



Research Article

www.ijrap.net



FORMULATION AND EVALUATION OF SILDENAFIL CITRATE FAST DISSOLVING TABLETS USING FENUGREEK SEED MUCILAGE

Naazia Zafar^{1*}, V. Neeharika², P. K. Lakshmi³

¹Postgraduate, Department of Pharmacognosy and Phytochemistry, G. Pulla Reddy College of Pharmacy, Hyderabad, Andhra Pradesh, India

²Associate Professor, Department of Pharmacognosy and Phytochemistry, G. Pulla Reddy College of Pharmacy, Hyderabad, Andhra Pradesh, India

³Professor, Department of Pharmaceutics, G. Pulla Reddy College of Pharmacy, Hyderabad, Andhra Pradesh, India

Received on: 05/04/14 Revised on: 24/05/14 Accepted on: 13/06/14

*Corresponding author

Naazia Zafar, Department of Pharmacognosy and Phytochemistry, G. Pulla Reddy College of Pharmacy, Hyderabad, Andhra Pradesh, India

E-mail: naazia284@gmail.com

DOI: 10.7897/2277-4343.05373

ABSTRACT

In the present study, the effect of natural superdisintegrant was compared with synthetic superdisintegrant and conventional disintegrants in the formulation of fast dissolving tablets (FDTs) of Sildenafil citrate prescribed in the treatment of erectile dysfunction and pulmonary arterial hypertension. Isolated mucilage of Fenugreek seed was evaluated for physico-chemical parameters and it complies with the official specifications. Various formulations of Sildenafil citrate tablets were prepared by direct compression method using different concentrations of natural superdisintegrant i.e. isolated mucilage of *Trigonella foenum-graecum* seed and synthetic superdisintegrants like sodium starch glycolate (SSG) and conventional disintegrants like microcrystalline cellulose (MCC) 101 and 102. The initial compatibility study carried out by FTIR spectroscopy which revealed no interaction between drug and excipients. The blend was evaluated for pre compression parameters like angle of repose, bulk density, tapped density and compressibility index. The tablets were evaluated for post compression parameters like drug content, hardness, wetting time, *in-vitro* disintegration and drug release study. The optimized formulations of Fenugreek mucilage (SF5), SSG (SS5), MCC 101 (SM5) and MCC 102 (SMC5) showed disintegration time of 15, 40, 37 and 30 seconds respectively. In comparison formulation SF5 showed less disintegration time than SS5, SM5 and SMC5 at same concentrations. The *in-vitro* drug release profile of all optimized formulations was above 90 % within 20 minutes. The optimized formulations were subjected to stability studies as per ICH guidelines and were found to be stable with insignificant change in hardness, drug content, disintegration time and *in-vitro* drug release pattern.

Keywords: Fast dissolving tablet (FDTs), Sildenafil citrate, mucilage of *Trigonella foenum-graecum*, sodium starch glycolate (SSG), microcrystalline cellulose (MCC).

INTRODUCTION

Tablet is the most popular conventional solid dosage form because of its convenience in terms of self administration, compactness, accurate dosage and ease in manufacturing. One important drawback of conventional tablets is difficulty in swallowing experienced by geriatric and pediatric patients leading to poor patient compliance. To beat these issues, scientists have developed novel drug delivery systems known as fast dissolving tablets (FDTs).¹⁻³ These are novel type of tablets that disintegrate/disperse/dissolve in few seconds in the mouth when they come in contact with saliva without the requirement of water.⁴ The target populations for these oral disintegrating dosage forms have usually been geriatric, pediatric and mentally disadvantaged patients who suffer from dysphagia. Patients with incessant nausea, fulminant incidence of allergic attacks or sudden coughing, who are traveling or who have very little or completely no access to water are also sensible candidates for FDTs. The advantages in terms of patient compliance, fast onset of action, increased bioavailability and good stability make these tablets alternative as a dosage form of choice in the current market. In such cases bioavailability of drug is considerably greater than that observed from

