FORMULATION AND EVUALATION OF HERBAL CAPSULE IN TREATMENT OF MIGRANE

[1]Mr. Shubham Santosh Shinde, [2]Mr. Swapnil P. Kulthe
[1]Student, [2]Assistant Professor
[12]Raosaheb Patil Danve College of Pharmacy

***Abstract*—Migraine is a neurological disorder that causes intense headaches, often accompanied by nausea, sensitivity to light, and vomiting, significantly affecting the quality of life. Despite the availability of pharmacological treatments, there is growing interest in herbal remedies due to their minimal side effects and holistic benefits. This study focuses on the formulation and evaluation of a herbal capsule combining Amla (Emblica officinalis), Ginger (Zingiber officinale), Yashtimadhu (Glycyrrhiza glabra), and Ashwagandha (Withania somnifera), all known for their anti-inflammatory, analgesic, and neuroprotective properties. These herbs are traditionally used to reduce inflammation, improve circulation, and calm the nervous system, which may help alleviate migraine symptoms. The herbal capsule was prepared by incorporating standardized extracts of these plants, ensuring consistent potency. The evaluation of the capsules included tests for weight variation, disintegration time, moisture content, drug content uniformity, and stability. The results indicated that the formulated herbal capsules met the required quality standards and demonstrated promising potential in providing relief from migraines. This study suggests that the combination of these medicinal herbs could offer a safe and effective alternative for migraine management, warranting further clinical investigation.**

***Index Terms*—Herbal capsule formulation, Migraine Remedy, Natural migraine relief**

I. Introduction

Migraine is a collection of perplexing neurological conditions in which the brain and its associated tissues have been implicated as major players during an attack. Once considered exclusively a disorder of blood vessels, compelling evidence has led to the realization that migraine represents a highly choreographed interaction between major inputs from both the peripheral and central nervous systems. Migraine is a common problem worldwide with significant morbidity and economic impact. The direct costs of migraine are directly related to the severity of migraine pain and disability, and rise dramatically with prescription medication usage. [5]

Migraine is the commonest cause of recurrent, severe headache. It is experienced at some point by over 20% of women and over 10% men. The tendency to suffer from migraine has a genetic basis, but individual attacks may be triggered by internal or external influences, or simply come by themselves for no apparent reason. The name ‘migraine’ originally comes from the Greek word hemicrania, meaning ‘half of the head’, represent- ing one of the most striking features of the condi- tion: that in many cases pain only affects one half of the head. Equally commonly, however, pain is felt bilaterally, at the front or the back of the head, more rarely in the face, and rarer still in the body (‘migrainous corpalgia’). The pain is generally throbbing in nature, and

typically made worse by any form of movement or even modest exertion. The majority of migraine attacks are severe or at least moderately. [19]

In a cross-sectional study of headache disorders in a population of 1,000 persons the epidemiology of migraine with aura (MA) and migraine without aura (MO) was analysed in relation to sex and age distribution, symptomatology and precipitants. The headache disorders were classified on the basis of a clinical interview as well as a physical and a neurological examination using the operational diagnostic criteria of the International Headache Society (IHS). Lifetime prevalence of MA was 5%, male: female ratio 1:2. Lifetime prevalence of MO was 8%, M:F ratio 1:7. Women, but not men, were significantly more likely to have MO than MA. Neither MA nor MO showed correlation to age in the studied age interval (25–64 years). Premonitory symptoms occurred in 16% of subjects with MA and in 12% with MO. One or more precipitating factor was present in 61% with MA and in 90% with MO.

