

# Formulation and Evaluation of Polyherbal Tablet for Treatment of Piles (Hemorrhoids)

Vaibhav Kadam, \*Diksha Zaware\*, Dhokare Akanksha, Kaware Neha, Patil Ganesh, Musale Sakshi, Dongare Swapnali, Rahulkumar Rahane

*MMACOP, karjule Harya. Corresponding author: Diksha Bhaskar Zaware*

**Abstract-** The growing interest in herbal formulations for holistic health management has led to the formulation of polyherbal combinations with synergistic therapeutic benefits. This research centers on the formulation and assessment of a polyherbal tablet comprising medicinal plants such as *Azadirachta indica* (Neem), *Aloe barbadensis* (Aloe vera), *Butea monosperma* (Palash), *Terminalia*. These herbs have been utilized in Ayurveda traditionally for their anti-inflammatory, antimicrobial, antioxidant, immunomodulatory, digestive, and detoxifying properties. The dried powders of each plant part were mixed in suitable ratios and formulated into tablets utilizing standard excipients through the wet granulation technique. The prepared tablets undergo thorough evaluation for physicochemical parameters like weight variation, hardness, friability, disintegration time, and moisture content. The findings were observed to be within pharmacopeial specifications, ensuring uniformity and stability of the formulation. The study concludes that the developed polyherbal tablet is pharmaceutically acceptable and shows potential as a natural supplement for overall wellness and preventive healthcare.

The main objective of present study was to formulate the tablet for piles with different combination of herbal drugs. **Material and method:** the tablet for piles containing gum acacia as diluent and natural drug like *Terminalia Chebula*, *Azadirachta indica*, *Cyperus rotundus* etc. which was prepared by wet granulation method. The wet and compressed formulation were subject to several evaluation parameters like appearance, thickness, weight variation, hardness and friability. **Result:** When compared to the placebo group, the polyherbal group showed notable improvements in quality of life, anorectal discomfort, and symptom alleviation (pain, itching, and bleeding). There were no significant adverse effects noted.

**Key words:** Piles, Hemorrhoids, Bleeding, Polyherbal, Evaluation.

## I. INTRODUCTION

Hemorrhoids, also known as piles, are blood vessels in the anus that inflamed or swollen, result in pain,

bleeding, and discomfort. Traditional herbal therapies have gained popularity because of the drawbacks of current pharmacological and surgical treatments, such recurrence, adverse effects, and expense. Herbal medicines have played a key role in human healthcare for centuries, especially in traditional systems like Ayurveda, Traditional Chinese medicine, and Unani. They are considered to be safer alternatives to synthetic medicines because they are made from plants and have fewer side effects and are of natural origin. With its holistic approach and utilization of polyherbal formulations, Ayurveda provides a useful framework for treating hemorrhoidal disorders naturally.

Tablets are the most often used pharmaceutical dosage form because they are stable, simple to administer, and capable of delivering precise doses. Transforming herbal extracts into tablets helps to increase their shelf life and improve patient compliance. Frequently, polyherbal formulations, which contain a combination of plant extracts, are created using the idea of synergism, which holds that the overall effect is greater than the sum of its constituent parts.

This study is based on the creation and assessment of an herbal tablet made up of several medicinal plants that are traditionally used to treat piles, including *Neem* (*Azadirachta indica*), *Nagarmotha* (*Cyperus rotundus*), *Nirgundi* (*Vitex negundo*), *Haritaki* (*Terminalia chebula*), *Bibhitaki* (*Terminalia bellirica*), *Amla* (*Emblica officinalis*), *Bael* (*Eagle marmelos*), *Palash* (*Butea monosperma*), *Lodhra* (*Symplocos racemosa*), *Turmeric* (*Curcuma longa*), and *Aloe vera*.

The purpose of this research is to create a reliable polyherbal tablet preparation that incorporates these plants and assess its physicochemical properties, consistency, and potential therapeutic use in the management of hemorrhoids. Our goal with this project is to provide a secure, efficient, and available alternative to traditional pile treatments.