conventional tablet dosage form. The fundamental approach utilized in the development of the FDTs is that the use of superdisintegrants. Several approaches are developed in the manufacture FDTs like lyophilization, moulding, direct compression and vacuum drying. Direct compression method is inexpensive and convenient for manufacturing tablets of adequate mechanical strength.^{5,6} Sildenafil is an orally-active, potent and selective inhibitor of the enzyme phosphodiesterase 5 (PDE5) found in high concentrations in the pulmonary vascular smooth muscle. PDE5 causes the breakdown of cyclic guanosine monophosphate (cGMP) to form guanosine 5' - cyclic phosphate. Inhibition of PDE5 leads to an increase in Nitric oxide (NO) and thereby promoting vascular smooth muscle relaxation resulting in reduced pulmonary arterial pressure.^{7,8} Sodium starch glycolate is extensively used as a disintegrant in oral pharmaceutical dosage forms as it gives rapid and uniform disintegration. MCC 101 and MCC 102 are conventional disintegrants with different particle sizes and moisture grades used in the formulation of tablets by direct compression method.⁹ Fenugreek seed mucilage was obtained from the seeds of *Trigonella foenum-graecum* Linn. (Family: Fabaceae).



Isolated mucilage of Fenugreek seeds



Dried powder of isolated mucilage of Fenugreek seeds

MATERIAL AND METHODS

Fenugreek seeds were purchased from local market of Hyderabad, India. Sildenafil citrate was purchased from S.K. Pharma, Kanpur, India. MCC 101 and MCC 102 were obtained as gift samples from Ankit Pulps and Boards, Nagpur, India. Sodium starch glycolate, magnesium stearate, talc and lactose were purchased from S.D. Fine Chemicals, Mumbai, India. Analytical grade chemicals and deionized water were used throughout the study.

Isolation of Fenugreek seed mucilage

The seeds of Fenugreek were soaked in sufficient quantity of distilled water for 4-5 hours, boiled for 30 minutes and kept aside for 1 hour for complete release of the mucilage into the water. The contents were squeezed through eight fold muslin cloth to remove the marc from the solution. To the filtrate three volumes of acetone was added to precipitate fenugreek mucilage which was dried in a hot air oven at a temperature of less than 40°C. Dried mucilage of fenugreek was collected, grounded and passed through sieve number 80 and stored in dessicator at 30°C and 45 % relative humidity till use.¹⁰

Preparation of Standard Graph

Standard solutions in the range of 2 to 35 µg/ml were prepared and absorbance values were recorded at 294 nm against the 0.01N HCl. From this data, the standard curve of sildenafil citrate was obtained by plotting concentration on x-axis against absorbance on y-axis.⁸

Pre-formulation Studies

Preparation of powder blend of drug and excipients

Pure drug and the excipients were passed through mesh no # 60. Required amount of excipients were taken for every formulation (Table 2) and each one of the excipient was subjected to grinding to a degree of fineness. The mixed blend was evaluated for flow properties.^{10,11}

Drug - excipients compatibility study by FTIR

The spectrum analysis of pure drug and mixture of drug with excipients in 1:1 ratio were subjected to IR spectroscopy studies using Fourier Transform Infra Red spectrophotometer (FTIR 8400 S, Shimadzu, Tokyo, Japan).¹² The spectra were scanned over the range of 4000 to 400 cm⁻¹ range. The IR spectra of pure drug and physical mixture of drug and fenugreek seed mucilage are shown in Figures 1-6.

Angle of Repose

Angle of repose was assessed by funnel method. The powder blend was poured through a funnel that may be

raised vertically till maximum cone height (h) was attained. Radius of the heap (r) was measured and angle of repose (θ) was calculated using the subsequent formula,^{12,13}

$$\theta = \text{Tan}^{-1} (h / r)$$

Where, θ = angle of repose, r = radius of the pile, h = height of the pile

Bulk density

Bulk density is given as mass of the powder divided by the bulk volume. Apparent bulk density (*b) was assessed by pouring the powder blend into a graduated measuring cylinder. The bulk volume (V_b) and the actual weight of the powder (M) were determined. The bulk density was calculated by the formula,

$$*b = M / V_b$$

Where, M = weight of the powder, V_b = bulk volume

Tapped density

The graduated measuring cylinder having a weighed mass of powder blend was subjected to 100 tappings. The least volume (V_t) occupied in the measuring cylinder and the actual weight (M) of the powder blend was noted down. The tapped density (*t) was calculated using the formula,

$$*t = M / V_t$$

Where, M = weight of the powder, V_t = tapped volume

Compressibility Index

The simplest technique of measurement of free flow of powder is compressibility and an indication of the ease with which a material can be induced to flow is given by compressibility index (C.I) which is calculated as follows,

$$C.I (\%) = \text{Tapped density} - \text{Bulk density} / \text{Tapped density} \times 100$$