1.1 Phases Of Migraine:

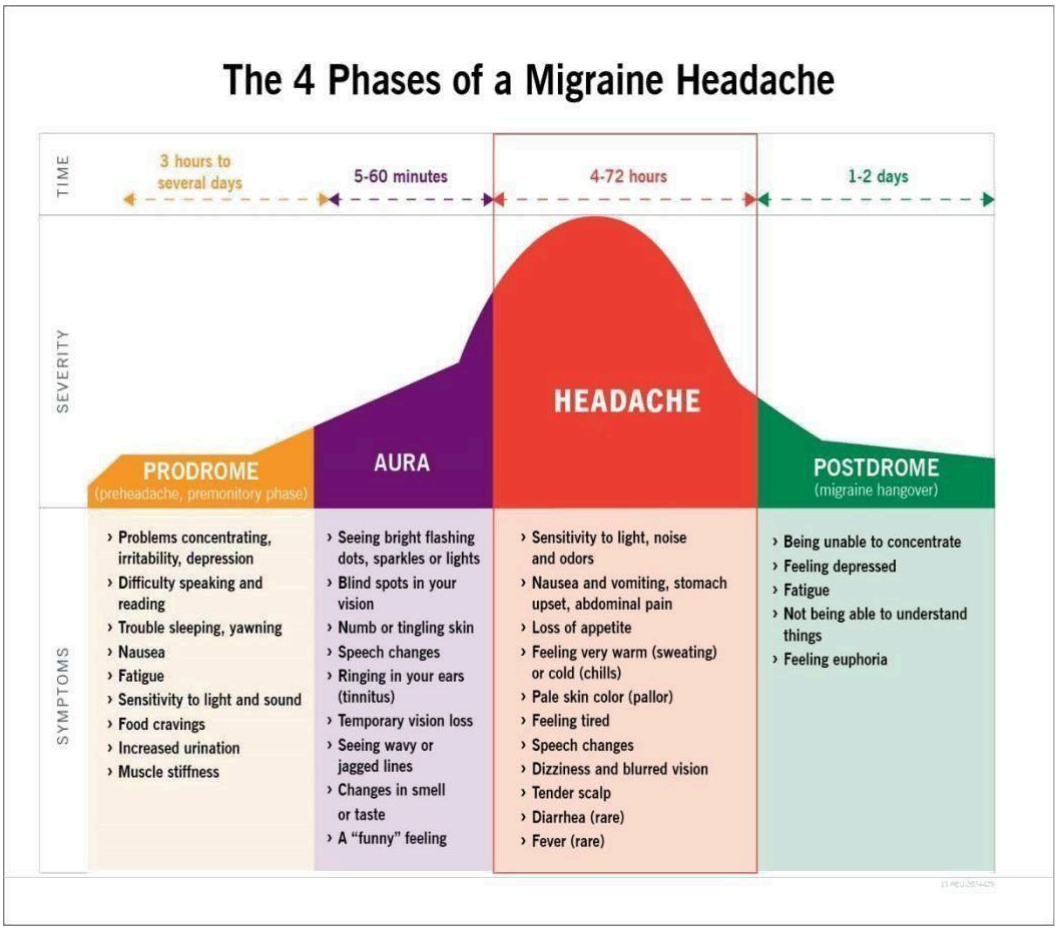


Fig.no.1 Phases of Migraine

Prodrome-

The premonitory phase of migraine can begin as early as 3 days before a migraine headache and allows some patients to correctly predict migraine headache up to 12 hours

before its onset. Common symptoms experienced during this phase, including fatigue, mood changes, food cravings, yawning, muscle tenderness, and photophobia, point to the involvement of the hypothalamus, brainstem, limbic system, and certain cortical areas during the early stages of an attack. Migraine may also display a diurnal periodicity and is commonly triggered by alterations in homeostasis.These findings suggest the involvement of chronobiological mechanisms in migraine pathogenesis and have led to the investigation of the hypothalamus as a potential site of origin of the migraine attack.[14]

Aura –

Approximately one-third of migraine attacks are preceded by aura. The International Classification of Headache Disorders 3rd edition (ICHD-3) defines migraine with aura as recurrent attacks, lasting minutes, of unilateral, fully reversible, visual, sensory or other CNS symptoms that usually develop gradually and are usually followed by headache and associated migraine symptoms.The most prevalent aura symptoms are visual disturbances; however, other common symptoms include sensory, speech/language, and motor disturbances, as well as disruption of higher cortical function.[14]

Headache-

Approximately one-third of migraine attacks are preceded by aura.The International Classification of Headache Disorders 3rd edition (ICHD-3) defines migraine with aura as recurrent attacks, lasting minutes, of unilateral, fully reversible, visual, sensory or other CNS symptoms that usually develop gradually and are usually followed by headache and associated migraine symptoms. The most prevalent aura symptoms are visual disturbances; however, other common symptoms include sensory, speech/language, and motor disturbances, as well as disruption of higher cortical function.

