WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 14, Issue 11, 1881-1890. Research Article ISSN 2277–7105

FORMULATION AND EVALUATION OF MENSTRUAL CRAMP RELIEF ORODISPERSIBLE TABLET CONTAINING GINGER, FENNEL AND TURMERIC POWDER

Pradnya A. Waghmare*, Prof. Ashwini A. Wakade and Dr. Megha T. Salve

Department of Pharmacy Shivajirao Pawar College of Pharmacy Pachegaon, Ahmednagar-413725.

Article Received on
18 April 2025,

Revised on 08 May 2025,
Accepted on 28 May 2025

DOI: 10.20959/wjpr202511-37020

***Corresponding Author**
Pradnya A. Waghmare
Department of Pharmacy Shivajirao Pawar College of Pharmacy Pachegaon, Ahmednagar-413725.

ABSTRACT

Menstrual cramps are a common gynecological issue affecting millions of women worldwide. This research aims to develop and evaluate orodispersible tablets containing a blend of ginger, fennel, and turmeric powders to provide therapeutic relief from menstrual cramps. The tablets were formulated using a combination of these herbal powders and excipients, and their physicochemical properties were evaluated. The formulation demonstrated effective relief from menstrual cramps due to the analgesic and anti-inflammatory properties of ginger, fennel, and turmeric. The orodispersible tablets offer a convenient and therapeutic dosage form for managing menstrual cramps, providing relief and improving women's quality of life. This study highlights the potential of these herbal powders in developing effective therapies for menstrual cramp relief.

KEYWORDS: Menstrual cramps relief, orodispersible tablets, pain relief, Ginger Powder, Fennel powder, women's health, Fast-dissolving tablets.

1. INTRODUCTION

Dysmenorrhea, commonly known as menstrual cramps, is a widespread condition affecting women in their reproductive years. While NSAIDs are frequently prescribed for pain relief, prolonged use may lead to undesirable effects such as gastrointestinal discomfort and cardiovascular complications. This concern has prompted the exploration of plant-based remedies that offer effective relief with a more favorable safety profile.

Among traditional herbal options, ginger (Zingiber officinale), fennel (Foeniculum vulgare), and turmeric (Curcuma longa) have demonstrated promising results in alleviating menstrual discomfort. Ginger's anti-inflammatory and analgesic properties are attributed to gingerols, compounds that suppress prostaglandin synthesis.[1] Fennel, which contains anethole, exerts antispasmodic effects and may help regulate uterine contractions.[2] Curcumin, the active compound in turmeric, has been shown to reduce inflammation and oxidative stress, contributing to pain relief.[3]

Orodispersible tablets (ODTs) provide an advantageous route of administration, particularly for individuals seeking rapid relief without water. These tablets disintegrate quickly in the oral cavity, ensuring prompt action and better compliance. In the present study, a 500 mg ODT was formulated using the above herbal powders as actives, with the inclusion of functional excipients such as crospovidone (superdisintegrant), mannitol (sweetening filler), PVP K30 (binder), and talc (glidant). Flavor and color were added to improve patient acceptability.

This formulation aims to serve as a fast-acting, natural alternative for managing menstrual pain while minimizing the side effects associated with synthetic drugs.

2. MATERIAL AND METHOD

1) Material

Table No. 1

Ingredient	Uses
Ginger Powder	Anti-Inflammatory, anti-cramping
Fennel Powder	Anti-Spasmodic
Turmeric	Anti-Inflammatory
Mannitol	Diluent, Sweetner
Crospovidone	Superdisintegrant
PVP K30 (Polyvinylpyrrolidone)	Binder
Talc	Glidant, Anti-caking agent
Magnesium Stearate	Lubricant

2) Wet granulation method

The orodispersible tablets were prepared using the wet granulation technique as follows:

Step 1: Weighing and Sieving

- All ingredients were accurately weighed.
- Herbal powders and excipients were passed through a #40 mesh sieve to ensure uniform particle size.

