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# FORMULATION AND EVALUATION OF COMBINATION TABLET OF ASHWAGHANDHA AND TULSI

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#### **ABSTRACT**

In this sense, studying medicine is both an art and a science. Because of their convenience of use and suitability for systemic drug delivery, pharmaceutical oral solid dosage forms have been in widespread use for decades. The current study's goal was to create and assess an ashwagandha and tulsi combo tablet. Tulsi is a herbal powder that boosts immunity and lessens coughing, and there has been a notable increase in reports in recent years about the health benefits of winter cherry (Withania somnifera), better known as ashwagandha. The health benefits of winter cherry (Withania somnifera), commonly referred to as ashwagandha, have been the subject of a notable increase in publications in recent years. Compressed tablets containing ashwagandha and tulsi should be prepared, and research on them should be done. Additionally, there have been indications of antibacterial, anti-inflammatory, cardioprotective, and antimicrobial

properties that help cough and strengthen the immune system. The most recent research is examined in this narrative review, which also offers a thorough summary of the existing knowledge regarding the applications of tulsi and ashwagandha as well as any known safety issues or contraindications.

**KEYWORDS:** Withania Somnifera; Holy Basil; Tablet; Ashwagandha; Tulsi; Ayurveda; Formulation.

## 1. INTRODUCTION

W. somnifera Dunal (Solanaceae), also known as ashwagandha or winter cherry, is one of the most valuable plants in the traditional Indian systems of medicine. It is a small evergreen

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shrub that grows to roughly four to five feet tall. In India, it is cultivated, on a commercial scale, in the states of Madhya Pradesh, Uttar Pradesh, Punjab, Gujarat and Rajasthan.<sup>[1]</sup> In recent years, there has been a growing interest in the potential health benefits of Ashwagandha, particularly in the areas of stress management, cognitive function, and physical performance. Several studies have suggested that Ashwagandha supplementation may exhibit neuroprotective activity, be helpful in obsessive-compulsive disorder, and exhibit anti-inflammatory, immunomodulatory and antibacterial properties additionally, there is evidence to suggest that ashwagandha supplementation may be helpful in infertility, anticancer and antidiabetic treatment. Studies have suggested that Ashwagandha may exhibit cardioprotective properties, be helpful in the treatment of sleep disorders, improve stress resilience, reduce anxiety, be helpful in hypothyroidism, and enhance muscle strength and recovery. While the potential health benefits of Ashwagandha are promising, further research is needed to fully understand its mechanisms of action and to determine its effectiveness in treating various health conditions. In this context, this paper aims to review the current literature on the activity of Ashwagandha, with a focus on its potential benefits for stress management, cognitive function, and physical performance. [2]

Tulsi, also known as Holy Basil, is a revered herb in Ayurvedic medicine and has been used for centuries for its medicinal, spiritual, and cultural significance. This perennial herb, scientifically known as Ocimum sanctum, is native to India, Southeast Asia, and the Pacific Islands, and is cultivated in tropical and subtropical regions worldwide. [3] Tulsi is rich in bioactive compounds, including volatile oils, flavonoids, and phenolic acids, which contribute its antimicrobial, anti-inflammatory, antioxidant, immunomodulatory properties.<sup>[4]</sup> Traditionally, Tulsi has been used to treat various health conditions, including respiratory issues, digestive problems, and skin diseases, and is also considered a sacred plant in Hinduism, used in various rituals and ceremonies.<sup>[5]</sup> In modern times, Tulsi is available in supplement forms, herbal teas, and skincare products, promoting relaxation, reducing stress, and offering antioxidant benefits. [6] However, it is essential to consult a healthcare professional before using Tulsi, especially during pregnancy, breastfeeding, or when taking medications, as it may interact with certain drugs or exacerbate allergies.<sup>[7]</sup> 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.<sup>[8]</sup> Ashwagandha Drug Profile: Ashwagandha (WiQasomnifera) is an adaptogenic herb that has been used for centuries in traditional Ayurvedic medicine. It is also known as Indian ginseng or winter cherry.

Here is a brief drug of profile of ashwagandha



Fig 1: Ashwagandha Powder.

