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DESIGN AND EVALUATION OF VALSARTAN FAST DISSOLVING TABLETS AS A NEW SUPER DISINTEGRANT OF OCIMUM GRATISSIMUM MUCILAGE

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ABSTRACT

The main objective of present investigation is to evaluate Ocimum gratissimum mucilage as a super disintegrate in the formulation of fast dissolving tablets of poorly soluble drugs employing 2^3 factorial design. The mucilage was obtained by isolation process and it was subjected to physical and micromeritic evaluation. To establish as mucilage as a super disintegrate, fast dissolving tablet of valsartan was prepared employing Ocimum gratissimum mucilage in different proportions in each case by direct compression method employing 2^3 factorial design. All fast dissolving tablets prepared were evaluated for drug content, hardness, friability, disintegration time and other dissolution characteristics like percent dissolved in 5 min (PD5), Dissolution efficiency in 5 Min (DE5%) and first order rate constant(K1). The mucilage was found to be fine, free flowing slightly crystalline powder and it exhibited good swelling in water. Fourier transform infrared spectra (FTIR) and Differential scanning calorimetry (DSC) study indicated the absence of interaction between valsartan and mucilage. All the fast dissolving tablets formulated employing mucilage were of good quality with regard to drug content (100±5%), hardness (3.6–4 kg/sq. cm), and friability (0.05-0.19%). Disintegration time for FDTs was determined using USP disintegration apparatus 0.1 N HCl buffer. The volume of medium was 900 ml and the temperature was 37±0.2 °C. The time in second taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured. Mucilage was found to be a superdisintegrant which enhanced the dissolution efficiency when combined with sodium starch glycolate, croscarmellose sodium, with the valsartan and hence it could be used in the formulation of fast dissolving tablets to provide immediate release of the contained drug within 5 min.

KEYWORDS: ***Fast dissolving, Superdisintegrant, Ocimum gratissimum mucilage, Dissolution efficiency***

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INTRODUCTION

Under the category of solid dosage forms, the fast dissolving tablets contain substances which disintegrate rapidly, usually within a few seconds when placed upon tongue requiring additional water to facilitate swallowing. Fast dissolving tablets contribute immense advantages for the patients having difficulty in swallowing. It has been reported that dysphasia (difficulty in swallowing) is usual among all groups and more specific with pediatric, geriatric population along with patients have nausea, retching, and motion sickness complications[1]. Fast dissolving tablets overcome this problem and provide the advantages for pediatrics, geriatric[2], bedridden, disabled patients and for who may have difficulty in swallowing tablets, capsules, and liquid orals. Fast dissolving tablets (FDT) will disintegrate rapidly in the mouth without the need of water[3-4]. Fast dissolving tablet formulation provides sufficient strength, quick disintegration/ dissolution in the mouth without water[5], rapid dissolution and absorption of the drug, which will produce the quick onset of action. Pre gastric absorption of FDT can result in improved bioavailability and as a consequence of reduced dose[6]. Various techniques can be used to formulate fast dissolving tablets. To achieve fast tablet disintegration, direct compression is one of the techniques used in the incorporation of superdisintegrant or highly water-soluble excipients into the formulation. Direct compression is the ideal method for moisture and heat-liable medication and does not require the use of water or heat during the formulation procedure. The aim of the work was to optimize and evaluate Ocimum gratissimum mucilage as a superdisintegrant in the formulation of fast dissolving tablets by employing 2^3 factorial design. i.e., Ocimum gratissimum mucilage. The present investigation deals with an attempt of systematic formulation an approach for optimization of valsartan fast dissolving tablets employing Ocimum gratissimum mucilage, sodium starch glycolate, croscarmellose sodium as superdisintegrants. A 2^3 factorial design was applied to investigate the main and interaction effects of the three formulation variables i.e., Ocimum gratissimum mucilage (A), sodium starch glycolate (B), croscarmellose sodium (C) in each case to find the formula with less disintegration time and more dissolution efficiency 10 min and to permit arbitrary selection of tablets with immediate release of drug within 10 min.

MATERIALS AND METHODS

Materials

Valsartan pure drug obtained from yarrow chemicals Mumbai. Valsartan pure drug obtained from yarrow chemicals Mumbai. Mannitol, Sodium starch glycolate, Croscarmellose sodium was obtained from merkc chem. products, Mumbai. Microcrystalline cellulose was bought from lab India fine chemicals, Mumbai. Talc and magnesium stearate was obtained from Molychem, Mumbai.

