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FORMULATION AND EVALUATION OF AYURVEDIC HYPERTENSION TABLET

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Abstract:

Hypertension is common problem facing many peoples today. "Hypertension is a prevalent issue affecting numerous individuals in modern society. Despite substantial financial investments in conventional cardiovascular disease treatments, they have shown limited efficacy in reducing hypertension cases. Alternative medicine presents a viable approach to tackling the increasing prevalence of high blood pressure. Research has identified various alternative therapies, such as dietary adjustments, exercise regimens, stress management techniques, and the use of supplements and herbs, as effective in lowering blood pressure levels. Additionally, ongoing studies continue to explore the efficacy of herbal remedies for hypertension, including Ashwagandha, Amla, Clove, Garlic, Black pepper, Cinnamon, and Black cumin. This review aims to underscore the scientific evidence supporting the use of herbs in hypertension treatment prevalence of high blood pressure.

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INTRODUCTION:

Herbal medicine is the oldest form of healthcare known to mankind. Herbs had been used by all cultures Throughout history, natural products derived from plants, animals, and minerals have served as the foundation for treating various human ailments. Presently, an estimated 80% of individuals in developing nations rely on traditional medicine, predominantly sourced from plant and animal species, for primary healthcare needs. The demand for herbal medicines is steadily increasing, with approximately 500 plants referenced for their medicinal properties in ancient texts and around 800 plants utilized in indigenous medical systems. India, particularly, boasts a rich reservoir of medicinal plants integral to traditional healing practices.

A Numerous traditional herbal medical practices have been integrated into modern healthcare for diagnosing, preventing, and treating various diseases. Many of these practices have been scientifically validated, shedding light on the rationale behind their traditional usage. This validation aims to substantiate the scientific basis underlying their traditional adoption. The preference for drugs of natural origin is often attributed to their lower toxicity, enhanced therapeutic efficacy, improved patient adherence, and cost-effectiveness. Tablets represent a versatile dosage form with several advantages, including oral drug administration without the need for water, ease of ingestion, the stability benefits of solid dosage forms, and patient-centered drug delivery."

Aim & Objective:

The aim of present study is to formulate Ayurvedic tablets Using various Ayurvedic Drugs by direct compression method and to evaluate the formulation for various pharmaceutical parameters.

"The oral route stands out as one of the most favored methods of drug delivery owing to its simplicity in administration, patient compliance, minimal sterility requirements, and the adaptability of dosage form designs."

The aim of this preparation of Ayurvedic tablets for the hypertension with more efficacy and safety with minimum side effects. These Tables are required to be swallow with water. Numerous OTC medications are available in community pharmacies for hypertension and Digestion but, Herbal drugs acts with negligible side effects.

Tablets are evaluated by chemical and physical evaluation methods. Physical methods that include appearance, Hardness, Friability, Disintegration, Dissolution and chemical methods include drug content, Dosage uniformity.

Characteristics of Tablet

1. Solid Form: Tablets are solid pharmaceutical dosage forms.
2. Ease of Administration: They are convenient to administer orally.
3. Precise Dosing: Tablets allow for accurate dosing, ensuring uniformity across units.

4.Stability: They offer good stability, protecting active ingredients from degradation.

5.Customization: Tablets can be modified for various drug release profiles.

6.Cost-Effectiveness: They are generally economical to manufacture and distribute

7.Appropriate size & shape

8.Are simple and helpful to take Improve consistence

Advantages:

Tablets are unit dosage form and offer the greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability.

1. They are easiest and cheapest to package and strip.
2. Low in cost.
3. Lighter and compact.
4. Having greatest chemical and microbial stability over all oral dosage forms.
5. Suitable for large scale production.
6. Easy to swallow with least tendency for hang-up.
7. Objectionable odour and bitter taste can be masked by coating technique.
8. Sustained release product is possible by enteric coating.
9. Easy to handling.
10. Patient convenience.