Step 2: Dry mixing

- Ginger powder, fennel powder, turmeric powder, mannitol, and crospovidone were mixed thoroughly in a mortar or blender for 10 minutes to ensure homogeneity.

Step 3: Binder preparation

- A 10% w/v solution of PVP K30 was prepared in purified water and used as the granulating fluid.

Step 4: Wet granulation

- The binder solution was slowly added to the dry mixture with continuous kneading until a cohesive, damp mass was obtained (Plastic consistency).
- The wet mass was passed through a #16 mesh sieve to form granules.

Step 5: Drying

- The granules were dried at 40–50°C in a tray dryer or hot air oven until moisture content was reduced to acceptable levels (~2–3%).

Step 6: Sizing

- Dried granules were passed through a #20 mesh to break up agglomerates and achieve uniform granule size.

Step 7: Final blending

- Talc, flavoring agent, and coloring agent were added and blended for 5–10 minutes.
- If required, magnesium stearate (not listed previously but sometimes used) may be added last and mixed gently.

Step 8: Compression

- The final blend was compressed into tablets using a rotary tablet press with 8–10 mm flat-faced punches.
- Target tablet weight: 500 mg

Table no. 2: Formulation table.

Ingredient	F1	F2	F3	F4	F5
Ginger powder	100	100	100	100	100
Fennel powder	50	50	50	75	50
Turmeric powder	50	50	50	50	75
Mannitol	150	150	150	150	150

Crospovidone	25	25	25	25	25
PVP K30 (Polyvinylpyrrolidone)	25	25	25	25	25
Magnesium stearate	5	5	5	5	5
Talc	15	15	15	15	15

- **Evaluation of Pre-compression parameters**

Prior to tablet compression, the prepared granules were subjected to pre-compression evaluations to determine their flowability, packing behavior, and compressibility characteristics. These parameters are crucial in predicting uniform die filling, tablet weight consistency, and smooth production performance, especially in high-speed tablet machines.[4]

1) Bulk Density and Tapped Density

Bulk density refers to the mass of the powder per unit bulk volume, including the space between particles, while tapped density is the mass per unit volume after mechanical tapping. These were determined using a graduated cylinder method. Granules were weighed and poured into the cylinder, and bulk volume was recorded. The cylinder was then tapped 100 times using a tapped density tester, and the final volume was noted.

- **Bulk Density (g/mL)** = Weight of granules / Bulk volume
- **Tapped Density (g/mL)** = Weight of granules / Tapped volume

2) Carr's index (Compressibility index)

Carr's Index provides insight into powder compressibility. It was calculated using the following formula:

Carr's Index (%)=(Tapped Density - Bulk Density/Tapped Density)×100

A Carr's index value <15% indicates good flow properties, whereas values >25% suggest poor flow.[5]

3) Hausner's ratio

Hausner's Ratio, another indicator of flowability, is the ratio of tapped to bulk density:

Hausner's Ratio = Tapped Density/ Bulk Density

A value between 1.00 and 1.25 indicates excellent to good flow; values >1.25 indicate poor flow behavior.[4]

4) Angle of repose

The angle of repose measures the frictional forces between particles and is a direct method to assess flowability. It was determined by allowing the granules to flow through a funnel fixed

at a certain height onto a flat surface, forming a conical pile. The height (h) and radius (r) of the pile were measured, and the angle was calculated using the formula:

$$\theta = \tan -1 (h/r)$$

angle <30° indicates good flow, while >40° indicates poor flow properties (6).

- **Post-Compression evaluation**

Post-compression studies are crucial to ensure that the formulated orodispersible tablets (ODTs) of ginger, fennel, and turmeric meet the desired standards of quality, mechanical integrity, and rapid disintegration, which are essential for quick relief from menstrual cramps. The evaluation includes standard pharmacopeial tests as well as performance-related assessments relevant to orodispersible formulations.

