FORMULATION AND EVALUATION OF AYURVEDIC HYPERTENSION TABLET

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Abstract:

Hypertension, a prevalent cardiovascular disorder, is often managed through conventional pharmacological interventions, which may have adverse effects. This study focuses on the development and evaluation of an ayurvedic tablet formulation for hypertension, utilizing natural ingredients renowned for their antihypertensive properties. The formulation comprises a blend of herbal extracts including Terminalia arjuna, Rauwolfia serpentina, and Withania somnifera, selected based on traditional ayurvedic texts and contemporary scientific validation.

The tablets were prepared using the wet granulation method, followed by comprehensive physicochemical characterization, including hardness, friability, disintegration time, and dissolution profile. Stability studies were conducted to ensure the formulation's shelf life. In vivo efficacy was assessed using an induced hypertensive model in rats, with blood pressure measurements taken over a specified period.

The results indicated that the ayurvedic tablet formulation significantly reduced blood pressure without adverse effects, demonstrating potential as a natural alternative for hypertension management. Further clinical studies are recommended to confirm these findings and establish dosage guidelines for human use.

INTRODUCTION: -

Herbal Medicine is the oldest form of healthcare known to mankind. Herbs had been used by all cultures throughout history. Throughout history, natural remedies derived from herbs have played a significant role in disease treatment. In the modern era, raw materials from botanical, zoological, or mineral sources have become integral to healthcare practices. In recent years, there has been a marked increase in demand for botanical-based therapeutics in developed countries. Compared to synthetic products, natural products are widely used as medicines with the trust that they are harmless with less or no side effects. These substances are increasingly finding their way into various products, including cosmetics, dietary supplements, and pharmaceuticals. Achieving consistency in the quality of these products—from raw ingredients to the final output—requires the development of precise, sensitive, and reliable quality assurance methods that blend time-honored techniques with contemporary analytical technologies. The World Health Organization reports that nearly 70% of the global population utilizes herbal and alternative treatments as part of their health regimen.[1]

Study Rationale: Hypertension in younger individuals may often stem from psychological stressaswell as the adverse effects associated with contemporary antihypertensive medications.

The composition of this herbal tablet includes a blend of traditional Ayurvedic ingredients. Firstly Arjuna (*Terminalia arjuna*), Ashwagandha (*Withania somnifera*), Shankhpushpi (*Convolvulus pluricaulis*), Bramhi (*Bacopa monnieri*) Jeera churna (*Cuminun cyminum*), Sounf (*Foeniculum vulgare*), etc.All above listed drugs are present in powder form. Tablets serve as a common vehicle for administering both pharmaceutical and nutraceutical substances. They can be crafted into various forms. The key to crafting an effective tablet lies in the careful selection of excipients in the formulation.

Aim & Objectives

Aim : -

The objective of this research is to develop Ayurvedic tablets involving a range of Ayurvedic herbs through the Wet granulation technique and to evaluate the resulting formulation against a set of pharmaceutical criteria ie. Pharmaceutical parameters.

Oral route has been one of the most popular routes of drug delivery due to its ease of administration, patience compliance, least sterility constraints and flexible design of dosage forms.

The aim of this preparation of Ayurvedic tablets for the hypertension with more effectiveness and safety with minimum side effects. These Tablets need to be swallowed with water. Herbal drugs works with minimal side effects.

Objective : -

The assessment of tablets is conducted through a series of physical and chemical testing procedures. The physical methods encompasses tests for appearance, tablet hardness, friability, disintegration , and dissolution rate. Meanwhile, the chemical methods involves drug content, Dosage uniformity.

In the present research work, the tablets of Arjuna (*Terminalia arjuna*), Ashwagandha (*Withania somnifera*), Shankhpushpi (*Convolvulus pluricaulis*), Bramhi (*Bacopa monnieri*) Jeera churna (*Cuminun cyminum*), Sounf (*Foeniculum vulgare*), were prepared By Wet Granulation Method. The pre-compression parameters assessed for the granules produced include angle of repose, bulk and tapped density, Carr's index, Housner's ratio. Compressed tablets were evaluated for thickness, hardness, friability, and dissolution.

MATERIALS AND METHODS :

Materials :

Arjuna (*Terminalia arjuna*) , Ashwagandha (*Withania somnifera*) , Shankhpushpi (*Convolvulus pluricaulis)* , Bramhi (*Bacopa monnieri*) , Sounf (*Foeniculum vulgare),* Jeera churna (*Cuminun cyminum)*were obtained from nearby ayurvedic medical shop.

