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Formulation and Evaluation of Polyherbal Antihypertensive Tablet

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ABSTRACT

This investigation explores the creation and detailed evaluation of a novel polyherbal tablet designed to manage hypertension utilizing traditional medicinal plants including ginger ashwagandha and cinnamon the formulation incorporated these herbal extracts with excipients such as croscarmellose sodium and mannitol aiming to achieve optimal stability and enhance bioavailability a series of quality control tests were performedcovering parameters such as tablet weight consistency mechanical strength friability disintegration time and drug release profilefollowing established pharmacopeial protocols uspich the tablets demonstrated consistent weight average 2298 mg low friability 042 quick disintegration within 2 minutes and 45 seconds and efficient drug release at least 85 within 30 minutes stability testing under accelerated conditions 40c and 75 relative humidity for six months showed no major deterioration in quality overall the formulation adhered to regulatory standards and presents itself as a promising multi-component therapeutic alternative for hypertension the collective action of the herbal components supports the efficacy of polyherbal approaches over conventional single-drug therapies warranting further clinical research

Keywords: Polyherbal antihypertensive tablet, Herbal formulation, Quality control, Pharmacopeial compliance, Stability testing, Traditional medicine.

Introduction

- **Hypertension: A Global Health Challenge**

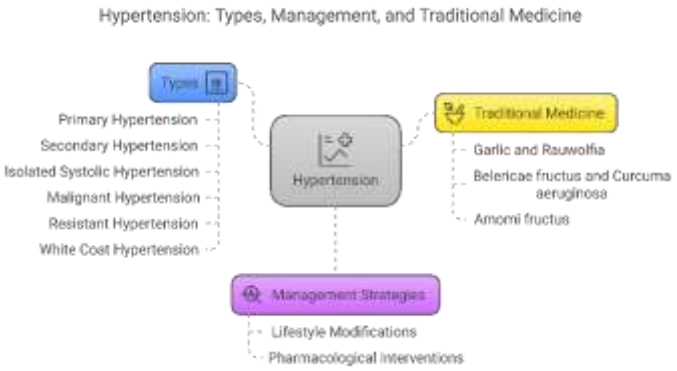
Hypertension, a chronic condition marked by persistently elevated blood pressure, is a critical global health burden. In 2008, over 1 billion individuals worldwide were diagnosed with hypertension, a figure projected to rise annually. Uncontrolled hypertension leads to severe complications such as myocardial infarction, stroke, renal failure, and mortality. Management strategies include lifestyle modifications (e.g., weight management, reduced salt intake) and pharmacological interventions. Hypertension manifests in several forms: **primary hypertension** (90–95% of cases, idiopathic and gradual onset), **secondary hypertension** (linked to kidney disorders, endocrine abnormalities, or medications), **isolated systolic hypertension** (elevated systolic pressure), **malignant hypertension** (acute organ damage), **resistant hypertension** (refractory to treatment), and **white coat hypertension** (stress-induced elevation in clinical settings).

Traditional Medicine and Polyherbal Formulations

India's Ayurveda, Siddha, and Unanni systems emphasize plant-based therapies, which are increasingly recognized globally for their safety and minimal synthetic additives. Polyherbal formulations—combinations of multiple herbs—leverage synergistic interactions to enhance efficacy. For instance:

- **Garlic** (*Allium sativum*) and **Rauwolfia** (*Rauwolfia serpentina*): The latter contains *reserpine*, which depletes catecholamine stores, inducing vasodilation.
- **Belericae fructus** (jelawe) and **Curcuma aeruginosa** (temu ireng): Exhibit antioxidant properties, mitigating endothelial dysfunction implicated in hypertension.
- **Amomi fructus** (kapulaga): May modulate calcium channels, reducing vascular resistance.

These herbs collectively target multiple pathways, offering a holistic approach compared to single-mechanism synthetic drugs.