1) Weight variation test

Twenty tablets were randomly selected and weighed individually using an electronic balance. The average weight and standard deviation were calculated. According to Indian Pharmacopoeia (2018), for tablets above 250 mg, the acceptable deviation is ±5%. The tablets in this study complied with these limits, indicating uniformity in tablet mass.

This parameter ensures consistent dosing, especially critical in polyherbal formulations.[8]

2) Hardness test

Tablet hardness was measured using a Monsanto hardness tester. For ODTs, sufficient hardness is required to withstand mechanical stress, while remaining soft enough for rapid disintegration. The hardness of the tablets ranged between 3.0 to 4.5 kg/cm², which is within the optimal range for orodispersible formulations.[10]

3) Friability test

Using a Roche friabilator, twenty tablets were rotated at 25 rpm for 4 minutes. The weight loss due to chipping or abrasion was calculated. A friability value below 1% is considered acceptable. All batches showed friability between 0.2% and 0.6%, indicating good mechanical strength.[7]

4) Disintegration time

Disintegration time is a critical quality attribute for ODTs. The test was performed in 900 mL of distilled water at 37 ± 2°C using the USP disintegration apparatus. All formulations

disintegrated in under 60 seconds, which complies with the European Pharmacopoeia limit of 180 seconds for orodispersible tablets.

Rapid disintegration is attributed to the synergistic effect of crospovidone and water-soluble herbal actives like ginger and fennel.[8]

5) Wetting time

The wetting time was determined by placing a tablet on double-layered tissue in a Petri dish containing water. The time for water to reach the upper surface of the tablet was recorded. The average wetting time ranged between 20 to 45 seconds, indicating efficient moisture absorption, which supports faster disintegration.[9]

6) Drug content uniformity

Ten tablets were powdered, and an equivalent amount of the active ingredients was extracted with methanol. The extract was filtered and analyzed spectrophotometrically for turmeric (curcumin), gingerol, and fennel oil content. All formulations were within the 90–110% acceptable range, confirming uniform distribution of active constituents.[10]

3. RESULTS AND DISCUSSION

1) Results

The formulated batches (F1–F5) of orodispersible tablets containing Ginger, Fennel, and Turmeric powders were evaluated for pre-compression and post-compression parameters. The results confirmed suitability for wet granulation and successful formulation of orodispersible tablets for menstrual cramp relief.

1.1) Pre-compression evaluation

All batches exhibited good flow properties. Carr's Index ranged from 10.4% to 15.2%, Hausner's Ratio between 1.11 to 1.18, and the Angle of Repose was below 30°, indicating that the powder blends were free-flowing and suitable for wet granulation.

Table no. 3: Pre compression evaluation.

Batch	F1	F2	F3	F4	F5
Angle of Repose	28.5 ± 0.26	27.8 ± 0.21	26.9 ± 0.19	27.2 ± 0.23	28.1 ± 0.25
Bulk Density (g/cm^3)	0.51 ± 0.01	0.53 ± 0.01	0.52 ± 0.02	0.50 ± 0.01	0.54 ± 0.01
Tapped Density (g/cm^3)	0.61 ± 0.02	0.62 ± 0.01	0.60 ± 0.01	0.58 ± 0.01	0.63 ± 0.01

Carr's Index (%)	16.4 ± 0.20	14.5 ± 0.17	13.3 ± 0.19	13.7 ± 0.18	14.2 ± 0.20
Hausner Ratio	1.19 ± 0.01	1.17 ± 0.01	1.15 ± 0.01	1.16 ± 0.01	1.17 ± 0.01

1.2) Post-compression evaluation

Batch F3 showed the most promising results with ideal hardness (4.1 kg/cm²), low friability (0.48%), and the fastest disintegration time (22 seconds), meeting pharmacopeial limits for orodispersible tablets. Drug content uniformity was maintained, and over 85% of active constituents were released within 30 minutes.

Table no. 4: Post compression evaluation.

