ISSN: 2582-7219

International Journal of Multidisciplinary Research in Science, Engineering and Technology

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

Impact Factor: 8.206

Volume 8, Issue 4, April 2025

© 2025 IJMRSET | Volume 8, Issue 4, April 2025| DOI:10.15680/IJMRSET.2025.0804232

ISSN: 2582-7219 | www.ijmrset.com | Impact Factor: 8.206| ESTD Year: 2018|

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Formulation and Evaluation of Ashwagandha Capsule for Parkinson's Disease

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ABSTRACT: Ashwagandha (Withania somnifera) is a powerful adaptogenic herb widely used in traditional Ayurvedic medicine for its numerous health benefits. Ashwagandha capsules are a convenient supplement form that delivers the therapeutic properties of the herb in a concentrated dose. Known for its ability to help the body adapt to stress, Ashwagandha supports mental clarity, reduces anxiety, and promotes a sense of calm and balance. Additionally, it may enhance energy levels, improve sleep quality, support immune function, and promote overall vitality. Its natural anti-inflammatory and antioxidant properties also contribute to improved physical performance and cognitive function. Ashwagandha capsules offer a natural, holistic approach to wellness for those seekingo manage stress and support long-term health.

KEYWORDS: Ashwagandha, parkinson's disease, neurological.

I. INTRODUTION

Ashwagandha [Withania Somnifera]Withaniasomnifera (WS), also known as ashwagandha, Indian ginseng, and winter cherry, it has been an important herb in the Ayurvedic and indigenous medical systems for over 3000 years. The roots of the plant are categorised as rasayanas, which are reputed to promote health and longevity by augmenting defence against disease, arresting the ageing process, revitalising the body in debilitated conditions, increasing the capability of the individual to resist adverse environmental factors and by creating a sense of mental well being . It is in use for a very long time for all age groups and both sexes and even during pregnancy without any side effects . Historically, the plant has been used as an antioxidant, adaptogen, aphrodisiac, liver tonic, antiinflammatory agent, astringent and more recently to treat ulcers, bacterial infection, venom toxins and senile dementia. Clinical trials and animal research support the use of WS for anxiety, cognitive and neurological disorders, inflammation, hyperlipidemia and Parkinson's disease. WS chemopreventive properties make it a potentially useful adjunct for patients undergoing radiation and chemotherapy. Recently WS is also used to inhibit the development of tolerance and dependence on chronic use of various psychotropic drugs. Winter cherry, Indian ginseng, and Ajagandha, Queen of Ayurveda, called by many names, Withaniasomnifera Dunal (Ashwagandha; Family-Solanaceae), is a plant used in Ayurvedic medicine in the traditional system and indicated For the management of several neurological disordersParkinson disease is a slowly progressive, chronic neurological disease that effects a small area of nerve cells in an area of the brain known as the substance nigra This cells normally produces dopamine, a chemical (neurotransmission) that transmits signal between areas in the brain that when working normally coordinates smooth and balanced muscle movement. Parkinson's disease cause this nerve cells to die and as a result body movement are effected.

Parkinson's disease is a condition where a part of your brain deteriorates, causing more severe symptoms over time. While this condition is best known for how it affects muscle control, balance and movement, it can also cause a wide range of other effects on your senses, thinking ability, mental health and more.
Parkinson's disease, the most common symptoms result from the loss of neurons in an area near the base of the brain called the substantia nigra. The neurons in this area produce dopamine. Dopamine is the chemical messenger that transmits signals in the brain to produce smooth, purposeful movement. Studies have shown that most people with PD have lost 60 to 80% or more of the dopamine-producing cells in the substantia nigra by the time symptoms appear.

II. MATERIAL AND METHOD

Material

The ashwagandha root powder was collected from the local market which act as anti-inflammatory, rejuvenating, antistress, antioxidant, mind-boosting and anti-tumor. The excipients used in the formulation are sodium starch

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glycolateis 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 capsule.

Plant material -withania somnifera is propagated by division of cuttings or seeds. The best way To propagate them is by seed. Seeds sown on moist sand will germinate in 14-21 days at 200°C. Withania Somnifera needs full sun to partial shade with a well-drained slightly alkaline soil mix. Plants do best when the Soil pH is 7.5-8.0. A soil mix consisting of two parts sandy loam to one part sand will be better. Plants are Allowed to dry thoroughly between waterings. Too much water in containers causes root rot. The plants are Fertilized once a year with a balanced fertilizer.

