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Formulation Of Herbal Drug into Modern Dosage Form

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ABSTRACT
Herbal medicine, as defined by the World Health Organization (WHO), encompasses the use of herbs, herbal components, preparations, and finished products derived from botanical sources. These remedies are abundant in phytochemicals bioactive compounds such as saponins, flavonoids, glycosides, tannins, alkaloids, and terpenoids - which contribute to their diverse therapeutic effects. Herbal treatments are employed in the management of various health conditions, including gastrointestinal disorders, skin infections, inflammation, migraines, and fatigue. Compared to conventional pharmaceuticals, herbal medicines are generally associated with fewer side effects and greater affordability, enhancing their appeal and accessibility. Recent advancements in pharmaceutical technology have led to the development of novel herbal drug delivery systems such as transfersomes, ethosomes, microspheres, phytosomes, liposomes, polymeric nanoparticles, and nanocapsules that significantly improve the solubility, stability, bioavailability, and targeted delivery of herbal compounds. Among these innovations, phytosome technology stands out as a patented approach that combines herbal extracts with phospholipids to enhance absorption and therapeutic efficacy. These advanced systems not only optimize the pharmacological performance of herbal medicines but also ensure better protection of active ingredients against degradation. The integration of modern delivery technologies with traditional herbal remedies marks a significant evolution in the field, expanding the clinical utility and reinforcing the relevance of herbal medicine in modern healthcare. Ongoing research and development in this area hold promising potential for further innovations and broader therapeutic applications.

Keywords: *Herbal medicines, phytochemicals, novel drug delivery system, phytosome, bioavailability, therapeutic efficacy.*

1. INTRODUCTION

Herbal medicines are key to alternative therapies, gaining global acceptance due to affordability, low toxicity, and efficacy in hard-to-treat conditions [1–3]. Their composition includes herbs, minerals, animal products, and fungi [4]. Despite benefits, they can cause side effects from natural compounds like secondary metabolites [5–6]. Misuse due to poor knowledge remains a challenge [7–8]. Healthcare professionals must promote awareness about safety, efficacy, regulation, and R&D [9]. Adverse effects may include cardiac, neurological, renal, and carcinogenic outcomes, influenced by ingredients, preparation, and co-medication risks [10]. Innovative delivery systems, including nanoscale formulations like liposomes and nanoemulsions, enhance solubility, targeting, and safety [11–12]. These novel systems can overcome limitations and improve therapeutic outcomes [12].

1.1 FORMULATION OF HERBAL EXTRACTS INTO MODERN DOSAGE FORMS

Formulating herbal extracts into contemporary dosing forms requires expertise in pharmaceutical technology and herbal medicine. Here is an overview regarding formulating herbal extracts into contemporary dosing forms.

A. Herbal extract types

1) Dry extracts (powders or granules)
2) Liquid extracts (tinctures, solutions)
3) Semi-solid extracts (ointments, creams)

B. Modern dosage forms

1) Tablets
2) Capsules (hard/soft gelatin)
3) Oral liquids (solutions, suspensions)
4) Topical creams/ointments
5) Transdermal patches
6) Injectables (rarely used)

C. Formulation considerations

1) Bioavailability enhancement
2) Stability (chemical, physical)
3) Solubility
4) Taste masking
5) Standardization (marker compounds)
6) Excipient selection

D. Excipients used

1) Fillers (microcrystalline cellulose, lactose)
2) Binders (starch, gelatine)
3) Disintegrates (sodium starch glycolate)
4) Lubricants (magnesium stearate)
5) Coatings (enteric, film)

E. Herbal extracts formulation techniques

1) Spray drying
2) Freeze-drying (lyophilization)
3) Granulation
4) Encapsulation
5) Emulsification
6) Nanotechnology

F. Regulatory considerations

1) GMP (Good Manufacturing Practice)
2) Quality control (QC) testing
3) Labeling and packaging compliance
4) Regulatory submissions (e.g., FDA, EMA)

G. Examples of herbal extract formulations

1) Black Mulberry Extract Cream (anti- acne)
2) Turmeric extract tablets (curcuminoids)
3) Ginkgo biloba extract capsules (flavonoids, terpenoids)
4) St. John's Wort extract oral liquids (hyperforin)
5) Aloe vera gel topical creams (aloe-emodin)

