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Research Article

Formulation And Evaluation Of Orodispersible Tablet Using Natural Active Ingredients Like Fennel, Turmeric And Fennel

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ABSTRACT

Dysmenorrhea is a serious illness that has a high prevalence among women in the reproductive age and is usually managed with the help of NSAIDs and hormonal medications with side effects that may have adverse effects when taken over an extended period. This research paper set out to design and test an herbal orodispersible tablet that included Cinnamomum, Curcuma longa and Foeniculum vulgare as a menstrual pain and gastric pain reliever. Wet granulation was used to prepare three formulations (F1 to F3) and was tested in terms of pre-compression parameters (angle of repose, bulk and tapped density, Carr index, Hausner ratio) and post-compression parameters of hardness, friability, weight variation, wetting time, disintegration time and content uniformity. All formulations had good flow characteristics and satisfied pharmacopeial quality. Formulation F3 was better performing, exhibiting the highest level of hardness, the lowest friability, the quickest wetting and the shortest disintegration period (28 s), which means the best level of tablet integrity and the quickest dispersion. The results imply that the created herbal orodispersible tablet can be a useful and patient-compliant substitute to dysmenorrhea and gastric pain therapy.

INTRODUCTION

Dysmenorrhea, widely known as menstrual cramps, is a prevailing condition affecting most of the women in their reproductive years. Though NSAIDs are frequently prescribed for pain relief, prolonged and extended use may lead to undesirable effects such as gastrointestinal discomfort and cardiovascular complications. This concern has encouraged the exploration of plant-based formulations that offer effective relief with a more favorable safety profile [1]. However the main and foremost pharmacological treatments for managing dysmenorrhea symptoms are Non-steroidal anti-inflammatory drugs (NSAIDs), but their long-term and frequent use have some adverse effects including nephrotoxic and liver

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toxicity, bronchospasms, fluid buildup, edema [2-4], and gastrointestinal symptoms such as nausea, dyspepsia, stomach ulcer, and diarrhea. Hormonal contraceptives are other treatment options but their use have many contraindications and limitations [5]. Past few years, researchers have considered the use of medicinal herbs as the substitute of chemical drugs. There are a lot of studies about herbal medicines used for reducing pain in primary dysmenorrhea such as cumin [6], fennel [7].

In the global market herbal medicines are becoming increasingly favoured and consistent as pharmaceutical scientists procure better understanding of the physicochemical and biochemical parameters and their evaluation by current techniques [8]. The need for plant-based therapeutics is increasing in both developed and developing countries due to the expanding acceptance that these are natural products, easily biodegradable, non-narcotic, have no adverse effects, and easily accessible at affordable prices. As per the World Health Organization (WHO) estimation 80% of the population of African and Asian regions now days uses herbal medicine for basic health care [9]. The use of herbal remedies throughout the world exceeds that of the traditional drugs by two to three times, stated by the World Health Organization (WHO) [10]. The use of plants for healing purposes come before human history and forms the source of much modern medicine. Most of the traditional drugs sourced from plant sources: a century past, most of the few effective drugs were plant based. As it is Exemplified by digoxin (from foxglove), aspirin (willow bark), quinine (from the cinchona bark), and morphine (opium poppy) [11].

Drug delivery systems (DDS) are a strategic tool for broadening markets/indications, lengthining product life cycles and generating opportunities. DDS has made a significant contribution to global pharmaceutical sales through market segmentation, and are moving rapidly. Orodispersible tablets (ODT) are oral solid dosage forms that disintegrate in the oral cavity in easy swallow residue [12]. Orodispersibletablets are also known as“Mouth dissolving tablets”, “Orally disintegrating tablets”,” Melt- in- mouth”,” Fast dissolving drug delivery”, ” Rapimelts tablets”, “Porous tablets”, Quick dissolving tablets” [13].

For most therapeutic agents used to produce systemic effects, the oral route still represents the preferred way of administration owing to its several advantages and high patient compliance compared to many other routes. [14] Many patient groups such as the elderly, children and patients who are mentally retarded, uncooperative, nauseated or on reduced liquid-intake/diets have difficulties swallowing these dosage forms. Those who are traveling or have little access to water are similarly affected [15-17].\

