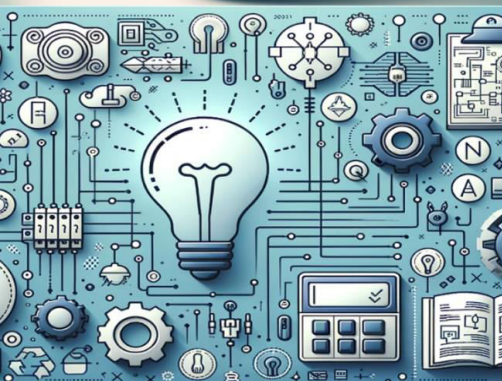




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Formulation and Evaluation of Herbal Capsule for Epilepsy

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ABSTRACT: Herbal capsule for epilepsy is used to treat epilepsy containing Withania somnifera, natively known as Ashwagandha, is a multipurpose restorative plant of the family Solanaceae. Clinical and preclinical trials suggest the ability to cure hepatotoxicity, Parkinson's, hyperlipidemia, and neurological disarranges Phytochemical investigation of W. somnifera uncovered the nearness of pharmacologically dynamic steroidal lactones named withanolides, along with major phytochemicals including saponins, steroids, flavonoids, phytophenols, and glycosides. Withanine, a bunch of alkaloids disconnected from the roots of the plant, shapes 38 % of the full weight of alkaloids. It has an antioxidative component that increments the levels of gamma-aminobutyric corrosive (GABA) and cortical muscarinic acetylcholine (Ach), as well as upgrading neurite recovery all through the brain). This plant has been specifically recommended in Ayurvedic texts for the management of Apasmara (epilepsy) due to its ability to balance Vata and Kapha, which are believed to be implicated in the pathogenesis of the disorder.

KEYWORDS: Epilepsy, Withania Somnifera, neurological disorders, phytochemical constituents.

I. INTRODUCTION

1.1 Epilepsy

Epilepsy is a brain disease where nerve cells don't signal properly, which causes seizures. Seizures are uncontrolled bursts of electrical activities that change sensations, behaviors, awareness and muscle movements. Although epilepsy can't be cured, many treatment options are available.

Seizure episodes are a result of excessive electrical discharges in a group of brain cells. different parts of the brain can be the site of such discharges.

Seizures can vary from the briefest lapses of attention or muscle jerks to severe and prolonged convulsions. Seizures can also vary in frequency, from less than one per year to several per day. One seizure does not signify epilepsy (up to 10% of people worldwide have one seizure during their lifetime). Epilepsy is defined as having two or more unprovoked seizures.

Epilepsy is one of the world's oldest recognized conditions, with written records dating back to 4000 BCE. Fear, misunderstanding, discrimination and social stigma have surrounded epilepsy for centuries.

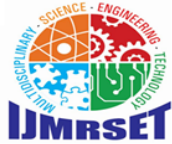
Epilepsy has many possible causes, but about half of people living with epilepsy do not know the cause. In some cases, epilepsy is clearly linked to genetic factors, developmental brain abnormalities, infection, traumatic brain injury (TBI), stroke, brain tumors, or other identifiable problems.

1.2 Types of epilepsy Epilepsy is a common seizure disorder that can be classified into four main types based on the type of seizures a patient experiences:

- **Generalized epilepsy** Seizures that start in widespread areas of the brain. Subtypes include tonic clonic seizures, myoclonic seizures, absence seizures, and atonic seizures.

- **Focal epilepsy** Seizures that start in a specific area of the brain. Subtypes include temporal lobe epilepsy and frontal lobe epilepsy.

- **Generalized and focal epilepsy** Patients with this type of epilepsy experience both generalized and focal seizures.



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•Unknown onset

A type of epilepsy where the onset of the seizure is unknown. This could be because the seizure happened at night or in a person who lives alone, or because it wasn't witnessed by anyone.

A doctor can use various tests to determine the type of epilepsy a patient has, including a physical exam, blood tests, imaging scans, and an EEG. Treatments for epilepsy can include drugs, surgery, vagus nerve stimulation, and/or a high-fat diet.