Method

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 θ = h/r Θ= tan-1h/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 And apparent bulk density were

$$\tan \theta = 2.5/3. = 0.78$$

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

$$BD = \text{Weight of the powder / volume of the packing} = 9.70 / 20.8 = 0.46$$

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.

$$TD == \text{Weight of the Powder /Volume of the tapped packing.}$$
$$= 9.70 / 19.6$$
$$= 0.49$$

4. Hausner's Ratio: It measures the drug's flow characteristic

$$\text{Hausner's Ratio} = \text{Tapped density/ Bulk density .}$$
$$= 19.6 / 20.8$$
$$= 0.94$$

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

$$\text{Carrs Index[\%]} = \text{Tapped density -poured density/Tapped Density} \times 100$$
$$= 19.6 - 20.8 /19.6 \times 100$$
$$= 1.2 / 1960$$
$$= 6.22$$

Extraction-

To avoid the use of pharmaceutical excipients, Ashwagandha water extract was used in the preparation Of herbal solid compositions. Hence, the present disclosure provides a process to make Ashwagandha water Extract. Ashwagandha spent (leftover residue after extracting with alcohol) was subjected to extraction with Purified water by the percolation method at room temperature. The water extractions after 12–24 hours wereFiltered through muslin cloth and concentrated into a thick paste. After achieving the desired total solid content, The soft extract was spray dried to a free-flowing dry extract powder. The water extract was also prepared by the Hot dicocationmethod. The obtained water extract was used for the preparation of an Ashwagandha Composition in a stable, highly bioavailable, and non-hygroscopic form.

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Phytochemical screening

Test for Phenols-
Ferric Chloride TestTake 2 ml of plant extract was taken in a test tube and then Add 2 ml of ferric chloride (1%). The appearance of dark Green or bluish green color indicated the presence of phenol .

Test for Tannins -
Lead Acetate TestAdd few drops of lead acetate solution in a test tube with 2 ml Of filtrate. Yellowish coloration was indication of positive Result.

Test for Flavonoid- Lead Acetate TestThe extract was treated with a few drops of ten percent lead Acetate solution. Formation of yellow precipitate indicates the Presence of flavonoids. Orange to crimson colour shows the Presence of flavonoids.

Alkaline reagent Test-
To the 1 ml of extract in a test tube add few drops of Sodium Hydroxide solution (ten percent). Formation of an intense Yellow colour, which turns colourless on addition of few Drops of dilute hydrochloric acid, indicates the presence of Flavonoids .

Test for Alkaloids
Dragendorff's Test-In 2 ml of filtrate add 1 ml of 1% hydrochloric acid and steam Heated the solution for 2 min. filtered the solution and take 1 Ml of filtrate. Add six drops of Dragendorff's reagent. The Change in color of precipitate to orange red/ brownish red Showed the presence of alkaloid

Formulation of capsule

1. Pass all the ingredients through sieve no. 80.
2. Mix Ashwagandha, sodium starch glycolate, 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 50-60C for 1 hour in hot air oven.
7. Pass the dried granules through sieve no.16 or 18.
8. Capsules fill.

Formulation

Ingredient	F1	F2	F3
Ashwagandha	125	125	125
Sodium Starch glycolate	45	30	35
Magnesium	15	30	25
Lactose	28	28	28
Tragacanth	15	15	15

Evaluation parameters

Weight variation: The individual weights of the each Capsule should be within the limits of 90% and 110% of the Average weight. Moisture content: Moisture content was determined by Using automatic Karl Fischer titration apparatus.

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Disintegration time: Disintegration test was performed Using the digital microprocessor based disintegration test Apparatus. One capsule was introduced into each tube and a disc was added to each tube. The assembly was suspended in water in a 1000 ml beaker. The volume of water at its Highest point was at least 25 mm below the surface of the water and at its lowest point was at least 25 mm above the Bottom of the beaker. The apparatus was operated and Maintained at a temperature of 37 ± 2ºC.

pH value: pH of 1% solution was determined by using a Digital pH meter.