One study looked at these plants for creating formulations with digestive activity. Curcuma longa is more popularly identified as turmeric. Curcuma are the species that are perennial rhizomatous herbs from the Zingiberaceae family. They are important for their medicinal value and play a major role in the economy and the culture. Within herbal medicine systems across the world, turmeric is regarded for its reputation as a blood purifier and as a beneficial remedy for; common cold, leprosy, intermittent fevers, dropsy, purulent ophthalmia, indolent ulcers, pyogenic infections [18] and various other inflammatory conditions. Turmeric is also applied externally for bruises and leech bites, and is known to eliminate many parasitic infections. The active ingredients in turmeric are curcuminoids, and their proportions are as follows: curcumin (the most abundant), desmethoxycurcumin, and bisdesmethoxycurcumin. Curcumin, responsible for most therapeutic effects of turmeric, provides

the yellow color. Approximately 2-5 percent of turmeric consists of curcumin. The first isolation of curcumin happened in 1815, and in 1910 its structure was identified as diferuloylmethane [19]. Turmeric also has antiinflammatory effects, and in this case it lowers histamine and raises the natural cortisone production from adrenal glands. It acts on the pro-inflammatory cytokine TNF-α as well as the genes that synthesize inflammatory COX-2 enzymes and inhibits their release. Maybe the most important anti-inflammatory action of turmeric is the modulation of Prostaglandins (PGs), a very important group of lipids synthesized by the body. PG1 and PG3 are anti-inflammatory, while PG2 is pro-inflammatory. Turmeric is a strong inhibitor of cyclooxygenase 5- lipoxygenase and also 5-HETE production in neutrophils. The reduction of these enzymes results in decreased metabolism of arachidonic acid which results in decreased PG2, thus, decreased pain and inflammation [20].

Foeniculum vulgare is known as fennel and is widely used in folk medicine for a variety of ailments. Its stems, fruits, leaves, and even seeds are used for different forms of medicine for numerous diseases. In ethnobotany, the processes of composition, procedure, and application for F. vulgare are well recorded[19]. Additionally, fennel is used widely in the veterinary field [20]. F. vulgare is used in multiple ethnomedicinal regions such as Northern and Southern America, Europe, Asia, and Indonesia. It is used for treating abdominal pain, as an antiemetic, an appetizer stimulant, arthritis, cancer, pediatric colic, conjunctivitis, constipation, depurative, diarrhea, febrile conditions, gastritis, renal disorders, and as a laxative, liver pain, mouth ulcers, and a stomachache [21].

Cinnamon, scientifically known as Cinnamomum, is part of the Lauraceae family. Egyptians and Chinese have historically used it in food as well as in medicine. It is recognized for its potent oxidant, antibacterial, antifungal, and anti-inflammatory effects [22]. In the field of medicine, it is used for treating cough, indigestion, abdominal cramps, intestinal spasms, nausea, and also for reducing serum glucose and total cholesterol in diabetic patients. However, there are no conclusive studies that utilize cinnamon for dysmenorrhea. Thus, this research was aimed at investigating the effect of cinnamon on primary dysmenorrhea [23]. Cinnamomum Zeylancium, which belongs to the Lauraceae family, is one of the spices widely used in the cuisine of the South American, Asian, and Caribbean people and is valued in their conventional and modern medicine [24, 25].

In view of the facts, this study aims to synthesize one orodispersable herbal formulation employing Cinnamomum, curcuma longa, and F. vulgare. The aim of this study is to modify these three herbal powders to prepare antispasmodic orodispersable tablets to be used for gastric and menstrual pain relief.

1. MATERIAL AND METHODS

➢ MATERIALS:

Table No. 1 INGREDIENTS AND IT'S ROLES:

Ingredient	Function
Cinnamon Powder	Anti-inflammatory, pain-relief [26]
Fennel Powder	Anti-spasmodic [27]
Turmeric Powder	Anti-inflammatory, antioxidant [28]
Mannitol	Sweetener, diluent [29]
Gaur Gum	Super disintegrant [30]

PVP K30 (Polyvinylpyrrolidone)	Binder [31]
Talc	Glidant [32]
Magnesium Stearate	Lubricant [33]

- **METHODS:** The Oro dispersible tablets were made using the wet granulation technique, using a digital balance, carefully measure each of the components, and using a #40 mesh sieve, separate all powders to ensure a uniform size. Using a mortar and pestle, mix cinnamon, fennel, turmeric, mannitol, and gaur gum for a period of 10 minutes to get a homogeneous blend. In a separate container, create a 10% w/v PVP K30 solution by adding 1 g of PVP K30 to 10 mL of vicinal water, serves as the granulating fluid. While kneading the granules, manually add the binder solution to the dry mixture. This combination will create a damp mass and pass this wet mass through a #16 sieve to form granules. Dried granules using a tray or oven dryer, set to 40-50 degrees Celsius until about 2-3% of moisture content is achieved. Using a #20 mesh sieve, separate the granules to remove lumps and assure uniform size. For 5-10 minutes, add your desired coloring, flavoring, and talc, and mix thoroughly. Finally, compress the mixture into tablets using a rotary tablet machine employing 8-10 mm flat-faced punches. Aim for a tablet weight of 300 mg. [1]

Table no. 2: Formulation table.