Disadvantages:

1. Difficult to swallow in case of children and unconscious patients.
2. Some drugs resist compression into dense compacts, owing to amorphous nature, low density character.
3. Bitter testing drugs, drugs with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, capsule may offer the best and lowest cost.
4. Irritant effects on the GI mucosa by some solids (e.g., aspirin).
5. Possibility of bioavailability problems resulting from slow disintegration and

dissolution.

6. The tablets have lower mechanical quality, so cautious dealing with in packaging and Transportation.

MATERIAL AND METHODS:

Material:

Ashwagandha Powder, Amla Powder, Clove churna, Garlic, Black pepper Powder, Cinnamon Powder, and Black cumin churna were obtained from the Medical Store, local market and Shop in the City Chh. Sambhajinagar District.

All excipients Microcrystalline cellulose (MCC), Dibasic calcium phosphate, Peg 4000, Methyl paraben taken from College Practical Store House. All ingredients used were of analytical grade.

PREPARTION OF POWDERS:

Tablets containing Ashwagandha, Amla, Clove Churna, Garlic, Black pepper Powder, Cinnamon Powder, and Black cumin Churna. were prepared by direct compression method. Other ingredients Microcrystalline cellulose (MCC), Dibasic calcium phosphate, Peg 4000, Methyl Paraben.

The excipient along with API weighed as shown in Table 1 and passed through sieve no. 20. Then, all ingredients were mixed following geometric mixing excluding lubricant thoroughly for 15 min. The powder blend was thoroughly mixed with gum acacia, Talcum powder compressed into a 500 mg tablet using single rotatory punching machine.

Formulation and Composition

Formula:

Ashwagandha Powder: 60mg , Amla Powder: 100mg,
Clove Churna:110mg , Garlic:50mg,
Black pepper Powder:40mg , Cinnamon Powder:40mg ,
Black cumin Churna:4 0mg , Excipients:60mg

DIRECT COMPRESSION METHOD

Direct compression is the most popular choice because it provides the shortest, most effective and least complex way to produce tablets. This method is mainly used when a group of ingredients can be blended. This is more suitable for moisture and heat sensitive API.

Tablets of Ashwagandha Powder, Amla Powder, Clove Churna, Garlic, Black pepper Powder, Cinnamon Powder, and Black cumin Churna

by direct compression method as per the composition.

DIRECT COMPRESSION METHOD:

1] Sieving :

The active ingredients was passed through the sieve # 40. The other ingredients given in the formulation table were passed separately through the same sieve.

2] Dry mixing: All the materials (including the active ingredient) were weighed and taken in a Vessel and mixed for 10 minutes.

3] Lubrication : The magnesium stearate was passed through the sieve # 60 and mixed together with the powder mixture in a polybag for 5 minutes to get a uniform blend.

4] Compression : Finally, the powder mixture was compressed into tablets using single rotatory punching machine to prepare tablets each weighing ---mg.

5] Packing : The prepared tablets were packed in closed container.

Table No. 1

Sr.no	Name of Ingredients	Quantity Taken
1	Ashwagandha Powder	60 mg
2	Amla Powder	100 mg
3	Clove Churna	110mg
4	Garlic	50mg
5	Black pepper Powder	40mg
6	Cinnamon Powder	40mg
7	Black cumin Churna	40mg
8	Microcrystalline cellulose (MCC)	30mg
9	Dibasic calcium phosphate	20mg
10	Peg 4000	10mg
11	Methyl paraben	0.1mg

Table No. 2

Sr.No	Name of Ingredients	Role
1	Ashwagandha Powder	Antidepressant
		Antioxidant
		cardioprotective
2	Amla Powder	Antioxidant
		cardiotoni
3	Clove Churna	Antihypertensive
		Antithrombotic
		Antioxidant
		Antiinflammatory
4	Garlic	Reduce blood pressure
5	Black pepper Powder	Antihypertensive
		Anti inflammatory
		Antioxidant
6	Cinnamon Powder	Improving blood pressure and circulation, and reducing blood lipid levels, like LDL cholesterol.
7	Black cumin Churna	Reduce blood pressure,
		Regulate blood sugar level
8	Microcrystalline cellulose (MCC)	Disintegrant
9	Dibasic calcium phosphate	Flowing Agent
10	Peg 4000	Binder
11	Methyl paraben	Preservative