Hausner's ratio

It is the ratio of tapped density to bulk density. It is an indirect index of ease of simple powder flow. It is calculated by the subsequent formula,

$$\text{Hausner's ratio} = *t / *b$$

*t = Tapped density, *b = Bulk density

Preparation of Sildenafil citrate fast dissolving tablets

Fast dissolving tablets of Sildenafil citrate were prepared by direct compression method. All ingredients were triturated individually in a mortar and passed through sieve (# 60) separately to ensure better mixing. Then required quantity of all ingredients were weighed and mixed uniformly in a mortar except magnesium stearate. Finally magnesium stearate was added as a lubricant. This uniformly mixed blend was compressed in to 50 mg tablets. 50 tablets batch from each formulation was prepared for all the designed formulations using 6 mm flat

face surface punches on a Rimek-1 rotary tablet machine by direct compression method.¹⁴ The working formula is represented in Table 2.

EVALUATION OF TABLETS

All the prepared Sildenafil citrate tablets were evaluated for the following parameters as per IP guidelines. The calculations are represented in Table 3.

Weight variation

Twenty tablets were selected randomly and their average weight was noted. Then all the individual tablets were weighed and percentage difference from the average weight was noted.^{14,15}

Hardness

The strength of the each tablet is given as its tensile strength having units Kg/cm². The tablet breaking load is the force required to crush the tablet in to pieces. It was measured with a tablet hardness testing apparatus known as Monsanto tablet hardness tester.^{14,15} Three tablets were selected randomly from each formulation batch and the average reading was noted.

Thickness

The thickness in millimeters (mm) was measured using vernier calipers. Ten pre weighed tablets were selected randomly from every formulation batch and their average thickness and standard deviation were reported.

Friability

Friability of the tablets was assessed using an apparatus Roche Friabilator (Electro lab, India). The friabilator consists of a chamber made of plastic that is set to revolve at about 25 rpm for 4 minutes and drops the tablets at a height of 6 inches with every revolution. Twenty tablets were randomly selected, weighed and placed in the friabilator for 100 revolutions in duration of 4 minutes. Tablets were dusted clean with a soft muslin cloth and weighed again. The friability (% F) is given by the formula,

$$F \% = (1 - W_0 / W) \times 100$$

Where, W₀ is weight of the tablets before test and
W is the weight of the tablets after testing

Wetting time

Five round shaped 10 cm diameter tissue papers were placed in a petridish of same size. 10 ml of deionized water at 37°C ± 0.5°C having eosin, a water-soluble dye was poured to the petridish. A single tablet was gently placed on the surface of the tissue paper. The time needed for the water to succeed on to the surface of the tablet was noted as the wetting time.^{14,16}

Water absorption ratio

A piece of tissue paper twice folded was placed in a small petridish having 6 ml of deionized water. A tablet was put on the paper and the time taken for its complete wetting was noted. The wetted tablet was then weighed.¹⁵⁻¹⁷ Water absorption ratios was determined using the subsequent equation,

$$R = W_a - W_b / W_b \times 100$$

Where R = Water absorption ratio,
W_a = weight of the tablet after absorption and
W_b = weight of the tablet before absorption

In-vitro disintegration time

Disintegration time was measured using a modified disintegration method. For this purpose, a petridish was filled with 10 ml of water at 37°C ± 0.5°C. The tablet was gently put within the center of the petridish and the time required for the tablet to completely disperse in to very small particles was noted.¹⁵⁻¹⁷

Content uniformity

Twenty tablets were individually weighed and crushed using mortar and pestle. A quantity equivalent to the mass of 25 mg of drug is weighed and extracted with 100 ml of 0.01 N HCl. The solution was filtered through Whatman filter paper. The drug content was analyzed spectrophotometrically at a wavelength 294 nm after suitable dilution with 0.01 N HCl. The amount of drug was calculated using standard graph.

In-vitro drug release

In-vitro drug release of Sildenafil citrate fast dissolving tablets was determined using USP dissolution apparatus II (Paddle type) (Electro lab TDT- 0.8L, India). The dissolution test was performed using 900 ml of 0.01N Hydrochloric acid at 37°C ± 0.5°C. The speed of rotation of basket was set at 100 revolutions per minute. 5 ml each samples were withdrawn at different time points of 1, 3, 5, 10, 15, 20, 25, 30 minutes and the same volume was replaced with fresh 0.01 N HCl. The absorbance of solution was checked by UV spectrophotometer (ELICO-164 double beam spectrophotometer, Hyderabad, India) at a wavelength of 294 nm and drug release was determined from standard curve. Dissolution studies were performed in triplicate and the results were expressed as mean values ± standard deviation. Graph was plotted by taking time in minutes on x-axis and % cumulative drug release on y-axis^{7,15,16}. The graph is represented in Figure 7.