Postdrome-

The postdrome stage is also known as a migraine hangover. It starts when the peak pain of the headache has lessened. Migraine can affect the entire body. During the postdrome stage, the resulting pain or discomfort can occur anywhere in the body. Postdrome can last 24 to 48 hours, but it doesn’t affect everyone, and it doesn’t have to occur after each headache. People with migraine can experience the stage differently, and not everyone’s symptoms will be the same. Symptom of postdrome include, fatigue, bodyaches, mental “fogginess”, dehydration depressed moodeuphoric moodtrouble concentrating.

Migraine is a common disabling condition mostly in adult population and is more prevalent in female predominance .Unilateral throbbing type which is from moderate to severe intensity, headache is a common symptom of the migraine though it may be present with varied presentation.[14]

1.2 Headache caused by migraine has at least two of the following four characteristics:

1. Unilateral location
2. Pulsating quality
3. Moderate or severe pain intensity
4. Causing avoidance of routine physical activity (e.g. walking or climbing stairs)

Migraine may be accompanied with nausea, vomiting. Migraine constitute 15% of primary headache and affects 10-20% of general population. Migraine may be triggered from various factors like; dietary, physical, hormonal and genetic factors.

The indirect costs exceed the costs of medical care, however, and work-related disability is the most important determinant of the economic impact of migraine.Migraineurs often miss work (absenteeism) or have reduced productivity at work (presenteeism). The use of herbal therapies is ancient and increasing worldwide.

There is a growing body of evidence supporting the efficacy of various **"**complementary**"** and alternative medicine approaches in the management of headache disorders. Promising tools to treat migraine patients are herbal products.

1.3 Trigger Factors Of Migraine -

The common trigger factors were emotional stress(79%), sleep disturbance (64%) and dietary factors(44%) sleep and stress were significant trigger factor in patients with migraine with aura, whereas environmental factors were important trigger factors in patients with migraine without aura. Stress,sleep and environmental factors were.important trigger factors in women and differed significantly from men.(18)

Stress: High levels of stress or sudden changes in stress can trigger

migraines.

Hormonal Changes: Hormonal fluctuations, especially in women (e.g., during menstruation pregnancy, or menopause), can lead to migraines.

Sleep Changes: Poor sleep quality, too little sleep, or even oversleeping can trigger migraines.

Weather Changes: Changes in weather or barometric pressure (such as storms or rapid temperature shifts) can also trigger migraines.

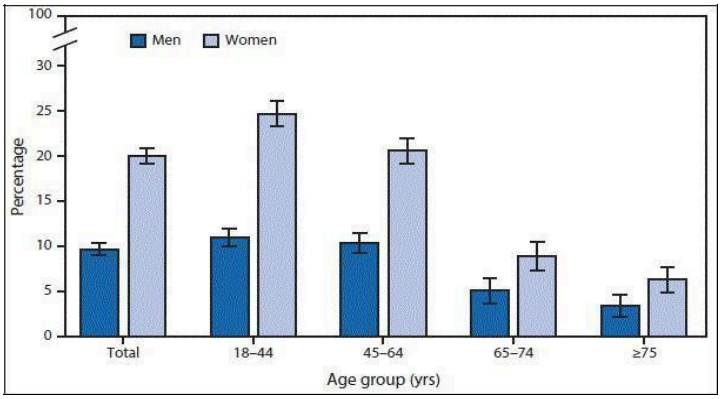
Medications: Certain medications, especially those used to treat high blood pressure or hormonal therapy, can sometimes lead to migraines.

Physical Exertion: Intense physical activity, especially in hot weather, can sometimes lead to migraines.

Neck or Back Strain: Tension in the neck and back muscles can sometimes trigger migraines.

1.4Epidemiology-

Migraine is highly prevalent, affecting 12% of the population, attacking up to 17% of women and 6% of men each year. The adjusted prevalence of migraine is highest in North America, followed by South America, Central America, Europe, Asia, and Africa. It is ranked as the second leading cause of disability worldwide.] Migraine tends to run in families] It is consistently the fourth or fifth most common reason for emergency visits accounting for an annual 3% of all emergency visits. Its prevalence increases in puberty but continues to increase until 35 to 39 years of age, decreasing later in life, especially after menopause. [20]