Ingredients Information

1.Ashwagandha

Synonyms Ashwagandha,
Indian ginseng, Winter cherry

Biological Sources: Ashwagandha is o:btained from the roots and, to a lesser extent, the leaves and berries of the plant Withania somnifera.

Family: Ashwagandha belongs to the Solanaceae family.

Chemical Constituents

The primary chemical constituents of ashwagandha are:

1.Alkaloids: These include somniferine, tropine, and pseudotropine, which contribute to the plant's pharmacological activities.

2.Sitoindosides and Acylsterylglucosides: These compounds are known for their anti-stress and anti-oxidant properties.

3.Saponins: These contribute to the immunomodulatory effects of the herb. Fatty acids: Such as linoleic acid, which contribute to the overall health benefits.

These compounds collectively confer a range of therapeutic properties to ashwagandha, including adaptogenic (stress-relieving), anti-inflammatory, anti-oxidant, immunomodulatory, and neuroprotective effects.

Uses: Ashwagandha is commonly used in traditional and modern formulations for treating various health conditions, particularly those related to stress and anxiety, inflammation, and general vitality.

2. Amla

Synonyms: Amla, Indian gooseberry
Biological Sources
Amla is obtained from the fruit of the tree Phyllanthus emblica (synonym: Emblica officinalis).
Family: Amla belongs to the Phyllanthaceae family, a family of flowering plants that is part of the larger order Malpighiales.

Chemical Constituents
Cinnamaldehyde: This is the main component of cinnamon oil, contributing to its distinctive aroma and many of its health benefits.
Eugenol: Found in Ceylon cinnamon, it has antiseptic and anesthetic properties.
Coumarin: Present in higher amounts in cassia cinnamon, this compound has anticoagulant properties but can be toxic in large quantities.
Tannins: These contribute to the astringent properties of cinnamon.
Polyphenols: Including proanthocyanidins, which have strong antioxidant properties.
Terpenoids: Such as linalool and beta-caryophyllene, contributing to the spice's aroma and potential therapeutic effects.
Mucilage and Starch: Found in the bark, these contribute to its texture and nutritional properties.
Uses: Helps in reducing oxidative stress.
May reduce inflammation and pain.
May reduce risk factors like high cholesterol and blood pressure.

3.Cinnamon:

Synonyms: Cinnamon Tavk, Dalchini
Biological Sources
Cinnamon is obtained from the inner bark of trees from the genus Cinnamomum. The two most commonly used species are: Cinnamomum verum Cinnamomum cassia
Family: Lauraceae
Chemical Constituents
Cinnamaldehyde: This is the main component of cinnamon oil, contributing to its distinctive aroma and many of its health benefits.
Eugenol: Found in Ceylon cinnamon, it has antiseptic and anesthetic properties.
Coumarin: Present in higher amounts in cassia cinnamon, this compound has anticoagulant properties but can be toxic in large quantities.
Tannins: These contribute to the astringent properties of cinnamon.
Polyphenols: Including proanthocyanidins, which have strong antioxidant properties.
Terpenoids: Such as linalool and beta-caryophyllene, contributing to the spice's aroma and potential therapeutic effects.

Uses
Helps in reducing oxidative stress.
May reduce inflammation and pain.
May reduce risk factors like high cholesterol and blood pressure.
Helps in alleviating digestive issues such as indigestion, bloating, and gas

4. Black pepper

Synonyms
Black pepper, pepper
Biological Sources: Black pepper is obtained from the dried unripe fruit of Piper nigrum, a flowering vine.

