

Formulation And Evaluation of Polyherbal Oral Disintegrating Tablet for The Treatment of Hypertension: A Comprehensive Review

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Abstract- Hypertension is a chronic cardiovascular disorder characterized by elevated blood pressure and is considered one of the leading causes of mortality worldwide. Conventional antihypertensive drugs are effective but are often associated with adverse effects such as dizziness, fatigue, electrolyte imbalance, and poor patient compliance. Herbal medicines have gained increasing attention due to their natural origin, safety, and therapeutic efficacy. The present review focuses on the formulation and evaluation of polyherbal oral disintegrating tablets (ODTs) using *Terminalia arjuna* bark and *Withania somnifera* root for the management of hypertension. *Terminalia arjuna* possesses cardioprotective, antioxidant, anti-inflammatory, and antihypertensive properties, while *Withania somnifera* exhibits adaptogenic, anti-stress, and cardiogenic activities. Oral disintegrating tablets are advantageous because they disintegrate rapidly in saliva without water, improving patient compliance, especially in geriatric patients. This review discusses hypertension, herbal management, phytochemistry, formulation methods, evaluation parameters, mechanisms of action, and future prospects of polyherbal ODTs.

Keywords: Hypertension, Polyherbal formulation, Oral disintegrating tablets (ODTs), *Terminalia arjuna*, Herbal medicine, Superdisintegrants

I. INTRODUCTION

Hypertension is a major public health issue affecting millions of people globally. It is commonly known as high blood pressure and contributes significantly to cardiovascular diseases such as stroke, myocardial infarction, renal failure, and heart disease. Modern lifestyle factors including stress, obesity, sedentary habits, smoking, alcohol consumption, and unhealthy diet are major contributors to hypertension.

Synthetic antihypertensive medications including beta blockers, calcium channel blockers, ACE inhibitors, and diuretics are widely prescribed for blood pressure control. However, long-term therapy may produce adverse effects and poor patient adherence. Herbal medicines are increasingly being explored as safer alternatives because of their minimal side effects and holistic therapeutic benefits.

Terminalia arjuna has long been used in Ayurveda as a cardiogenic herb. Its bark contains flavonoids, tannins, triterpenoids, and glycosides that improve cardiovascular function and vascular health. *Withania somnifera*, commonly known as Ashwagandha, is an adaptogenic herb that reduces stress-induced hypertension and improves cardiac performance.

Oral disintegrating tablets (ODTs) are solid dosage forms that rapidly disintegrate in the oral cavity without water. These dosage forms improve patient compliance, especially among geriatric and hypertensive patients with swallowing difficulties.

1.1 Hypertension

Hypertension is defined as a persistent increase in systolic blood pressure above 140 mmHg and diastolic blood pressure above 90 mmHg.

1.2 Classification of Hypertension

Category	Systolic BP	Diastolic BP
Normal	<120 mmHg	<80 mmHg
Elevated	120–129 mmHg	<80 mmHg

Category	Systolic BP	Diastolic BP
Stage 1 Hypertension	130–139 mmHg	80–89 mmHg
Stage 2 Hypertension	≥140 mmHg	≥90 mmHg
Hypertensive Crisis	≥180 mmHg	≥120 mmHg

- Cost-effective
- Natural origin
- Synergistic activity

Common medicinal plants used in hypertension include:

- Terminalia arjuna
- Withania somnifera
- Rauwolfia serpentina
- Allium sativum
- Ocimum sanctum

1.3 Causes of Hypertension

- Genetic factors
- Obesity
- Stress
- High salt intake
- Smoking
- Alcohol consumption
- Sedentary lifestyle
- Kidney disorders

III. PROFILE OF TERMINALIA ARJUNA

1.4 Symptoms

- Headache
- Dizziness
- Fatigue
- Palpitations
- Chest pain
- Shortness of breath

3.1 Biological Source

Terminalia arjuna consists of dried bark of the plant belonging to family Combretaceae.

1.5 Complications

- Stroke
- Heart failure
- Renal failure
- Retinopathy
- Coronary artery disease

3.2 Taxonomical Classification

Category Classification

Kingdom Plantae

Family Combretaceae

Genus Terminalia

Species Terminalia arjuna

II. HERBAL MANAGEMENT OF HYPERTENSION

Medicinal plants have been extensively used in traditional systems for cardiovascular disorders. Herbal medicines possess antioxidant, anti-inflammatory, vasodilatory, and cardioprotective activities.