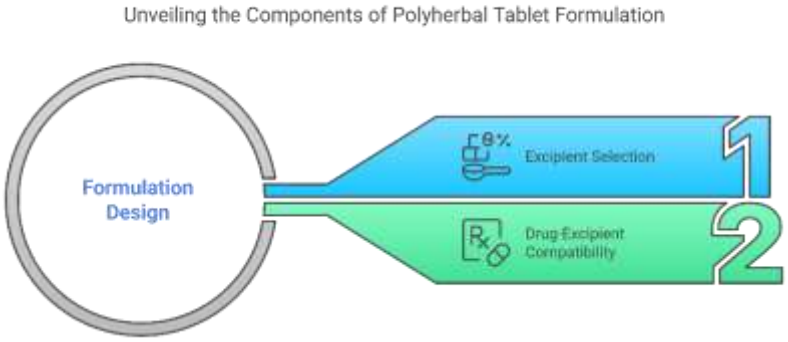


Formulation and Evaluation of Polyherbal Tablets

1. Formulation Design

Polyherbal tablets integrate active phytoconstituents with excipients to optimize stability, dissolution, and bioavailability. Key considerations include:

- **Excipient Selection**: Inert additives like **crospovidone** (a hygroscopic disintegrant) enhance tablet disintegration. Excipients must comply with regulatory standards for inertness, stability, and commercial availability.
- **Drug-Excipient Compatibility**: Pre-formulation studies assess interactions (e.g., moisture sensitivity) to ensure stability.



2. Quality Control and Evaluation

- **In-Process Testing**: Monitors parameters such as granule size, moisture content, and compression force during manufacturing.
- **Finished Product Testing**:
    - **Physical Tests**: Weight variation, hardness, friability.
    - **Chemical Tests**: Identification (HPLC/TLC for phytoconstituents), assay (potency), dissolution (using USP/BP/IP apparatus mimicking gastrointestinal fluids).
    - **Biological Tests**: Disintegration time (≤30 minutes for uncoated tablets).

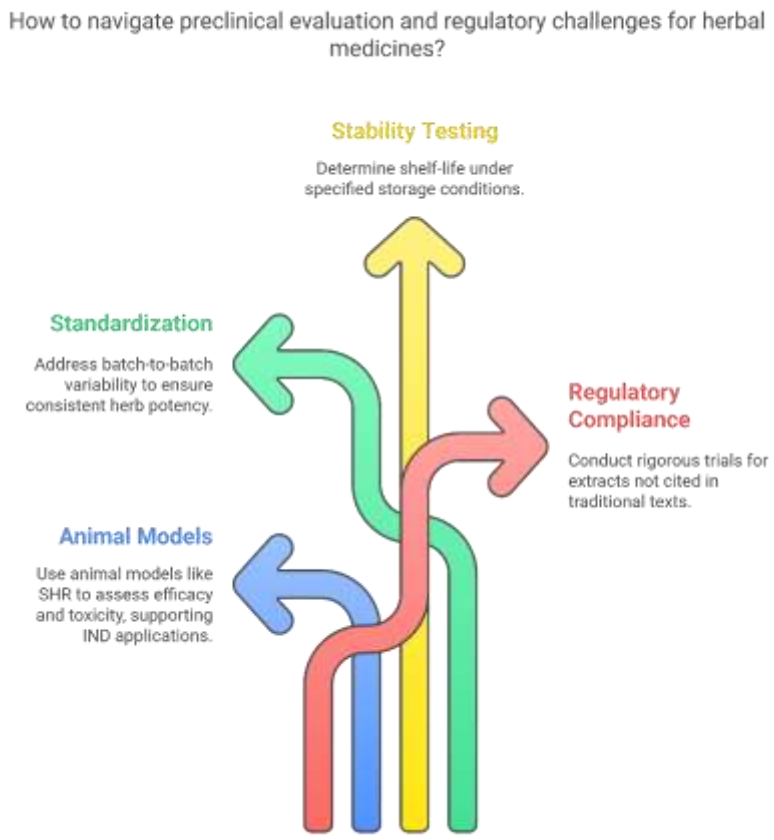
3. Preclinical Evaluation

Animal models like **spontaneously hypertensive rats (SHR)** assess efficacy and toxicity. Studies establish dose-response relationships, pharmacokinetics, and safety profiles (e.g., hepatotoxicity, teratogenicity). Data from these studies support **Investigational New Drug (IND)** applications, detailing manufacturing protocols, stability, and preclinical safety.

