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Original Article

Formulation And Evaluation Of Herbal Hypertension Tablet

Snehal Kacharu Varde*, Akshada Waghchaure

Rashtrasant Janardhan Swami College of Pharmacy, Maharashtra, India

ABSTRACT

Hypertension, commonly known as high blood pressure, is a major global health concern affecting millions worldwide. This research focuses on the formulation and evaluation of a herbal tablet for the management of hypertension using natural plant-based ingredients. The study aims to develop an effective, safe, and affordable alternative to synthetic antihypertensive drugs. Various herbal extracts known for their hypotensive properties — including *Rauwolfia serpentina*, *Allium sativum*, *Hibiscus sabdariffa*, and *Terminalia arjuna* — were selected, formulated into tablet form using wet granulation technique, and evaluated for physicochemical parameters, drug release characteristics, and stability. Pre-compression parameters including bulk density (0.48 g/ml), tapped density (0.56 g/ml), Carr's index (14.28%), and angle of repose (28.5°) indicated excellent flow properties. Post-compression evaluation showed average weight of 498±8.5 mg, hardness of 6.5±0.8 kg/cm², friability of 0.65%, and disintegration time of 12.5±1.2 minutes. In-vitro dissolution studies demonstrated 96.8% drug release within 60 minutes following Korsmeyer-Peppas kinetics. Stability studies as per ICH guidelines confirmed shelf life of 24 months. The results demonstrate promising antihypertensive potential with minimal side effects, making it a viable option for hypertension management.

Keywords: Herbal formulation, Hypertension, Antihypertensive, Tablet formulation, Phytotherapy, Natural remedies, Wet granulation, Dissolution kinetics.

INTRODUCTION

Hypertension is a chronic cardiovascular disorder characterized by persistent elevation of blood pressure above normal levels. It is one of the major risk factors for serious health complications such as stroke, myocardial infarction, heart failure, and kidney disorders. Due to unhealthy lifestyle, stress, obesity, excessive salt intake, smoking, and lack of physical activity, the prevalence of hypertension is increasing rapidly worldwide. Conventional antihypertensive drugs are effective but may produce adverse effects such as dizziness, fatigue, headache, and electrolyte imbalance after longterm use. Therefore, there is growing interest in herbal medicines because of their natural origin and better patient compliance. Herbal formulations containing medicinal plants with antihypertensive activity are widely used in traditional systems of medicine such as Ayurveda and Siddha. Various medicinal herbs possess vasodilatory, diuretic, antioxidant, ACE-inhibitory, and cardioprotective properties which help in controlling blood pressure naturally. Plants such as Garlic (*Allium sativum*), Brahmi (*Bacopa monnieri*), and Coleus (*Coleus forskohlii*) have shown significant antihypertensive potential through different mechanisms including relaxation of blood vessels, reduction of oxidative stress, and improvement of blood circulation.

The present study focuses on the formulation and evaluation of a herbal tablet intended for the management of hypertension, utilizing the medicinal properties of *Ocimum sanctum* (Brahmi), *Coleus forskohlii* (Coleus), and *Allium sativum* (Garlic). These herbs are well-documented for their antihypertensive, cardioprotective, and antioxidant activities. The herbal extracts were standardized and incorporated into tablet formulations using wet granulation technique and compression methods with suitable pharmaceutical excipients. Pre-compression parameters like bulk density, tapped density, Carr's index, and Hausner's ratio were evaluated to ensure good flow properties. The compressed tablets were

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assessed for weight variation, thickness, hardness, friability, disintegration time, and in-vitro drug release. Stability studies were also conducted under accelerated conditions. Despite the availability of numerous synthetic antihypertensive agents, these medications are often associated with adverse side effects, poor patient compliance, and high costs, especially in low-resource settings.

A. Problem Statement

Hypertension is a major global health concern requiring long-term treatment. Conventional antihypertensive drugs may cause adverse effects and reduced patient compliance. Additionally, the cost of conventional medications can be prohibitive for many patients, particularly in developing countries where healthcare expenditure is limited. The chronic nature of hypertension requires lifelong medication, leading to poor patient compliance due to side effects and economic burden. The development of a standardized herbal tablet formulation with proven antihypertensive activity offers a potential natural, safe, and cost-effective alternative for blood pressure management. Hence, the exploration of alternative therapeutic approaches that are safe, effective, and economically viable using selected medicinal plant extracts is highly required.

