Formulation And Evaluation of Herbal Tablet By Using Fennel And Ginger For Menstrual Cramps

Prerana B. Kale[1], Prof.Babasaheb L. Chopade[2], Dr. Megha T. Salve[3]
[1, 2, 3] Dept of Pharmacy
[1, 2, 3] Shivajirao Pawar College Of Pharmacy, Pachegaon, Ahmednagar- 413725

Abstract- *Menstruation is a natural aspect of a woman's life, yet it often brings along a host of uncomfortable symptoms and challenges. From painful cramps to mood swings and irregular periods, managing menstrual problems requires a holistic approach tailored to each individual's needs. Few studies have shown the effectiveness of herbal drugs in the treatment of dysmenorrhoea. Herbal medicine has been commonly used to treat primary dysmenorrhea-rhea. As commonly used natural product fennel (Foeniculum vulgare), and ginger (Zingiber Officinale). Fennel is an herbal therapy that is proposed to alleviate menstrual pain by lowering the prostaglandin levels in blood. Fennel seeds contain compounds that help regulate menstrual flow and reduce bloating and cramps. Ginger is known to have outweighing benefits among many conventional remedies. It is useful in minimizing menstrual cramps, and it relaxes the muscular spasms as well. It is considered as an anti-inflammatory agent in folk remedies. The main aim is to determine the efficacy and safety of herbal and dietary therapies for the treatment of primary and secondary dysmenorrhoea when compared to each other. Pain relief by using both ginger and fennel seed have anti-inflammatory properties that can help allivate menstrual cramp and pain.*

Keywords- Menstruation, Dysmenorrhea , Menstrual cramps, Menstrual flow, Uncomfortable symptoms, Bloating, Remedies ,Anti-inflammatory properties.

I. INTRODUCTION

Menstruation, or period, is normal vaginal bleeding that occurs as part of a woman's monthly cycle. Every month, your body prepares for pregnancy. If no pregnancy occurs, the uterus, or womb, sheds its lining. The menstrual blood is partly blood and partly tissue from inside the uterus. It passes out of the body through the vagina.

Periods usually start between age 11 and 14 and continue until menopause at about age 51. They usually last from three to five days. Besides bleeding from the vagina, you may have:

- Abdominal or pelvic cramping pain
- Lower back pain
- Bloating and sore breasts
- Food cravings
- Mood swings and irritability
- Headache and fatigue

Premenstrual syndrome, or PMS, is a group of symptoms that start before the period. It can include emotional and physical symptoms[1].

Menstruation is a natural aspect of a woman's life, yet it often brings along a host of uncomfortable symptoms and challenges. From painful cramps to mood swings and irregular periods, managing menstrual problems requires a holistic approach tailored to each individual's needs. Many individuals struggle with the monthly challenges of mood swings and menstruation pains in the hectic city life[2]. Few studies have shown the effectiveness of herbal drugs in the treatment of dysmenorrhoea, which highlighted the role of nutritional and metabolic factors as an important role in triggering menstrual problems and their treatment. The effectiveness of herbal and dietary treatment is still under investigation and needs more careful studies[3].

In recent years, herbal medicine has been commonly used to treat primary dysmenorrhea-rhea [4].As commonly used natural product fennel(Foeniculum vulgare), and ginger (Zingiber Officinale) all warm meridians, disperse Cold, and remove dampness. With its contra stimulant and analgesic effects, fennel is considered an acceptable herbal treatment for dysmenorrhea despite its unpleasant taste. Ginger is helpful for relieving pain associated with dysmenorrhea, rheumatoid arthritis, osteoarthritis, and gastrointestinal symptoms such as diarrhoea,nausea, and vomiting. Some studies also revealed that ginger can be used to relieve pain among women with dysmenorrhea[5].

Fennel:

Fennel or Foeniculum vulgare is an herbal therapy that is proposed to alleviate menstrual pain by lowering the prostaglandin levels in blood [6]. A few studies have used

fennel as an alternative therapy for the treatment of primary dysmenorrhea. It aims to assess the effectiveness and safety of fennel for reducing pain in primary dysmenorrhea[7].

Fennel has been widely used as an herbal medicine worldwide[8]. Its antispasmodic effect on spasms induced by oxytocin and PGE2 has been confirmed in uteri dissected from mice[9].A study on the association between fennel and colicky pain in infants suggested that fennel seed oil emulsion can reduce colic intensity in infants.In addition, fennel has been recommended for the treatment of primary dysmenorrhea in various studies[10]. Fennel seeds contain compounds that help regulate menstrual flow and reduce bloating and cramps. Dried fennel seeds are a storehouse of various nutrients, with low calories and high in different micro and macronutrients. When it comes to exploring the health benefits of fennel seeds, they are mainly rich in – Vitamin C, Vitamin E, Vitamin K, Minerals like Calcium, Magnesium, Zinc, Potassium, Selenium, and Iron and antioxidants such as polyphenols Fibre and Organic compounds like Anethole [11].