Statistical Analysis of Data

Disintegration time, wetting time and water absorption ratio of optimized formulations of fenugreek seed mucilage, sodium starch glycolate, MCC 101, and MCC 102 were taken as parameters for ANOVA analysis at 5 % significance levels using Graph Pad software. Results are shown in Table 4.

Accelerated stability studies

The optimized formulations of Sildenafil citrate were subjected to stability studies at 40°C ± 2°C and 75 % ± 2 % RH according to the guidelines of International Conference on Harmonization (ICH). Each tablet was individually wrapped in aluminum foil, packed in an amber colored bottle and kept at above specified conditions in a stability chamber (Oswald, Mumbai, India) for three months. For every one month tablets were analyzed for the hardness, drug content, and in-vitro drug release and disintegration time.

RESULTS AND DISCUSSION

Table 1: Standardization of dried powder of isolated Fenugreek seed mucilage

Parameters	Result
State	Amorphous powder
Color	Off-white to light brown color
Odor	Odorless
Taste	Mucilaginous
Identification : Ruthenium red test	Powder particles are stained red
Solubility	Slightly soluble in cold water. Dissolves in warm water but forms a viscous colloidal solution. Insoluble in methanol, acetone, chloroform, ether.
Test for carbohydrates – Mollish test	+
Swelling index	9.75
p ^H (1% w/v)	6.4
Ash value	0.79 %
Water-soluble ash	0.52 %
Acid insoluble ash	0.38 %
Sulphated ash	0.68 %
Loss on drying	2.2 %
Angle of repose	25.36 °
Bulk density	0.625 g/cm ³
Tapped density	0.760 g/cm ³
Hausner's ratio	1.23
Compressibility index	18.73 %
Viscosity (1% w/v)	13.2 m Pa
Yield	22.8 %w/w

FTIR Studies of Drug and excipients

Table 2: Tablet Formulations of Sildenafil citrate containing different superdisintegrants

Formulation	Sildenafil citrate (mg)	Fenugreek mucilage powder (mg)	Sodium starch glycolate (mg)	MCC 101 (mg)	MCC 102 (mg)	Lactose (mg)	Talc (mg)	Magnesium stearate (mg)	Total weight of tablet (mg)
SF1	25	2.5	-	-	-	22	0.25	0.25	50
SF2	25	3	-	-	-	21.5	0.25	0.25	50
SF3	25	3.5	-	-	-	21	0.25	0.25	50
SF4	25	4	-	-	-	20.5	0.25	0.25	50
SF5	25	4.5	-	-	-	20	0.25	0.25	50
SS1	25	-	2.5	-	-	22	0.25	0.25	50
SS2	25	-	3	-	-	21.5	0.25	0.25	50
SS3	25	-	3.5	-	-	21	0.25	0.25	50
SS4	25	-	4	-	-	20.5	0.25	0.25	50
SS5	25	-	4.5	-	-	20	0.25	0.25	50
SM1	25	-	-	2.5	-	22	0.25	0.25	50
SM2	25	-	-	3	-	21.5	0.25	0.25	50
SM3	25	-	-	3.5	-	21	0.25	0.25	50
SM4	25	-	-	4	-	20.5	0.25	0.25	50
SM5	25	-	-	4.5	-	20	0.25	0.25	50
SMC1	25	-	-	-	2.5	22	0.25	0.25	50
SMC2	25	-	-	-	3	21.5	0.25	0.25	50
SMC3	25	-	-	-	3.5	21	0.25	0.25	50
SMC4	25	-	-	-	4	20.5	0.25	0.25	50
SMC5	25	-	-	-	4.5	20	0.25	0.25	50

S = Sildenafil Citrate, F = Fenugreek seed mucilage, S = Sodium starch glycolate, M = MCC 101, MC = MCC 102,

SF = Formulations of Sildenafil citrate with fenugreek seed mucilage, SS = Formulations of Sildenafil citrate with sodium starch glycolate,

SM = Formulations of Sildenafil citrate with MCC 101, SMC = Formulations of Sildenafil citrate with MCC 102