Ingredient	F 1 (%)	F 2 (%)	F 3 (%)
Cinnamon powder	19.66	13.67	13.67
Fennel	13.67	19.66	13.67
Turmeric	13.67	13.67	19.66
Mannitol	40	40	40
Gaur gum	1	1	**3**
PVP K30	6	6	6
Mg Stearate	1	1	1
Talc	5	5	**15**
Total / Tablet	100	100	100

- **Evaluation of Pre-compression parameters/Powders blend assessment:** The produced granules underwent pre-compression assessments to ascertain their flowability, packing behavior, and compressibility properties prior to tablet compression. These factors are essential for forecasting tablet weight and consistent die filling, uniformity and seamless output, particularly in tablet machines operating at high speeds.

1. **Bulk Density and Tapped Density**: It is the ratio of bulk mass of powder to the bulk volume. It is denoted by ρb. Tapped density It is the ratio of the weight of powder to the minimum volume occupied in measuring cylinder.

Bulk density $(\boldsymbol{\rho b}) = M/Vb$ *Where,M is the mass of the sample,Vb bulk volum*
Tapped density $(\boldsymbol{\rho t})$ = *weight of powder blend/ Minimum volume occupied by cylinder* [35]

2. **Carr's index (Compressibility index)**: Carr's Index provides insight into powder compressibility.

$$\textbf{\textit{Carr's Index}}\ (\%) = (Tapped\ Density - Bulk\ Density / Tapped\ Density) \times 100$$

(A Carr's index value 25% suggest poor flow.) [36]

3. **Hausner's Ratio:** Another indicator of flowability, is the ratio of tapped to bulk density. [37]

Hausner's Ratio = Tapped Density/ Bulk Density [35, 36]

(A value between 1.00 and 1.25 indicates excellent to good flow; values >1.25 indicate poor flow behavior).

1) **Angle of repose:** It is the maximum angle that can be obtained between the freestanding surface of powder heap and the horizontal plane. It was determined by using fixed funnel method.

$$\textbf{\textit{Angle of repose}}\ (\boldsymbol{\theta}) = tan - 1\ h/r$$ [38]

- **Post-Compression evaluation**: Post-compression studies are crucial to ensure that the formulated orodispersible tablets (ODTs) of cinnamon, 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.

1) Weight variation test: Twenty tablets were randomly selected and weighed individually using an electronic balance (Panther USA) Model BM-320 available in the university lab. The average weight and standard deviation were calculated. According to the **United States Pharmacopeia (USP <905> Uniformity of Dosage Units), permissible weight deviation for 300 mg tablet is ± 7.5%** from the average tablet weight. [39]

2) Thickness: The tablet thickness was calculated by using a Galvano Scientific hardness tester Model GHT-21TS. The tablet was placed vertically and force is applied by pressing button. USP **does not provide any numerical limits** for tablet thickness.

3) Hardness test: Tablet hardness was measured using a Galvano Scientific hardness tester Model GHT-21TS. For ODTs, sufficient hardness is required to withstand mechanical stress, while remaining soft enough for rapid disintegration [40]. USP treats hardness as a **non-compendial (informational) test.** Tablet hardness is addressed under USP <1217> as an informational test.

4) Friability test: Using a Galvano Scientific Fraibiliator Model FT-L, twenty tablets were rotated at 25 rpm for 4 minutes operated for 100 revolutions. 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. [38]

$$\%\ \textbf{\textit{Friability}} = Initial\ weight - Final\ weight\ /\ Initial\ weight.$$ [41]

5) Wetting time: The wetting time was determined by placing a tablet on in a Petri dish containing water. The time for water to reach the upper surface of the tablet was recorded [42].Wetting time is not specified in USP for orodispersible tablets. However, pharmaceutics literature reports an optimal

wetting time range of approximately 5–30 seconds, depending on formulation and superdisintegrant used. [44]

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, cinamon, and fennel oil content. All formulations were within the 90–110% acceptable range, confirming uniform distribution of active constituents. [40]

7) **Disintegration time:** Disintegration time is a critical quality attribute for ODTs. The test was performed in 1000 mL of distilled water at 37 ± 2°C using the USP disintegration apparatus. According to European Pharmacopoeia limit pf 180 seconds for orodispersible tablets is acceptable. Rapid disintegration is attributed to the synergistic effect of guargum and water-soluble herbal actives like fennel [35].

2. RESULT AND DICUSSION

➢ Results:

The formulated batches (F1-F3) of orodispersible tablets containing Cinnamon, 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 tablet for menstrual cramp relief.

3.1) Pre-compression Evaluation

For every formulation, the pre-compression parameters showed appropriate flow characteristics. Passable to fair flow characteristics was indicated by the angle of repose values (~41–42°). Excellent flow properties and outstanding packing ability were further validated by Hausner ratio (1.06–1.07) and Carr's index (5.88–6.67%). Overall, the findings show that the powder mixtures were appropriate for wet granulation.