Isolation of Ocimum gratissimum mucilage (a novel disintegrant)

The seeds of *Ocimum gratissimum* were soaked for 12 hrs in distilled water and then added to a blender to separate mucilage from seeds. After blending for 15 min the mass was passed through eight folds of muslin cloth. The mucilage was precipitated from the filtrate by adding 3parts of acetone (75%) to the mucilage. The powder was weighed to calculate the yield after drying at 45 ^{0}C for 6 hrs.

Characterization of Ocimum gratissimum mucilage (a novel disintegrant)

The Ocimum gratissimum mucilage prepared was evaluated for the following Solubility Ocimum gratissimum mucilage solubility was tested in various solvents like distilled water, aqueous buffers of pH 1,2,3,4,6 mentioned in IP and organic solvents such as alcohol, dichloromethane, chloroform, acetone and petroleum ether[6]

pH

The pH of 1% w/v slurry was measured by pH meter[6]

Melting point

Melting point was determined by using melting point apparatus [6]

Viscosity

Viscosity of 1% dispersion in water was measured using Ostwald viscometer [6]

Swelling index

Mucilage powder (200 mg) was added to 10 ml of water and light liquid paraffin taken in two different graduated test tubes and mixed. The dispersion in the tubes was allowed to stand for 12 h. The volumes of the sediment in the tubes were recorded. The swelling index (%) of the material was calculated as follows[6]

$$SI\% = \frac{\text{Volume of sediment in water-volume of sediment in light liquid paraffine}}{\text{volume of sediment in light liquid paraffine}} \times 100$$

Test for gelling property

Mucilage prepared were evaluated for their gelling property by heating a 7% w/v dispersion of each in water at 100 °C for 30 min[6].

Particle size

Particle size analysis was done by sieving using standard sieves. [7]

Density

Density (g/cc) was determined by liquid displacement method using benzene as liquid [7]

Bulk density

Both loose bulk density (LBD) and tapped bulk density (TBD) were determined by transferring the accurate weighed amount of sample in 50 ml measuring cylinder, measured the volume of packing and tapped 50 times on a plane surface and tapped volume of packing recorded and LBD and TBD calculated by following formula[7]

$$LBD = \frac{\text{Mass of powder}}{\text{Volume of packing}}$$

$$TBD = \frac{\text{Mass of powder}}{\text{Tapped volume of packing}}$$

Percentage compressibility index

Percentage compressibility of the powder mixed was determined by Carr's Compressibility Index calculated by the following formula[8]

$$\% \text{ Carr's Index} = \frac{TBD-LBD}{TBD} \times 100$$

Angle of repose

The frictional forces in loose powder or granules can be measured by the angle of repose. This is the maximum angle possible between the surface of a mass of powder or granules and the horizontal plane. The angle of repose is calculated.

Fourier transform infrared (FTIR) spectroscopy

FTIR spectra of mucilage were recorded on samples prepared in potassium bromide (KBr) disks using , FTIR (Tokyo, Japan). The scanning range was 500 to 4000 cm^{-1}. Samples were mixed with (KBr) to form disks by means of a hydrostatic press at 6-8 tons pressure[8]

Differential scanning calorimetry (DSC)

DSC thermo grams of valsartan and their mixtures (1: 1) with Ocimum gratissimum were recorded on Perkin Elmer thermal analyser samples (2-5 mg) were sealed into aluminum pans and scanned at a heating rate of 10 °C min^{-1} over a temperature range 30–350 °C[8]

Preparation of valsartan fast dissolving tablets

The tablets were prepared by direct compression method employing 2^3 factorial design in which 3 independent variables {superdisintegrants i.e., Ocimum gratissimum (A), sodium starch glycolate (B), croscarmellose sodium (C)} and 1 dependent variable (dissolution efficiency in 10 min) were selected. The composition of formulation given in table no 1 For Ocimum gratissimum (A), the lower level i.e., 10% concentration and upper level i.e. 10% concentration. Sodium starch glycolate (B), croscarmellose sodium (C)} and 1 dependent variable (dissolution efficiency in 10 min) were selected. The composition of formulation given in table no 1 Ocimum gratissimum, sodium starch glycolate, croscarmellose sodium, mannitol and microcrystalline cellulose were accurately weighed and mixed using mortar and pestle, and the added to valsartan. Finally, talc and magnesium stearate were added to the powder mixture.