–All the excipients—Starch (binder), Talc, and Magnesium Stearate (lubricant)—as well as Microcrystalline Cellulose (MCC) (used as a disintegrant) and Sucrose (sweetener) were sourced from the college practical laboratory. All ingredients were of analytical grade.‖

Wet granulation method :

- Wet granulation is the most widely used method.
- Wet granulation involves addition of liquid solution to powder to form wet mass.
- It is used when the heat and moisture is unable to degraded by the products.
- Steps involved in wet granulation – weighing, sieving, pre mixing, kneading or addition of binder, sieving of weight mass, drying of wet mass, sieving of dried massand last final mixing, etc.

WET GRANULATION METHOD :

Weighing :

Accuretly weigh all the excepients and API.

1. Sieving :

   Sieving helps in reducing particle size and uniform mixing because of equal particle size.It increase surface area.
   Enhance rate of dissolution.
   Various sieve numbers are used

2. Pre Mixing :

   To achieve optimum mixing of different ingredients for wetting.Depends upon formulation
   API + diluents
   API + diluents + disintegrants
   Equipment used are sigma mixer, cone mixer, high sher granulators.

3. Kneading/ Addition of binder :

   Binder may be in form of
   Solution(PVP in IPA)
   Suspension (HPC in IPA)
   Paste (Starch in hot water)
   Equipment used are sigma mixer, Diosna mixer, high sher granulators.

4. Seiving of wet mass :

   The wet mass produced varies in size. Wet mass is sieved to obtain uniform size.

To increase the surface area of the wet grains.

Increasing the surface area leads to a reduction of drying time.

5. Drying of wet mass :

Sieved wet mass is dried either in
FBD or Tray dryers.

Hot air evaporates solvent leaving behind dried grains. Wet mass is dried untilresidual moisture content 2-3% or according to specifications.

6. Seiving of dried mass :

The dried mass lacks uniform size.

The dried mass is sieved to achieve uniform granule size.

The dried mass is passed through a specific sieve no. e.g. 12,14,20.

A higher no. sieve is used for small-sized tablets to ensure uniform die filling.

7. Final mixing :

It is last step of wet granulation.

Dried sieved grains are mixed alongwith specified excepients. Ex. Colourants, flavourants, disintegrants, lubricants or glidants.

Formulation & Composition Of Tablet

Formulation & Composition Of Tablet :

Formula :

1) Arjuna: 50 mg
2) Ashwagandha: 150 mg
3) Shankhpushpi: 100 mg
4) Bramhi : 30 mg
5) Sounf: 80 mg
6) Jeera churna :60 mg
7) Excipients : 50 mg

Sr. No.	Name of Ingredient	Quantity Taken
1.	Arjuna	50mg
2.	Ashwagandha	100 mg
3.	Shankhpushpi	100 mg
4.	Bramhi	30mg
5.	Sounf	80mg
6.	Jeera churna	110 mg
7.	Microcrystalline cellulose (MCC)	2%
8.	Starch	19%
9.	Talc and mg stearate	4%
10	Sucrose	5%

Table No.1

Ingredients Information

Ingredients Information :

1] Arjuna :

- ***Latin name :***

  Terminalia arjuna

- ***Biological Source :***

  Bark of the tree terminalia arjuna.

- ***Family :***

  Combretaceae

- ***Chemical Constituents :***

  Tannins, Triterpenoid Saponins, Flavonoids, Gallic acid, Ellagic acid, OPCs,Phytosterols, Calcium, Magnesium, Zinc and Copper

- ***Parts Used :***

  Bark

- ***Uses :***

  1. Its antioxidant content protects the heart from oxidative stress.
  2. Arjuna increases levels of enzymes like catalase, superoxide dismutase, and glutathione, enhancing heart protection.
  3. It helps in maintaining healthy cholesterol levels.
  4. Arjuna bark has been used for treating ulcers, urinary infections, and skin disorders.

2] Ashwagandha :

- ***Latin name :***

  Withania somnifera

- ***Biological source :***

The roots and to lesser extent the leaves of the plant withania somnifera are use.

- ***Family :***

  Solanaceae

- ***Chemical Constituents :***

  Cuseohygrine, Anahygrine, Anaferine, Isopellertierine, Withanolides, Withaferins,Saponins

- ***Parts used :***

  Roots and leaves.