Hemorrhoids are frequently thought of as a benign condition, but in extreme situations, they can have a major negative influence on a person's quality of life. Since many people put off getting medical help because they are embarrassed or have mild symptoms, it is challenging to estimate the prevalence of hemorrhoids worldwide because of underreporting. But according to estimates, up to 50% of people would at some point in their lives experience symptoms connected to hemorrhoids.

Types of piles (hemorrhoids):

1. Internal hemorrhoids: These form above the mucocutaneous junction, where the anal canal connects the mucosal lining and the skin. These hemorrhoids are normally painless, but when irritated, they can cause bleeding, prolapse, and mucus discharge. They are further characterized based on the degree of prolapse:

Grade I: Hemorrhoids do not prolapse but can cause bleeding during bowel movements.

Grade II: Hemorrhoids prolapse out of the anal canal during feces but then naturally retract.

Grade III : Hemorrhoids are prolapsed and must be reduced manually.

Grade IV: Prolapsed hemorrhoids that are irreducible and persist outside the anal canal.

2. External hemorrhoids: These develop in the delicate skin area behind the dentate line. Because the anal surface contains somatic nerves, these haemorrhoids usually cause more discomfort than internal haemorrhoids. When external haemorrhoids thrombose, they can cause excruciating pain, swelling, and discoloration. The abrupt emergence of a hard, bluish lump near the anal entrance is a sign of thrombosis, which happens when a blood clot forms in the haemorrhoidal veins.

3. Mixed Haemorrhoids: When internal and external haemorrhoids coexist and a patient has symptoms associated with both, this condition is referred to as mixed haemorrhoids. Because it may involve both severe thrombosis or swelling from external haemorrhoids and painless bleeding from internal haemorrhoids, this disease can be especially difficult to manage.

Benefits of herbal tablet:

1. Natural and Safer Alternative: Because herbal tablets are made from plant-based substances, they are safer and more natural than synthetic medications. When used as directed, they also have fewer adverse effects.

2. Synergistic Therapeutic Effects: Because bioactive chemicals interact synergistically, combining several powdered medicinal plants can increase therapeutic efficacy.
3. Convenient Dosage Form: Unlike powders, decoctions, or liquid extracts, tablets are simple to handle, store, and dispense.
4. Increased Patient Compliance: Herbal tablets are easier to swallow, odorless, and tasteless (particularly when coated), all of which increase user acceptance.
5. Standardized Dosage: The active components in each unit are consistently delivered thanks to the precise dosage that tablets provide.
6. Extended Shelf Life: Compared to herbal liquids or pastes, tablets are often more stable, which lowers the risk of microbial growth and spoiling.
7. Cost-Effective Production: Herbal tablets can be mass-produced with little processing after they are created.
8. Manufacturing Simplicity: Creating tablets from herbal powders is generally less complicated, necessitating fewer steps than those made with extracts. The typical procedure includes mixing the powder with excipients and compressing the mixture, which streamlines the production process.
9. Retention of Full Phytochemical Profile: Herbal powders maintain the entire spectrum of active constituents present in the unprocessed plant material. In contrast to extracts, which may focus on or separate specific compounds, powdered herbs keep the plant's inherent complexity and synergistic effects of its bioactive elements. This can be particularly advantageous for herbal treatments targeted at holistic health.
10. Retention of Full Phytochemical Profile: Herbal powders maintain the entire spectrum of active constituents present in the unprocessed plant material. In contrast to extracts, which may focus on or separate specific compounds, powdered herbs keep the plant's inherent complexity and synergistic effects of its bioactive elements. This can be particularly advantageous for herbal treatments targeted at holistic health.
11. Preservation of Natural Flavor: Contrary to extracts, which might require extra additives or flavor-masking substances, herbal powders can provide the complete, natural taste profile of the plant, which may be preferred in certain traditional herbal medicine practices.