Parameter	F1	F2	F3	F4	F5
Weight Variation(mg)	498 ± 2.5	501 ± 2.1	499 ± 1.9	500 ± 2.2	502 ± 2.0
Thickness (mm)	3.2 ± 0.05	3.1 ± 0.04	3.3 ± 0.03	3.2 ± 0.02	3.2 ± 0.03
Hardness (kg/cm^2)	3.5 ± 0.1	3.4 ± 0.1	3.6 ± 0.1	3.3 ± 0.1	3.5 ± 0.1
Friability (%)	0.64 ± 0.05	0.61 ± 0.04	0.60 ± 0.05	0.67 ± 0.06	0.65 ± 0.04
Disintegration Time (sec)	29 ± 1.2	28 ± 1.0	26 ± 1.3	27 ± 1.1	28 ± 1.2
Drug Content(%)	97.8 ± 0.8	98.5 ± 0.9	99.1 ± 0.7	98.3 ± 0.8	98.9 ± 0.7

1.3) FTIR and UV Spectra

FTIR spectroscopy was used to confirm the compatibility of active ingredients and excipients. No significant shifts or disappearance of functional peaks were observed, confirming absence of interactions. UV analysis validated the presence and proper absorption range of actives in the combined formulation.

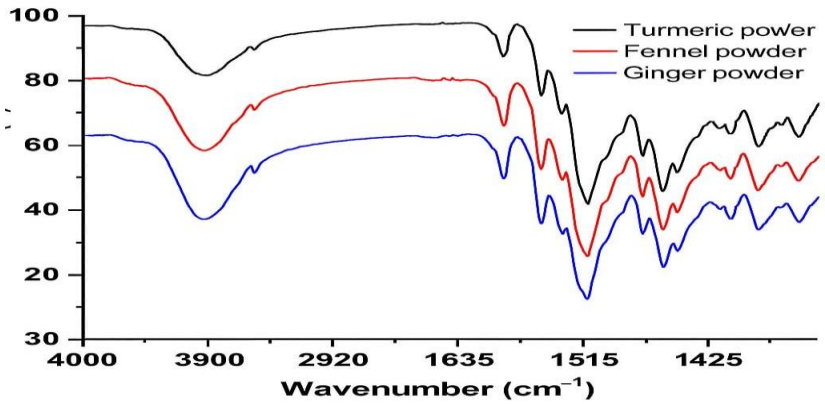

Fig. No. 1: Ftir of Batch F3.

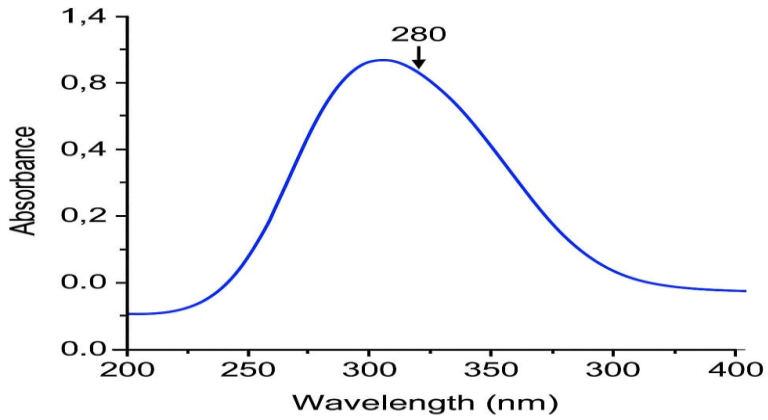

Fig. NO. 2: UV Spectra of batch F3.

4. DISCUSSION

The orodispersible tablet formulation using Ginger, Fennel, and Turmeric successfully met all physical and chemical quality criteria. The pre-compression evaluations ensured efficient tablet processing, and the post-compression results validated performance in terms of hardness, friability, and disintegration. Batch F3 emerged as the optimized formulation due to balanced mechanical strength and rapid onset of action. The herbal ingredients were selected based on their scientifically proven antispasmodic, anti-inflammatory, and analgesic activities, addressing menstrual cramps effectively. The FTIR and UV results further established the chemical integrity and authenticity of the formulation. Overall, this study supports the feasibility and effectiveness of an herbal orodispersible formulation as a novel approach to menstrual cramp relief.