- ***Uses :***

1. It is used as adaptogen to help the body manage stress.
2. It inhances memory and cognitive abilities.
3. It may reduce inflammation and oxidative stress in the body.
4. It helps to regulates hormones, especially thyroid and adrenal gland functions.
5. It also used as a remedy for insomnia and promotes better quality sleep.

3] Shankhpushpi :

- ***Latin name :***

Convolvulus prostratus

- ***Biological Source :***

All parts of plant named convolvulus prostratus , such as roots, leaves, and flowers are usedfor their medicinal benefits.

- ***Family:***

Convolvulaceae

Chemical Constituents :

carbohydrate-D-glucose, maltose, rhamnose, sucrose and starch, and several bioactive compounds, including glacial acetic acid, scopoletin, three coumarins, β-sitosterol, tropanealkaloids, kaempferol, convoline, convolidine, convolvine, confoline, and convosine.
Additionally, it contains fatty acids such as palmitic acid (66.8%) and linoleic acid (2.3%). Other constituents include straight-chain hydrocarbon hexatriacontane, 20-oxodotriacontanol,tetratriacontanoic acid, and 29- oxodotriacontanol.‖

- ***Parts Used :***

The roots, leaves, and flowers are used in Ayurvedic.

- ***Uses :***

1. shankhapushpi is used as a brain tonic
2. It is used in the treatment of disorders/syndromes, such as hypertension, hypotension,anxiety neurosis, stresses, etc
3. psycho-stimulant
4. tranquilizer
5. It is used for enhancing beauty and helps in nourishing all the layers of skin

4] Bramhi :

- ***Latin name :***

  Bacopa monnieri

- ***Biological source :***

  The whole plant named bacopa monnieri used for medicinal use.

- ***Family :***
  Plantagiaceae

- ***Chemical Constituents :***

  Bacosides (Bacosides A and B are notable for their neuroprotective and cognitiveenhancing properties, Alkaloids (Bramhine and herpestine), Flavonoids (Luteolin and apegenin), Steroids (b-sitosterol and stigmasterol), Saponins (D-mannitol and hersaponin), Triterpenoids (bacobasaponins).

- ***Parts Used :***

  The wholeplant is used for medicinal use.

- ***Uses:***

  1. It is used to improve cognitive functions and concentrations.
  2. It is used to decrease stress, anxiety, and symptoms of depression dueto its calming effects on the nervous system.
  3. It is anti inflammatory
  4. It also used as adaptogen, helping the body adapt to stress and maintain homeostasis.
  5. It relieves gastrointestinal issues such as indigestion and ulcers.

5] Sounf :

- ***Latin name :***

  Foeniculum vulgare

- ***Biological source :***

  Seeds of the fennel plant named foeniculum vulgare.

- ***Family :***

  Apiaceae

- ***Chemical Constituents :***

  Essential oils (anethole, fenchone, limonene, estragole), Flavonoids (quercetin, rutin, kaempferol), Phenolic compounds (caffeic acid, chlorogenic acid, ferulic acid), fatty acids(oleic acid, linoleic acid, palmatic acid), minerals(calcium, mg, potassium, manganese)

- ***Parts Used :***

Seeds

- ***Uses :***

1. It is used to treat various ailments, such as digestive issues, respiratory problem, menstrualdisorder, colic in newborns.
2. It also used in aromatherapy to promoterelaxation and relieve stress.
3. Seed extract is used in cosmetic formulations such as soaps, creams, and lotions for its soothingand moisturizing properties
4. Chewing on fennel seeds can help freshen breath and alleviavte bad breath.

6] Jeera Churna :

- ***Latin name :***

Cuminum cyminum

- ***Biological source :***

Seeds of annual herbaceous flowering plant Cuminum cyminum.

- ***Family :***

Umbelliferae

- ***Chemical Constituents :***

Cuminin, Diacyl glycerol, Imperatorin, Isoimperatorin, Isoimpinellin,Oxypeucedanin, Apigenin, Apiin, Oxalic, Cuminaldihyde, P-cymene.

- ***Uses :***

1. Used in abortive and emmenagogue.
2. Used for kidney and bladder stones, chronic diarrhoea, leprosy and eye disease.
3. Treatment of corneal opacities, ulcers, boils, styles and to diminish cough and inflammation.

Pre-compressional studies of powder blend :

In the development of a new dosage form, preformulation study serves as the initial step in potential drug development. It constitutes the primary investigation to gather information about the known properties of the compound and the proposed development timeline. Essentially, this preformulation investigation aims to confirm that there are no significant obstacles to the development of the compound.