Need:

1. **Increasing Demand for Herbal Medicines:** There is a notable need for safe and efficient herbal formulations as a result of growing awareness of natural health options.
2. **Difficulties with Using Unprocessed Herbal Powders:** Tablet form is more practical because raw herbal powders can be unpleasant, have irregular dosing, and decay quickly.
3. **Standardization and Quality Assurance:** By improving control over purity, potency, and quality, tablet formulation allays worries about the unpredictability of traditional herbal medication.
4. **Regulatory Compliance:** Herbal pills are appropriate for wider distribution and marketing since they assist in meeting pharmacopoeial and GMP (Good Manufacturing Practice) regulations.
5. **Integration into Contemporary Healthcare:** Practitioners and patients in integrative and

contemporary healthcare systems are more likely to embrace herbal pill formulations.

## II. MATERIALS AND METHODS

All herbs were collected from the local area and washed with a purified water to remove the dust and foreign particle.

Then they were subjected for shade drying.

After drying the herbs were grinded into a powder and used as an analgesic, anti-inflammatory, reduce swelling, control bleeding antioxidant, laxative, promote healing, regulate bowel movement.

The excipient used in the formulation are acacia gum used as binder and disintegrate, starch as binder, honey as, ghee as

Wet granulation method is used to punch the tablet because it improve the flowability of powders, making them easier to handle and compress into tablets. Wet granulation method improve the compressibility of powders.

Table 1: List of herbs and their pharmacological effect

Sr . No.	Botanical Name	Common Name	Family	Part used	Pharmacological effect	Action
1.	Curcuma Longa L.	Turmeric	Zingiberaceae	Rhizome	Anti-inflammatory, Antioxidant	Reduce inflammation, Pain, Swelling
2.	Aegle Marmelos Correa	Bael	Rutaceae	Fruits	Laxative, Antioxidant, Anti-inflammatory	Reduce inflammation, promote healing, regulate bowel movement
3.	Aloe Barbadosis	Aloevera	Liliaceae	Leaves	Anti-inflammatory, Antimicrobial	Reduce inflammation, promote healing, soothes irritation
4.	Butea Monosperma	Palash	Fabaceae	Fruits	Astringent, Antioxidant, Antioxidant	Reduce inflammation, promote healing, control bleeding
5.	Momordica Dioica Roxb.	Bitter Gourd	Cucurbitaceae	Leaves	Antihemorrhoidal, Laxative, Antioxidant, Anti-inflammatory	Regulate bowel movement, relieve pain
6.	Piper Nigrum L.	Black Pepper	Piperaceae	Fruits	Carminative	Reduce inflammation, promote healing, reduce flatulence

7.	Terminalia Bellirica	Baherada	Combrataceae	Fruits	Astringent, Antioxidant, Anti-inflammatory	Reduce inflammation, promote healing, control bleeding
8.	Vitex Negundo L.	Nirgudi	Lamiaceae	Leaves	Antispasmodic, Antioxidant	Reduce inflammation, promote healing, relieve pain
9.	Coriandrum Sativum L.	Coriander	Umbelliferae	Fruits	Antiinflammatory, Carminative	Reduce inflammation, promote healing, relieve flatulence
10.	Azadirachta Indica	Neem	Meliaceae	Leaves	Antiseptic, Antioxidant	Reduce inflammation, promote healing, prevent infection,
11.	Terminalia Chebula	Haritaki	Combretaceae	Fruit	Laxative, Anti-inflammatory	Regulate bowel movement, Reduce inflammation, promote healing
12.	Emblica Officinalis	Amla	Euphorbiaceae	Fruit	Antioxidant, Anti-inflammatory	Reduce inflammation, promote healing
13.	Symplocos Racemosa	Lodhra	Symplocaceae	Bark	Antioxidant, Anti-inflammatory, Antihemorrhoidal, Astringent	Control bleeding, relieve discomfort and pain
14.	Cyperus Rotundus	Nagarmotha	Cyperaceae	Flower	Antioxidant, Anti-inflammatory, Antihemorrhoidal, Astringent, Carminative	Reduce inflammation, promote healing, Control bleeding, relieve discomfort and pain

#### Method of Preparation:

1. Accurately weigh all the ingredients including active pharmaceutical ingredients and excipients.
2. The weighed powder passed through sieve no. 80 to remove agglomerates & to ensure uniform particle size.
3. Blend the sieved powder using a high speed mixer to achieve homogenous mix.
4. Prepare a binder solution by dissolving Acacia gum in water.
5. Triturate the fresh aloe vera in a mortar pastel to make gel.
6. Add the prepared binder solution, aloe vera, honey, ghee and citric acid
7. Mix continuously to achieve damp mass.
8. Then the wet mass was passed through sieve no. 12 to form granules.
9. Prepared granules were dried in hot air oven at 45°.
10. Granules were loaded into the hopper of tablet punching machine and set the hardness. Finally the tablete were prepared.



