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Research Article

FORMULATION AND DEVELOPMENT OF FAST DISINTEGRATING TABLETS CONTAINING FENUGREEK SEED POWDER

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ABSTRACT

The dosage uniformity and patient compliance can be increased and adultration can be decreased in ayurvedic powders by formulating them into tablets. In the present research work, fast disintegrating tablets (FDTs) of fenugreek seeds powders (FSP) were prepared by wet granulation technique. Crospovidone and Platego ovata powder were used as superdisintegrants and also by taking the advantage of self-disintegration property of fenugreek seeds. Preformulation studies indicated that the powder blend was not having free flowing nature. So wet granulation technique was adopted and appropriate tablet formulations were developed. Formulations were optimized to develop tablets having minimum possible disintegration time. Tablets were evaluated for hardness, weight variation, friability, wetting time, disintegration time and stability. Results revealed that FDT of FSP could be prepared at any level of superdisintegrants. Stability study was also conducted as per ICH guidelines and all formulations were found to be stable. The results concluded that FDT of FSP will leads to improved effectiveness and hence better patients compliance.

Key words: Fenugreek seed powder, fast disintegrating tablets, crospovidone, plantego ovata.

INTRODUCTION

Medicinal herbs and minerals have been in use for thousands of years in one form or the other under indigenous systems of medicines like Ayurveda, siddha, and Unani in adition to natural products used for their pharmaceutical actions[1]. Different ayurvedic companies formulating different ayurvedic powders, which are being widely prescribed by the ayurvedic physicians.

They are intend to be dispersed or mixed in liquids like water, milk, honey and fruit juices etc prior to oral administration. In such cases dose of powders is poorly regulated, as in most of the houses powder measuring devices are different. In addition, the powders and devices are difficult to carry while traveling[2].

The rate of adulteration is also more in powders compared to tablets. To over come from all these problems we can convert the powder form into tablet form. However, many elderly persons and Childs are having problem in taking the conventional tablets because of dysphagia, hand tremors and under developed muscular and nervous system[3]. So we planed to formulate the fast disintegrating tablets.

Fast disintegrating drug delivery is rapidly gaining acceptance as an important new drug delivery technology [4].These dosase forms dissolve or disintegrate within few minutes[5]. Usually, superdisintegrants are added to a drug formulation to facilitate the break up or disintegration of tablet content into smaller particles, that can dissolve more rapidly then in the absence of disintegrants[6,7].

Many substances like microcrystalline cellulose[8], crospovidone [9], croscarmellose sodium [10], sodium starch glycolate [11], have been widely used as superdisintegrating agents in the formulation of FDT. Similarly, various natural substances like gum karaya, modified starch and agar have been used in the formulation of FDT. Mucilage of natural origin is preferred over semi –synthetic and synthetic substances because they are comparatively cheaper, abundantly available, non- irritating and non-toxic in nature.

Fenugreek is an erect, strongly scented, robust, annual herb, about 30-80 cm high. It has compound leaves of light green color, 2 - 2.5 cm long; with Yellow flowers and thin pointed pods. The seeds are brownishyellowand have peculiar odor. It has been used since ancient times both as a food and medicine by the people living on the shores of Mediterranean and across Asia. Fenugreek seeds are also used for removing dandruff. Two table spoons should be soaked overnight in water. In the morning softened seeds can be ground to a fine paste and applied on scalp and left on for half an hour. The hair is then thoroughly washed with soap-nut. Fenugreek is rich in Vitamin A and D. It also contains oil that resembles cod liver oil.

Fenugreek Herb

Fenugreek Seeds

FDTs containing Fenugreek

Fenugreek seeds powder

Fenugreek is rich in minerals and is high in protein. It has Vitamin B1, B2, B3 and contains chlorine, lecithin and iron. Fresh Fenugreek leaves are available at many Indian and Middle Eastern Grocery stores, while the seeds are available in almost all grocery stores. Fenugreek can minimize the menopause symptoms, as it contains chemicals like diosgenin and estrogenic isoflavone, which closely resembles the female hormone estrogen. Fenugreek has been studied extensively to find out its health benefits. Such studies have pointed out that, fenugreek seeds contain some really important chemicals, proteins, vitamin C, niacin, thiamine and minerals like potassium, iron, selenium, silicon and sodium. The important chemicals found in fenugreek seeds are diosgenin, alkaloids, lysine, saponins, and L- tryptophan. These active compounds or chemicals can be attributed for much of the fenugreek seeds benefits, a few of which are enlisted below [12].

Fenugreek is considered as a great aid to digestion. It contains a type of non-dissolving fiber, due to which the seeds swell, when soaked in

water. This fiber can ensure proper digestion to cure some common digestive problems including indigestion.