Advantages of Herbal Medicines

- Fewer side effects
- Better patient compliance

3.3 Phytochemical Constituents

- Flavonoids
- Tannins
- Saponins
- Glycosides
- Arjunolic acid
- Triterpenoids

3.4 Pharmacological Activities

- Cardioprotective activity
- Antioxidant activity
- Antihypertensive activity
- Anti-inflammatory activity
- Hypolipidemic activity

3.5 Mechanism of Action

Terminalia arjuna improves endothelial function, induces vasodilation, and reduces oxidative stress.

IV. PROFILE OF WITHANIA SOMNIFERA

4.1 Biological Source

Withania somnifera consists of dried roots of the plant belonging to family Solanaceae.\

4.2 Common Names

- Ashwagandha
- Indian Ginseng
- Winter Cherry

7.3 Phytochemical Constituents

- Withanolides
- Alkaloids
- Steroidal lactones
- Flavonoids

4.4 Pharmacological Activities

- Adaptogenic activity
- Anti-stress activity
- Antioxidant activity
- Cardioprotective activity

4.5 Mechanism of Action

Ashwagandha reduces stress hormones and improves autonomic balance, thereby lowering blood pressure.

V. POLYHERBAL CONCEPT

Polyherbal formulations contain more than one medicinal herb to produce synergistic therapeutic effects.

Advantages

- Improved efficacy
- Reduced toxicity

- Multiple mechanisms of action
- Better therapeutic effect

The combination of *Terminalia arjuna* and *Withania somnifera* provides cardioprotection, stress reduction, antioxidant activity, and blood pressure control.

VI. ORAL DISINTEGRATING TABLETS (ODTS)

ODTs are tablets that rapidly disintegrate in the mouth without water.

6.1 Advantages

- Rapid onset of action
- Easy administration
- Improved patient compliance
- Suitable for geriatric patients

6.2 Disadvantages

- Moisture sensitivity
- Fragility
- Taste masking problems

VII. SUPERDISINTEGRANTS USED IN ODTs

Superdisintegrant	Function
Crospovidone	Rapid swelling
Sodium starch glycolate	Water uptake
Croscarmellose sodium	Fast disintegration

VIII. METHODS OF PREPARATION

8.1 Direct Compression

Direct compression involves direct compression of powders into tablets without granulation.

Advantages

- Simple method
- Cost effective
- Suitable for heat-sensitive drugs

8.2 Wet Granulation

Wet granulation uses liquid binders to form granules.

Advantages

- Better compressibility
- Uniform granules

8.3 Dry Granulation

Dry granulation forms granules without liquid binders.

Advantages

- Suitable for moisture-sensitive drugs.
- Less processing time.

IX. EXTRACTION METHODS

9.1 Maceration

Plant material is soaked in solvent for extraction.

9.2 Soxhlet Extraction

Continuous hot extraction technique.

9.3 Hydroalcoholic Extraction

Uses ethanol-water mixture for extraction of phytochemicals.

X. FORMULATION INGREDIENTS

Ingredient	Role
Terminalia arjuna extract	Antihypertensive
Withania somnifera extract	Adaptogen
MCC	Diluent
Croscopovidone	Superdisintegrant
Aspartame	Sweetener
Talc	Glidant
Magnesium stearate	Lubricant

XI. GENERAL METHOD OF PREPARATION OF POLYHERBAL ORAL DISINTEGRATING TABLETS

11.1. Extraction of Herbal Drugs

The crude drugs such as Terminalia arjuna (bark) and Withania somnifera (root) are subjected to extraction using suitable methods like maceration, Soxhlet extraction, or hydroalcoholic extraction. This step helps in isolating the active phytoconstituents responsible for antihypertensive activity.

11.2. Drying and Sieving

The obtained extracts are dried using tray dryer or vacuum dryer to remove residual moisture. The dried mass is then passed through a suitable sieve (e.g., sieve no. 40) to obtain uniform particle size, which improves flow properties and mixing.

11.3. Mixing of Ingredients

The dried herbal extracts are accurately weighed and mixed with excipients such as diluents (e.g., microcrystalline cellulose) and sweetening agents. Proper blending ensures uniform distribution of active constituents throughout the formulation.

11.4. Addition of Superdisintegrants

Superdisintegrants like croscopovidone, sodium starch glycolate, or croscarmellose sodium are added to the mixture. These agents promote rapid disintegration of tablets in the oral cavity by swelling and wicking action.

11.5. Lubrication

Lubricants such as magnesium stearate and glidants like talc are added to the blend. This step reduces friction during compression and prevents sticking of powder to punches and dies.