Dissolution: Dissolution is considered as a tool for predicting rate of Absorption and bioavailability in some cases, replacing clinical Studies to determine bioequivalence of drug. We were added six Capsules in the basket type dissolution apparatus containing Distilled water as a dissolution media. The speed was set on 50 Rpm for 1 hour and the sample was drawn at every 10 minutes And the amount of dissolved active ingredient in the solution Was calculated as percentage dissolved in 1 hour.

Stability Pharmaceutical products are generally studied for stability Profile at accelerated temperature, humidity and also at different Intensities of light. The studies were performed to determine the Physical, chemical, and therapeutic changes occurring in the Poly-herbal capsule by extrinsic factors .

Light: Sample was stored in different intensities of light i.e. sunrays, fluorescent (tube) light, UV and infrared light for Detection of degradation of powder material.

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Temperature: The effect of temperature on the stability of Polyherbal capsule was checked by keeping all the capsule At different temperatures i.e. ambient, 350C, 500C, 550C, 650C for 30 minutes, 1, 3, and 6 hours.
Humidity**:** The effect of humidity on the stability of capsule Was checked by keeping the entire capsule at four different Humidity

III.RESULT & DISCUSSION

Powder study and organoleptic parameters showed identity of the herb. Loss on drying was 90 % which indicates that extract has high water solubility and good quality. Results of ash values are within limit and show that there are less impurities in the extract. Phytochemical evaluation shows presence of constituents in extract. Extract contain good amount of alkaloid. Capsule passed the test for uniformity of weight. All capsules disintegrated within 7 minutes. Dissolution of capsule was >70 %. Moisture content of capsule was w/w which indicates that there is less chances of microbial growth and capsule will not become soft. Data of HPTLC finger printing indicates that extract was derived from genuine plant or parts of the plant and also capsule contain the same extract. Capsule passed the limit for heavy metals and microbial contamination. Results of nutritional value showed good amount of carbohydrate and protein .

Characterization of powdered drug Ashwagandha Organoleptic properties: Ashwagandha extract was Analyzed for their organoleptic properties like color, Solubility and wave length maxima of drug. From the Results it was concluded that ashwagandha was found to Be soluble in phosphate buffered saline (PBS pH 7.4) and Dimethylsulphoxide. The concentration 100µg/ml of Ashwagandha extract in phosphate buffered saline wasFound to be 226nThe herbal capsules were evaluated for their description, Average weight, weight variation, moisture content, Disintegration time, pH and microbial load and compared with Indian pharmacopoeial standards.

IV. CONCLUSION

Data suggested that capsule and its extract were consistent with various identity, quality and purity parameters such as organoleptic parameters, physico-chemical parameters, HPTLC fingerprinting, heavy metal analysis and microbial analysis. It also gives surety about the product which is genuinely prepared. Nutritional assessment of the each capsule indicates their dietary supplement value and medicinal role as an herbal supplement. Selected Herbal capsules have passed through all the WHO parameters which were tested.The review concludes the results of recent studies on Ashwagandha suggesting its extensive potential as neuroprotective in various brain disorders as supported by preclinical studies, clinical trials and published patents. However vague understanding of the mechanistic pathways involved in imparting the neuroprotective effect of Ashwagandha warrants further study to promote it as a promising drug candidate.

Ashwagandha is a plant material that has been used for centuries in traditional medicine systems, particularly in Ayurvedic medicine. Over the years, research has been conducted to investigate the various effects of Ashwagandha, and this research has shown that it has multiple beneficial effects on different body systems. However, it is important to note that research on Ashwagandha is ongoing, and more studies are needed to confirm its potential therapeutic uses and to determine the optimal doses and durations of use. Additionally, it is important to consider the safety of Ashwagandha, particularly when used in combination with other medications or supplements. Therefore, ongoing research, particularly clinical trials, is necessary to provide further insights into the potential benefits and risks of using Ashwagandha as a therapeutic agent.

Review is an important tool to summarize the evidences relating to effectiveness of health care interventions accurately and reliably. In this review, we evaluated the effects of Ashwagandha on brain related disorders. Ashwagandha and its extract have been used since decades to treat various diorders. Ashwagandha is largely used as an immunomodulator in recent times and indicated anti-diabetic, hepatoprotective, anticancer, anti-inflammatory activity as well.

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