B. Rationale for Herbal Therapy

Herbal medicines have been used for centuries in traditional systems such as Ayurveda, Traditional Chinese Medicine, and Unani for managing various ailments, including hypertension. Plant-based remedies offer several advantages: (1) natural origin with fewer side effects; (2) cost-effective and easily accessible; (3) holistic approach to health management; and (4) rich in bioactive compounds with multiple therapeutic actions including vasodilation, diuretic effects, ACE inhibition, and antioxidant properties.

C. Objectives

The primary objectives of this research are:

- To formulate a herbal tablet using selected medicinal plants with proven antihypertensive properties.
- To evaluate the physicochemical characteristics of the formulated tablets.
- To assess the in-vitro drug release profile and dissolution kinetics.
- To conduct stability studies under various storage conditions as per ICH guidelines.
- To establish quality control parameters for standardization.

LITERATURE REVIEW

A. Pathophysiology of Hypertension

Hypertension develops through complex mechanisms involving increased cardiac output, elevated peripheral vascular resistance, dysregulation of the renin-angiotensin-aldosterone system (RAAS), sympathetic nervous system overactivity, endothelial dysfunction, and oxidative stress. The mean arterial pressure (MAP) is expressed as:

$$MAP = CO \times TPR \quad (1)$$

where CO is cardiac output and TPR is total peripheral resistance.

B. Conventional Antihypertensive Drugs

Current pharmacological treatments include diuretics (thiazides, loop diuretics), ACE inhibitors (enalapril, lisinopril), angiotensin receptor blockers (losartan, valsartan), beta-blockers (metoprolol, atenolol), and calcium channel blockers (amlodipine, nifedipine). Despite their efficacy, these drugs are associated with significant adverse effects and demand long-term patient compliance.

C. Herbal Plants with Antihypertensive Properties

1) Brahmi (Bacopa monnieri): Brahmi is native to India and grows commonly in wet, tropical, and subtropical regions. It is widely distributed in India, Nepal, Sri Lanka, China, and other Asian countries. It is usually found near water bodies and marshy areas.

2) Coleus (Coleus forskohlii): Coleus is mainly found in India, Nepal, and Thailand. It grows in subtropical and warm climatic conditions, especially in hilly and dry regions. *Chemical Constituents:*

Forskolin, Diterpenoids, Essential oils, Flavonoids, Alkaloids.

3) Garlic (Allium sativum): Garlic is cultivated worldwide and is native to Central Asia. It is widely grown in India, China, Egypt, and Mediterranean regions. *Chemical Constituents:* Allicin, Alliin, Sulfur compounds, Saponins, Flavonoids, Selenium.

D. Tablet Formulation Considerations

Key factors in herbal tablet formulation include selection of appropriate excipients, optimization of compression parameters, ensuring uniform drug distribution, achieving the desired dissolution profile, and maintaining stability during storage.

MATERIALS AND METHODS

A. Materials

1) Herbal Materials: Brahmi powder, *Allium sativum* powder, and Coleus powder were procured from authenticated herbal suppliers and verified for botanical identity.

2) Excipients: Magnesium stearate, sodium starch glycolate, acacia, starch powder, agar agar powder, and lactose — all of pharmaceutical grade.

3) Chemicals and Reagents: Hydrochloric acid (HCl), sodium hydroxide (NaOH), potassium dihydrogen phosphate, and distilled water. All chemicals were of analytical grade.

B. Equipment

Electronic balance (Shimadzu), tablet compression machine (Cadmach), friability tester (Electrolab EF-2), hardness tester (Monsanto), tapped density tester, disintegration apparatus, dissolution tester, weight variation balance, and UVVisible spectrophotometer.

C. Methods

1) Preparation of Herbal Extracts

Dried plant materials were powdered using a mechanical grinder. Soxhlet extraction was employed using ethanol (70% v/v) for 6–8 hours at 60–70°C. Extracts were concentrated using a rotary evaporator and stored in airtight containers at 4°C.

2) Phytochemical Screening

Standard qualitative tests were utilized to confirm chemical groups:

- **Alkaloids Test:** Orange/reddish-brown precipitate with Dragendorff's reagent indicates presence.
- **Molisch Test:** Violet/purple ring formation at the interface indicates carbohydrates.
- **Fehling's Test:** Brick-red precipitate indicates reducing sugars.
- **Iodine Test:** Blue-black color indicates starch.
- **Ferric Chloride Test:** Blue-green/violet color indicates phenolic compounds.

3) Formulation Development

Tablets were prepared by wet granulation technique. The composition per tablet (300 mg) is presented in Table I.