II. PATHOPHYSIOLOGY OF MIGRAINE

There are four phases to a migraine attack: prodrome, aura, headache and postdrome.The prodrome, caused by hypothalamic activation, is associated with dopaminergic symptoms of yawning, fatigue and polyuria as well as altered food cravings. It can precede the rest of the migraine by hours to days. One-third of patients experience an aura, caused by a spreading wave of cortical depolarisation, which gives the classical phenotypic 'spreading' description. Visual auras (photopsias, flickering lines) are most common, experienced by 65–99% of patients who have migraine with aura.6,7 Sensory, motor and speech aura symptoms may also be seen. The trigger for the headache phase is still debated but involves activation of trigeminal afferents that innervate the dura as well as the trigeminal ganglion. Activation of these structures results in a release of vasoactive peptides including calcitonin gene-related peptide (CGRP), substance P, neurokinin A,and pituitary adenylate cyclase-activating peptide (PACAP), causing local vasodilation. The trigeminal ganglion is a key structure as it exists outside the blood–brain barrier and is rich in CGRP and serotonin receptors, making it a therapeutic target. From here, nociceptive signalling is relay to the trigeminocervical complex and through ascending connections to many other area.

the brain, contributing to the cognitive and autonomic symptoms of migraine. Finally, 60–94% of patients have symptoms following the headache, termed the postdromal phase. These include fatigue, mood disturbance and difficulty concentrating, which are likely continued from the prodromal phase. Patients may attribute these symptoms to side effects of their acute therapies; however, a meta-analysis has confirmed these as features of the disease. [22]

Domestication of plants by man started since the dawn of civilization to meet its basic needs of food, shelter and clothing's. Besides these requirements nature has provided plants for health care, healing and other comforts1. With the emerging interest in the world to adopt and study the traditional system and to exploit their potentials based on different health care systems, the evaluation of the rich heritage of the traditional medicine is essential. Now a days, herbal extracts, and herbal powders are used in the preparations to enhance beauty and increase the attractiveness of the person. These herbal preparations are used as sunburn, complexion brighter, hair remover etc. Herbal cosmetics can be classified on the basis of Dosage Form like- cream, powder, soaps, solutions etc Herbal preparations are also found to be useful drugs in treatment of various disorders.[3]

III. ADVANTAGES OF HERBAL MEDICINE

- Herbal medicine have long history of use and better patient tolerance as well

as acceptance.

- Medicinal plants have a renewable source, which is our only hope for sustainable supplies of cheaper medicines for the world growing population.
- Availability of medicinal plants is not a problem especially in developing countries like India having rich agro-climatic, cultural and ethnic biodiversity.
- The cultivation and processing of medicinal herbs and herbal products is environmental friendly.
- Prolong and apparently uneventful use of herbal medicines may offer testimony of their safety and efficacy.
- Throughout the world, herbal medicine has provided many of the most potent medicines to the vast arsenal of drugs available to modern medical science.[6]

Natural Herbal Products are becoming more popular across world. Plants have been found to be useful for treating various ailments in humans and animals, and people tend to use natural produced substances due to their psychological feeling that natural product is safer.

Following crude drugs are used to formulate the herbal capsule for treatment in

migraine symptoms.

Emblica officinalis -

Common name – Amla

Family – phyllanthaceae

Use – Amla (Indian Gooseberry, *Emblica officinalis*) is used in traditional Ayurvedic medicine as part of migraine treatment due to its anti-inflammatory, antioxidant, and cooling properties.

Withania somnifera-

Common name- Indian Ginseng
Family – solanaceae
Use- Indian Ginseng (Ashwagandha, *Withania somnifera*) is widely used in Ayurvedic medicine and has shown promise in helping manage migraines due to its adaptogenic, anti-inflammatory, and neuroprotective properties.

Zingiber officinale –

Common Name – Ginger
Family – Zingiberaceae
Use - Ginger (*Zingiber officinale*) is a well-researched and effective natural remedy for migraine relief, often used both in traditional and modern medicine. Its benefits stem from its anti-inflammatory, anti-nausea, and pain-relieving properties.

Glycyrrhiza glabra –

Common Name – Liqourice
Family – Fabaceae
Use - Licorice (*Glycyrrhiza glabra*), known as "Yashtimadhu" in Ayurveda, is traditionally used to support migraine treatment due to its anti-inflammatory, adaptogenic, and neuroprotective properties.