Ginger:

Traditionally, a range of folk medicine has been used to treat every day minor ailments such as menstrual cramps, headache, vomiting, indigestion, and nausea. Ginger is known to have outweighing benefits among many conventional remedies. It is useful in minimizing menstrual cramps, and it relaxes the muscular spasms as well. It is considered as an anti-inflammatory agent in folk remedies[12]. The compounds found in ginger may help to protect against the increases in inflammation, by inhibiting the body's production of prostaglandins (a class of pro-inflammatory chemicals involved in triggering the muscle contractions that help the uterus shed its lining)[13].It contains several constituents such as gingerol, gingerdiol, and gingerdione, beta-carotene, capsaicin, caffeic acid and curcumin[14]. Ginger and its pungent isolated compounds are known to have many potent biological activities. It has the potentiality to modulate the enzymatic profile and act as the prevention of diseases. It possesses various medicinal activities including anti-Inflammation, anti-tumor, insect repellent, anti-bacterial, anti-mutagen, anti-carcinogenic and antioxidant properties[15].

Aim:

To determine the efficacy and safety of herbal and dietary therapies for the treatment of primary and secondary dysmenorrhoea when compared to each other.

The aim of herbal tablet prepared with ginger and fennel seeds powder for menstrual cramps is to provide effective and natural relief from menstrual comfort, including pain, cramps, and associated symptoms, while promoting overall wellbeing and hormonal balance.

Objectives:

- Pain relief: Both ginger and fennel seed have anti-inflammatory properties that can help allivate menstrual cramp and pain.
- Muscle relaxation: These herbs may help relax the uterine muscles, reducing the intensity of cramps.
- Hormonal balance: Certain compounds in ginger and fennel seeds could help balance hormone levels, potentially easing menstrual discomfort.
- Natural alternative: Herbal tablets offer a natural alternative to conventional pain relief medication, with potentially fewer side effects.
- Digestive aid: Fennel seeds are known for their digestive benefits, which can help with any gastrointestinal discomfort associated with menstrual cramps.

II. MATERIALS AND METHODS

Materials:

Herbal drug:

Fennel:Local Market, Newasa
Ginger: Local Market, Newasa

Collection and Drying of the plant material:

The plant part of the (rhizome) ginger and seed of fennel procured to the market.The plant part (rhizome) of ginger and seeds of fennel were collected As a whole and dried in shade. In fresh condition, it is then Oven-dried at reduced temperature (40°C) to make suitable for Grinding purpose. The seeds were crushed in the mixed grinder To a coarse powder. The coarse powder is then stored in an Airtight container or polybags and kept in a cool, dark, and dry Place for further. All other ingredients used to college.

Preparation of ginger powder:

- Fresh ginger (rhizome)
- Drying
- Washing Until clean with running water
- Sizes cut using knife with thickness
- Using themortar pestle or blender to reduce the size
- Use a 60 no mesh sieve

- Powder of ginger.

Preparation of fennel powder:

- Use fennel seeds
- Drying
- Using the mortar pestle or blender to reduce the size
- Use a 40 no mesh sieve
- Powder of fennel seeds

Chemicals:

Acacia, Magnesium stearate, Lactose, Crospovidone
(Chemical store- Shivajirao Pawar College Of Pharmacy, Pachegaon)

Methods:

Herbal tablet containing ginger and fennel seed powder prepared by wet granulation method. Other ingredients like starch as a diluents and lactose, crospovidone as a disintegrating agent, acacia as a binder magnesium stearate as a lubricant. Firstly weigh the required amount of API and all excipients. Then diluent starch and half amount of disintegrating agent crospovidone and lactose are mixed with API. And then these mixture take and add binder solution in it. And then these damp mass is screened using sieve and forms granules. Now these wet granules are dried in hot air oven at 60. After drying these granules are screened through a sieve to get uniform size granules. Then these granules mixed with stearic acid and crospovidone and then punch the granules in punching machine to give proper size and shape to the tablet.

Formula:

Formulation of 500mg herbal tablet

	Quantity	Quantity	Quantity
Ingredients	F1	F2	F3
Fennel seeds powder	250mg	250mg	250mg
Ginger Powder	150mg	150mg	150mg
Crospovidone	50mg	50mg	50mg
Magnesium Stearate	10mg	30mg	10mg
Acacia	10mg	10mg	30mg
Lactose	30mg	10mg	10mg

Table-1

Pre-compressional studies of powder blend:

In development of new dosage form preformulation study is the prior step in the potential drug development. It is the principal investigation in the drug development to obtained information on the known properties of compound and the proposed development schedule. So, this preformulation investigation may merely confirm that there are no significant barriers to compound development. Following pre-compressional parameters were studied like angle of repose, bulk density, tapped density, compressibility indices etc.