H. Challenges and future directions

1) Standardization and quality control
2) Bioavailability enhancement

3) Nanotechnology applications
4) Clinical trials and efficacy studies

Regulatory harmonization

1.2 APPLICATION OF HERBAL MEDICINE

Herbal medicine includes plant-derived substances used for treatment and prevention, based on active and co-active constituents [13–14]. It remains central to primary healthcare in many rural Asian and African regions and is culturally significant worldwide [15]. Herbs exert pharmacological effects through complex bioactive compounds, used in both minor and severe conditions, and for disease prevention [16–17]. Dosage forms vary with disease type, route, culture, and patient needs, ranging from decoctions and poultices to tablets and capsules [18]. Pharmaceutical formulations improve dosing accuracy, compliance, and appeal. Efficacy and safety depend on active compounds, contaminants, and production quality. Herbal products show promise in treating chronic and infectious diseases like HIV, malaria, cancer, diabetes, and infertility. Proper regulation, identification, and public awareness are essential to ensure their safe use [19].

1.3 EFFICACY OF HERBAL MEDICINE

Herbal remedies are widely used for treatment, pain relief, and disease prevention, with efficacy linked to their active constituents [23]. While some herbs show proven benefits, many local remedies lack scientific validation. Increased interest has led to research supporting several herbal claims, aiding drug development [23]. However, limited data on efficacy and herb-drug interactions raise safety concerns. Research is needed to evaluate the combined use with pharmaceuticals, and such findings should be included in product labelling as per regulatory requirements [24].

1.4 REASONS FOR ENHANCING HERBAL MEDICINE USE

Herbal medicine (HM) use is rising due to:

A. Personal Preference:

Rooted in tradition, HM remains a primary health choice in Asia and Africa, regardless of socioeconomic status [28].

B. Perceived Safety:

Many view HM as safer with fewer side effects, despite risks. In nations like India and China, herbalists outnumber conventional doctors.

C. Accessibility:

In remote areas, HM is more accessible and affordable than modern medicine, often available without prescription [28].

D. Low Cost:

HM is community-based, often bartered, and relies on local resources, making it cheaper than conventional drugs.

E. Proven Efficacy:

Scientific studies confirm HM's efficacy and safety in some cases, increasing trust and preference among users [28].

1.5 NOVEL APPROACHES TO HERBAL DRUG DELIVERY

Modern Novel Drug Delivery Systems (NDDS) improve the bioavailability, targeting, and safety of herbal medicines by overcoming barriers like poor solubility, degradation, and low absorption [29].

NDDS Technologies:

1) **Phytosomes:** Lipid-compatible complexes enhance oral absorption of polyphenols like *Ginkgo biloba* [30, 34].
2) **Liposomes:** Spherical carriers improve delivery of hydrophilic/lipophilic herbal actives, enhancing therapeutic action [33].
3) **Nanoparticles:** Increase solubility, absorption, and targeted delivery of active compounds [35].
4) **Niosomes/Proniosomes:** Cost-effective vesicular systems more stable than liposomes, suitable for various actives [36, 37].
5) **Microspheres:** Prolong drug action and reduce side effects through controlled release [40, 41].
6) **Transdermal Systems:** Enable sustained herbal drug release through skin (e.g., curcumin, *Boswellia*) without injections [38, 39].
7) **Controlled Release Tablets:** Ensure sustained herbal compound delivery for 4–18 hours (e.g., *Hypericum* spp.) [32].
8) **Oral Dissolving Tablets (ODTs):** Rapidly dissolving polyherbal forms (e.g., Res Q) bypass first-pass metabolism [31].

9) **Emulsions/Nanoemulsions:** Enhance lymphatic targeting and bioavailability of lipophilic herbal components [42, 43].

10) **Ethosomes/Transfersomes:** Flexible vesicles for deeper skin penetration and intracellular delivery [44–45].

2. MATERIAL AND METHODS

2.1 Plant material and authentication

Identification of plant was done by Dr. C.K. Nigwal (Department of Botany), P.G. College of Mandsaur (M.P.). Fruits of *Morusnigra*Linn.was collected from Sabakheda,Mandsaur region. The taxonomical identification of plant was done by Dr. C.K. Nigwal (Department of Botany), P.G. College of Mandsaur (M.P.). The voucher specimen of *MorusnigraM.* Linn. was deposited in the herbarium of the Department of Pharmacognosy, B.R. Nahata College of Pharmacy, Mandsaur.