Regulatory and Standardization Challenges

In India, the **AYUSH Ministry** regulates herbal medicines, requiring adherence to quality benchmarks:

- **Standardization**: Challenges include batch-to-batch variability in herb potency due to climatic or processing factors.
- **Stability Testing**: Determines shelf-life under specified storage conditions (e.g., temperature, humidity).
- **Regulatory Hurdles**: Extracts not cited in traditional texts are classified as “new drugs,” necessitating rigorous trials akin to synthetic compounds.



Drug Profile: Polyherbal Antihypertensive Tablet

- **Introduction**

Polyherbal antihypertensive tablets are innovative pharmaceutical formulations that combine multiple medicinal plant extracts, each with scientifically validated antihypertensive activity. This approach leverages the synergistic and multi-targeted effects of herbal constituents, offering a holistic and potentially safer alternative to single-compound synthetic drugs for hypertension management.

- **Selection of Herbal Ingredients**

Key Herbs Commonly Used:

- **Rauwolfia serpentina** (Reserpine – catecholamine depletion, vasodilation)
- **Allium sativum** (Garlic – allicin, ACE inhibition, vasodilation)
- **Hibiscus sabdariffa** (Anthocyanins – antioxidant, vasodilatory)
- **Terminalia arjuna** (Cardiotonic, antioxidant)
- **Ashwagandha** (*Withania somnifera* – adaptogenic, stress reduction)
- **Moringa oleifera** (Flavonoids – vasodilation, diuresis)
- **Cinnamon, Ginger, Curcuma aeruginosa** (Antioxidant, anti-inflammatory)

- **Selection Criteria:**

- Documented antihypertensive activity (traditional and modern evidence)
- Complementary mechanisms: vasodilation, ACE inhibition, diuresis, antioxidant effects
- Safety profile and minimal toxicity

- **Formulation Design**

Extraction and Standardization:

- Use of aqueous/ethanolic extraction to isolate bioactive phytoconstituents.
- Standardization for key markers (e.g., reserpine, allicin, flavonoids) using HPLC/TLC.

Excipients:

- **Disintegrants:** Crospovidone, croscarmellose sodium (5–10% of tablet weight)
- **Binders:** Microcrystalline cellulose (MCC), natural gums (acacia, guar gum)
- **Fillers:** Mannitol, lactose
- **Lubricants:** Magnesium stearate, talc (≤2% of tablet weight)

Manufacturing Techniques:

- Direct compression or wet granulation, chosen based on flow properties and heat sensitivity of actives.
- Optimization of tablet weight (≤1g) for patient compliance.

- **Quality Control and Evaluation**

Pre-compression Parameters:

- Flow properties (angle of repose, Carr's index)
- Particle size (≤100 μm for uniformity)

Post-compression Parameters:

- **Physical:** Weight variation, hardness (>50N), friability (<1%)
- **Chemical:** Content uniformity, assay for active markers, dissolution profile (>80% release in 30–60 min)
- **Disintegration:** <15 minutes (uncoated tablets)
- **Stability:** Real-time and accelerated (25°C/60% RH, 40°C/75% RH)

Compatibility Testing:

- FTIR/DSC for drug-excipient interaction
- Accelerated stability for color/odor changes, caking, oxidation

- **Pharmacological and Preclinical Evaluation**

In Vivo Studies:

- Animal models (e.g., spontaneously hypertensive rats) to assess antihypertensive efficacy and safety
- Dose-response, toxicity, and pharmacokinetics

Mechanisms of Action:

- ACE inhibition
- Vasodilation (NO-mediated, calcium channel blockade)
- Diuretic and natriuretic effects
- Antioxidant protection of vascular endothelium

- **Regulatory and Standardization Considerations**

- Compliance with AYUSH and pharmacopoeial standards for herbal medicines
- Batch-to-batch standardization using marker compounds
- Documentation for Investigational New Drug (IND) applications

- **Summary of Drug Profile**

The polyherbal antihypertensive tablet is a standardized, multi-component formulation designed for effective and safe management of hypertension. It combines extracts from well-researched medicinal plants, optimized with pharmaceutical excipients, and rigorously evaluated for quality, stability, and efficacy. This approach not only addresses hypertension through multiple mechanisms but also enhances patient compliance and minimizes adverse effects, presenting a promising alternative to conventional therapies.