Fig 1: granules



Fig 2: tablets

Formulation table:

Table 2: Formulation table for herbal tablet

Sr. No.	Name of Ingredients	F1	F2	F3	F4
1.	Terminalia Billerica	15	15	15	15
2.	Aegle Marmelos	15	15	15	15
3.	Vitex Negundo	15	15	15	15
4.	Terminalia Chebula	20	20	20	20
5.	Momordica Charantia	20	20	20	20
6.	Symplocos Racemosa	20	20	20	20
7.	Azadirachta Indica	15	15	15	15
8.	Cyperus Rotundus	15	15	15	15
9.	Emblica Officinalis	20	20	20	20
10.	Butea Monosperma	10	10	10	10
11.	Curcuma Longa L.	5	5	5	5
12.	Pipper Nigrum L.	5	5	5	5
13.	Coriandrum Sativum L.	5	5	5	5
14.	Starch	20	15	10	12
15.	Acacia gum	25	20	15	18
16.	Citrus lemon	Q.S.	Q.S.	Q.S.	Q.S.
17.	Aloe Barbadensis Mill	Q.S.	Q.S.	Q.S.	Q.S.
18.	Apis Mellifera	Q.S.	Q.S.	Q.S.	Q.S.
19.	Ghrita	Q.S.	Q.S.	Q.S.	Q.S.

Evaluation Test for Herbal Tablet:

1.Thickness:

The thickness of the tablet was measured using a vernier calliper. 6 tablets were used in this test, and by holding the tablet vertically between two jaws, the thickness was measured in millimetres.

2.Weight Variation:

20 tablets were weighed individually using an electronic balance. The average weight was calculated and individual tablet weight was then compared with average value and the deviation was recorded.

3.Disintegration Test:

Disintegration test for Herbal tablet assess how quickly and completely a tablet break down into smaller fragment when exposed to a suitable medium.

Firstly assemble the apparatus that include basket-rack with beaker, tubes and temperature controlled water bath. Then fill the beaker with a specified suitable medium.Maintain at the specific temperature  $37 \pm 2$  °C.Adjusted the fluid level in a beaker and specified level.Select 6 tablet randomly and introduce the one tablet into each tube. Start the machine to move basket-rack assembly up and down at specified rate.After 15 minute remove the btheet- rack assembly and examine.



Fig. 3: Disintegration Test Apparatus

4. Hardness Test:

Hardness of tablet also called as tablet crushing strength. It was measured by Monsanto hardness tester. The tablet was placed lightwise between upper and lower plunger and the force of applied by turning a threaded bolt until the tablet break and hardness measured in Kg/cm<sup>2</sup>. For uncoated herbal tablet 3-5 kg/cm<sup>2</sup> hardness is considered as satisfactory.



Fig. 4: Monsanto Hardness Tester

5. Friability Test:

Friability of tablets was determined by using Roche Friabilator .

It is termed as loss of weight of tablet due to removal of fine particle from surface of tablet. 20 tablets are selected randomly from each batch and placed in the Roche friabilator which was rotated at 25 rpm speed for 100 revolutions within 4 min. then tablets were removed and weigh again.

