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Novel approaches in the formulation and evaluation of Ashwagandha tablets

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Abstract

Herbal tablets are solid dosage forms of powdered herbs, herbal extracts or their ingredients prepared by compression. They vary greatly in shape, size, and weight which depend on the amount of drug used and mode of administration. Pharmaceutical oral solid dosage forms have been used extensively form long time, substantially due to their ease of administration and suitability for systemic medicine delivery. Withania somnifera member of Solanaceae family generally known as Ashwagandha, Indian Ginseng, or winter cherry has been used in Ayurveda, Indian system of traditional medicine. Ashwagandha root is among the most well known herbal medicine used in Ayurveda, a comprehensive system of medicine that originated in India. Ashwagandha is referred to as the "Prince of Herbs" in Ayurveda because it has an impressively wide range of remedial effects. The treatment of numerous terrible diseases in the modern day has benefited greatly from the traditional. Ashwagandha powder, an ayurvedic medicament made from the herb withania somnifera is used to treat a variety of conditions including osteoarthritis, type 2 diabetes, anxiety-related issues, and tumour mending capabilities. It's an unique Indian herb, has significant stress-relieving properties analogous to those of powerful medicines used to treat depression and anxiety..

Keywords: *Withania Somnifera*; Tablets; Ashwagandha; Ayurveda; Formulation.

1. Introduction

Herbal tablets are solid dosage forms of powdered herbs, herbal extracts or their ingredients prepared by compression. These dosage forms are commonly referred to as solid unit dose forms because they each contain a certain amount of medication that is administered as a single unit. Tablet is defined as a solid dosage form containing medicaments with or without excipients. According to the Indian pharmacopoeia tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drugs or a mixture of drugs, with or without excipients. About 70% of all medications are given out in the form of tablets, making them the most Common dose form .[1] Ashwagandha is an evergreen shrub which is found in India, Africa and numerous corridor of the Middle East.[2] *Withania somnifera* (Family: Solanaceae) is an ayurvedic herb that has been used for periods in India as an adaptogenic herbal remedy to improve overall health, life and durability. It is a well-liked Indian medicinal plant and is also known as Ashwagandha, Ginseng, and Winter cherry.[3] It is in use form decades, for all age groups and both gender and even during pregnancy without any side effects.[4] Ashwagandha is used to calm the mind, relieve weakness and nervous depletion, build sexual energy and promote healthy sleep.[5] The herb has typically been used for nervous exhaustion, calming the mind, arthritis, relieving weakness and for building sexual energy.. Various other effects like immunomodulation, hypolipidemic, antibacterial, cardiovascular protection, sexual behaviour, tolerance and dependence have also been studied.[6] It is an erect, greyish, subshrub with faint yellow or greenish flowers followed by small, spherical, orangish-red berries containing yellow, kidney shaped seeds. It grows three to five feet tall, mainly on waste land, but grow widely as the whole plant. Most commonly the root and leaf are used medicinally.[7] The plant requires the dry stony soil with sun to partial requirement of shade. In most of the countries this herb is sold as salutary supplement. The various part of Ashwagandha works as

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anthelmintic, tangy, diuretics, narcotics, thermogenic and as tonic. Its powder is given to the children with milk and works as tonic and able to gives the power of horse. This herb is used against nervous breakdown, insomnia, vitiated conditions of vata, rheumatism, constipation, leukoderma etc.[8] Ashwagandha root drug finds an important place in treatment of rheumatic pain, inflammation of joints, nervous disorders and epilepsy. Dried roots are used as stimulants for hiccup, cold, cough, female disorders, as a sedative, in care of senile debility, ulcers, etc. Leaves are applied for carbuncles, inflammation and bumps. Leaf juice is useful in conjunctivitis. Bark decoction is taken for asthma and applied locally to bed blisters. Ashwagandha and its extracts are used in preparation of herbal tea, powders, tablets and syrups.[9]

2. Materials and Method

2.1. Materials

The ashwagandha root powder was collected from the local market which act as anti-inflammatory, rejuvenating, anti-stress, antioxidant, mind-boosting and anti-tumor. The excipients used in the formulation are Crospovidone is used as disintegrate, Magnesium stearate is used as a Lubricant, Lactose is used as the diluent, Talc is used as a lubricant and gives better appearance to tablets.

Table 1 Experimental Material & Uses

Ingredients	Role
Ashwagandha	Renovate mind & body
Lactose	Diluent, Binder
Tragacanth	Binder
Magnesium stearate	Lubricant
Crospovidone	Disintegrant
Kaolin	Glidant

2.2. Method

2.2.1. Wet granulation method

Weigh all ingredients accurately, mix well and triturate by using mortar and pestle. The prepared 1% lactose was added slowly to form a damp mass. Damp mass was transfer through sieve no. 12. Prepared granules are dried in hot air oven. The completely dried granules are ready for compression.