Generalized epilepsy People with this type of epilepsy have generalized seizures. These affect both the left and right sides of the brain. Additionally, these seizures may be either motor, which involve physical movement, or non-motor, which do not.

If someone has a motor seizure, they may experience:

- jerking movements
- weakness or limp limbs
- tense, rigid muscles
- muscle twitching
- full-body epileptic spasms

Focal epilepsy

People with focal epilepsy have focal seizures. Unlike generalized seizures, focal seizures only affect one part of the brain. They can start in one area and move to others.

These seizures can begin with an aura, which are minor symptoms signifying the seizure's onset. This can feel like an uneasy feeling in the stomach, similar to the feeling of riding a roller coaster. As the seizure progresses, a person can experience motor and non-motor symptoms. Some motor symptoms of focal seizures include:

Combined generalized and focal epilepsy

Someone with combination epilepsy has both generalized seizures and focal seizures. Therefore, they can experience a mixture of the symptoms discussed above. Combined epilepsy is linked to Dravet syndrome, which is a rare, lifelong form of epilepsy. It is usually caused by a mutation in the SCN1A gene. Because it is often misdiagnosed, people who think they or a family member may have these seizures should contact a doctor.

1.3 Symptoms or warning signs may include

- Staring.
- Jerking movements of the arms and legs.
- Stiffening of the body.
- Loss of consciousness.
- Breathing problems or breathing stops.
- Loss of bowel or bladder control.

Falling suddenly for no apparent reason, especially when associated with loss of consciousness. The main symptom of epilepsy is repeated seizures, which are caused by abnormal electrical activity in the brain. The symptoms of a seizure can vary depending on the area of the brain that is affected :

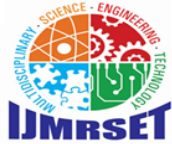
•Physical symptoms

Uncontrolled movements, such as jerking, twitching, or convulsions; loss of muscle tone, also known as a drop attack; stiffening of the body; breathing problems or breathing stops; loss of bladder or bowel control

•Mental symptoms

Temporary confusion, difficulty thinking, speaking, or understanding; psychological symptoms such as fear, anxiety, or déjà vu

•Sensory symptoms Changes in hearing, vision, taste, smell, numbness, or tingling



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Other symptoms

Staring spells, drooling or frothing at the mouth, lip-smacking, hand-rubbing, chewing motions, finger motions, falling suddenly for no apparent reason.

After a seizure, a person may experience a postictal phase, which can last from minutes to hours. During this time, they may feel sleepy, confused, dizzy, sad, scared, anxious, or frustrated. They may also have nausea, a headache, or weakness. People from all races, ethnicity, age, and genders can develop epilepsy. Seizure episodes can vary among individuals. Some stare blankly.

4 Causes Of Epilepsy

Epilepsy can have various causes, which may include:

- **Genetics:** Some types of epilepsy can be linked to specific genetic factors or familial predispositions.
- **Brain Conditions or Injuries:** Brain injuries due to trauma, tumors, strokes, or infections like meningitis or encephalitis can trigger epilepsy.
- **Developmental Disorders:** Conditions present at birth, such as neurodevelopmental disorders or brain malformations, may increase the risk of epilepsy.
- **Infections:** Certain infections affecting the brain, such as meningitis, encephalitis, or parasitic infections like neurocysticercosis, can lead to epilepsy.
- **Prenatal Injury or Exposure:** Injuries to the brain before birth due to lack of oxygen, infections, or other prenatal factors can contribute to epilepsy.
- **Neurological Diseases:** Neurological conditions like Alzheimer's disease or multiple sclerosis can increase the risk of developing epilepsy.
- **Stroke and brain damage.**

Possible seizure triggers include:

- Alcohol.
- Flashing lights.
- Illicit drug use.
- Skipping doses of antiseizure medicines or taking more than prescribed.
- Lack of sleep.
- Hormone changes during the menstrual cycle.

Pathophysiology of epilepsy

The normal brain continuously generates tiny electrical impulses in an orderly pattern. Chemical messengers (neurotransmitters) help in the transmission of impulses along neurons (the network of nerve cells in the brain) and all over the body. The pathophysiology of epilepsy is not fully understood. Comorbidities and persistent early mortality suggest a systemic component.