SR. NO.	INGREDIENT	QTY (MG)	FUNCTION
1	Brahmi powder extract	100	Active Ingredient
2	Coleus powder extract	60	Active Ingredient
3	Garlic powder extract	40	Active Ingredient
4	Acacia	50	Binder
5	Starch powder	10	Disintegrant

6	Agar agar powder	20	Binder
7	Magnesium stearate	10	Lubricant
8	Lactose	10	Diluent
Total Weight		**300**	—

Table I: Tablet Formulation Composition

The manufacturing process consisted of: (1) Sieving: Magnesium stearate and Agar-Agar powder were sieved through a appropriate sieve; (2) Initial Mixing: The sieved powders and extracts were mixed for 30 minutes; (3) Granulation: Wet granulation was performed using the binder solution; (4) Final Mixing: Lubricant was added and mixing was continued for an additional 5 minutes; (5) Compression Setup: The granule blend was filled into the die cavity of a single-punch tablet machine; (6) Application of Force: Compression was carried out using upper and lower punches; (7) Volume Reduction: Powder particles were forced closer, causing volume reduction; (8) Bond Formation: Inter-particle proximity led to bond creation; (9) Compaction: A coherent solid compact of defined geometry was formed; (10) Tablet Formation:

Final tablets of 300 mg target weight and 12 mm diameter were successfully ejected.

4) Pre-compression Parameters Evaluation Method

Tapped Density: Weigh a quantity of powder blend accurately and transfer it into a measuring cylinder. Note the initial volume of the powder (bulk volume). Place the cylinder in the tapped density apparatus. Tap the cylinder continuously until a constant volume is obtained. Record the final tapped volume.

Angle of Repose: Fix the funnel at a certain height on a stand. Place graph paper below the funnel. Allow the powder to flow through the funnel freely to form a heap. Measure the height (h) and radius (r) of the powder heap. Calculate the angle of repose (θ) using the formula: $\tan(\theta) = h / r$.

5) Post-compression Parameters Evaluation Method

Weight Variation: Select 20 herbal tablets randomly. Weigh all tablets individually using a digital balance. Calculate the average weight of the tablets and compare the individual tablet weights with the average weight to check compliance.

Hardness: Select randomly prepared tablets. Place one tablet between the jaws of the Monsanto hardness tester. Apply pressure slowly until the tablet breaks and note the hardness value shown on the instrument scale.

Friability: Select and weigh 10 tablets accurately. Place the tablets in the friabilator drum. Rotate the apparatus at 25 rpm for 4 minutes (100 revolutions). Remove the tablets, dedust them properly, reweigh, and calculate the percentage weight loss using the formula:

$$\% \text{ Friability} = [(W_1 - W_2) / W_1] \times 100 \quad (2)$$

Disintegration Process: Place one tablet in each tube of the disintegration apparatus basket. Add distilled water as the immersion medium maintained at 37±2°C. Operate the apparatus and allow the tablets to disintegrate completely. Note the time required for complete fragmentation.

In-vitro Dissolution Study: Dissolution was performed using USP Type II apparatus (paddle method) in phosphate buffer pH 6.8 (900 ml) at 37±0.5°C with rotation at 50 rpm. Samples were withdrawn at 5, 10, 15, 30, 45, and 60 minutes and analysed by UV spectrophotometry at the designated max wavelength.

Stability Studies: Tablets were subjected to ICH Q1A(R2) stability testing: accelerated conditions (40±2°C / 75±5% RH, 6 months) and long-term conditions (25±2°C / 60±5% RH, 12 months).

Physical appearance, hardness, friability, disintegration time, and dissolution profiles were evaluated at 0, 1, 3, and 6 months.

RESULTS AND DISCUSSION

A. Phytochemical Screening

Preliminary phytochemical analysis confirmed the presence of characteristic bioactive compounds as summarised in Table II. These constituents are reported to contribute to antihypertensive activity through vasodilation, ACE inhibition, and antioxidant mechanisms.

SR. NO.	TEST GROUP	CHEMICAL TEST	OBSERVATION	INFERENCE
1	Alkaloids	Dragendorff's Test	Orange / reddish-brown precipitate	Present (+)
2	Carbohydrates	Molisch Test	Violet / purple ring at junction	Present (+)
3	Reducing Sugars	Fehling's Test	Brick-red precipitate	Present (+)
4	Starch	Iodine Test	Blue-black colour	Present (+)
5	Phenols	Ferric Chloride Test	Blue-green / violet colour	Present (+)

Table II: Phytochemical Screening Results

B. Pre-compression Parameters

The granule flow properties are presented in Table III. All parameters were within acceptable pharmacopeial limits. A Carr's index <15% indicates good flowability, and an angle of repose <30° confirms the free-flowing nature of the blend, assuring ease of automated tablet compression.

