: Pharmacokinetic profiling of key markers (glycyrrhizin, curcumin, folic acid) in human subjects after churna administration.
- Nanoformulation approaches: Nanosized herbal-folic acid composites to overcome poor bioavailability of curcumin and improve mucosal delivery.
- Microbiome studies: Impact of the churna and folate on gut microbiome composition and its relation to *H. pylori* eradication.
- Sustained-release churna granules: Granulation techniques to control release and improve patient compliance.
- Economic evaluation: Cost-effectiveness analysis vs. standard PPI-based therapy.

13. CONCLUSION

The herbal antiulcer churna enriched with Vitamin B9 represents a scientifically rationalized, multi-mechanistic approach to peptic ulcer management. The formulation harnesses the synergistic antiulcer, anti-inflammatory, antioxidant, and antimicrobial properties of time-tested Ayurvedic herbs while incorporating the proven mucosal healing and DNA-repair benefits of folic acid. Comprehensive evaluation strategies — spanning physicochemical characterization, phytochemical profiling, HPLC standardization, in vitro and in vivo biological activity, and stability testing — ensure a safe, effective, and quality-consistent product. This review provides the scientific framework for further preclinical optimization and clinical translation of this promising herbal nutraceutical formulation.

REFERENCES

1. Tarnawski AS. Cellular and molecular mechanisms of gastrointestinal ulcer healing. *Dig Dis Sci.*, 2005; 50(Suppl 1): S24–S33.
2. Malfertheiner P, Megraud F, O'Morain CA, et al. Management of *Helicobacter pylori* infection — the Maastricht V/Florence Consensus Report. *Gut.*, 2017; 66(1): 6–30.
3. Borrelli F, Izzo AA. The plant kingdom as a source of anti-ulcer remedies. *Phytother Res.*, 2000; 14(8): 581–591.
4. Rao ChV, Sairam K, Goel RK. Experimental evaluation of *Bocopa monniera* on rat gastric ulceration and secretion. *Indian J Physiol Pharmacol*, 2000; 44(4): 435–441.
5. Singh SK, Patel JR, Dangi A, Bachle D, Kataria RK. A complete over view of *Glycyrrhiza glabra* (Mulethi). *J Med Plants Stud.*, 2017; 5(2): 328–334.
6. Krishnaveni M, Mirunalini S. Therapeutic potential of *Phyllanthus emblica* (amla): the Ayurvedic wonder. *J Basic Clin Physiol Pharmacol*, 2010; 21(1): 93–105.
7. Prasad S, Aggarwal BB. Turmeric, the golden spice. In: Benzie IFF, Wachtel-Galor S, eds. *Herbal Medicine: Biomolecular and Clinical Aspects*. 2nd ed. CRC Press; 2011.
8. Haniadka R, Saldanha E, Sunita V, et al. A review of the gastroprotective effects of ginger (*Zingiber officinale* Roscoe). *Food Funct*, 2013; 4(6): 845–855.
9. Lucock M. Folic acid: nutritional biochemistry, molecular biology, and role in disease processes. *Mol Genet Metab*, 2000; 71(1-2): 121–138.
10. Mete R, Oran M, Topcu B, et al. Effects of folic acid on oxidative stress and inflammation in *H. pylori*-infected gastric mucosa. *World J Gastroenterol*, 2013; 19(11): 1809–1814.

11. World Health Organization. Quality Control Methods for Herbal Materials. WHO Press; 2011.
12. Ayurvedic Pharmacopoeia of India. Government of India, Ministry of AYUSH; 2020.
13. ICH Harmonised Guideline Q1A(R2): Stability Testing of New Drug Substances and Drug Products. ICH; 2003.
14. ICH Harmonised Guideline Q2(R1): Validation of Analytical Procedures: Text and Methodology. ICH; 2005.
15. Surendiran A, Bhatt M, Bhakta CS, Nair A, Bhatt P. Adverse drug reactions to proton pump inhibitors. *Indian J Pharmacol*, 2013; 45(4): 437.
16. Dhiman KS. Terminalia chebula: a review of its traditional uses, phytochemistry and pharmacology. *Int J Drug Dev Res.*, 2012; 4(2): 27–44.
17. Triphala — Ayurvedic Pharmacopoeia of India. Vol. 1. Government of India; 1986.
18. OECD. Guidelines for the Testing of Chemicals. Test No. 423: Acute Oral Toxicity. OECD Publishing; 2002.