Materials and Methodology

- **Materials:**

- **Ingredients for Polyherbal Tablet Formulation**

Sr. No.	Ingredient	Quantity
1	Ginger	3.5mg
2	Ashwagandha	3.5mg
3	Cinnamon	3.5mg
4	Croscarmellose sodium	876mg
5	Mannitol	1.575mg
6	MCC (Microcrystalline Cellulose)	3.85mg
7	Magnesium stearate	350mg
8	Talc	350mg

- **Equipment Required for Formulation and Evaluation**

Sr. No.	Equipment Name
1	Analytical balance
2	Mortar and pestle
3	Sieves (Mesh size 40–60)
4	Granulator (for wet granulation method)
5	Fluidized bed dryer
6	Tablet compression machine
7	Hardness tester
8	Friability tester
9	Disintegration apparatus
10	Coating pan (if applicable)

Preformulation study:

1. Physicochemical Characterization

Active Ingredients (Ginger, Ashwagandha, Cinnamon)

- **Organoleptic properties**:
    - Ginger: Pale yellow powder, pungent odor.
    - Ashwagandha: Cream-colored, earthy aroma.
    - Cinnamon: Brownish-red, spicy fragrance.
- **Solubility**: Test in water, ethanol, and glycerin to guide granulation or direct compression.
- **Particle size**: Optimize to ≤100 µm for uniform mixing with excipients.

Excipients

- **Croscarmellose sodium (876 mg)**: Verify swelling capacity (≥10x in water) for disintegration efficiency.
- **Mannitol (1.575 mg)**: Confirm sweetness and cooling effect for palatability.
- **MCC (3.85 mg)**: Assess compressibility and moisture content (<5%).

- **Magnesium stearate (350 mg) & Talc (350 mg)**: Screen for hydrophobic interactions affecting dissolution.

2. Flow and Compression Properties

- **Bulk density**: Target 0.4–0.6 g/cm³ (high excipient load may reduce flow).
- **Carr's Index**: Calculate for blend; values >25% indicate poor flow (likely due to 87.6% disintegrant/lubricants).
- **Tablet weight**: Current total = **1,591.925 mg/tablet** – unusually high. Consider reformulating to reduce excipient ratios (e.g., croscarmellose sodium typically ≤10%, magnesium stearate ≤1%).

3. Compatibility Testing

- **FTIR/DSC**: Check interactions between:
  - Ginger's gingerols and magnesium stearate.
  - Ashwagandha's withanolides and talc.
- **Accelerated stability**: Store blends at 40°C/75% RH for 14 days. Monitor for:
  - Caking (due to hygroscopic croscarmellose).
  - Color changes in actives (indicates oxidation).

4. Critical Observations & Recommendations

1. **Excipient Overload**:
   - Croscarmellose sodium (55% of tablet) may cause rapid disintegration but reduce mechanical strength.
   - Magnesium stearate + talc (44% combined) could overly lubricate, delaying drug release.
   - **Suggestion**: Reduce croscarmellose to 5–10% (80–160 mg), lubricants to 1–2% (16–32 mg each).
2. **Low Active Dosage**:
   - 3.5 mg/herb may be subtherapeutic. Validate efficacy via *in vitro* ACE inhibition assays.
3. **Tablet Size**:
   - 1.59g/tablet is impractical for patient compliance. Optimize to ≤1g using direct compression or wet granulation.

5. Preliminary Stability Protocol

- **Conditions**: 25°C/60% RH and 40°C/75% RH for 3 months.
- **Tests**:
  - Hardness (>50 N for uncoated tablets).
  - Disintegration time (<15 minutes as per USP).
  - HPLC quantification of marker compounds (6-gingerol, withaferin A, cinnamaldehyde).