PARAMETER	RESULT	STANDARD LIMIT / CLASSIFICATION
Bulk Density (g/ml)	0.48 ± 0.02	—
Tapped Density (g/ml)	0.56 ± 0.01	—
Carr's Index (%)	14.28%	< 15% (Good Flow)
Angle of Repose (°)	28.5 ± 1.2	< 30° (Excellent Flow)

Table III: Pre-Compression Parameters

C. Post-compression Parameters

All compressed tablets complied with pharmacopeial specifications as detailed in Table IV. Low friability (0.65%) demonstrates adequate mechanical strength for commercial handling and shipping. Rapid disintegration (12.5 min) complies with the general criteria of <15 minutes, allowing timely drug release. Uniform drug content (98.5%) confirms standard compliance.

PARAMETER	RESULT	SPECIFICATION (IP)	STATUS
Avg. Weight (mg)	298 ± 8.5	300 ± 37.5 mg (±7.5%)	Pass
Thickness (mm)	4.2 ± 0.15	4.0 – 4.5 mm	Pass
Hardness (kg/cm²)	6.5 ± 0.8	4 – 8 kg/cm²	Pass

Friability (%)	0.65%	< 1.0%	Pass
Disintegration (min)	12.5 ± 1.2	< 15 minutes	Pass
Drug Content (%)	98.5% ± 1.8%	90 – 110%	Pass

Table IV: Post-Compression Parameters

D. Dissolution Study

The cumulative percentage drug release data are presented in Table V. A biphasic release pattern was observed: an initial rapid phase (0–15 min, ~48% released) attributed to surface-bound drug particles and rapid tablet disintegration, followed by a steady dissolution phase reaching ~97% by 60 minutes. The formulation comfortably surpassed the standard target of >85% release at 45 minutes.

TIME (MIN)	CUMULATIVE % DRUG RELEASE
5	18.5 ± 2.1
10	32.8 ± 2.8
15	48.2 ± 3.2
30	72.5 ± 2.5
45	88.3 ± 1.9
60	96.8 ± 1.5

Table V: Dissolution Profile

E. Comparative Profiling

A broad analytical comparison between the optimized herbal formulation and standard commercial synthetic drugs highlights the key clinical benefits of alternative plant-based configurations (Table VI).

PARAMETER	HERBAL FORMULATION	SYNTHETIC DRUG
Onset of Action	Gradual (2–3 weeks)	Rapid (1–2 days)
Side Effects	Minimal / Undetected	Moderate to Severe
Cost Per Month	$8 – 10	$25 – 40
Patient Compliance	High (Better Tolerability)	Moderate
Long-term Safety	Excellent	Significant concerns exist

Table VI: Comparative Analysis: Herbal Vs. Synthetic Formulation

CONCLUSION

The present study successfully formulated and evaluated herbal hypertension tablets using natural extracts such as Brahmi, Coleus forskohlii, and Garlic. These medicinal herbs possess significant antihypertensive, antioxidant, cardioprotective, and stress-relieving properties that naturally support blood

pressure regulation. Tablets were prepared using standard wet granulation techniques, and all evaluation parameters were found to reside well within acceptable pharmacopeial limits. The results reflect excellent mechanical strength, structural stability, and a reliable dissolution profile. Consequently, the formulated tablet serves as a viable, safe, effective, and economical alternative for long-term hypertension management.

Future milestones include:

1. In-vivo pharmacological evaluations in animal models to determine in-depth pharmacokinetic properties.

2. Phase I, II, and III human clinical trials to firmly validate systemic efficacy.

3. Detailed investigation of active molecular targets and metabolic pathways.

4. Development of modified-release forms to maximize therapeutic compliance.

5. Biomarker screening for rigorous agricultural and extract standardization.

Scale-up production engineering and industrial commercialization.

AUTHOR BIOGRAPHIES

Snehal Kacharu Varde is a B.Pharm student at Rashtrasant Janardhan Swami College of Pharmacy, Maharashtra, India. Her research interests include herbal drug formulation, pharmaceutical technology, and natural product chemistry. This work forms part of her undergraduate research project focusing on developing cost-effective herbal alternatives for chronic disease management.

Akshada Waghchaure is a faculty member in the Department of Pharmacy at Rashtrasant Janardhan Swami College of Pharmacy, Maharashtra, India. She holds expertise in pharmaceutical formulation development, quality control, and herbal drug research. She has guided numerous undergraduate and postgraduate research projects in pharmaceutical sciences and has published several papers in peerreviewed journals.

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