IV. STATEMENT OF PROBLEM

Migraine is a prevalent and debilitating neurological condition characterized by recurring episodes of severe headache, often accompanied by nausea, sensitivity to light, and visual disturbances. Conventional pharmacological treatments, while effective for some, are frequently associated with side effects, limited efficacy in long-term use, and the potential for medication overuse headaches. Moreover, there is growing consumer demand for safer, more natural alternatives to synthetic drugs. Despite the documented traditional use of various medicinal plants in managing migraine symptoms, there is a lack of scientifically formulated and standardized herbal products specifically targeting migraine relief. Therefore, there is a pressing need to develop a safe, effective, and standardized herbal capsule using evidence-based medicinal herbs with known anti-migraine properties to offer a natural alternative or complementary option for migraine management.

V. HYPOTHESIS

The development of a herbal capsule using plant-derived bioactive compounds, when properly formulated and standardized, can serve as an effective therapeutic intervention for migraine management. It is hypothesized that the capsule will reduce the frequency, intensity, and duration of migraine episodes through its natural pharmacological actions. Furthermore, the capsule is expected to pass standard evaluation parameters including uniformity of weight, disintegration time, dissolution profile, and stability, thereby ensuring its safety, efficacy, and quality as a herbal dosage form.

VI. AIM AND OBJECTIVE

Aim: Formulation and evaluation of herbal capsule in treatment of migraine

Objective of the study:

- To formulate and evaluate such a herbal powder that is useful in treating migraine.
- It also reduces the frequency of migraine attacks.
- To formulate an easy to administer product.
- Helps to tackle nausea and vomiting caused during migraine attacks.

VII. LITERATURE REVIEW

Narendra singh, et al., (2011)

Withania somnifera (Ashawagandha) is very revered herb of the Indian Ayurvedic system of medicine as a Rasayana (tonic). It is used for various kinds of disease processes and specially as a

nervine tonic. Considering these facts many scientific studies were carried out and its adaptogenic / anti-stress activities were studied in detail. In experimental models it increases the stamina of rats during swimming endurance test and prevented adrenal gland changes of ascorbic acid and cortisol content produce by swimming stress.

Shashikant M Prajapati, et al., (2013)

Glycyrrhiza glabra Linn. commonly known as Licorice/Liquorice, Sweet wood, Mulahatti and Yashtimadhu. The present review study is an attempt to provide reported information on its phyto-constituents and pharmacological activities.

Daniela Pietrobon, et al., (2013)

Migraine is a collection of perplexing neurological conditions in which the brain and its associated tissues have been implicated as major players during an attack. This review focuses on emerging concepts that drive the science of migraine in both a mechanistic direction and a therapeutic direction.

Neeru Bhatt, et al., (2013)

Ginger is a rhizomatous plant and has been used as a spice and medicine in the Indian subcontinent since ancient times. The herb serves as a stimulant and carminative and is used in dyspepsia and colic. It is known to have blood thinning and cholesterol lowering properties, due to which it is used in treating heart diseases. The major phenolic compounds and essential oils act as potent antioxidant and exhibit free radical scavenging properties.

Sankaran Mirunalini, et al., (2013)

Medicinal plants are natural gift to human lives to promote disease free healthy life. Phyllanthus emblica, commonly known as amla is widely distributed in tropical and subtropical areas and has therapeutic potential against deleterious diseases. Earlier it becomes a notable fruit for its rich amount of vitamin C, polyphenols such as tannins, gallic acid, ellagic acid, flavonoids like quercetin and rutin.

G. D Andrea, et al., (2014)

A miscellaneous of recreational drugs and other herbal remedies have been supposed to have a role in headache treatment but quality of clinical studies in this field is low and inconclusive. Further research is warranted in this area.

G. D Andrea, et al., (2014)

A miscellaneous of recreational drugs and other herbal remedies have been supposed to have a role in headache treatment but quality of clinical studies in this field is

VIII. MATERIAL AND METHOD

Material

Procurement of crude powder of –

- *Emblica officinalis*
- *Zingiber officonale*
- *Withania somnifera*
- *Glycyrrhiza glabra*

Phytochemical screening tests Method-

- Seiving
- Mixing

Methodology-

The powders of *Emblica officinalis, Zingiber officinale, Withania somnifera* and *Glycyrrhiza glabra* are sieved separately to get a uniform size.