Evaluation of valsartan fast dissolving tablets

Hardness test

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablet was determined using Monsanto hardness tester and expressed in kg/cm^2 [9]

Uniformity of weight

Weight variation test was done with 20 tablets. It is the individual variation of the tablet weighed from the average weight of 20 tablets [10]

Table 1

Formulae of Valsartan fast dissolving tablets employing Ocimum gratissimum mucilage.

Ingredient(Mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8
Valsartan	40	40	40	40	40	40	40	40
Ocimum gratissimum	---	20	---	20	---	20	---	20
SSG	---	---	20	20	---	---	20	20
CCS	---	---	---	---	20	20	20	20
Mannitol	30	20	20	10	20	10	10	---
MCC	122	112	112	102	112	102	102	92
Talc	4	4	4	4	4	4	4	4
Magnesium Stearate	4	4	4	4	4	4	4	4
Total weight	**200**	**200**	**200**	**200**	**200**	**200**	**200**	**200**

Friability

The friability of tablets was measured using a Roche fribilator. Tablets were rotated at 25 rpm for 4 min or up to 100 revolutions. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated[10.]

Drug content uniformity

For content uniformity, ten tablets were weighed and powdered a quantity of powder equivalent to 10 mg of valsartan was extracted into pH 1.2 Hcl buffer and filtered. The Valsartan content was determined by measuring the absorbance spectrophotometrically at 205 nm after appropriate dilution with pH 1.2 Hcl buffer. The drug content was calculated as an average of three determinations [10]

Wetting time

The wetting time of tablets was measured by placing five circular tissue papers in a petri dish of 10 cm in

diameter. 10 ml of water containing a water-soluble dye (amaranth) was added to the petri dish. A tablet was carefully placed on the tissue paper. The time required for water to reach the upper surface of the tablet was noted as wetting time [11,12]

Water absorption ratio

A piece of tissue paper folded was kept in a small petri dish to which 6 ml of water was added. A tablet was kept on the tissue paper and allowed to completely wet. The wetted tablet was then weighed. Water absorption rationR was determined using the following equation[11-12]

In–vitro disintegration time

Disintegration time for FDTs was determined using USP disintegration apparatus 0.1 N HCl buffer. The volume of medium was 900 ml and the temperature was 37±0.2 °C. The time in second taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured.

In–vitro dissolution studies

The *in vitro* dissolution rate study of valsartan fast dissolving tablets were performed using 8 stage dissolution test apparatus (lab India) fitted with paddles (50 rpm) at 37±0.5 °C, using pH 6.8 phosphate buffer (900 ml) as a dissolution media. At the predetermined time intervals, 5 ml samples were withdrawn, filtered through a 0.45µ membrane filter, diluted and assayed at 205 nm using an Analytical technology Elico SL 218 UV/Visible Double beam spectrophotometer. Cumulative percentage release was calculated using standard absorbance from the calibration curve. All the dissolution experiments were conducted in triplicate (n=3)[13]

RESULTS AND DISCUSSION

The isolation of Ocimum gratissimum mucilage was found to be fine, free-flowing good swelling powder (7%). The physical and micromeritic properties of the Ocimum gratissimum mucilage are summarized in table 2. It was insoluble in aqueous solvents and insoluble in organic solvents tested (methanol, petroleum ether, dichloromethane, and chloroform). The pH of 0.1% aqueous dispersion was found to be 7.62±0.001. Ocimum gratissimum mucilage exhibited good swelling in water. The swelling index was found to be 100%±0.003% indicating that it is suitable for superdisintegrant. All micrometric properties indicated good flow properties needed manufacturing of tablets. The density of Ocimum gratissimum mucilage was found to be 0.3012±0.0004g/cc. The angle of repose and compressibility index showed good flow properties of Ocimum gratissimum mucilage. The FTIR spectrum of Ocimum gratissimum mucilage is shown in Fig. (1,2&3). The presence of peaks absorption at 1434.10 cm^{-1} characteristic peak of ester, so from FTIR studies it was concluded that Ocimum gratissimum mucilage (ester) was formed when mucilage was allowed to react with formic acid. The DSC studies showed in (Fig 4,5,& 6) of Ocimum gratissimum mucilage showed characteristic peaks, which indicates that the structure is slightly crystalline. As the Ocimum gratissimum mucilage was slightly fine powder and it had got all the characteristic of superdisintegrants it was concluded that Ocimum gratissimum mucilage can be used as novel superdisintegrant in the formulation of fast dissolving tablets.