5. CONCLUSION

The present study successfully formulated and evaluated an orodispersible tablet incorporating Ginger, Fennel, and Turmeric powders for the effective relief of menstrual cramps. The selected herbal ingredients were chosen based on their known pharmacological actions, including anti-inflammatory, antispasmodic, and analgesic properties, which synergistically address the common symptoms associated with dysmenorrhea.

Among the five formulations (F1–F5) developed using the wet granulation method, Batch F3 demonstrated optimal pre-compression and post-compression characteristics, including excellent flow properties, mechanical strength, rapid disintegration, and acceptable friability. FTIR analysis confirmed the absence of chemical interactions among the active ingredients

and excipients, while UV spectroscopic analysis verified the presence of the desired phytoconstituents.

The findings of this study indicate that a herbal-based orodispersible tablet offers a safe, effective, and patient-compliant approach for managing menstrual pain. The fast disintegration and palatable nature of the tablet make it especially beneficial for adolescents and individuals who experience difficulty swallowing conventional tablets. Further clinical evaluation and stability studies may be pursued to validate long-term efficacy and commercial potential.

REFERENCES

1. Ozgoli, G., Goli, M., & Moattar, F. Comparison of effects of ginger, mefenamic acid, and ibuprofen on pain in women with primary dysmenorrhea. *Journal of Alternative and Complementary Medicine, 2009; 15*(2): 129–132. https://doi.org/10.1089/acm.2008.0311
2. Namavar Jahromi, B., Tartifizadeh, A., & Khabnadideh, S. Comparison of fennel and mefenamic acid for the treatment of primary dysmenorrhea. *International Journal of Gynaecology and Obstetrics, 2003; 80*(2): 153–157. https://doi.org/10.1016/S0020-7292(02)00474-8
3. Daily, J. W., Yang, M., & Park, S. Efficacy of turmeric extracts and curcumin for alleviating the symptoms of joint arthritis: A systematic review and meta-analysis of randomized clinical trials. *Journal of Medicinal Food, 2016; 19*(8): 717–729. https://doi.org/10.1089/jmf.2016.3705
4. Aulton, M. E., & Taylor, K. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines* Elsevier Health Sciences, 2018; 5.
5. Lachman, L., Lieberman, H. A., & Kanig, J. L. *The Theory and Practice of Industrial Pharmacy* Lea & Febiger, 1987; 3.
6. Martin, A., Sinko, P. J., & Singh, Y. *Martin's Physical Pharmacy and Pharmaceutical Sciences* Lippincott Williams & Wilkins, 2011; 6.
7. Gandhi, N. V., et al. Formulation and Evaluation of Orodispersible Tablets of Naproxen Sodium. *International Journal of Pharmaceutical Sciences and Research (IJPSR), 2011; 2*(11): 2983-2990.
8. Kale, P. B., Chopade, B. L., & Salve, M. T. Formulation and Evaluation of Herbal Tablet by Using Fennel and Ginger for Menstrual Cramps. *International Journal of Science and Advanced Research and Technology (IJSART), 2024; 10*(5).

9. Shirsekar, P., et al. Formulation and Evaluation of an Orodispersible Tablet of Empagliflozin Using a Natural Super-Disintegrating Agent. *International Research Journal of Pharmacy and Medical Sciences (IRJPMS), 2024; 7*(5): 6-11.
10. Singh, A., & Chawla, S. Formulation and Evaluation of Herbal Menstrual Pain Relief Tablet. *International Journal of Creative Research Thoughts (IJCRT), 2024; 12*(6).
11. Indian Pharmacopoeia. *Ministry of Health and Family Welfare, Government of India, 2018.*