Fenugreek can loosen up cough and mucus, thereby helping to expel them from the body. This is the reason why it is used in conditions like bronchitis, cough and congestion. Fenugreek is an excellent home remedy for lowering cholesterol. By lowering the level of cholesterol, it can reduce the risk for developing heart and cardiovascular diseases.

Lowering blood sugar level can be termed as one of the most significant fenugreek benefits. Diabetes, both type 1 and type 2 diabetes can be treated by using fenugreek seeds.

Fenugreek is an effective home remedy for heartburn and acid reflux disease. It contains mucilage, which is a sticky or gelatinous substance that can provide a protective coating to the lining of the stomach and gastrointestional tract. Fenugreek seeds can also be used for skin inflammation, minor burns and skin conditions like eczema and boils. The seeds are usually ground to make a thick paste to be applied for skin problems. Fenugreek can also help to control acne by purifying the blood.

Fenugreek is known to stimulate perspiration that helps to bring down body temperature or reduce fever. The mucilage found in fenugreek, on the other hand, provides relief in sore throat. Fenugreek can remove dandruff from the scalp and prevent excessive hair fall, especially in men.

For women, fenugreek has some additional benefits. Inducement of childbirth or labor, relief in menstrual discomforts are some of the noteworthy fenugreek benefits for women. Moreover, fenugreek for lactation

Men too can benefit from fenugreek in conditions like premature ejaculation and decreased libido. So, fenugreek is one of those few natural products, with numerous health benefits for men as well as women. However, like other herbal medicine, fenugreek should also be used in moderation. Excessive intake of fenugreek can cause nausea, stomach upset and other side effects. So, use this herbal medicine judiciously in order to realize the fenugreek benefits without experiencing any adverse effect. So here dose of seeds powder is most important, in order to meet this target we have formulated FDT of FSP.

MATERIALS AND METHODS

Materials Fenugreek and plantego ovata seeds were purchased from the local market of Gulbarga, Karnataka. Poly vinyl pyrrolidone (PVP), D-Mannitol, Crospovidone, Magnesium stearate and talk were purchased from S.D. Fine chemicals Mumbai. All other materials were of analytical grade

Preparation of seed powder of plantego ovata: The dried plantego ovata seeds were comminted and sieved through mesh no.80 and stored in desicator.

Preparation of Fenugreek seeds powder: The dried fenugreek seeds were collected and size reduction was don in the grinder then sieved through mesh no 80 and stored in desicator.

Designing of Fenugreek fast dissolving tablets: Fenugreek fast dissolving tablets were prepared by non –aqueous wet granulation method using absolute alcohol as the solvent. Fenugreek seeds powder and other ingredients with the half the quantity of superdisintegrants (Intra granular disintegrants) were mixed together, sufficient quantity of alcohol was added and mixed to form a coherent mass. The wet mass was granulated using sieve no 12 and granules formed were dried in the dryer at 40 ^{o}c for 30 min .The granules were further blended with the remaining quantity of superdisintegrants (extra granular disintegrants), purified talc and magnesium stearate were added and compressed into tablets.

EVALUATION OF FENUREEK FAST DISSOLVING TABLETS

The prepared fenugreek fast disintegrating tablets were evaluated for weight variation, hardness, friability, disintegration time, wetting time and stability studies. In weight variation study, twenty tablets were selected at a random and average weight was calculated. Then individual tablets were weighed and weight was compared with an average weight. The Pfizer hardness tester was used for the determination of the hardness of tablets. Tablets was placed in contact between the plungers, and the handle was pressed, the force of the fracture was recorded. The friability of tablets was determined using Roche friabilator (Cambel Electronics, Mumbai, India). Six tablets were tested from each formulation. In the disintegration time study[13] tablets was put into 100 ml distilled water at 37 ± 2 ^{o} c. Time required for complete dispersion of a tablet was measured with the help of digital tablet disintegration test apparatus and in wetting time [14] study a piece of tissue paper folded twice was placed in a small Petri dish containing 5 ml distilled water. A tablet was placed on the paper, and the time for complete wetting of the tablet was measured in seconds. The stability study of the tablets was carried out according to International conference on Harmonization guidelines (ICH guidelines). The formulations were stored at 40 ± 2 ^{o}c /75 ± 5 %RH for 3 months by storing the samples in stability chamber (Lab care Mumbai India) .

RESULTS AND DISCUSSION

The valves of precompressional parameters were within prescribed BP limits and indicated good free flowing property. The results are shown in Table 2.

