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Ashwagandha - An Ayurvedic Tablet

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Abstract

The study of medicine is a science as well as an art. Pharmaceutical oral solid dosage forms have been used widely for decades, mainly due to their ease of administration and suitability for systemic drug delivery. The tablets may be produced directly from powders, granule pellets, or film-coated multiple units. Nowadays, tablets are the most widely used dosage form, making up over 70% of all manufactured ethical pharmaceutical formulations. Tablets are solid pharmaceutical unit dosage forms that can be manufactured by compression or moulding. They can include medicinal ingredients with or without acceptable diluents. The treatment of numerous disastrous diseases in the modern day has benefited greatly from the traditional. Ashwagandha powder, an ayurvedic remedy made from the herb *withania somnifera* is used to treat a variety of conditions including osteoarthritis, type 2 diabetes, anxiety-related issues, and tumour healing abilities. Withaferin-A, Stigmasterol glucoside, and withanolide-D are the three chemical components of ashwagandha.

Keywords – Ashwagandha, crospovidone, Disintegration.

Introduction

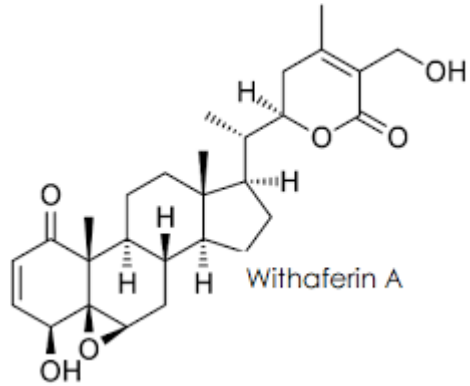
Solid medications can be taken orally as tablets, powders, capsules, cachets, or capsules. These dosage forms are collectively referred to as solid unit dose forms because they each contain a certain amount of medication that is administered as a single unit. Even in the case of preparations for sustained action, which technically include the equivalent of many standard dosages. Tablets and capsules, on the other hand, currently make up well over two thirds of the total number and cost of medicines produced worldwide. This is due to the stringent formulation requirements of modern medications, the numerous advantages of tablet and capsule medication, expanding health services, and the commitment need for large-scale economic manufacture. Tablets are a traditional solid dose form that have many advantages over other dosage forms.

About 70% of all medications are given out in the form of tablets, making them the most common dose form.^[1] Depending on the therapeutic ingredients and the intended manner of administration, tablets came in a variety of shapes, sizes, and weights. The basic ingredients that are frequently present in tablets, preparation techniques, and the many varieties of tablets are all briefly described in this paper along with some of their benefits and drawbacks.^[2]

1. Drug – Excipients Profile

1.1 Drug Profile

Table No. 1 Drug Profile

Structure	 <p>Withaferin A</p>
Molecular formula	C ₂₈ H ₃₈ O ₆
Molecular Weight	470.6 g/mol
Family	Solanaceae
Uses	Antistress, Depression, Joint pain.
Solubility	Soluble in water
Appearance	Whitish cream fine powder



1.2 Excipients Profile

Table No. 2 Excipients Profile

	Lactose	Magnesium Stearate	Tragacanth	Crospovidone	Talc
Appearance	White crystalline powder	Light white powder	White to yellowish white	White to creamy white powder	White powder
Solubility	Soluble in water & ethanol	Practically insoluble in ethanol & water	Practically insoluble in ethanol & water	Insoluble in water	Insoluble in water
% Used in Tablets	60-70	4-5	2-6	2-5	5-30
Category	Diluent	Lubricant	Binder	Disintegrant	Glidant

Materials & Methods

Table No. 3 Experimental Material & Uses

Ingredients	Role
Ashwagandha	Rejuvenates Mind & Body
Lactose	Diluent, Binder
Magnesium Stearate	Lubricant



Tragacanth	Binder
Crospovidone	Disintegrant
Talc	Glidant

Method of Preparation

Wet granulation method

1. Pass all the ingredients through sieve no. 80.
2. Mix Ashwagandha, Crospovidone, Tragacanth & Magnesium stearate.
3. Prepare separately Lactose solution with water (Q.S).
4. Add the solution to the mixture to form a damp coherent mass.
5. Pass the coherent mass through sieve no.12 to form granules.
6. Dry the granules at 50-60⁰C for 1 hour in hot air oven.
7. Pass the dried granules through sieve no.16 or 18.
8. Add Talc and mix thoroughly.
9. Evaluate the preparation for preformulation studies.^[3]

Preformulation Studies

1. **Angle of repose:** Angle of repose: The funnel method was used to calculate the angle of repose. The carefully weighed mixture was poured into a funnel. The funnel's height has been modified so that the tip barely brushes the top of the heap or head of blend. The mixture of drug excipients was permitted to freely flow down the funnel and onto the surface. The powder cone's diameter was measured. the following equation was used to get the angle of repose: $\tan \theta = h/r$

$$\theta = \tan^{-1} h/r$$



Where h is the height of the newly generated powder heap and r is its radius.

A weighed amount of the mixture was poured into a graduated cylinder, and the volume and apparent bulk density were measured.

- 2. Bulk Density:** The apparent bulk density was calculated by pouring a predetermined amount of the mix into a graduated cylinder, weighing it, and then measuring the volume.

$BD = \text{Weight of the powder} / \text{volume of the packing.}$

- 3. Tapped Density:** Tapped density was calculated by setting a graduated cylinder with a known mass of the drug excipient mixture on top of it. The cylinder was allowed to land on a hard surface as a result of its own weight. The tapping was kept up until there was no longer any loudness change.