SF5, SS5, SM5, SMC5 = Optimized formulations of fenugreek seed mucilage, sodium starch glycolate, MCC101 and MCC 102 respectively

Table 3: Evaluation of Sildenafil citrate FDTs prepared with different superdisintegrants

Formulation	Weight Variation (mg) ^{***}	Hardness (kg/cm ²) [*]	Thickness (mm) ^{***}	Friability (%) [*]	Wetting time (sec) ^{**}	Water Absorption Ratio ^{**}	Disintegration Time (sec) ^{**}	Content uniformity (%) [*]
SF1	51 ± 1.56	2.9 ± 0.73	1.8 ± 0.02	0.52 ± 0.24	69 ± 1.24	38 ± 1.24	84 ± 1.29	98.3 ± 1.12
SF2	50 ± 1.20	3.1 ± 0.54	2.0 ± 0.05	0.24 ± 0.32	48 ± 1.21	45 ± 1.29	72 ± 1.19	99.4 ± 0.58
SF3	50 ± 0.45	2.8 ± 0.49	1.7 ± 0.04	0.21 ± 0.05	26 ± 1.36	52 ± 1.53	25 ± 1.52	98.5 ± 1.35
SF4	52 ± 1.98	3.0 ± 0.38	1.8 ± 0.02	0.36 ± 0.35	24 ± 1.25	66 ± 1.18	17 ± 1.36	99.6 ± 0.09
SF5	50 ± 1.43	3.0 ± 0.42	1.9 ± 0.04	0.54 ± 0.42	21 ± 1.34	104 ± 1.36	15 ± 1.52	99.7 ± 1.21
SS1	51 ± 1.68	3.1 ± 0.29	2.0 ± 0.05	0.56 ± 0.28	94 ± 1.28	21 ± 1.59	105 ± 1.42	98.1 ± 1.42
SS2	50 ± 1.67	2.9 ± 0.35	2.1 ± 0.03	0.42 ± 0.08	61 ± 1.37	27 ± 1.48	67 ± 1.26	99.4 ± 0.51
SS3	51 ± 1.73	3.2 ± 0.28	2.0 ± 0.04	0.21 ± 0.53	32 ± 1.52	36 ± 1.72	60 ± 1.29	99.7 ± 1.32
SS4	50 ± 0.45	2.8 ± 0.43	1.9 ± 0.05	0.35 ± 0.37	28 ± 1.25	58 ± 1.61	58 ± 1.34	97.5 ± 0.58
SS5	50 ± 1.56	3.1 ± 0.61	1.9 ± 0.02	0.52 ± 0.29	24 ± 1.36	88 ± 1.90	40 ± 1.38	99.8 ± 1.05
SM1	50 ± 0.83	3.0 ± 0.53	2.0 ± 0.04	0.36 ± 0.61	131 ± 1.5	12 ± 1.35	273 ± 1.21	98.7 ± 1.32
SM2	50 ± 0.74	2.9 ± 0.21	1.8 ± 0.08	0.54 ± 0.67	124 ± 1.8	15 ± 1.46	189 ± 1.19	98.6 ± 0.89
SM3	50 ± 0.66	3.1 ± 0.62	1.7 ± 0.05	0.25 ± 0.51	105 ± 1.5	19 ± 1.52	120 ± 1.25	99.1 ± 0.19
SM4	50 ± 0.87	3.0 ± 0.85	1.8 ± 0.04	0.31 ± 0.26	81 ± 1.24	22 ± 1.38	54 ± 1.36	97.8 ± 1.07
SM5	50 ± 0.70	2.9 ± 0.54	1.6 ± 0.05	0.34 ± 0.43	40 ± 1.62	44 ± 1.28	37 ± 1.32	99.9 ± 1.25
SMC1	50 ± 0.74	3.0 ± 0.24	1.9 ± 0.02	0.53 ± 0.27	108 ± 1.2	18 ± 1.15	240 ± 1.26	99.6 ± 0.89
SMC2	50 ± 0.66	3.2 ± 0.63	2.0 ± 0.04	0.67 ± 0.34	99 ± 1.31	22 ± 1.29	182 ± 1.37	98.3 ± 0.92
SMC3	50 ± 0.63	3.3 ± 0.52	1.8 ± 0.03	0.28 ± 0.25	73 ± 1.09	26 ± 1.37	95 ± 1.15	98.7 ± 0.74
SMC4	50 ± 1.24	3.1 ± 0.46	1.8 ± 0.02	0.75 ± 0.09	52 ± 1.46	30 ± 1.53	50 ± 1.49	99.8 ± 1.05
SMC5	50 ± 0.30	3.0 ± 0.57	1.6 ± 0.02	0.59 ± 0.61	33 ± 1.51	56 ± 1.36	30 ± 1.35	99.6 ± 0.86

Values are expressed as mean ±SD, *n = 3, **n = 6, ***n = 10, ****n = 20.