2.2 Preparation of extracts

50gm of fruits were dried at 50°C and was exhaustively extracted with 96% methanol using Soxhlet extraction for 24 hours (twice). The concentrated extract was obtained using a rotary evaporator under vacuum. Finally, the percentage yields were calculated of the dried extracts.

2.3 Phytochemical screenings

To determine the presence of alkaloids, glycosides, flavonoids, tannins, steroids, saponins, and carbohydrates, a preliminary phytochemical study with various plants extracts was performed.

2.4 Physical evaluation of extract

The physical evaluation of the combination of all extract was done for following parameters. The results are shown in Table 1.

2.5 Determination of antibacterial activity

2.5.1 Microorganism used:

Staphylococcus epidermidis (MTCC 435) was obtained from IMTECH, Chandigarh.

2.5.2 Test organism:

Acne-causing *S. epidermidis* strains were tested using the disc diffusion method.

2.5.3 Disc Preparation:

100 mg of *Morusnigra*Linn. extract was dissolved in 1 ml of 4% DMSO. 0.2 ml of this solution was loaded onto 6 mm sterile Whatman No. 1 filter paper discs (20 mg/disc), dried under laminar airflow.

2.5.4 Antibacterial testing:

Discs were placed on agar plates inoculated with 0.1 ml bacterial suspension (10 CFU/ml). Plates were incubated at 37°C for 24 h. Gentamicin (20 µg/disc) served as a positive control; methanol discs as negative control. Zones of inhibition were measured to assess activity.

2.6 Formulation of anti-acne cream

The cream was formulated using oil (stearic acid, cetyl alcohol, liquid paraffin) and aqueous (glycerine, methyl paraben, triethanolamine) phases, each heated to 75°C. The aqueous phase was gradually added to the oil phase with continuous stirring. Black mulberry extract was incorporated at 2% (F1) and 4% (F2) concentrations with added fragrance.

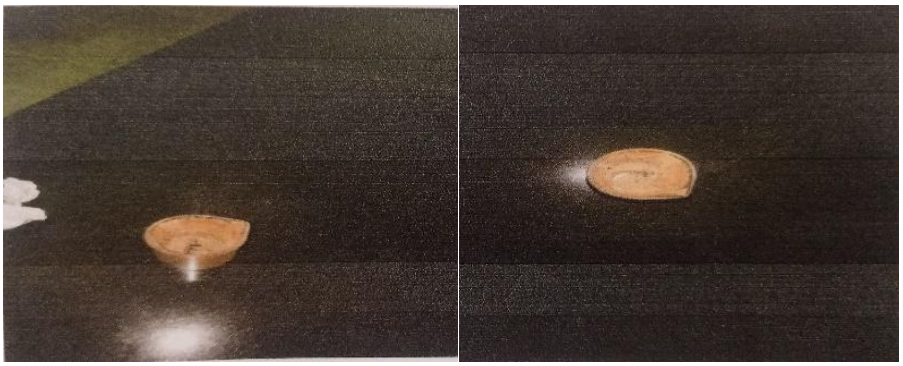


Figure 10: F1 **F2**

Table 1: F1 Composition of the anti-acne cream containing Black Mulberry extract.

Components	Amount (2% w/w)
Active ingredients	
Black mulberry extract	1 gm
Oily phase	
Stearic acid	5 gm
Cetyl alcohol	2 gm
Liquid paraffin	2 gm
Aqueous phase	
Glycerin	2.5 gm
Methyl paraben	0.05 mg
Thiethanolamine	0.05 mg
Distilled water q.s	50 ml

Table 2: F2 Composition of the anti-acne cream containing Black Mulberry Extract.

Components	Amount (4% w/w)
Active ingredients	
Black mulberry extract	2 gm
Oily phase	
Stearic acid	10 gm
Cetyl alcohol	4 gm
Liquid paraffin	4 gm
Aqueous phase	
Glycerine	5 gm
Methyl paraben	0.05 mg
Thiethanolamine	0.05 mg
Distilled water q.s	50 ml

2.7 Evaluation of anti-acne cream

The cream was evaluated for pH (0.5 g in 50 ml distilled water), homogeneity (visual/touch), appearance (color, texture), after-feel (emolliency, slipperiness, residue), smear type, and removal (ease with tap water). Stability was assessed at 8°C, 27°C, and 40°C over 1 month.

3. RESULTS AND DISCUSSION

Dye test confirmed F1 and F2 were oil-in-water emulsions. The pH ranged from 4.6–4.8, suitable for skin application. Both formulations showed uniform extract distribution, good emolliency, non-greasy smear, easy washability, and no color change during storage. Stability was maintained at 8°C, 25°C, and 40°C over 4 weeks.