Each powder are measured and taken.

The powders each are mixed together.

The mix of all the four powders is packed in a container.

IX. PLAN OF WORK

The present research work was planned as followed

1. Literature Survey
2. Selection of Plant Material
3. Seiving
4. Mixing
5. Formulation of product
6. Evaluation of formed product
7. Observation table
8. Result and Discussion
9. Conclusion

X. DRUG PROFILE

XI. Emblica officinalis-

Kingdom- Plantae

(Plants) **Division**-

Angiospermae

Class-

Dicotyledone

Order- Geraniales

Family- Euphorbiaceae

Genus- Emblica

Species- Officinalis Geartn

Part used- Seeds

Use - In migraine Amla control internal secretion of chemical and reduces chances of blood pressure which is a major cause of migraine.

Chemical Constituent – Ascorbic Acid

Fig.no. 3 – Amla

Zingiber officinale-

Kingdom-

Plantae

Division-

Tracheophyta

Class-

Monocotyledon

Order-

Zingiberale

Family-

Zingiberacea

Genus- Ginger

Species- Zingiber Officinale

Part used- Rhizome

Use - The chemical compounds in this oil which include gingerols and shogaols have anti-inflammatory and pain-relieving effects and are also effective at treating nausea and

vomiting, two symptoms associated with migraine attacks.

Chemical Constituent- Gingerol , Shagol

Fig.no. 4- Ginger

Withania somnifera-

Kingdom-

Plantae **Class**-

Magnoliopsida

Order-

Solanales

Family-

Solanacea

Genus- Withania

Species- withania Somnifera

Part use- Root

Use - Ashwagandha may directly reduce migraines by controlling stress.

Chemical Constituent- Sitanosides , Acylstrylglucoside

Fig.no. 5 - Ashwagandha

Glycyrrhiza glabra-

Kingdom-
Plantae **Class –**
Dicotyledonae
Order -
Rosales **Family**
– Fabaceae
Genus -
Glycyrrhiza
Species –
Glabra **Part**
used - Root

Use - It has its effectiveness in stress relieving and memory enhancing.

Chemical Constituent - Glycyrrhizin

XII. FORMULATION OF PRODUCT

- The powders of Emblica officinalis, Zingiber officinale, Withania somnifera and Glycyrrhiza glabra are sieved from # 120 seive separately to get a uniform size.
- Then each drug is triturated in mortal and pestle for homogeneous powder formation.
- After the homogenous powder formation phytochemical screening test of each powder drug are performed to check the presence of desired chemical constituent.
- Then each drug is weighed, in order to calculate the dose and the powders are mixed together accordingly.
- The formulated powder drug is evaluated.
- The formulated powder drug is then filled in the capsule shell.
- After capsule filling, Disintegration test for capsule is carried out.

Sr.no.	Crude Drug	Quantity
1	Amla powder	4.50 mg
2	Ginger powder	10.50 mg
3	Indian ginseng powder	2.50 mg
4	Liquorice powder	2.50 mg

Table no. 1 - Formulation Table

XIII. EVALUATION TEST

Organoleptic Properties

TEST	OBSERVATION
APPEARANCE	HARD GELATIN CAPSULE
COLOUR	TRANSPARENT PINK
ODOR	GINGER LIKE SMELL
TEST	BITTER

Table .2 – Organoleptic Properties

Dissolution Test-

This test checks how quickly a capsule breaks apart in the body.

1. Use a disintegration testing machine with water or simulated gastric fluid at 37 ± 2°C.
2. The capsule is placed in a tube with mesh at the bottom and repeatedly dipped in the medium.
3. The capsule should **completely break down within 15 minutes** with no visible intact shell or core.
4. It confirms that the capsule will release its contents properly in the stomach.

Disintegration Test-

This test measures how much of the active ingredient dissolves in a specific time.

5 Use a USP dissolution tester (either paddle or basket method).

6 Capsules are placed in 900 mL of a buffer solution (like pH 1.2 for stomach or pH 6.8 for intestine), kept at 37 ± 0.5°C.