The results of post compressional parameters like weight variation, hardness, friability, disintegration and wetting time are shown in Table 3. In all the formulations hardness test indicates good mechanical strength, hardness of the tablets was in the range of 5.15-6.25 kg/cm^2. Friability was less then 1% in all the formulations, indicated that tablets had a good mechanical resistance

The tablets were subjected for evaluation of in- vitro disintegration time. The formulations containing both super disintegrants (crospovidone and plantego ovata) (F7) were showed disintegration time of 14.52 seconds. It may be due to wicking action of crospovidone and swelling nature of the plantego ovata and fenugreek powder. In all other set of formulations, the disintegration time of tablets was decreased with increased concentration of superdisintegrants. The measurement of wetting time may be used as another confirmative test for the evaluation of fast dissolving tablets. In wetting time study, the wetting time was decreased with increased concentration of superdisintegrants. The least average wetting time and disintegration time of formulation F7 proved the combined effect of both crospovidone and plantega ovata . In all the formulations the disintegrantion may be influenced by the self-disintegration property of Fenugreek seed powder.

The stability study for tablets was carried out according to ICH guidelines by storing the tablets in stability chamber (Lab-care Mumbai). No appreciable change in physical characteristics like hardness, disintegration time and wetting time was observed even after the evaluation for 3 months. Stability study results are compiled in Table4.

CONCLUSION

It can be concluded that, instead of taking fenugreek seeds, it is better to take fenugreek fast disintegrating tablets. There by patient compliance can be increased and percent of adulteration can be decreased and most importantly dose of the fenugreek seeds can be accurately maintained. On the basis of disintegration and wetting time results, it can be concluded that the formulation F7 was best compared to all other formulations.

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Table -1: Formula used in the formulation of fenugreek fast dissolving tablets

Ingredients (mg/tab)	F1	F2	F3	F4	F5	F6	F7
Fenugreek seeds powder	500	500	500	500	500	500	500
D-Mannitol	124	117.5	104.5	124	117.5	104.5	104.5
Plantego ovata powder	6.5	13	26	6.5	13	26	13
Crospovidone	-	-	-	6.5	13	26	13
PVP	6.5	6.5	6.5	6.5	6.5	6.5	6.5
Magnesium stearate	6.5	6.5	6.5	6.5	6.5	6.5	6.5
Talc	6.5	6.5	6.5	6.5	6.5	6.5	6.5

Table -2: Precompressional parameters of granules containing fenugreek seeds powder

Formulations	Angle of repose(ɵ) (±SD), n=3	Compressibility(%) (±SD), n=3	Hausnersratio (±SD), n=3
F1	24.61(1.14)	18.37(2.34)	1.25(0.00)
F2	25.22(0.33)	20.3290.65)	1.23(0.03)
F3	23.49(2.32)	19.1292.500	1.29(0.05)
F4	28.32(2.27)	20.4891.670	1.24(0.03)
F5	27.62(0.96)	21.80(3.22)	1.22(0.04-)
F6	29.35(2.22)	22.59(1.60)	1.25(0.06)
F7	23.15(1.33)	18.65(2.30)	1.30(0.04)

Table -3: Post compressional parameters of fenugreek fast dissolving tablets

Formulations	Weight variation (%) (±SD),n=20	Hardness (kg/cm^2)(±SD),n=6	Friability (%) (±SD),n=6	Disintegration time (sec.) (±SD),n=10	Wetting time(sec.) (±SD),n=3
F1	650.00 (1.90)	5.15 (0.22)	0.11(0.02)	19.67(1.51)	39.55(1.80)
F2	651.50 (1.50)	6.22 (0.35)	0.22(0.04)	18.55(1.71)	38.42(2.20)
F3	650.65 (1.54)	5.58 (0.40)	0.09(0.03)	15.1890.98)	36.20(1.80)
F4	649.80 (1.44)	5.72 (0.41)	0.10(0.02)	20.52(1.22)	40.84(1.40)
F5	651.10 (1.58)	6.25 (0.42)	0.32(0.03)	19.42(2.21)	39.58(2.20)
F6	650.00 (1.42)	5.58 (0.45)	0.44(0.08)	18.48(2.52)	38.22(1.70)
F7	652.10 (1.44)	5.42 (0.78)	0.42(0.06)	14.52(1.55)	34.21(2.28)

Table -4: Results of stability study

Formulations	Hardness(kg/cm^2) (±SD),n=6	Disintegration time(sec.) (±SD),n=10	Wetting time(sec.) (±SD),n=3
F1	5.11(0.27)	19.22(1.23)	39.22(1.77)
F2	5.98(0.42)	17.92(1.55)	38.55(1.50)
F3	5.10(0.48)	16.20(1.10)	36.58(1.20)
F4	5.20(0.55)	21.20(2.20)	42.82(1.50)
F5	6.10(0.90)	20.40(2.10)	41.32(1.20)
F6	5.33(0.88)	19.42(1.1.)	39.50(2.17)
F7	5.17(0.24)	14.32(1.55)	34.58(1.75)

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