$TD = \text{Weight of the powder} / \text{volume of the tapped packing.}$

- 4. Compressibility Index:** Carr's compressibility index was used to calculate the blends' compressibility indices.

$\text{Compressibility index (\%)} = (TD - BD) \times 100 / TD$

- 5. Hausner's Ratio:** It measures the drug's flow characteristic.

$\text{Hausner's Ratio} = \text{Tapped density} / \text{Bulk density.}^{[4]}$

Lubricated Formulations

Table no. 4 Lubricated Formulations

Formulations	Angle of Repose (θ)	Compressibility Index (%)	Hausner's Ratio
AG1	16.31	10.1	1.20
AG2	15.21	8.9	1.10
AG3	18.61	15.3	1.12
AG4	14.3	11.6	1.25
AG5	20.52	14	1.3
AG6	22.61	18	1.09



AG7	13.87	9.2	1.08
AG8	14.57	7.4	1.05
AG9	17.74	4.1	1.04

Unlubricated Formulations

Table No. 5 Unlubricated formulations

Angle of Repose (θ)	Compressibility Index (%)	Hausner's Ratio
47	32.2	0.8

- ❖ Based on result obtained the batch AG8 & AG9 for the compression of the tablet was selected.

Table No. 6 Optimized Formula

Ingredients	Formulations	
	AG8	AG9
Ashwagndha	500	500
Lactose	114	114
Magnesium Stearate	6	12
Tragacanth	6	6
Crospovidone	18	12
Talc	6	6
Total	650	650

Evaluation of Tablets (Non – Official Test)

- 1. General Appearance:** For general acceptance, control of lot-to-lot uniformity, and management of tablet-to-tablet uniformity, a tablet's overall design, identity, and elegance



are crucial. Size, form, colour, the presence or absence of odour, taste, etc. are all measured as basis of parameters of overall appearance.

- 2. Unique Identification Markings:** To assist breaking or to create a reduced dose, the tablets may be scored in half or quadrants. Tablets with complete, distinct, and legible identification markings are permitted.
- 3. Tablet thickness:** The single dimensional variable connected to the compression process of tablets is the thickness of the tablet. Typically, a micrometre is used to measure it. In addition to controlling for patient approval and simplifying tablet packing, the thickness should be within 5% of a defined value.
- 4. Hardness:** To withstand mechanical handling during production, packaging, and shipping, tablets need to have a specific level of strength or hardness and resistance to friability. The strength of a tablet's crushing is typically measured by hardness.
- 5. Friability:** A tablet's friability can be assessed in a lab setting using a Roche friabilator. This consists of a plastic chamber that rotates at 25 revolutions per minute, dropping the tablets into the friabilator through a distance of six inches, and then operating for 100 revolutions. The tablets are weighed again. Tablet compression that loses between 0.5 and 1.0 percent of the tablet weight is acceptable.

$$\text{Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100. \text{ [5]}$$

Evaluation of Tablets (Official Test)

- 1. Weight Variation Test (U.S.P.):** Take 20 tablets, each to be weighed separately. Calculate the average weight before comparing it to the weight of each tablet. If no more than two tablets fall outside the allowed percentage range and no tablet deviates by more than twice the allowed range, the tablet passes the USP test.
- 2. Wetting Time:** A piece of tissue paper was folded twice and placed in a Petri dish. Distilled water was used to wet the tissue paper. A tablet was positioned on the paper,



and it took how long for it to completely wet was recorded. Three tablets were chosen at random from each formulation, and the average wetting time was recorded.

3. Disintegration Test (U.S.P.):

- i) The U.S.P. disintegration test apparatus consists of six 3cm long glass tubes that are open at the top and 10 mesh screens at the bottom.
- ii) One tablet is inserted in each tube, and the basket rack is placed in a 1L beaker of water, simulated gastric fluid, or simulated intestinal fluid at 37⁰C such that the tablet remains 2.5 cm below the liquid surface.
- iii) On their upward movement and not more than 2.5 cm from the bottom of the beaker on their downward movement.
- iv) At a frequency of 28 to 32 cycles per minute, move the basket containing the tablets up and down over a distance of 5 to 6 cm.
- v) Placing perforated plastic discs on each tablet will stop it from floating.
- vi) For the test to pass, the tablet must disintegrate and all particles must pass through the 10-mesh screen in the allotted amount of time. If any residue is left, it must have a soft bulk.^[6]

Result & Discussion

Pre-formulation studies on the powder included measuring its compressibility index and angle of repose. The findings showed that the particles weren't freely flowing. So the compression of tablets was achieved by using wet granulation method. The tablet's hardness, weight variation, friability, disintegration time and wetting time were all evaluated.



Table No. 8 Preformulation Studies

Formulations	Angle of Repose (θ)	Compressibility Index (%)	Hausner's Ratio
AG8	17.74	4.1	1.04
AG9	14.57	7.4	1.05

Table No. 9 Evaluation of Tablets

Formulations	Hardness (kg/cm²)	Friability (%)	Weight variation Test (\pmSTD)	Disintegration Time (MIN)	Wetting Time (MIN)
AG8	3.0	0.3	5	8	5
AG9	3.1	0.7	5	7	4

Conclusion

The findings showed that formulations might be employed successfully in the clinical formulation of fast-dissolving tablets. Crospovidone was the best super disintegrant for the formulation of Ashwagandha, and wet granulation is clearly a factor. Using this process, it is possible to create ashwagandha preparation tablets that dissolve quickly.



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