7 The medium is stirred, and samples are taken at specific time intervals such as 5, 10, 15, 30, 45, and 60 minutes.

8 The amount of dissolved active ingredient is measured using UV or HPLC.

9 At least **75% of the active ingredient should dissolve within 45 minutes**

XIV. RESULT AND DISCUSSION

The Herbal capsule made up of Amla, Ashwagandha, Yashtimadhu and Ginger powders mixed together is formulated to manage and treat various symptoms associated with migraine.

Phytochemical screening tests and assay were also performed to check the presence of the required chemical constituents. The tests showed positive result for the presence of the chemical constituents.

XV. SUMMARY AND CONCLUSION

Summary

Aim of study is to formulate herbal capsule in treatment of migraine. Study of review article was done, selection of crude drug was done and Amla, ashwagandha, ginger , yasthimadhu were selected as crude drug. Phytochemical screening test was done to check Ascorbic acid, Gingerol, shagoal, Sitanosides, Acylstrylglucosides, Glycyrrhizin

. And Evaluation test was done.

Conclusion

From the present study it is concluded that the formulated Capsule is easy to administer and has a disintegration time within permissible range. Evaluation tests on college laboratory scale are performed with positive results. Further in vivo efficacy testing of the capsule can be done.

XVI. EXPECTED OUTCOMES

- **acological Effectiveness:**

- Improved overall symptom relief compared to baseline or placebo.

 Safety and Tolerability:

- Minimal or no adverse effects reported during the evaluation period.
- Good patient compliance due to natural origin and low side-effect profile.

Physicochemical Properties:

- Capsules show uniform weight, acceptable moisture content, and consistent appearance.
- Disintegration time within pharmacopeial limits, ensuring timely release of active compounds.

Dissolution and Bioavailability:

- Adequate and consistent release of active constituents, indicating good dissolution behavior.
- Stable bioactive content throughout the shelf-life period.

Stability:

- Capsule formulation remains stable under accelerated and normal storage conditions over time.
- No significant degradation of active components or change in capsule integrity.

Standardization and Quality Control:

- Active constituents are present within specified limits in every batch.

References

[1] Lopresti AL, Smith SJ, Drummond PD. “Herbal treatments for migraine: A systematic review of randomi controlled studies.” Phytotherapy Research. 2020;34(10):2493–2517.

[2] Ernst E, Pittler MH. “The efficacy and safety of feverfew (Tanacetum parthenium L.): an update of a systematic review.” Public Health Nutrition. 2007;3(4A):509–514.

[3] Lopresti AL, Smith SJ, Drummond PD. “Herbal treatments for migraine: A systematic review of randomised-controlled studies.” Phytotherapy Research. 2020;34(10):2493–2517.

[4] Ernst E, Pittler MH. “The efficacy and safety of feverfew (Tanacetum parthenium L.): an update of a systematic review.” Public Health Nutrition. 2007;3(4A):509–514.

[5] Diener HC, Pfaffenrath V, Schnitker J, Friede M, Henneicke-von Zepelin HH. “Efficacy and Safety of Feverfew CO2-Extract (MIG-99) in Migraine Prevention.” Cephalalgia. 2005.

[6] DeWeerdt CJ, Bootsma HPR, Hendriks H. “Herbal medicines in migraine prevention.” Phytomedicine.Martins LB, Rodrigues AMS, Monteze NM, et al. “Double-blind placebo-controlled randomized clinical trial of ginger (Zingiber officinale Rosc.) in the prophylactic treatment of migraine.” Cephalalgia. 2020.

[7] Rajapakse T, Davenport WJ. “Phytomedicines in the Treatment of Migraine.” CNS Drugs. 2019;33(5):399–415.National Center for Complementary and Integrative Health (NCCIH). “Headaches and Complementary Health Approaches: What the Science Says.” 2023.

[8] Yarnell E. “Herbal Medicine and Migraine.” Alternative and Complementary Therapies. 2017;23(5).

[9] Wells RE, Beuthin J, Granetzke L. “Complementary and Integrative Medicine for Episodic Migraine: An Update of Evidence from

[10] the Last 3 Years.” Current Pain and Headache Reports. 2019.

[11] Verywell Health. “7 Ways Ginger Can Help Relieve Migraines Naturally.” 2025.

[12] Verywell Health. “9 Evidence-Based Supplements for Migraine Relief.” 2016.

[13] Verywell Health. “7 Teas That Can Help Relieve Headaches Naturally.” 2026.