1. Ion homeostasis: Disturbances to the balance of ions outside of cells

2. Energy metabolism: Changes to how the body obtains energy

3. Receptor function: Changes to the function of receptors

4. Transmitter uptake: Changes to how transmitters are taken up

1.6 Diagnosis of epilepsy

Blood test

Seizures are occasionally caused by an acute underlying toxic or metabolic disorders in which case appropriate therapy should be directed to the specific abnormality e.g. hypocalcaemia. Blood samples are often screened for metabolic or genetic disorders that

may be associated with the seizures. Blood samples are also tested for the problems such as infections, lead poisoning, anemia and diabetes that may be causing or triggering the seizure.

1. **Complete Blood Count (CBC):** Checks the different types of blood cells and can reveal infections, anemia, or other blood disorders.



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2. **Blood Chemistry Panel:** Measures levels of various substances in the blood, including electrolytes, kidney function markers, and liver function markers.
3. **Toxicology Screen:** Detects the presence of drugs or toxins in the blood that could be causing seizures.
4. **Genetic Testing:** Analyzes DNA to identify genetic mutations associated with epilepsy.
5. **Prolactin Levels:** Measuring prolactin level help determine if an epileptic seizure has occurred.
1. **Electroencephalogram (EEG)**
2. **Medical History**
3. **EEG Monitoring**
4. **Brain Scan**

Medication for epilepsy

An accurate diagnosis of the type of epilepsy (not just the type of seizure, because most seizure types occur in different types of epilepsy) a person has is very important in choosing the best treatment. The type of medication prescribed will also depend on several factors specific to each patient, such as which side effects can be tolerated, other illnesses they may have, and which delivery method is acceptable. Below is a list of some of the most common brand-name drugs currently used to treat epilepsy.

- **Carbamazepine (Tegretol):** Used for partial seizures and generalized tonic-clonic seizures.
- **Gabapentin (Neurontin):** Used to treat focal onset seizures and nerve pain.
- **Lamotrigine (Lamictal):** Used for various seizure types, including partial and generalized seizures.
- **Levetiracetam (Keppra):** Used for different seizure types, including partial and generalized seizures.
- **Oxcarbazepine (Trileptal):** Used for partial seizures and generalized tonic-clonic seizures.
- **Phenytoin (Dilantin):** Used for various seizure types, including partial and generalized seizures.
- **Pregabalin (Lyrica):** Can be used for epilepsy, but also for nerve pain and anxiety.
- **Sodium Valproate (Depakene, Depakote):** Used for various seizure types, including partial and generalized seizures.
- **Topiramate (Topamax):** Used for various seizure types, including partial and generalized seizures.

1. Sodium channel blocker

The firing of an action potential by an axon is accomplished through sodium channels. Each sodium channel dynamically exists in the following 3 states:

A resting state, during which the channel allows passage of sodium into the cell
An active state, in which the channel allows increased influx of sodium into the cell

An inactive state, in which the channel does not allow passage of sodium into the cell
During an action potential, these channels exist in the active state and allow influx of sodium ions.

2. Calcium channel blockers

Calcium channels exist in 3 known forms in the human brain: L, N, and T. These channels are small and are inactivated quickly. The influx of calcium currents in the resting state produces a partial depolarization of the membrane, facilitating the development of an action potential after rapid depolarization of the cell.

Herbal treatment for epilepsy

- **Ashwagandha (Withaniasomnifera)**
- Ashwagandha is known to treat epilepsy. This, along with rich sources of omega 3 fatty acids like flax seeds, is said to delay the occurrence of Epileptic Seizures.
- Ashwagandha is a prominent herb in Ayurveda, often referred to as the "King of Herbs" for its rejuvenating properties. Its name translates to "smell of the horse," indicating its ability to impart strength and vigor.
- **Botanical Information**
- **Family:** Solanaceae (nightshade family)
- **Parts Used:** Roots (most potent), leaves (milder effects)
- **Active Constituents:** Withanolides, alkaloids, saponins, sitoindosides
- **Pharmacological Actions**
- Ashwagandha (Withaniasomnifera) shows potential anticonvulsant activity, possibly by modulating GABAergic neurotransmission, enhancing antioxidant defenses, and reducing oxidative stress.