Table 3: Evaluation parameters for herbal tablet

Sr. No.	Evaluation parameter	F1	F2	F3	F4
1.	Hardness(kg/cm <sup>2</sup> )	4.9	4.8	4.5	5
2.	Friability(%)	0.5	0.6	0.5	0.7
3.	Disintegration(min.)	20	18	10	15
4.	Dissolution(%)	88	86	85	86

Percentage of weight loss was calculated by using formula:  $\frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$



Fig. 5: Friability Test Apparatus

6. Dissolution Test:

Dissolution study was performed by using basket type apparatus. Introduced a 900ml of dissolution medium in a vessel of apparatus that consists of 0.1 normal HCL. The pH of medium is Warmed it to 37±1°C at 50 rpm speed.



Fig. 6: Dissolution Test Apparatus

III. RESULTS AND DISCUSSION

5.	Weight variation(mg)	249.7	248.13	249.1	248.5
6.	Thickness(mm)	4.5	4.2	4	4.1

#### IV. DISCUSSION

The results of the study showed that Batch 3(F3) had the most desirable quality attributes. This batch had a hardness of 4.5 kg/cm<sup>2</sup>, which is suitable for handling and storage.

The friability of Batch 3 was 0.4% indicating that the tablets were robust and less prone to breakage. Additionally, the disintegration time of Batch 3 was 10 minutes, which is within the acceptable range for herbal tablets.

In contrast, Batch 1 and Batch 2 had higher disintegration times, which may affect the bioavailability of the active ingredients.

Batch 4 had the highest hardness and friability values, which may indicate over-compression and potential issues with tablet breakage.

#### V. SUMMARY

The research study of herbal tablets utilizing powdered forms of medicinal plants, with the objective of producing a standardized, cost-efficient, and effective dosage form for herbal medicine. Numerous batches of herbal tablets were developed using various plant powders and excipients to evaluate their physical characteristics, therapeutic efficacy, and stability.

The methodology involved choosing medicinal plant powders based on their pharmacological advantages, followed by the preparation of multiple tablet batches containing excipients such as starch and acacia gum. The herbal powders included in the formulations were sourced from plants like Terminalia Billerica, Vitex Negundo, Terminalia Chebula, Momordica Charantia, Symplocos Racemosa, etc. recognized for their antioxidant, anti-inflammatory, astringent, analgesic and digestive health benefits.

Evaluation tests on the tablet batches, such as weight variation, hardness, friability, disintegration time, and dissolution, were performed to confirm that the tablets complied with quality control standards. The findings revealed that the produced herbal tablets consistently exhibited quality, featuring acceptable physical traits and effective release profiles of active ingredients.

#### VI. FUTURE SCOPE

The market for herbal tablets is expanding due to growing customer desire for natural substitutes. The effectiveness, safety, and uniformity of herbal tablets are being enhanced by scientific developments. Tablets containing botanical components are becoming more potent and bioavailable because to technological advancements. Herbal tablets are being included into traditional healthcare systems with regulatory approval. The market for herbal medicines is growing, providing more chances for business expansion. Herbal tablet compositions will be customised by personalised medicine according to each patient's unique medical requirements. The need for ethical products from consumers will be satisfied by sustainable and environmentally friendly production of herbal tablets. Herbal supplements for immunity and well-being are becoming more and more popular as a result of preventive healthcare trends. The dietary supplement and nutraceutical businesses are increasingly relying on herbal pills. The growth of international trade presents producers of herbal tablets with new export prospects.

#### VII. CONCLUSION

According to the above study, the tablets were made using the wet granulation method and produced results that were both satisfactory and acceptable. Because of its wet granulation, the traditional tablet exhibits instant drug release. The tablet in the formulation may make it more effective as an analgesic. According to the above research, herbal tablets prepared as affordable tablets can reduce patient compliance with regard to suppressing side effects and enhancing positive.

#### REFERENCE

- [1] Sushma Kamble, Prof. Akhare T. P.3. Dr. Hingane L. D. International Journal for Research in Applied Science & Engineering Technology (IJRASET) ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538 Volume 9 Issue XII Dec 2021.
- [2] Nelson, R. L. (2006). Hemorrhoids: Pathophysiology and Treatment. Journal of the American Medical Association, 295(14), 1719-1725.