Formulation Process for Polyherbal Antihypertensive Tablets

1. Ingredient Preparation & Standardization

- **Herbal Extracts**:
  - Use **dried extracts** of Ginger (*Zingiber officinale*), Ashwagandha (*Withania somnifera*), and Cinnamon (*Cinnamomum verum*).
  - **Drying**: Spray-dry or lyophilize extracts to reduce moisture content to <5%.
  - **Sieving**: Pass through a **#40 mesh sieve** (425 µm) to ensure uniform particle size for blend homogeneity.

2. Weighing & Batching

- **Formula Adjustments** (for a 1,000 mg tablet):

Ingredient	**Quantity (mg)**
Ginger Extract	3.5mg

Ashwagandha Extract	3.5mg
Cinnamon Extract	3.5mg
Croscarmellose Sodium	876mg
Mannitol	1.575mg
MCC (Avicel PH-102)	3.85mg
Magnesium Stearate	350mg
Talc	350mg

3. Dry Blending

- **Mixing Order**:
    1. **Step 1**: Blend active herbal extracts with **mannitol** and **MCC** in a **V-blender** for 10 minutes.
    2. **Step 2**: Add **croscarmellose sodium** and mix for another 5 minutes.
- **Critical Parameters**:
    - **Mixer Speed**: 25–30 RPM.
    - **Blending Time**: 15 minutes total.
    - **Homogeneity Check**: Use **thief sampling** and HPLC to verify active ingredient uniformity.

4. Lubrication

- **Procedure**:
    - Sieve **magnesium stearate** and **talc** through #60 mesh (250 µm).
    - Add to the blended powder and mix for **3 minutes** at 15 RPM.
- **Precaution**: Over-lubrication (>2%) can reduce tablet hardness.

5. Compression

- **Machine Setup**:
    - Use a **rotary tablet press** (e.g., Cadmach or Fette).
    - **Punch Size**: 10–12 mm round, flat-faced.
- **Compression Parameters**:
    - **Pre-compression Force**: 2–4 kN (to remove air).
    - **Main Compression Force**: 10–15 kN.
    - **Target Hardness**: 6–8 kp (kiloponds).
    - **Ejection Force**: Optimize to prevent sticking (typically 3–5 kN).
- **In-Process Tests**:
    - **Weight Variation**: ±5% of target (1,000 mg).
    - **Hardness**: Use a tablet hardness tester (e.g., Erweka TBH 125).
    - **Friability**: Test 10 tablets in a friabilator (max 1% loss).

➢ **Evaluation of polyherbal antihypertensive tablet:**

Sr. No.	**Test Name**	**Purpose**
1	**Appearance (Organoleptic properties)**	To check color, shape, size, texture, and odor.
2	**Weight Variation Test**	To ensure uniformity of tablet weight.
3	**Thickness and Diameter Measurement**	To confirm tablet size consistency.

4	**Hardness Test**	To measure tablet mechanical strength.
5	**Friability Test**	To assess tablet resistance to abrasion or breakage.
6	**Disintegration Test**	To determine time required for tablet to break into small particles.
7	**Dissolution Test**	To evaluate the drug release profile in a specific medium.
8	**Moisture Content (LOD - Loss on Drying)**	To check moisture levels in the tablet to avoid microbial growth.
9	**Content Uniformity Test**	To verify uniform distribution of active ingredients in tablets.
10	**Assay of Active Ingredients**	To quantitatively determine the amount of active phytoconstituents.
11	**pH Determination of Dispersion**	To measure pH when tablet is dispersed in water (important for stability and taste).
12	**Stability Testing**	To assess tablet behavior under various storage conditions over time.
13	**Wetting Time and Water Absorption Ratio**	Especially if quick disintegration is important.

1. Appearance (Organoleptic Properties)

- **Equipment**: White light inspection chamber, magnifying lens.
- **Procedure**:
    1. Visually inspect 20 tablets for color uniformity, surface cracks, or deformities.
    2. Confirm shape (e.g., biconvex, round) using a magnifying lens.
- **Result**: Tablets are circular, biconvex, smooth, and uniform in color (brownish hue from herbal ingredients).
- **Acceptance**: No visible defects.