Table 2

Physical and micromeritic properties of the Ocimum gratissimum mucilage prepared

Parameters	Ocimum gratissimum
Solubility studies	Slightly Soluble in cold water and hot water, forming viscous
Water and all aqueous and organic solvents	colloidal solution.& insoluble in all aqueous and organic solvents
pH studies	7.6
Phytochemical tests	Pass
Molisch test	
Rhethenum test	Pass
Iodine test	Fail
Melting point	203 Cº
Swelling index	100%
Test for gelling property	Particle swelling
Density	0.30 gm/cc
Tapped density	0.48 gm/cc
Compressibility index	0.309
Hausner s ratios	1.60
Particle size	152 µm
Angle of repose	25º

SD standard deviation from mean, n=3

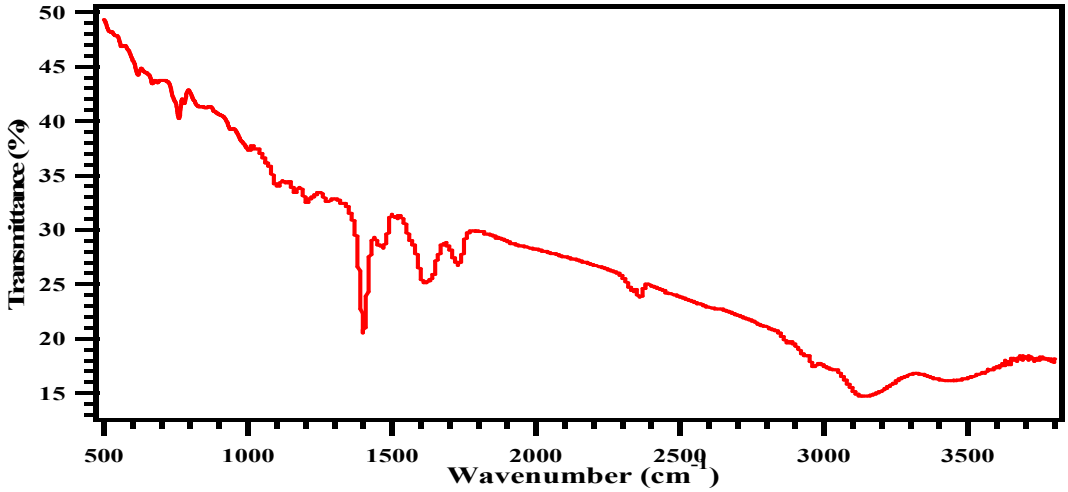

Figure 1
Fourier transform infrared pure Valsartan

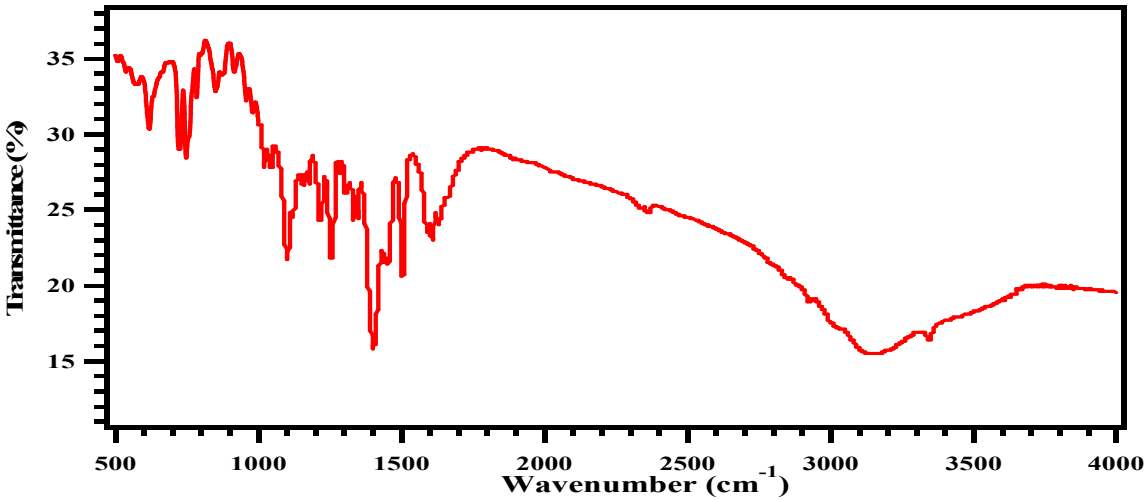

Figure 2
Fourier transform infrared pure mucilage

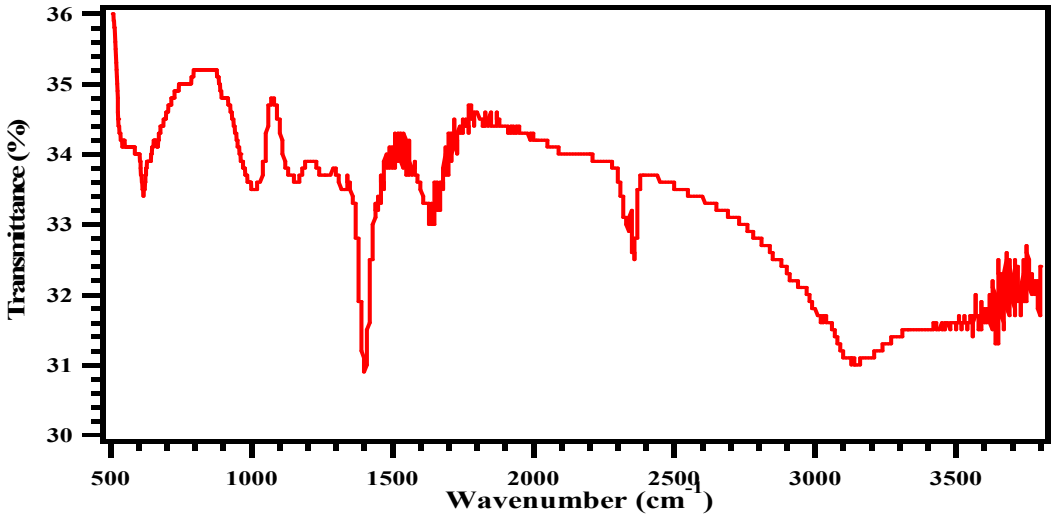

Figure 3