Family: Piperaceae
Chemical Constituents
1. Piperine: The major active compound responsible for the pungency and many of the health benefits. Piperine enhances the

bioavailability of various nutrients and drugs.
2. Volatile Oils: Including terpenes such as pinene, sabinene, limonene, and caryophyllene, which contribute to the aroma and flavor.
3. Alkaloids: In addition to piperine, other alkaloids contribute to its pungency and potential therapeutic effects.
4. Oleoresins: Complex mixtures of oils and resins that contribute to the flavor and aroma.
5. Phenolic Compounds: Such as chavicine, which contribute to the antioxidant properties.
6. Vitamins and Minerals: Contains small amounts of vitamins (like vitamin C and vitamin K) and minerals (like iron, calcium, and magnesium).

Uses:

Commonly used in spice blends, marinades, and rubs.
Used in food preservation due to its antimicrobial properties.
Stimulates the digestive enzymes and reduces gastrointestinal distress.

5. Clove:

Synonyms Clove Lavanga, Devakusuma
Biological Sources
Clove is obtained from the dried flower buds of the tree Syzygium aromaticum.
Family: Myrtaceae
Chemical Constituents:
Eugenol: The principal compound (70-90%) responsible for clove's aroma and many of its therapeutic properties, such as analgesic, anti-inflammatory, and antimicrobial effects.
Eugenyl acetate: Contributes to the aroma and flavor.
Caryophyllene: A sesquiterpene that also contributes to the spicy aroma and has anti-inflammatory properties.
Tannins: Including gallotannic acid, which has astringent properties.
Flavonoids: Such as kaempferol, rhamnetin, and eugenin, which contribute to its antioxidant activity.

Uses:

Reduces inflammation and associated symptoms.
Commonly used in mulled wine, chai, and other spiced drinks
Used to flavor meats, curries, marinades, and baked goods.

6. Garlic

Synonyms: Garlic Lashuna, Rasona
Biological Sources: Garlic is obtained from the bulb of the plant Allium sativum. It is a perennial plant but is typically grown as an annual crop.
Family: Amaryllidaceae
Chemical Constituents
Allicin: A sulfur-containing compound responsible for the distinctive smell and many of the health benefits, formed when garlic is crushed or chopped.
Alliin: A precursor to allicin, it is converted to allicin by the enzyme alliinase when garlic is damaged.
Diallyl Disulfide: Contributes to the characteristic odor and has antimicrobial properties.
S-allyl cysteine: A stable sulfur compound with antioxidant and anti- inflammatory effects.
Vitamins and Minerals: Contains vitamins C and B6, manganese, selenium, and small amounts of calcium, potassium, iron, and phosphorus.
Flavonoids and Phenolic Compounds: These compounds contribute to its antioxidant properties.
Uses
Used to enhance the flavor of a wide variety of dishes, including meats, vegetables, soups, sauces, and dressings.
Used in the form of garlic powder, garlic salt, and garlic oil.
CHelps in lowering blood pressure, reducing cholesterol levels, and improving blood circula *Institute of Pharmacy, Badnapur*.tion.

7. Black Cumin

Synonyms: Black cumin, black seed, black caraway, kalonji
Biological Sources: Black cumin is obtained from the seeds of the plant Nigella sativa.
Family: Ranunculaceae
Chemical Constituents
Thymoquinone: The major bioactive component with antioxidant, anti- inflammatory, and anticancer properties.
Nigellone: Another important constituent with antihistaminic and bronchodilator effects.
Volatile Oils: Including p-cymene, carvacrol, and alpha-thujene, which contribute to the aromatic and therapeutic properties.
Fixed Oils: Containing essential fatty acids like linoleic acid, oleic acid, and palmitic acid.
Alkaloids: Such as nigellimine and nigellidine, which contribute to the medicinal properties.
Saponins: Including alpha-hederin, known for its potential anticancer and immune-boosting effects.

Uses
Used to treat respiratory conditions like asthma, bronchitis, and allergies
May help in regulating blood sugar levels and improving lipid profiles.
Boosts the immune system and helps in the prevention of diseases.