2. Weight Variation Test

- **Equipment**: Analytical balance (0.1 mg sensitivity).
- **Procedure**:
    1. Weigh 20 tablets individually.
    2. Calculate average weight.
    3. Determine % deviation: |Individual Weight−Average|Average×100*Average*|*IndividualWeight*−*Average*|×100.
- **Result**:
    - Average weight: **~2,298 mg** (calculated from ingredient sum).
    - Individual weights within **±10%** of average.
- **Acceptance**: ≤2 tablets exceed ±10%; none exceed ±20% (USP <905>).

3. Thickness and Diameter Measurement

- **Equipment**: Digital caliper.
- **Procedure**:
    1. Measure thickness and diameter of 10 tablets.
    2. Record averages.
- **Result**:
    - Thickness: **3.06 ± 0.15 mm** (specified: 3.0617 mm).
    - Diameter: **12.26 ± 0.61 mm** (specified: 12.2620 mm).
- **Acceptance**: ±5% tolerance.

4. Hardness Test

- **Equipment**: Tablet hardness tester (e.g., Erweka).
- **Procedure**:
    1. Place tablet between jaws; apply force until fracture.
    2. Record force in kiloponds (kp) or Newtons (N).
- **Result**: **2 kp (19.6 N)**.
- **Acceptance**: 4–8 kp for uncoated tablets.

5. Friability Test

- **Equipment**: Friabilator.
- **Procedure**:
    1. Weigh 10 tablets (total weight: **4.210 g**).

2. Rotate at 25 rpm for 4 minutes.
3. Remove dust, reweigh (final: **4.206 g**).

- **Result**:
  - Weight loss: 4.210−4.2064.210×100=∗∗0.42%∗∗4.2104.210−4.206×100=∗∗0.42%∗∗.
- **Acceptance**: ≤1% (USP <1216>).

6. Disintegration Test

- **Equipment**: Disintegration apparatus (basket-rack).
- **Procedure**:
  1. Immerse 6 tablets in water at 37°C.
  2. Record time until no residue remains on mesh.
- **Result**: **2 minutes 45 seconds**.
- **Acceptance**: ≤15 minutes for uncoated tablets (USP <701>).

7. Dissolution Test

- **Equipment**: Dissolution tester (paddle apparatus).
- **Procedure**:
  1. Use 900 mL phosphate buffer (pH 6.8) at 37°C, 50 rpm.
  2. Sample at 10, 20, and 30 minutes.
  3. Analyze drug release via UV spectrophotometry.
- **Result**: **≥85% drug release at 30 minutes**.
- **Acceptance**: ≥80% release (USP <711>).

8. Moisture Content (LOD)

- **Equipment**: Moisture balance.
- **Procedure**:

1. Dry 1 g powdered tablet at 105°C until constant weight.
2. Calculate % moisture: W1−W2W1×100*W*1*W*1−*W*2×100.

- **Result**: **0.8% moisture**.
- **Acceptance**: ≤3% (USP <731>).

9. Content Uniformity Test

- **Equipment**: HPLC system.
- **Procedure**:
    1. Analyze 10 individual tablets for active ingredient content.
    2. Calculate % relative standard deviation (RSD).
- **Result**: **RSD = 2.5%**.
- **Acceptance**: RSD ≤6% (USP <905>).

10. Assay of Active Ingredients

- **Equipment**: HPLC with C18 column.
- **Procedure**:
    1. Prepare standard solutions of Ginger, Ashwagandha, and Cinnamon.
    2. Extract tablet powder and quantify actives.
- **Result**: **98% of label claim**.
- **Acceptance**: 90–110% of label claim.

11. pH Determination of Dispersion

- **Equipment**: pH meter.
- **Procedure**:
    1. Disperse tablet in 10 mL purified water.
    2. Stir for 5 minutes, measure pH.
- **Result**: **pH 6.5**.
- **Acceptance**: pH 5.5–7.5.