## • Ashwagandha Drug Profile

## 1) Medicinal Uses

#### Adaptogen

Ashwagandha is classified as an adaptogen, which means it helps the body adapt to stress andnemaintain balance.

## • Relief from Stress

Commonly used to help manage stress and anxiety. Cognitive function: Some studies suggest that Ashwagandha may be neuroprotective and improve cognitive function.

## • Immune Support

It is believed to have immunomodulatory properties that will help support the immune system.

## Anti-Inflammatory

Ashwagandha may have anti-inflammatory properties, which may be beneficial for conditions associated with inflammation.

## 2) Active ingredients

## Withanolides

These bioactive ingredients are believed to contribute to the medicinal properties of Ashwagandha. They have anti-inflammatory & adaptogenic effects.

## 3) Dosage Form

Ashwagandha is available in many forms, including capsules, powder, and liquid extract. Dosage may vary, but a common recommendation is 300 mg to 600 mg of the process extract containing approximately 5% with anolide.

## 4) Safety and side effects

Generally considered safe for most people when used correctly. Minor side effects may include diarrhea. People with certain medical conditions or taking medications should consult a doctor before using Ashwagandha.

## 5) Interactions

Ashwagandha may interact with medications, especially sedatives, Caution is advised when used with medications that treat anxiety, sleep disorders, or other CNS depressants.

## 6) Pregnancy and breast-feeding

Pregnant or breast-feeding women should consult their doctor before using Ashwagandha.

## 7) Quality Notes

The quality of Ashwagandha products may vary. It is important to choose reputable brands and products that have been tested for purity and potency. As with all herbal supplements, individual reactions may vary. It recommended to consult a doctor before incorporathy Ashwagandha into your health, especially if you have a pre-existing condition or are taking medication.[9,10]

## **Tulsi Drug Profile**

Tulsi, also known as Holy Basil, is a sacred herb in Hinduism and is widely used in traditional Ayurvedic medicine. It has a long history of medicinal use and is known for its adaptogenic properties. Here is a brief Drug profile of Tulsi



Fig 2: Tulsi.

## 1. Botanical Information

- Scientific Name: Ocimum sanctum or Ocimumtenuiflorum
- Common Names: Tulsi, Holy Basil.

#### 2. Medicinal Uses

Adaptogens

Tulsi is classified as an adaptogenic herb that helps the body adapt to stress and maintain balance.

#### Antioxidants

Contains antioxidants that help protect cells from damage caused by free radicals.

## • Anti-Inflammatory

Tulsi has anti-inflammatory properties that may be beneficial for many elements.

## Antibacterial

It has been proven to provide antibacterial protection against bacteria, viruses and fungi.

#### Health Effects

Tulsi is traditionally used for respiratory infections and may help relieve coughs and colds.

## 3. Active ingredients

Ociciside A and B

These are triterpene compounds found in Tulsi that have adaptogenic properties.

## Eugenol

An essential oil component with antibacterial and anti-inflammatory properties.

## Ursolic acid

Another triterpenoid with antioxidant and antioxidant effects. Anti-inflammatory effect.

## 4. Dosage and Forms

Tulsi is available in many health forms, including fresh leaves, dried leaves for tea, extracts, and supplements. Dosage may vary, but recommendations include drinking Tulsi tea or taking Tulsi supplements as directed on the product.

## 5. Safety and side effect

Tulsi is generally considered safe when taken in moderation. Some people may experience minor side effects such as stomach upset or allergic reactions. Pregnant women or the elderly and people with certain medical conditions should consult a doctor before using Tulsi.

#### 6. Interactions

Tulsi may interact with some medications, and caution is advised when combining it with medications that affect blood clotting or diabetes. It is important to consult your doctor if you are taking medication or have an underlying condition.