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- **1. Adaptogenic (Anti-Stress)**
 - Helps the body adapt to physical, mental, and emotional stress.
 - Regulates cortisol levels, reducing anxiety and fatigue.
- **2. Immunomodulatory**
 - Strengthens the immune system by enhancing white blood cell (WBC) activity.
 - Balances immune response, beneficial for autoimmune disorders like Myasthenia Gravis (MG).
- **3. Anti-inflammatory**
 - Suppresses pro-inflammatory cytokines, easing muscle pain and inflammation.
 - Helps reduce oxidative stress, which may worsen MG symptoms.
- **4. Neuroprotective**
 - Enhances cognitive function, memory, and focus.
 - Promotes nerve regeneration and supports synaptic plasticity.
- **5. Muscle Strength & Recovery**



- Increases muscle mass and reduces exercise-induced muscle damage.
- Beneficial in conditions involving muscle weakness, such as MG.
- **Benefits for epilepsy**
- In epilepsy, Ashwagandha can play a supportive role by:
 - Give anticonvulsant effect.
 - Improving muscle strength and endurance.
 - Enhancing energy levels and reducing fatigue.
 - Managing stress and anxiety, common MG triggers.
 - Reducing inflammation that may worsen neuromuscular symptoms.
- **Dosage & Forms**
- Ashwagandha is available in various forms:
- **4.0 Material and method**

4.1 List of chemical

S.no	Name of chemical	Role of chemical
1	Ashwagandha	Renovate Mind & Body



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2	Lactose	Diluent, Binder
3	Magnesium Stearate	Lubricant
4	Tragacanth	Binder
5	Starch	Disintegrant
6	talc	Glidant

4.2 List of Glassware

S.no	Glassware
1	Beaker
2	Funnel
3	Measuring cylinder
4	Glass road
5	Mortar Pestle
6	Pipette
7	Watch Glass

Preformulation studies

1. Organoleptic properties

- **Appearance:** Light brown to dark brown powder with a slightly fibrous texture. The roots are usually long, slender, and cylindrical.
- **Odor:** Characteristic earthy, slightly pungent, and musty aroma.
- **Taste:** Bitter, astringent, and slightly pungent.
- **Touch/Texture:** Root powder feels coarse or fibrous with a somewhat dry texture.