Table no. 4: Pre-compression Evaluation Table

Batch	F1	F2	F3
Angle of Repose	41.2	41	42.3
Bulk Density (g/cm³)	14	16	15
Tapped Density (g/cm³)	15	17	16
Carr's Index (%)	6.67	5.88	6.25
Hausner Ratio	1.07	1.06	1.07

3.2) Post-compression Evaluation

A. Hardness:

Batch F1 met pharmacopeial standards for sufficient mechanical strength and handling stability with an acceptable tablet hardness of 3.5 kg whereas Batch F2 significantly exhibited lower hardness of 3.0kg but within permissible pharmacopeial limits which suggests less mechanical toughness. According to pharmacopeial criteria, Batch F3 showed the maximum hardness value (4.0 kg), indicating outstanding mechanical integrity and ideal tablet compaction**.**

B. Weight Variation:

After testing, Batch F1's tablet weight slightly dropped (from 0.308 g to 0.296 g), indicating

satisfactory abrasion resistance in accordance with pharmacopeial restrictions. Although Batch F2 showed a relatively higher weight loss (0.285 g to 0.272 g), the data were within the pharmacopeial limit of less than 1% whereas Batch F3 demonstrated strong mechanical strength and conformity to pharmacopeial standards with minimal weight loss (0.286 g to 0.281 g).

C. Friability:

Batch F1 demonstrated sufficient mechanical strength and adherence to pharmacopeial limits during friability testing, as evidenced by a weight loss of 0.012 g while Batch F2 showed a weight loss of 0.013 g after friability testing, although this amount was still within the allowable pharmacopeial limit of less than 1%.Batch F3 demonstrated enhanced pharmacopeial compliance and abrasion resistance with a minor weight loss of 0.005 g.

D. **Disintegration Time:**

Batch F1 showed acceptable disintegration behavior within pharmacopeial limitations for orodispersible tablets, disintegrating in 52 seconds. Batch F2 disintegration time of 80 seconds was noticeably longer indicating a slower rate of pill breakdown but it was still meeting pharmacopeial criteria. According to pharmacopeial standards, Batch F3 demonstrated the fastest disintegration time of 28 seconds, indicating exceptional disintegration efficiency and optimal performance.

E. Wettability:

Batch F1 established a wetting time of 5 minutes and 27 seconds, showing relatively slower moisture penetration, despite falling within acceptable limitations whereas Batch F2's wetting time of 4 minutes and 09 seconds exhibited better wettability than Batch F1, while it was still slower than the optimized formulation. Batch F3 was the best formulation since it had the fastest wetting time of 2 minutes and 30 seconds. It showed great wettability and rapid water absorption, which supported faster disintegration.

DISCUSSION

The pre-compression and post-compression parameters of the prepared Oro dispersible tablet batches (F1–F3) comprising powders of turmeric, fennel, and cinnamon were good, indicating their appropriateness for wet granulation and tablet manufacture. According to USP guidelines for powder flow properties (USP <1174>), pre-compression evaluation revealed acceptable to fair flow properties as indicated by angle of repose values, while excellent flowability and packing efficiency were further supported by low Carr's index and favorable Hausner ratio values. These results guaranteed constant tablet compression and homogenous die filling. What made Batch F3 stand out showed up after testing its strength. Not only did it meet the highest standards set by USP rule <1217> but also hit the maximum hardness level. Its ability to withstand wear without breaking down marked strong physical strength. At the same time, minimal change in weight along with low surface wear confirmed alignment with USP <1216> criteria. Batch F3 achieved the fastest wetting and disintegration times among all tested formulations, which demonstrated its ability to penetrate water and dissolve tablets rapidly, which represents two essential attributes needed for orodispersible tablets to meet United States Pharmacopeia disintegration requirements (USP <701>). The combination of strong mechanical properties with minimal friability and rapid disintegration and enhanced wettability creates Batch F3 as the most effective formula. The product meets USP quality standards while delivering an effective dosage form that patients can use to treat menstrual cramps.

CONCLUSION

In conclusion, the performed study effectively formulated and evaluated herbal orodispersible tablets encompassing cinnamon, fennel, and turmeric using the wet granulation method. The three formulations exhibited acceptable pre-compression and post-compression characteristics in compliance with pharmacopeial standards, validating good flowability, mechanical strength, and uniformity. Among the three batches, formulation F3 showcased superior performance with optimal hardness, low friability, rapid wetting, and the shortest disintegration time, signifying enhanced tablet integrity and fast dispersion. These findings suggest that the formulated herbal orodispersible tablet could provided as an effective, patient-friendly, and secure alternative to conventional pharmacological therapies for menstrual and gastric pain relief.

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