Fourier transform infrared valsartan and mucilage

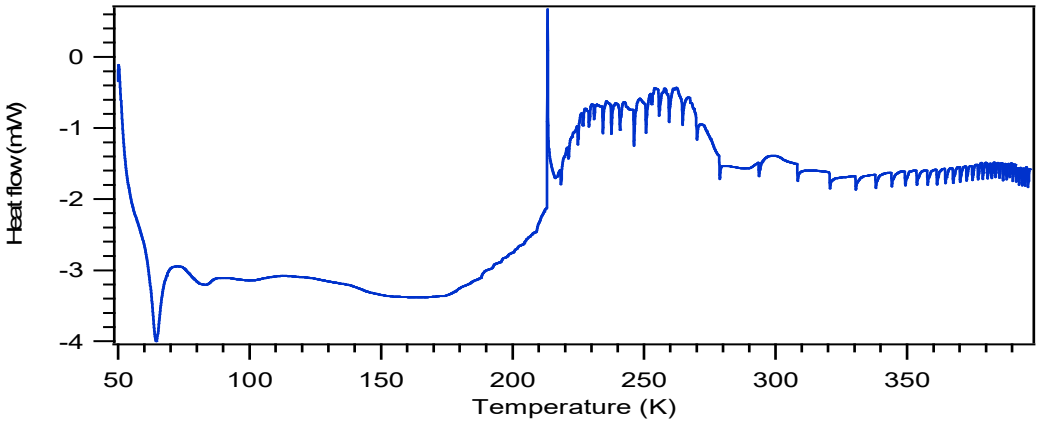

Figure 4
DSC thermo gram of valsartan pure drug

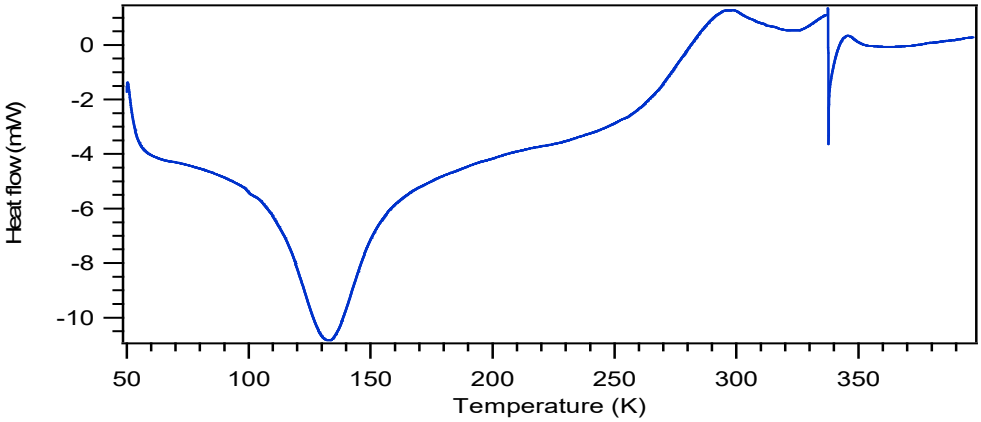

Figure 5
DSC thermo gram of mucilage pure drug

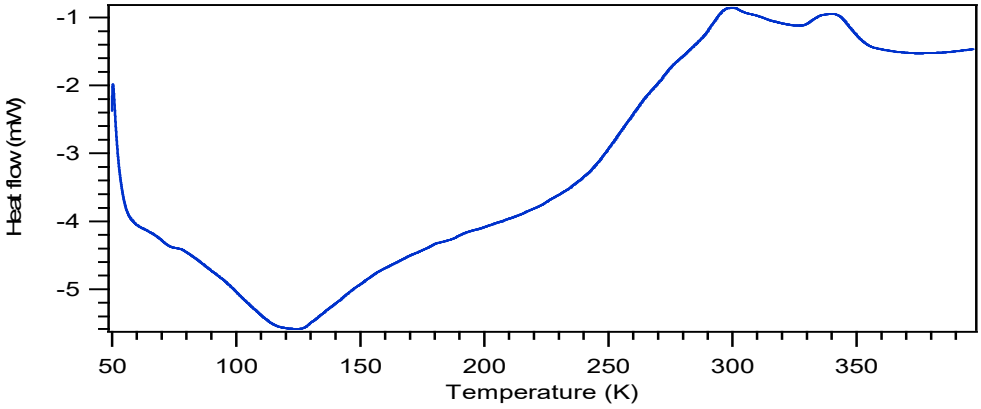

Figure 6
DSC thermo gram of valsartan and mucilage

Evaluation of tablets

Hardness

The hardness of tablets from all batches was found to be in the range of 3.3±0.03 kg/cm^2 to 4±0.01 kg/cm^2. The hardness of tablets from all batches was found to be in the range of 3.3±0.03 kg/cm^2 to 4±0.01 kg/cm^2.

Friability

All the formulations exhibited acceptable friability. The percent friability of all batches found in the range of 0.09%-0.19% indicating good mechanical resistance of tablets. The percent friability of all batches found in the range of 0.09%-0.19% indicating good mechanical resistance of tablets.

Drug content

Drug content of the tablets was found to be between 98.39±0.41 to 99.92±0.51. Hence, it can be concluded that all the tablets are having an accurate amount of drug distributed uniformly in powder mass and followed acceptable limits as per IP [14]. i.e. 85 to 115 % of average content table 3.

Disintegration studies

The USP disintegration apparatus did in vitro disintegration time. The *In vitro* disintegration time was found between 47±0.83 to 239±0.10s. The outcomes results data demonstrated in table 3. All the tablets showed disintegration time of less than 240s. It was

found that the formulation F8 is show least disintegration time 47s as compare to other tablets formulation. The order for a disintegration time in the fast dissolving tablet was found to be F8<F4<F3<F2<F7<F5<F6<F1. The order of disintegration time may be due to the interaction and main effects of the superdisintegrates used in the fast dissolving tablets.