SF = Formulations of Sildenafil citrate with fenugreek seed mucilage, SS = Formulations of Sildenafil citrate with sodium starch glycolate,

SM = Formulations of Sildenafil citrate with MCC 101, SMC = Formulations of Sildenafil citrate with MCC 102

SF5, SS5, SM5, SMC5 = Optimized formulations of fenugreek seed mucilage, sodium starch glycolate, MCC101 and MCC 102 respectively

Table 4: Comparison of disintegration time, wetting time and water absorption ratio of Optimized formulations of Sildenafil citrate FDTs using One-way ANOVA test

Parameters of FDT	SF5 Vs SS5	SF5 Vs SM5	SF5 Vs SMC5	p value
Disintegration time	**	**	**	** =< 0.001
Wetting time	*	**	**	* =< 0.01
Water absorption ratio	**	**	**	** =< 0.001

N = 6; One-way ANOVA test; ***High significance = p < 0.0001; **Moderate significance = p < 0.001; *Low significance = p < 0.01;

NS = non-significant

SF5, SS5, SM5, SMC5 = Optimized formulations containing fenugreek mucilage, sodium starch glycolate, MCC101 and MCC 102 respectively

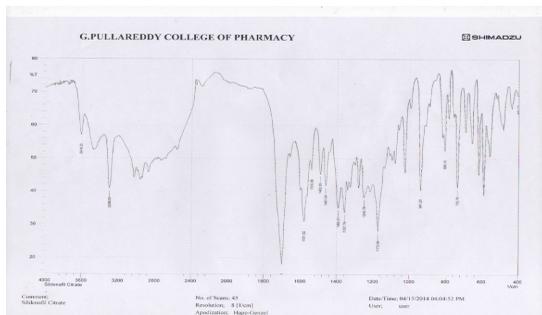


Figure 1: IR Spectra of Sildenafil citrate

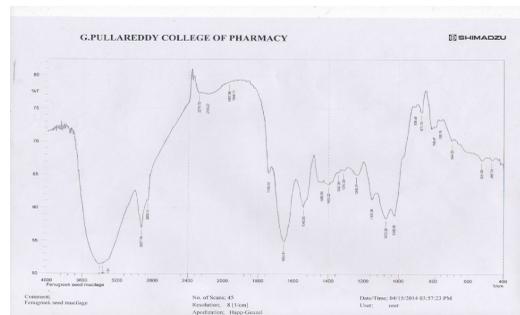


Figure 2: IR Spectra of Fenugreek seed mucilage

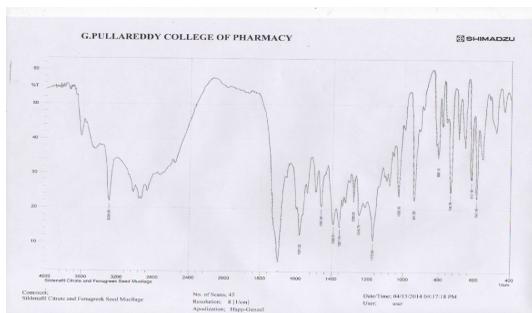


Figure 3: IR Spectra of physical mixture of Sildenafil citrate and Fenugreek seed mucilage

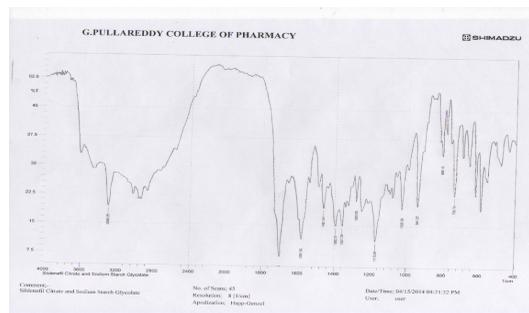


Figure 4: IR Spectra of physical mixture of Sildenafil citrate and Sodium starch glycolate