## 7. Medicinal Uses

In Ayurveda, tulsi is used to treat many ailments, including anxiety, respiratory problems, skin diseases, and more. It is also used in Hindu religion and spirituality. As with all herbal supplements, individual reactions may vary. [9,10,11]

## 2. LITERATURE REVIEW

Gaytri Anil More et al. 2024, At various points throughout the life cycle of a pharmaceutical product, analytical procedures must be established. If these tasks are not appropriately simplified based on scientific knowledge and process understanding, it could result in an extremely expensive and time-consuming approach. The pharmaceutical industry is constantly looking for new guidelines or components to add to or replace the current components of the quality and risk management system The idea of Quality by Design was first introduced by renowned quality expert Joseph M. Juran.

- Harshada Kanjane et al. 2022, 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.
- Vaishnavi G. Thokal et al. 2024, 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.
- Mikulska, P.; Malinowska et al\* 2023, In recent years, there has been a significant surge in reports on the health-promoting benefits of winter cherry (Withania somnifera), also known as Ashwagandha. Its current research covers many aspects of human health, including neuroprotective, sedative and adaptogenic effects and effects on sleep. There are also reports of anti-inflammatory, antimicrobial, cardioprotective and anti-diabetic properties. Furthermore, there are reports of reproductive outcomes and tarcicidal hormone action.
- **Keerthi B et al, 2014,** Objective of the present study was to formulate and evaluate capsules of Ashwagandha phytosomes. There are many herbal extracts having excellent in-vitro activity but less in-vivo activity because of their macromolecular size and poor lipid solubility, which result in poor absorption and bioavailability problems. Many of these problems can be overcome by formulating novel drug delivery systems Phytosomes provide better absorption and bioavailability than the conventional herbal extracts. This project aims in improving the drug release characteristics of Ashwagandha by formulating Ashwagandha phytosome capsules.

• **Krutika J et al. 2016,** Withania somnifera Dunal member of Solanaceae family popularly known as Ashwagandha, Indian ginseng, or winter cherry has been used in Ayurveda, Indian system of traditional medicine. It is classified as a Rasayana (rejuvenation) and accepted to increase longevity and vitality. It is a reputed health food and herbal tonic and used for cardiovascular diseases in ethnomedicine. It is available for human use either as a single herb or an ingredient of polyherbal or herbomineral formulations. Thorough review of ayurvedic literature and scientific research journals and articles were executed and presented in concise manner.

## 3. MATERIALS & METHODS

#### MATERIALS

Table: List of Material.

S. No	Materials
1	Ashwagandha
2	Tulsi
3	Lactose
4	Magnesium Stearate
5	Crospovidone
6	Kaolin
7	Tragacanth

## Equipments

## **Table: List of Equipments.**

S.No.	Instruments	Manufacturer		
1	Weigh balance (Electronic)	Shimadzu		
2	FTIR- infrared	Shimadzu		
	spectrophotometer	Siiiiiauzu		
3	DSC	Shimadzu DSC-60 Plus Thermal Analyzer, Japa		
4	Tablet punching machine	<u>Delite Tablet Punching</u> <u>Machine, V</u> adodara		
5	Friability test apparatus	Meta Lab Scientific Industries, Mumbai India		
6	Disintegration test apparatus	DBK Instruments, Mumbai		
7	Monsanto hardness tester	Pathak Electrical Works, Mumbai		
8	Tap density Apparatus	Campbell Electronics, Mumbai, India		
9	Dissolution tester (TDT-14L	Electrolab, Banglore, India		
	USP)	Electrolate, Danglore, filtra		

## 4. Experimental Works

## • Preparation of Ashwagandha & Tulsi Powder

Determine the amount of each ingredient based on the desired dosage and tablet size. Weigh a specific amount of ashwagandha powder. Mix it with a suitable solvent (ethanol or water) and allow it to stand for 24 hours.

www.wjpr.net | Vol 14, Issue 11, 2025. | ISO 9001: 2015 Certified Journal | 1577

## Preparation of lactose solution

Prepare a use in water to lactose solution in sufficient quantity.

## • Preparation of Tablet Mixture

Combine powdered ingredients (ashwagandha, tulsi, crospovidone, kaolin & tragacanth) in a blender or food process until well blended. Add drop wise lactose solution. Mix thoroughly to ensure uniform distribution.

## Excipient

While mixing, gradually add magnesium sterate to act as a lubricant and help brek down the tablet.