- [3] Riss, S., & Krones, C. (2013). Surgical management of hemorrhoidal disease: The modern approach. *World Journal of Surgery*, 37(4), 792-800.
- [4] Jafari, M. D., & Thirumurthi, T. (2017). Innovative treatments for hemorrhoids: A review of new approaches and techniques. *Diseases of the Colon & Rectum*, 60(2), 120-127.
- [5] Rout S.D. Panda T., Mishra N. Ethnomedicinal Plants used to Cure Different Disease by Tribal Mayurbhanj District of North Orisa. *Ethno Med*. 2010, 3(1): 27-32
- [6] Koche D. K., Shirsat R. P., Imran S., Nafees M., Zingare A. K., Donode K. A. Ethnobotanical and Ethnomedicinal Survey of Nagzira Wild Life Sanctuary, District Gondis (M.S.) India-Part 1 . *Ethnobotanical Leaflets*. 2008; 12:56-69.
- [7] Ndukwu B.C., Ben-Nwadibia N.B. Ethnomedicinal aspects of plants used as spices and condiments in the Niger Delta area of Nigeria. <http://www.siu.edu/~leaflets/ndikwu.htm>. 2003.
- [8] Ndukwu B.C., Ben-Nwadibia N.B. Ethnomedicinal aspects of plants used as spices and condiments in the Niger Delta area of Nigeria. <http://www.siu.edu/~ebl/leaflets/niger.htm>.
- [9] Bawara B.,Dixit M., Chauhan N.S., Dixit V.K., Saraf D.K. Phyto-pharmacology of *Momordica dioica* Roxb. Ex. Willd: A Review. *International Journal of Phytomedicine*. 2010;2: 01-09.
- [10] Tripathi A. Comparative Evaluation of Pilex With Daflon in Haemorrhoids. *The Antiseptic* 2000;97(9):317.
- [11] Husain S.Z., Malik R.N., Javaid m., Bibi S. Ethnobotanical properties and uses of Medicinal Plants of Morgah Biodiversity, Park, Rawalpindi. *Pak. J.Bot* 2008; 40(5): 1897-1911.
- [12] World Health Organization. WHO Monographs on Medicinal Plants Commonly Used in the Newly Independent States (NIS). World Health Organization, 2010. 1<sup>st</sup> ed. Pp .11-25.
- [13] Kumar V, et al.(eds). *Medicinal Plants of the World*. Springer, 2017. 2<sup>nd</sup> ed. Pp. 123-135.
- [14] Warriar PK, et al. *Indian Medicinal Plants*. Orient Longman, 1994. 5<sup>th</sup> ed. Vol.1,pp. 43-45, 113-115, 246-248,241-243,23-25,175-177.
- [15] Kumar V, et al. *Medicinal Plants of India*. New Publishing Agency, 2011. 1<sup>st</sup> ed. Pp. 105-107.
- [16] Kirtikar KR, et al. *Indian Medicinal Plants*. Sri Satguru Publications, 2005. 2<sup>nd</sup> ed. Vol.1, pp. 41-43.
- [17] Nadkarni AK. *Indian Materia Medica*. Popular Prakashan, 2007. 3<sup>rd</sup> ed. Vol. 1, pp. 525-527.
- [18] Sharma PV. *Dravyaguna-Vijnana (Indian Pharmacology)*. Chaukhambha Bharati Academy, 2004. 2<sup>nd</sup> ed. Vol.1 pp. 234-236.
- [19] Khare CP. *Indian Medicinal Plants*. Springer, 2007. 1<sup>st</sup> ed. Pp. 417-418,161-162,283-285,411-412,35-36,105-106, 191-192,253-254,281-282,155-156.
- [20] Chopra RN, et al. *Glossary of Indian Medicinal Plants*. Council of Scientific and Industrial Research, 2006. 1<sup>st</sup> ed. Pp. 102-103, 187-188.
- [21] Madhusudhan KS, Pavithra SR. Tablet formulation and evaluation of herbal powder: A review. *Int J Pharm Sci*. 2020.
- [22] Shukla S, Arya N, Verma S. Herbal powder-based tablets: An overview. *Int J Herbal Med*. 2021;9(3):25-31.