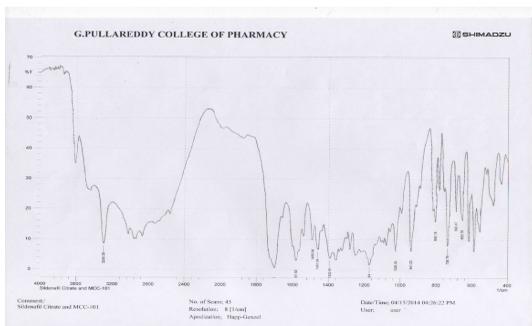


Figure 5: IR Spectra of physical mixture of Sildenafil citrate and MCC 101

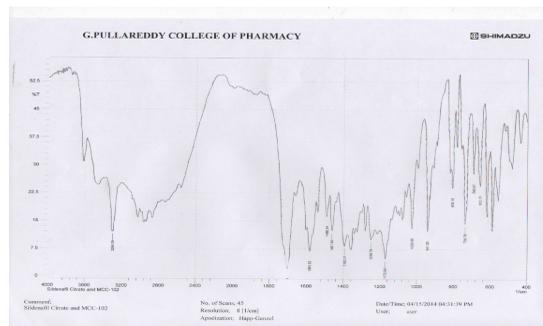


Figure 6: IR Spectra of physical mixture of Sildenafil citrate and MCC 102

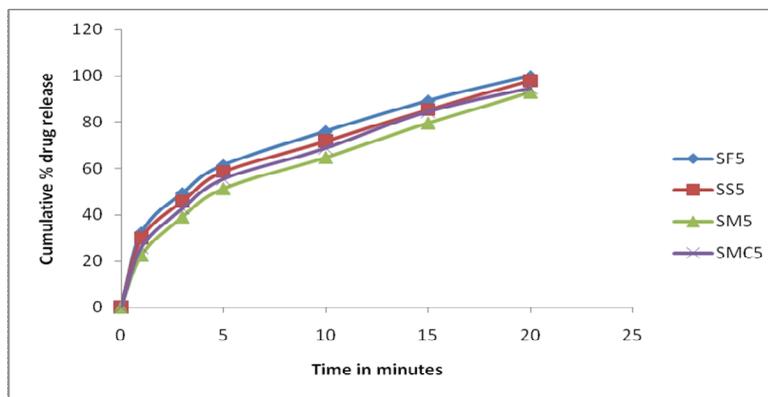


Figure 7: Cumulative % drug release of optimized formulations of Sildenafil citrate FDTs

The percentage yield of Fenugreek seed mucilage was 22.8 % w/w. Sildenafil citrate fast dissolving tablets were prepared by using natural superdisintegrant i.e. isolated mucilage of fenugreek seed, synthetic superdisintegrant sodium starch glycolate and conventional disintegrants like MCC 101 and MCC 102. IR spectroscopic studies revealed that sildenafil citrate was compatible with all the excipients. The peaks representing the pure drug were similar in all the graphs suggesting that there was no such interaction and the pure drug was not altered functionally. In the present study disintegration time of all optimized batches was in the range of 15 ± 1.52 to 40 ± 1.38 sec fulfilling the official requirement (3 minutes) for dispersible tablets. It was observed that disintegration time of the tablets decreased with increase in the concentration of disintegrants. Optimized formulations SF5, SS5, SM5 and SMCS showed disintegration time of 15, 40, 37 and 30 seconds respectively. In comparison MCC 102 showed less disintegration time than MCC 101 and sodium starch glycolate whereas fenugreek seed mucilage showed least disintegration time compared to all synthetic superdisintegrants. *In-vitro* drug release was found to be highest in the case of formulation SF5 at 99.98 % within 20 minutes. Upon comparison of disintegration time, wetting time and water absorption ratio by one way ANOVA test it was found that there was a significant difference ($p < 0.05$). All optimized formulations were found to be physically stable with

insignificant change (± 1.5 %) when stored at 40°C under 75 % RH for three months.

CONCLUSION

From the study, it was concluded that natural superdisintegrant like *Trigonella foenum-graecum* mucilage showed better disintegrating property than synthetic superdisintegrant like sodium starch glycolate and conventional disintegrants like microcrystalline cellulose (MCC) 101 and 102. Hence, natural superdisintegrant like fenugreek seed mucilage can be used at higher concentrations as it has an advantage of being non toxic, low cost, biodegradable and biocompatible with no side effects.