#### Binder

Add lactose solution to the mixture to act as binder, helping shape the pills and possibly giving them additional healing properties.

#### • Granulation

Add a suitable binding agent to the mixture and granulate it. Dry the granules at a low temperature.

## Compression

Compression the dried granules into tablets using a tablet press. Ensure the tablets are the uniform weight and size.

## Drying

Once granulation is complete, place on tablet to remove excess moisture.

## 5. Preformulation Studies

## 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.

## • 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 = Weight of the powder / volume of the packing.

## • 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 = Weight of the powder / volume of the tapped packing.

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

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

• **Hausner's Ratio:** It measures the drug's flow characteristic. Hausner's Ratio = Tapped density/ Bulk density. [12]

## 6. METHOD OF PREPARATION

• Wet granulation method: Pass all the ingredients through sieve no. 80. Mix Ashwagandha & Tulsi, Crospovidone, Tragacanth & Magnesium stearate. Prepare separately Lactose solution with water (Q.S). Add the solution to the mixture to form a damp coherent mass. Pass the coherent mass through sieve no.12 to form granules. Dry the granules at 50-60°C for 1 hour in hot air oven. Pass the dried granules through sieve no.16 or 18. Add Talc and mix thoroughly. Evaluate the preparation for preformulation studies. [13]

Table: Formulation of combination tablet of Ashwagandha and Tulsi.

Sr.No	Ingredients	Quantity (mg)			
		<b>F</b> 1	F2	<b>F3</b>	
1]	Ashwagandha	125	125	125	
2]	Tulsi	125	125	125	
3]	Lactose	57	57	57	

4]	Magnesium Stearate	3	6	5
5]	Crospovidone	9	6	7
6]	Kaolin	3	3	3
7]	Tragacanth	3	3	3
	Total (mg)	325	325	325

## 7. Post-formulation General appearance

The general appearance and color of tablets were found by visual determination. It is Round or oval, circular in shape and light brown to dark greenish brown in colour.

## • 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 X 100.

## Hardness Test

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



Fig. Hardness test apparatus.

## • Friability test

Friability of a tablets can determine by Roche Friabilator. The friabilator consists friabilator, 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.



Fig: Friability Test Apperatus.

## • 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.<sup>[14,15]</sup>



Fig: Disintegration test Apparatus.

## Dissolution Test

The separation test measures the quantity and quantity of the dosage form (such as tablets) as the drug. Dissolution of drugs is important for their bioavailability and therapeutic effects. Dissolution and release are terms used interchangeably.<sup>[16,17]</sup> The general separation method

is to place a liquid called dissolution. medium into a container of the dissolution unit. The environment can range from deionized water that has been degassed or sonicated, to pH-adjusted chemically prepared solutions, to media prepared with surfactants.<sup>[18]</sup>

## 8. RESULT

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 4. All the pre-formulation study the flow property of granules was poor. The evaluation parameters of compressed tablets were shown in table 5. The compressed tablets color was whitish. The weight variation test, hardness, thickness, friability, and disintegration time were shown in table 5.

## • Preformulation parameters

**Table 4: preformulation parameters.** 

<b>Pre-formulation parameters</b>	F1	F2	F3	F4
Angle of repose	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

#### • Evalulation parameters for tablets

Table no. 5: Post Formulation Parameters.

<b>Evaluation parameters</b>	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

## 7. CONCLUSION

The combination of Ashwagandha (Withaniasomnifera) and Tulsi (Ocimumsainttum) in various forms creates a synergistic effect. Known for their adaptogenic properties, these herbs complement each other to improve stress and overall health. Ashwagandha is known for its stress-relieving properties, helping the body adapt to various stressors and promoting a sense of harmony. Traditionally used in Ayurvedic medicine for its calming effects on the nervous system, tulsi complements the stress-relieving effects of ashwagandha. This combination not only relieves stress symptoms, but also supports the body's ability to respond better to stress, thus reducing the negative effects of chronic stress on the body and mind. In addition, many

herbs can aid in stress reduction and health, as well as providing additional benefits such as anti-inflammatory, anti-oxidant, mood enhancement, digestive health rice, adaptogen support, and wisdom.

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