Pre-compression study

Pre-compressional studies of powder blend :
In development of new dosage form preformulation study is the prior step in the potential drug development. It is the principal investigation in the drug development to obtained information on the known properties of compound and the proposed development schedule. So, this preformulation investigation may merely confirm that there are no significant barriers to compound development.
Following pre-compressional parameters were studied like angle of repose, bulk density, tapped density, compressibility indices etc.

Angle of repose:
It is the maximum angle that can be obtained between the freestanding surface of powder heap and the horizontal plane. It was determined by using fixed funnel method. Specified amount of powder drug was transfer to the funnel keeping the orifice of the funnel blocked by thumb. When powder was cleared from funnel then measured its angle of repose and measured in θ.

$$\text{Angle of repose } (\theta) = \tan^{-1} h / r$$

Bulk density
It is the ratio of bulk mass of powder to the bulk volume. It is denoted homogeneity.
It is denoted by ρb . Bulk density is used to find out homogeneity.

$$\text{Bulk density } (\rho b) = M / Vb$$

Where, M is the mass of the sample, Vb is bulk volume.

Tapped density:
It is the ratio of the weight of powder to the minimum volume occupied in measuring cylinder. Tapped density is determined by placing a graduated cylinder containing a known mass of drug or formulation on a mechanical tapper apparatus which is operated at fixed no. of taps (1000) until the powder bed reached a minimum volume.

Tapped density (ρt) = Weight of powder blend / Minimum volume occupied by cylinder.

Carr's index :
Based on the apparent bulk density and the tapped density, the percentage compressibility of the powder mixture was determined by the following formula :

Carr's index = Tapped density - Bulk density × 100 / Tapped Density

Hausner's ratio:
Hausner's ratio is an indirect index of ease of measuring of powder flow. Lower Hausner's ratio (1.25).

Hausner's ratio = Tapped density / Bulk density

Table No. 3

	Parameters	Result
	Moisture content (%)	4.31
	Angle of repose (θ)	26.565 ^{0}
	Bulk density (g/ml)	0.8
	Tapped density (g/ml)	1.14
	Carr's index (%)	42.5
	Hausner's ratio	1.425

Post-compression study:

Post-compression study : (Evaluation of Prepared Tablets) :

1.General appearance :

The general appearance of tablets, its visual identity and overall elegance is essential for consumer acceptance. The tablets were checked for the presence of cracks, depressions, pinholes, uniformity of color, and the polish of the tablet.

2.Uniformity of thickness and diameter :

Vernier caliper was used to measure the thickness and diameter of the tablets. The mean valueof five determination was recorded in each case.

3.Weight variation test[12] :

Twenty tablets were weighed individually and all together.

Average weight was calculated from the total weight of all tablets. The individual weights werecompared with the average weight. The percentage difference in the weight variation should bewithin the permissible limits.

The percent deviation was calculated using the following formula:

Percentage deviation = [(Individual weight - Average weight) / Average weight] × 100

Any deviation in the weight of tablet leads to either under medication or over medication. So, every tablet in each batch should have a uniform weight. Corrections were made during the compression of tablets to get uniform weight. The IP has provided limits for the average weight of uncoated compressed tablets. Example when the tablet contains 250mg or more of the drug substance or when the latter comprises (+ or -) 5% or more, by weight of the dosage form, then that tablet is having Weight Variation.

Twenty tablets were weighed individually and the average weight was calculated. The individual tablet weights are then compared to the average weight. Not more than two of the tablets must differ from the average weight by not more than the percentages stated.

No tablet must differ by more than double the relevant percentage.

4.Hardness test :

Hardness is generally measured as the force needed to break the tablet in a specific plane. Tablet hardness may be used to determine the chewing difficulty index. Six tablets prepared were randomly selected and tested for hardness strength using the official Pfizer Hardness Tester. Thus the mean of the six determinations was taken. The characteristics were conveyed in Kg/cm2.