ACKNOWLEDGEMENT

The authors are thankful to Principal Dr. B. Madhava Reddy, staff and management of G. Pulla Reddy College of Pharmacy for providing infrastructure and facilities to carry out this study.

REFERENCES

1. Venkateswara SS, Nyshadham JR, Joseph AF. Recent technological advances in Oral Drug Delivery - a review. *Pharmaceutical Science and Technology Today* 2000; 3: 138-145. [http://dx.doi.org/10.1016/S1461-5347\(00\)00247-9](http://dx.doi.org/10.1016/S1461-5347(00)00247-9)
2. Kuccherkar BS, Badhan AC, Mahajan HS. Mouth dissolving tablets. A novel drug delivery system. *Pharma Times* 2003; 35: 3-10.
3. Dobbetti L. Fast-melting tablets. *Developments and Technologies. Pharm Tech* 2001; 44-50.
4. Leon Lachman, Herbert A Liberman, Joseph L Kanig. *The Theory and Practice of Industrial Pharmacy*. 3rd Ed: Varghese Publishing House; p. 293-345, 346-373.

5. Habib W, Khankari R, Hontz J. Fast-dissolving drug delivery systems, critical review in therapeutics. Drug Carrier Systems 2000; 17(1): 61-72.
6. Park JH, Holman KM, Bish, GA, Krieger DG, Ramlose DS, Herman CJ, Wu SH. An alternative to the USP disintegration for orally dissolving tablet. Pharm Tech 2008; 32: 1-3.
7. Sildenafil citrate, Indian Pharmacopeia, 7th Ed: Govt. of India; 2014; 4: p. 2725-2727.
8. Ainley Wade, Paul J Weller, Handbook of Pharmaceutical Excipients. 2nd Ed. The Pharmaceutical Press, London; 1994. p. 84-87, 462-466.
9. Chang R, Guo X, Burnside B, Couch R. A review of fast dissolving tablets. Pharm Tech 2000; 24: 52-58.
10. Modasiya MK, Lala II, Prajapati BG, Patel VM, Shah DA. Design and Characterization of Fast Disintegrating Tablets of Piroxicam, International Journal of Pharm Tech Research 2009; 1(2): 353-357.
11. Paramita Dey, Sayasachi Maiti. Orodispersible tablets: a new trend in drug delivery. Journal of natural science, biology and medicine 2010; 1(1): 2-5. <http://dx.doi.org/10.4103/0976-9668.71663>
12. PV Swamy, SH Areefulla, SB Shirsand, Smitha Gandra and B Prashanth. Orodispersible tablets of meloxicam using disintegrant blends for improved efficacy. Indian Journal of Pharmaceutical Sciences 2007; 69(6): 836-840. <http://dx.doi.org/10.4103/0250-474X.39448>
13. Swathi S, Neeharika V and Lakshmi PK. Formulation and evaluation of fast dissolving tablets of freely and poorly soluble drug with natural and synthetic super disintegrants, Drug Invention Today 2011; 3(10): 250.
14. Gattu Jyothi and Lakshmi PK. Comparative evaluation of natural and synthetic superdisintegrants Kyron T-314, Acta Pharmaceutica Scientia 2011; 53: 35.
15. Rakesh Pahwa, Mona Piplani, Prabodh C Sharma, Dhirender Kaushik and Sanju Nanda. Orally Disintegrating Tablets - Friendly to Pediatrics and Geriatrics. Scholars Research Library. Archives of Applied Science Research 2010; 2(2): 35.
16. Viral Shah and Rucha Patel. Studies on mucilage from *Hibiscus rosasinensis* Linn. Oral Disintegrant. International Journal of applied Pharmaceutics 2010; 2(1): 18-21.
17. Neeharika V, Kavitha D, Husnien Ali MM, Lakshmi PK. Comparative study on effect of natural and synthetic superdisintegrants in the formulation of fast dissolving tablets of Hydroxyzine hydrochloride. World Journal of Pharmaceutical Research 2014; 3(1): 1293-1305.

Cite this article as:

Naazia Zafar, V. Neeharika, P. K. Lakshmi. Formulation and evaluation of sildenafil citrate fast dissolving tablets using fenugreek seed mucilage. Int. J. Res. Ayurveda Pharm. 2014;5(3):352-358 <http://dx.doi.org/10.7897/2277-4343.05373>

Source of support: Nil, Conflict of interest: None Declared