Water absorption ratio and wetting time

The water absorption ratio founded from 104.06±0.73 to 383.8±0.14s. This increased behavior due to the water taking the ability of superdisintegrants. The wetting time found between 40±0.39 to 171±0.84s. The outcomes were tabulated and data demonstrated in table 3 and fig. no. 8. It was found that the formulation F8 containing 10 % mucilage and 10 % croscarmellose sodium showed less wetting time i.e. 40±0.39s as compared to other formulations (Fig 7).

***In vitro* dissolution studies**

Dissolution rate depends on the wetting time of the disintegrate, among all the tablets formulations F8 has less wetting time and has higher dissolution rate and then this is the other conformance test for correct selection of desirable. *In vitro* dissolution studies of all the tablets formulation were done and given in fig. (8,9). In all formulations F8 formulation was selected as the promising formulation containing 10% mucilage and 10% croscarmellose sodium and sodium starch glycolate (10%) with 101.84% release in 10 min which may be due to the interaction effect between the three super disintegrants. The dissolution parameters of the formulation from (F1–F8) which were made by direct compression method were shown in the table: 1. In all these cases the PD_{10} (percent dissolved in 10 min) was more in F8 which consists at 10% mucilage, 10% croscarmellose sodium and sodium starch glycolate(10%). The same was in the case of $DE_{10\%}$ (dissolution efficiency in 10 min). The PD_{10} and $DE_{10\%}$ revels that mucilage was effective at 10% along with 10% croscarmellose sodium and sodium starch glycol ate when the formulations were made by direct compression using these superdisintegrants. The K_1 decreased in all the formulation when compared to F1 formulation which was given in table. Fast dissolving tablets formulated employing mucilage (10%), sodium starch glycolate (10%) and croscarmellose sodium (10%) as super disintegrants exhibited in disintegration and dissolution efficiency in 10 min. Formulation F8 gave release of 101.84% in 10 min fulfilling the official specification, based on disintegration time and dissolution efficiency in 10 min. Formulation F8 is considered as a good fast dissolving tablet formulations of Valsartan which was found to better than the Valsartan fast dissolving tablets formulated by Purkayastha *et al.*[15]

Table 3

Physical properties: hardness, friability drug content of valsartan fast dissolving tablets prepared by direct compression method involving mannitol as a diluents

Formulation code	Hardness (kg/cm2)	% Friability	Disintegration time (sec) mean	Wetting time (Sec) mean	Water Absorption ratio (%)	Uniformity of content mean
F1	3.4±0.003	0.8±0.067	239±0.10	171±0.84	104.06±0.73	40±0.37
F2	3.7±0.05	0.6±0.72	57±0.83	81±0.69	322.1±0.81	41±0.82
F3	3.5±0.07	0.99±0.35	53±0.35	43±0.68	116.16±0.93	40±0.91
F4	3.4±0.09	0.56±0.79	51±0.84	72±0.23	305±0.75	38±0.55
F5	3.6±0.03	0.79±0.78	62±0.84	119±0.15	175.3±0.78	40±0.46
F6	3.4±0.31	0.46±0.38	62±0.72	110±0.37	323.4±0.37	41±0.37
F7	3.5±0.032	0.67±0.71	60±0.46	40±0.39	109.13±0.52	39±0.28
F8	3.3±0.015	0.61±0.39	47±0.83	53±0.47	383.8±0.14	41±0.14

SD standard deviation from mean, n=3, mean±SD.

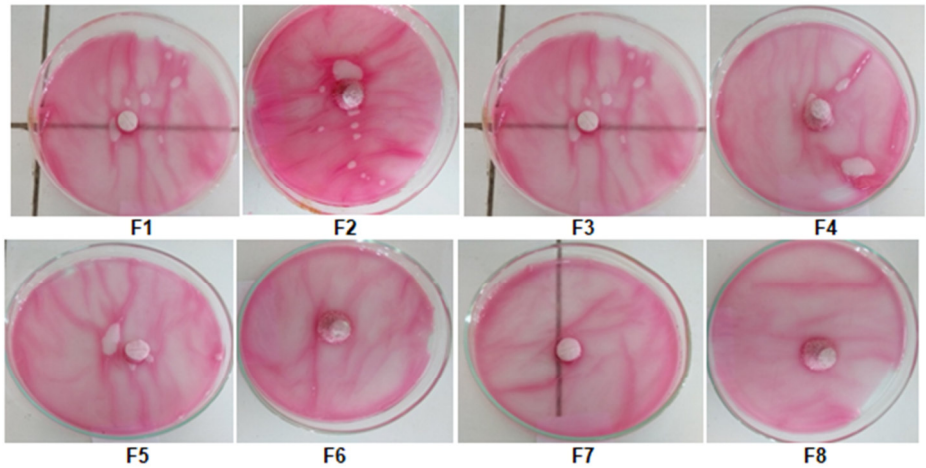

Figure 7

Wetting time of valsartan fast dissolving tablets prepared employing Ocimum gratissimum involving mannitol as a diluents.