Methanolic extract of *Morusnigra* showed antibacterial activity against *S. epidermidis*, with a 23 mm inhibition zone compared to 21 mm by Gentamicin, indicating effective anti-acne potential.

Table 3: Phytochemical screening test of fruit extract

Phytochemical screening	Result
Alkaloid	-
Flavanoid	+
Polyphenol	+
Tannin	+
Monoterpenoid and sesquiterpenoid	+
Steroid and triterpenoid	-
Quinone	-
Saponin	-

Table 4: Physiochemical evaluation of the formulated anti-acne cream

Parameter	Result	
Homogeneity	Good	Good
Appearance	No change in colour	No change in colour
Odour	Good	Good
Spreadability	Good	Good
After feel	Emollient and slipperiness	Emollient and slipperiness
Type of smear	Non-greasy	Non-greasy
Removal	Easy	Easy

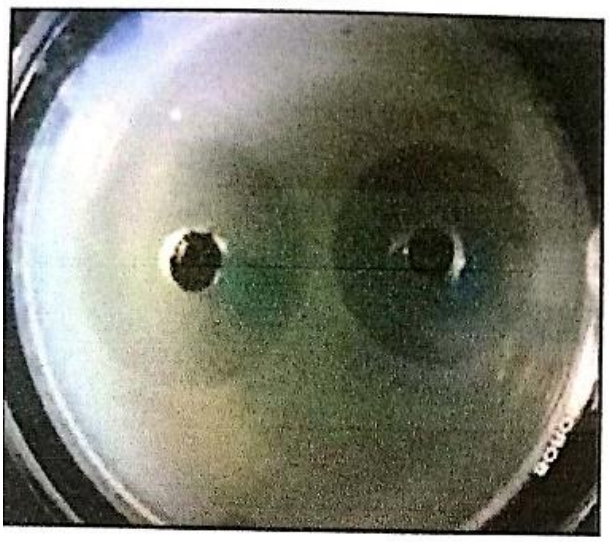
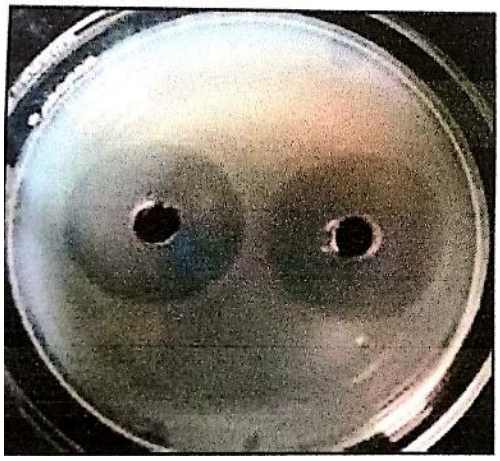


FIG.11: (A) Zone of inhibition of gentamicin against *S. epidermidis*.



(B) Zone of inhibition of*Morusnigra*Linn. extract against S. Epidermidis.

Table 5: Inhibitory activity of *Morusnigra*Linn. and Gentamicin

Zone of Inhibition		
Control	**Extract**	**Standard antibiotic Gentamicin**
9 mm	23 mm	21 mm

Table 6: Stability test of cream

Formula	**Evaluation**	**Days**					
		1	**3**	**7**	**14**	**21**	**28**
1	Color	Creamy white	Creamy white	Creamy white	Creamy white	Creamy white	Creamy white
	Odour	Good	Good	Good	Good	Good	Good
	Consistency	Semi solid	Semi solid	Semi solid	Semi solid	Semi solid	Semi solid
2	Color	Creamy white	Creamy white	Creamy white	Creamy white	Creamy white	Creamy white
	Odour	Good	Good	Good	Good	Good	Good
	Consistency	Semi solid	Semi solid	Semi solid	Semi solid	Semi solid	Semi solid

4. CONCLUSION

Herbal medicines require systematic formulation to enhance compliance and reduce toxicity. Novel delivery systems improve dosing efficiency and therapeutic outcomes. Acne, though non-lethal, impacts quality of life, and lifestyle factors contribute to its severity. Natural remedies, including plant extracts, offer safer alternatives to synthetic drugs. *Morusnigra* (black mulberry) demonstrated promising antibacterial activity against acne-causing bacteria, supporting its potential use in herbal anti-acne formulations.

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