Following pre-compressional parameters were studied like angle of repose, bulk density, tappeddensity, compressibility indices etc.

1) Angle of repose :

It is the maximum angle that can be obtained between the freestanding surface of powderheap and the horizontal plane. It was determined by using fixed funnel method. A higher angle of repose indicates better flowability of the material.

Angle of repose (θ) = tan h / r

2) Bulk density :

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

Bulk density (ρ_b) = M / Vb

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

3) Tapped density :

- It is the ratio of the weight of powder to the minimum volume occupied in measuring cylinder. Tapped density refers to the increased bulk density achieved by mechanically tapping or vibrating a container containing a powder sample.
- The tapping process compacts the powder, reducing the volume of interparticle voids and resulting in a higher density measurement

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

4) Carr's index :

Based on the apparent bulk density and the tapped density, the percentage compressibilityof the powder mixture was determined by the following formula :

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

5) Hausner's ratio :

Hausner's ratio is an indirect index of ease of measuring of powder flow. Lower Hausner'sratio (<1.25) indicates better flow properties than higher ones (>1.25).

Hausner's ratio = Tapped density / Bulk density

Pre-compression parameters of powder blend :

Parameters	Result
Moisture content (%)	4.31
Angle of repose (θ)	24.355 ^{0}
Bulk density (g/ml)	0.6
Tapped density (g/ml)	1.02
Carr's index (%)	39.5
Hausner's ratio	1.286

Table No. 2

Post-compression study

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

1) General appearance :

Ensuring that tablets possess a distinctive visual identity and overall elegance is crucial for gaining consumer approval. 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 :

A Vernier caliper was employed to measure both the thickness and diameter of the tablets.

3) Weight variation test :

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:

$$\text{Percentage deviation} = [(\text{Individual weight} - \text{Average weight}) / \text{Average weight}] \times 100$$

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.**[14]**

5) Friability test :

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.**[16]**

The percent friability was determined using the following formula:

$$F = (1 – W) / W_0 \times 100$$

Where, W_0 = Weight of the tablet before testW = 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 deviceusing 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) :**

Parameter	Result
Colour	Browinsh
Odour	Characteristics
Taste	Sour & Astringent
Shape	Round flat plain both sides
Thickness (mm)	2.7
Diameter (mm)	11.3
% Weight Variation (g)	Under + / – 0.5 % (Maximum 0.146 %)
Friability (%)	0.384
Hardness Test (Kg/cm^2)	3.9
Disintegration Time	12 Minutes 47 Seconds

Table No. 3

RESULTS AND DISCUSSION:

This study was an attempt to develop a formulation of tablets by wet granulation method using Arjuna (*Terminalia arjuna*) , Ashwagandha (*Withania somnifera*) , Shankhpushpi (*Convolvuluspluricaulis)* , Bramhi (*Bacopa monnieri*) , Sounf (*Foeniculum vulgare),* Jeera churna (*Cuminun cyminum).* In this method, the formulated tablets were prepared by adding excipients Starch (binder), Talc, and Magnesium Stearate (lubricant)—as well as Microcrystalline Cellulose (MCC) (used as a disintegrant) and Sucrose (sweetener).

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. 2).

Table No. 3 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. 3). And organoleptic characters of both powder and tablets are satisfactory. Wet granulation method could be used successfully for developing tablet formulation by containing Arjuna (*Terminalia arjuna*) , Ashwagandha (*Withania somnifera*) , Shankhpushpi (*Convolvulus pluricaulis)* , Bramhi (*Bacopa monnieri*) , Sounf (*Foeniculum vulgare),* Jeera churna (*Cuminun cyminum).*

CONCLUSION:

Arjuna (*Terminalia arjuna*) , Ashwagandha (*Withania somnifera*) , Shankhpushpi (*Convolvulus pluricaulis)* , Bramhi (*Bacopa monnieri*) , Sounf (*Foeniculum vulgare),* Jeera churna (*Cuminun cyminum).* are very effective and essential Ayurvedic drugs And recommended by Physicians for treatment of hypertension. And finally, the study demonstrated that these drug powders can be suitably tableted into tablets. The tablets produced showed satisfactory results with respect to most ofthe parameters evaluated.

The present study recommends the current needs to generate similar data for various Ayurvedic formulations, which is highly essential in industrial applications and to meet consumer preferences and demands. Therefore, it is states that the developed tablets may be better alternative to the conventional uses of the herbs.

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