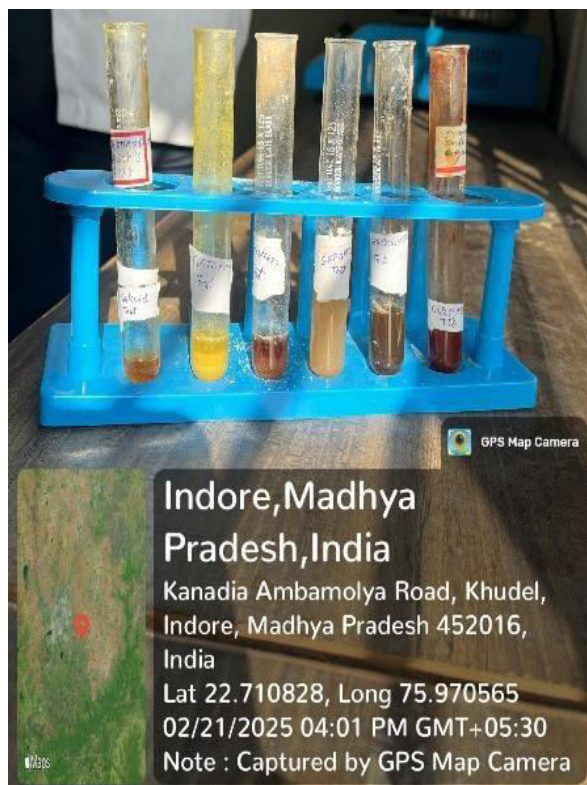
Phytochemical screening

1. **Test for Alkaloid Wagner's test:** About ten mg of extract was taken and few drops of Wagner's reagent (Dissolve 2 g of iodine and 6g of KI in 100 cm³ of water) was added and the formation of a reddishbrown precipitate indicates the presence of alkaloids.
2. **Test for Flavonoid Lead acetate test:** Ten mg of extract was taken and few drops of 10% lead acetate solution was added. Appearance of yellow colour precipitate indicates the presence of flavonoids.
3. **Test for Tannin Ferric Chloride Test:** To 5 ml of the sample, a few drops of 0.1% ferric chloride were added. The presence of a brownish green or blue black colour indicated that the material possessed tannins.
4. **Test for Saponin Foam test:** 0.5 mg of extract was diluted with 20 ml distilled water and shaken well in a graduated cylinder for 15 min. The formation of foam to a length of 1 cm indicated the presence of saponins.
5. **Test for Carbohydrates Fehling's test:** Five ml of Fehling's solution was added to 0.5 mg of extract and boiled in a water bath. The formation of yellow or red precipitate indicates the presence
6. **Test for Glycosides Glycoside test:** 0.5 mg of extract was dissolved in 1 ml of water and then aqueous NaOH solution was added. Formation of yellow colour indicates the presence of glycosides.



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Flow property of powder

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

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. Hausner's Ratio = Tapped density/ Bulk density.

6. Loss on drying at 105°C: 10g of sample was placed in tarred evaporating dish. It was dried at 105°C for 5 hours in hot air oven and weighed. The drying was continued until difference between two successive weights was not more than 0.01 after cooling in desiccator. Percentage of moisture was calculated with reference to weight of the sample.

7. Total Ash: 2g of sample was incinerated in a tared platinum crucible at temperature not exceeding 450°C until carbon free ash is obtained. Percentage of ash was calculated with reference to weight of the sample.



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II. METHOD OF PREPARATION

Wet granulation method

- Weigh all ingredients accurately.
- Mix well and triturate by using mortar and pestle.
- The prepare 1% lactose solution was added slowly to form a dump mass.
- Than dump Mass was transfer through sieve no.12
- Dry the granules at 50-600C for 1 hour in hot air oven.
- Pass the dried granules through sieve no.16 or 18.
- The complete dried granules are ready for capsula
- Evaluate the preparation for preformulation studies.

Ingridient	Formulation	Formulation	Formulation
	F1	F2	F3
Ashwagandha	250	250	250
Lactose	57	57	57
Magnesium Stearate	3	6	5
Tragacanth	3	3	3
Starch	9	6	7
Talc	3	3	3
Total	325	325	325



Evaluation parameter

1. **Weight Variation Test (U.S.P.):** Take 20 capsule , each to be weighed separately. Calculate the average weight before comparing it to the weight of each tablet. If no more than two capsule fall outside the allowed percentage range and no capsule deviates by more than twice the allowed range, the tablet passes the USP test.
2. **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 capsule 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 capsule 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.



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- iv) At a frequency of 28 to 32 cycles per minute, move the basket containing the capsule up and down over a distance of 5 to 6 cm.
- v) Placing perforated plastic discs on each capsule will stop it from floating.

III. RESULT AND DISCUSSION

Result The active ingredient tested in this paper exhibit the considerable properties as mentioned below.

Ashwagandha root Powder Preliminary qualitative phytochemical analysis was carried out to identify the secondary metabolites present in the ashwagandha root powder extracts of acetone, ethanol and aqueous. The following results had been made

Sr. No.	Parameters	Mean value
1	True Density (g/ml)	0.59
2	Bulk Density(g/ml)	0.35
3	Angle of Repose (°)	32.45
4	Carr Index (%)	26.45
5	Hausner Ratio	1.41
6	Ash (%)	5.3

FORMULATION	Weight variation Test (- + STD)	Disintegration test (Min)	Dissolution test (Min)
F	5	9	5
F	5	8	5
F	5	9	5

Discussion "Formulation and evaluation of herbal capsule for epilepsy " presents a comprehensive and well-structured approach to combining herbal medicine with pharmaceutical practices. Epilepsy is a neurological condition characterized by recurrent, unprovoked seizures resulting from abnormal electrical activity in the brain, affecting movement, behavior, and awareness explaining its causes, pathophysiology, types, and symptoms diagnosis .

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