Table 2 Formulation Parameters

Ingredients	F1	F2	F3	F4
Ashwagandha	250	250	250	350
Crospovidone	9	6	7	8
Mg stearate	3	6	5	4
Lactose	57	57	57	57
Tragacanth	3	3	3	3
Talc	3	3	3	3
Total	325	325	325	325

2.3. Evaluation test

2.3.1. Pre-formulation study

- Bulk density

Bulk density was done in 100 ml dried measuring cylinder. Pouring of dried granules in bulk density apparatus and calculated by using the following formula;

Bulk density = Mass of the granules/Bulk volume of the granules

- Tapped density

Tapped density is the ratio of weight of granules to the volume of tapped granules.

Tappedd density= Granules weight/Volume of tapped granules

- Hausner's ratio

Hausner's ratio is the ratio of the tapped density to the

bulk density of granules. Calculated by using the following formula.

Hausner's ratio= Tapped density/Bulk density

- Carr's index

Carr's index or compressibility index is determined by the following formula.

$$\text{Carr's index (\%)} = \frac{\text{Tapped density} - \text{Poured density}}{\text{Tapped density}} \times 100$$

- Angle of repose

Angle of repose is the height of pile is perpendicular to the horizontal surface. To calculate the angle of repose following formula was used. It shows the flow property of granules.

Θ = Tan-1[h/r]

Where

h = height of granule cone formed.

r = radius of the granule cone formed.[10]

Table 3 Preformation Parameters

Pre-formulation Parameters	F1	F2	F3	F4
Angle of repose (θ)	16.31	17.56	18.10	20.4
Bulk density g/cm3	0.267	0.29	0.18	0.15
Tapped density g/cm3	0.327	0.33	0.23	0.22
Hauser's ratio	1	1.04	1.06	1.05
Carr's index (%)	4.1	5	6.7	7.4

2.4. Evaluation/ Quality control test for Tablets

2.4.1. General appearance

The general appearance and color of tablets were found by visual determination.It is flat, circular in shape and whitish in colour.

2.4.2. Weight variation test

Take 20 tablets, each to be weighed separately. Calculate the average weight before comparing it to the weight of each tablet. The following formula is for weight variation method

Weight variation = (individual wt - Average wt)/ Average wt × 100

2.4.3. Hardness Test

Hardness Test is the most important feature for assessing tablet in the study it was found that Tablet passed the test of tablet breaking strength or hardness have acceptable breaking strength of between 5kKg/Cm2 to 10kg/ Cm2. This test done by Pfizer Tester.

2.4.4. Friability test

Friability of a tablets can determine by Roche Friabilator. The friabilator consistsfriabilator, which is then operated for 100 revolutions. The tablets are reweighed. Compress tablets loss less than 0.5% to 1.0% of the tablet weight are considered acceptable

2.4.5. Disintegration time

This test was a time required for the tablet to separate into particles, the disintegration test measure only of the time required under a given set of aconditions for a group of tablets to disintegrate into particles. This test was performed to identify the disintegration of tablet in a specific time period.[11], [12]

Table 4 Evaluation Parameters for tablets

Parameters	F1	F2	F3	F4
Wt Variation (±STD)	5	4.8	4.9	5
Friability (%)	0.3	0.2	0.6	0.7
Hardness (kg/cm2	2.8	2.9	2 .7	3
Disintegration (MIN)	8	8	9	7

3. Results

The formulation was prepared by wet granulation method were tested for pre-formulation studies for the effective evaluation of tablets. All The evaluated pre-formulation parameters shown in table 3.All the pre-formulation study the flow property of granules was poor. The evaluation parameters of compressed tablets were shown in table 4. The compressed tablets color was whitish. The weight variation test, hardness, thickness, friability and disintegration time were shown in table 4.

4. Discussions

Ashwagandha was traditional medicinal plant which having various medicinal activities but present research was focused on anti-stress, analgesic and anti-inflammatory activity. The root powder was used to formulate tablets. Pre-formulation studies on the powder included measuring its compressibility , bulk density tapped density and angle of Repose. Pre-formulation study was carried out and gives poor flow properties of prepared granules.

5. Conclusion

The findings showed that the particles weren't freely flowing. So the compression of tablets was done by using wet granulation method. Wet granulation was done by using making five batches like F1,F2,F3, F4. Crospovidone was the best super disintegrant for the formulation of Ashwagandha. The batch F3 was required more disintegration time as compared to F1 and F2 batch. Based on the results it is concluded that the formulation and evaluation are good. The pharmacological evaluation is required for the treatment of Anti-stress.

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest to be disclosed.

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