11.6. Compression into Tablets

The final blend is compressed into tablets using a tablet compression machine. Appropriate pressure is

applied to obtain tablets with desired hardness, thickness, and uniformity.

XII. EVALUATION PARAMETER

12.1. Pre compression parameter

1. Angle of Repose

Angle of repose is defined as the maximum angle formed between the surface of a pile of powder and the horizontal plane. It indicates the flow property of powder; smaller angle means better flow.

Where:

- h = height of powder heap
- r = radius of heap

Determines flow property.

$$\tan \theta = h/r$$

2. Bulk Density

Bulk density is the ratio of the mass of powder to its bulk volume (including void spaces). It indicates packing ability.

$$\text{Bulk Density} = M / V_b$$

Where:

- M = mass of powder
- V_b = bulk volume

3. Tapped Density

Tapped density is the ratio of mass of powder to the volume occupied after tapping. It indicates packing after settling.

$$\text{Tapped Density} = \text{Mass of powder} / \text{Tapped volume}$$

4. Carr's Index (Compressibility Index)

Carr's index indicates compressibility and flowability of powder. Lower values indicate better flow.

$$\text{Carr's Index} = (TD - BD) \times 100 / TD$$

Where:

- TD = tapped density
- BD = bulk density

5. Hausner Ratio

Hausner ratio is the ratio of tapped density to bulk density and indicates flow characteristics of powder.
 Hausner Ratio = Tapped density / Bulk density

12.2. Post-Compression Evaluation parameter of Tablet

1. Thickness

Thickness is the measurement of the tablet's size, ensuring uniformity in production. Vernier caliper / Digital micrometer is used to measure thickness of tablet.

2. Hardness

Hardness is the force required to break a tablet by compression. It indicates the mechanical strength of the tablet. Monsanto hardness tester / Pfizer hardness tester are used for hardness testing.

3. Friability

Friability measures the tablet's ability to resist abrasion during handling and transportation. Acceptable friability is less than 1%, Roche friabilator is used to measure the friability.

4. Weight Variation

Weight variation test is used to determine the uniformity of weight of tablets to ensure that each tablet contains a consistent amount of drug.

Average weight of tablet	% Deviation Allowed
≤ 80 mg	$\pm 10\%$
80 mg – 250mg	$\pm 7.5\%$
≥ 250 mg	$\pm 5\%$

5. Wetting Time

Wetting time is the time required for a tablet to become completely wet when placed in a liquid medium.

Petri dish with tissue paper method is used (no specialized instrument required, stopwatch is used)

6. Disintegration Time

Disintegration test is used to determine the time required for a tablet to break down into smaller particles under specified conditions.

The test measures how quickly a tablet disintegrates in a liquid medium at controlled temperature, simulating conditions in the gastrointestinal tract or oral cavity. Disintegration test apparatus is used to measure disintegration.

7. Drug Content

Drug content determines the amount of active ingredient present in the tablet and ensures dosage accuracy.

Drug Content= (Actual Amount/Theoretical Amount) ×100

UV-visible spectrophotometer is used to find out the drug content.

8. In-vitro Dissolution Study

In-vitro dissolution test is used to determine the rate and extent of drug release from a tablet into a dissolution medium under controlled laboratory conditions.

The tablet is placed in a suitable liquid medium maintained at body temperature, and the amount of drug released over time is measured to predict its availability in the body.

USP Dissolution apparatus (Type I – Basket, Type II – Paddle) is used for dissolution test

9. Pharmacological Evidence

Studies have demonstrated that Terminalia arjuna possesses cardioprotective and antihypertensive activities through vasodilation and antioxidant action. Withania somnifera reduces stress-induced hypertension and improves autonomic balance.

Some online community discussions also note gradual cardiovascular wellness support associated with Arjuna-based herbal preparations, although such anecdotal experiences should not replace medical evidence or physician guidance.

10. Future Prospects

Polyherbal oral disintegrating tablets offer a promising alternative for hypertension management. Future advancements in herbal standardization, nanotechnology, and bioavailability enhancement may improve therapeutic outcomes.

11. Conclusion

The present review highlights the potential of polyherbal oral disintegrating tablets containing Terminalia arjuna bark and Withania somnifera root for the treatment of hypertension. Both medicinal plants possess cardioprotective, antioxidant, anti-inflammatory, and antihypertensive properties. Oral disintegrating tablets improve patient compliance through rapid disintegration and easy administration. Polyherbal formulations provide synergistic therapeutic effects with minimal side effects. Further pharmacological and clinical investigations are necessary to establish their long-term safety and efficacy.

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