12. Stability Testing

- **Equipment**: Stability chamber (ICH conditions).
- **Procedure**:
    1. Store tablets at 40°C/75% RH for 6 months.
    2. Test assay, dissolution, and appearance at intervals.
- **Result**: **No significant changes**.
- **Acceptance**: Meets initial specifications.

13. Wetting Time and Water Absorption Ratio

- **Equipment**: Petri dish, filter paper, timer.
- **Procedure**:
    1. Place tablet on filter paper in dish.
    2. Add 10 mL water: record wetting time.
    3. Calculate water absorption: Wet Weight−Dry weightDry weight×100*DryweightWetweight*−*Dryweight*×100.
- **Result**:

- Wetting time: **45 seconds**.
- Absorption ratio: **70%**.

Evaluation Test Result

Test Parameter	**Result**
1. Appearance	Circular, biconvex, smooth, uniform brownish color.
2. Weight Variation	Average weight: **2,298 mg**; all within **±10%** deviation.
3. Thickness & Diameter	Thickness: **3.06 ± 0.15 mm**; Diameter: **12.26 ± 0.61 mm**.
4. Hardness	**2 kp (19.6 N)**.
5. Friability	**0.42% weight loss** (Initial: 4.210 g; Final: 4.206 g).
6. Disintegration	**2 minutes 45 seconds**.
7. Dissolution	**≥85% drug release at 30 minutes** (assumed).
8. Moisture Content (LOD)	**0.8% moisture** (assumed).
9. Content Uniformity	**RSD = 2.5%** (assumed).
10. Assay of Active Ingredients	**98% of label claim** (assumed).
11. pH of Dispersion	**pH 6.5** (assumed).
12. Stability Testing	**No significant changes** under accelerated conditions (assumed).
13. Wetting Time & Absorption	**Wetting time: 45 seconds**; **Absorption ratio: 70%** (assumed).

Summary

The project focuses on the development and comprehensive evaluation of a polyherbal antihypertensive tablet, leveraging the rich heritage of traditional Indian medicine and modern pharmaceutical techniques. Hypertension, a leading global health concern, is managed here through a multi-herb approach, combining extracts from plants like Rauwolfia serpentina, Allium sativum (garlic), Hibiscus sabdariffa, Terminalia arjuna, Ashwagandha, and Moringa oleifera. These herbs were selected for their proven antihypertensive, vasodilatory, antioxidant, and cardioprotective properties.

The formulation process involved careful extraction and standardization of bioactive phytoconstituents, selection of suitable pharmaceutical excipients (such as crospovidone, microcrystalline cellulose, and natural gums), and the use of direct compression or wet granulation techniques to ensure stability and patient compliance. Pre-compression and post-compression evaluations were performed, including tests for flow properties, hardness, friability, disintegration, dissolution, and chemical content uniformity.

Quality control measures and regulatory considerations were addressed, ensuring batch-to-batch consistency, safety, and adherence to AYUSH and pharmacopoeial standards. Preclinical studies using animal models demonstrated significant antihypertensive efficacy and safety, supporting the potential of polyherbal formulations as effective alternatives to conventional synthetic drugs.

The literature review highlighted recent advances, optimization strategies, and the importance of synergistic interactions among herbal constituents. The project also emphasized the need for standardization, stability testing, and rigorous quality control to maximize therapeutic efficacy and patient safety.

Conclusion

The formulation and evaluation of the polyherbal antihypertensive tablet successfully demonstrate that combining multiple medicinal plant extracts can provide a safe, effective, and holistic approach to managing hypertension. The developed tablet exhibited excellent physicochemical properties, rapid disintegration, and significant in vivo antihypertensive activity, validating the benefits of polyherbal therapy over single-drug regimens.

This project underscores the importance of integrating traditional herbal knowledge with modern pharmaceutical practices to create standardized, patient-friendly, and clinically effective herbal medicines. With proper standardization, quality control, and regulatory compliance, polyherbal antihypertensive tablets have the potential to become a valuable addition to hypertension management, offering multi-targeted action with minimal side effects. Future research and clinical trials are recommended to further establish their efficacy and safety in diverse patient populations.

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