5.Friability test[15] :

Friability is the loss of weight of tablet in the container or package, due to removal of fine particles from the surface. To ensure the ability of tablets to withstand the shocks during processing, handling, transportation, and shipment. Permitted friability limit is 1.0%. Roche friabilator was used to measure the friability of the tablets. 5 tablets were weighed collectively and placed in the chamber of the friabilator. In the friabilator the tablets were exposed to rolling, resulting free fall of tablets (6 inches) within the chamber of the friabilator. It was rotated at a rate of 25 rpm. After 100 rotations (4 min.) the tablets were taken out from the friabilator and intact tablets were again weighed collectively. The equation calculated the percent friability of the tablets

The percent friability was determined using the following formula:

$F = (1 – W) / W_0 \times 100$

Where, W_0 = Weight of the tablet before test$W$ = Weight of the tablets after test.

6. Dissolution test :

The analytical methodology used to evaluate dissolution followed United States Pharmacopeia (2007) specifications, which describe the general methodology for capsule and tablet dissolution tests. Tests were carried out on a Vankel VK 7000 Total Solution Dissolution device using USP apparatus 2 (paddle), HCl 0.1 M pH 1.2 medium, dissolution vessel volume of 900 mL, 37.5 ± 0.5 ºC temperature, stirring speed of 75 rpm, and sampling aliquots of 3 mL withdrawn at 0, 5, 10 and 30 minutes.

Post-compression study (Evaluation of prepared tablets)

Table No. 4

Parameter	Result
Colour	Brownish Black (Dark Khakhi)
Odour	Characteristics
Taste	Sour & Astringent
Shape	Round flat plain both sides
Thickness (mm)	3
Diameter (mm)	13.1
% Weight Variation (g)	Under + / – 0.5 % (Maximum 0.146 %)
Friability (%)	0.384
Hardness Test (Kg/cm^2)	4.06
Disintegration Time	15 Minutes 07 Seconds

RESULT AND DISCUSSION:

This study was an attempt to develop a formulation of tablets by direct compression method using Ashwagandha Powder, Amla Powder, Clove Churna, Garlic, Black pepper Powder, Cinnamon Powder, and Black cumin Churna In this method, the formulated tablets were prepared by adding excipients Microcrystalline cellulose (MCC), Dibasic calcium phosphate, Peg 4000, Methyl Paraben.

The pre-compression and post-compression studies were tested and compared with the studies performed on tablets and it showed within normal limits. The pre-compression parameters and the values were found to be within prescribed units for tablet formulation. The Powder blend produced however showed better flow property (Table No. 3).

Tablets are expected to disintegrate within 15 minutes. As the most commonly used solid dosage form, compressed tablets must meet several physical criteria, including hardness, friability, and uniformity.

Table No. 4 shows the results for uniformity of diameter and uniformity of thickness. These parameters are very important to select packaging material. The analysis of tablet were showed the satisfactory results (Table No. 4). And organoleptic characters of both powder and tablet also satisfactory. Direct compression method could be used successfully for developing tablet formulation by incorporating Ashwagandha Powder, Amla Powder, Clove Churna, Garlic, Black pepper Powder, Cinnamon Powder, and Black cumin Churna.

CONCLUSION:

Ashwagandha Powder, Amla Powder, Clove Churna, Garlic, Black pepper Powder, Cinnamon Powder, and Black cumin Churna, are widely recognized and highly effective Ayurvedic herbal remedies. Recent studies have indicated that these herbal powders can be successfully formulated into tablet form. The resulting tablets were evaluated and found to meet satisfactory standards in most tested parameters.

The study emphasizes the importance of generating comparable data for various herbal drugs and Ayurvedic formulations, which is crucial for industrial applications and meeting consumer preferences and demands. Consequently, it suggests that the tablets developed in this research could serve as a superior alternative to traditional uses of these herbs. Additionally, this research has the potential to advance the field of herbal technology in the future.

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