Precompressional Studies of Powder Blend

- **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. Specified amount of powder drug was transfer to the funnel keeping the orifice of the funnel blocked by thumb. When powder was cleared from funnel then measured its angle of repose and measured in θ 7.

Angle of repose (θ) = tan-1h/r

- **Bulk Density:**

Bulk density was determined by pouring the blend into graduated cylinder. The bulk volume (Vb) and the weight of powder (M) were determined. The bulk density was calculated using the formula:

Pb = M/Vb

It is the ratio of bulk mass of powder to the bulk volume.It is denoted by ρb. Bulk density is used to find out homogenecity. Where, M is the mass of the sample, Vb bulk volume

- **Tapped Density:**

It is the ratio of the weight of powder to the minimum volume occupied in measuring cylinder. Tapped density is determined by placing a graduated cylinder contain a known mass of drug or formulation on a mechanicalTapper apparatus which is operated at fixed no. of taps (1000) until the powder bed reached a minimum volume.

Tapped density (ρt) = weight of powder blend/Minimum volume occupied by cylinder.

Compressibility Indices

- **Carr's Index:**

The Carr's Index is a measure of powder flowability, used in pharmaceuticals and powder metallurgy. It's calculated by dividing the difference between the bulk and

tapped densities by the bulk density, then multiplied by 100. It helps assess the flow properties of powders, which is crucial for manufacturing processes like tablet compression or powder handling.

- **Hausner's Ratio:**

Hausner's ratio is the ratio of the tapped density of granules to the bulk density of granules.Hausner's ratio is another parameter used to assess powder flowability, similar to Carr's Index. It's calculated by dividing the tapped density by the bulk density of a powder.Calculated by using the following formula.

Hausner's ratio= Tapped density/Bulk density

Post compressional studies of Prepared Tablet

Physical appearance:

The general appearance and colour of tablets were found by visual determination.The general appearance of tablet was found to be round in shape, brown in colour, smooth texture, and odourless. The major physical parameters analysed for herbal tablets prepared for the study are hardness, water absorption ratio, weight variation, thickness, diameter, disintegration time.

- **Weight Variation:**

Twenty tablets were selected randomly from the formulation. Tablets were weighed one by one and then theaverage weight was calculated. Deviation of each tablet from average weight was calculated and then the percent deviation was computed.The individual weight was compared with the upper limit and lower limit. Not more than two of the tablets differs from the average weight by more than the % error listed, and no tablets differ by more than double that percentage.

- **Hardness:**

The hardness was being evaluated by using Monsanto hardness tester. For each formulation, the hardness and thickness of 20 tablets were determined. Hardness test was determined by Monsanto hardness tester and the thickness of tablets was determined by Vernier Callipers.

- **Friability:**

Friability test is carried out, using Friability apparatus. The weighted tablets are being placed in the apparatus and which is been rotated at 25 rpm for 5 minutes. After an interval tablets are taken out from apparatus and once again they are weight. The friability is calculated by given formula.

Friability = Initial weight (Wi) – Final weight (Wf)/Initial weight (Wi) *100

- **Disintegration Test:**

3 tablets were taken for the estimation of the disintegration time. The tablets were placed in the disintegration apparatus and then the time was observed up till the tablet were totally disintegrated. The temperature for the apparatus was maintained at 37º C.

Evaluation Parameters:

Pre-formulation parameters for herbal tablets

Evaluation Parameter	F1	F2	F3
Angle of Repose	22.3	24.5	24.9
Bulk Density(g/ml)	0.48	0.47	0.44
Tapped Density(g/ml)	0.45	0.44	0.42
Hausner's Ratio	1.205	1.197	1.157
Carr's Index	12.5	11.9	13.7

Table-2

Physical parameters for herbal tablets

Batch Code	F1	F2	F3
Weight Variation (%)	3	4	3.5
Hardness(kg/cm2)	6.2	6.1	6.3
Thickness(mm)	6	5.8	5.9
Friability	0.5	0.4	0.6

Table-3

III. RESULT

The formulation was prepared by wet granulation method were tested. For pre-formulation studies for the effective evaluation of tablets. All the evaluated pre-formulation parameters are shown in table 2. Based on the pre-formulation study the flow property of granules was good. The physical parameters of compressed tablets were shown in table. The compressed tablets colour was brownish. The

weight variation test, hardness, Thickness, and disintegration time were shown in table 3.

IV. DISCUSSION AND CONCLUSION

Herbal products may contain a single herb or combinations of several different herbs believed to have complementary and/ or synergistic effects. To minimize the patient compliance in regarding to suppress side effects. Perceiving the potential of herbal plants with higher levels of therapeutic activity, the present study was undertaken with an aim to formulate and evaluation of herbal tablet for menstrual cramps by using the fennel seeds powder and ginger powder both have anti inflammatory activity.

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