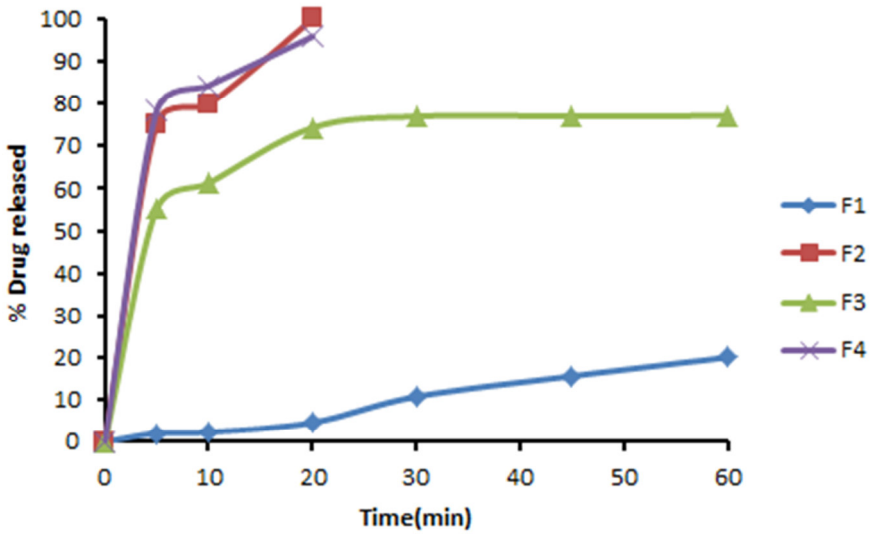

Figure 8
Dissolution profiles of valsartan fast dissolving tablets prepared employing occimum gratisimum mucilage involving mannitol as a diluent (F1-F4) (n=3, mean±SD)

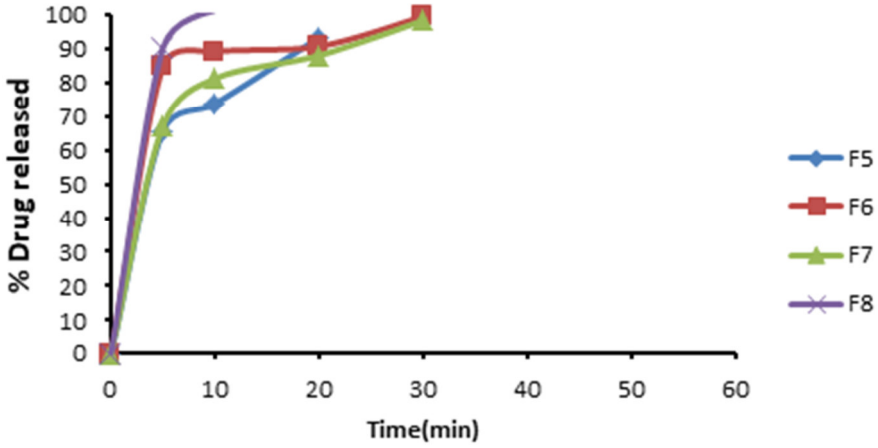

Figure 9
Dissolution profiles of valsartan fast dissolving tablets prepared employing occimum gratisimum mucilage involving mannitol as a diluent (F5-F8) (n=3, mean±SD)

Table 4
Kinetics data of all formulations

Time(min)	F1	F2	F3	F4	F5	F6	F7	F8
PD_{10}	1.13±0.11	5.56±0.63	13.41±0.51	33.85±0.47	99.84±0.19	53.53±0.23	99.17±0.46	90.76±0.28
DE_5 %	8.3±0.22	5.9±0.15	12.8±0.32	14.4±0.45	48.6±0.59	48.6±0.59	48.6±0.59	11.3±0.43
No of folds increase in DE_5%	0.60	0.43	0.93	1.05	3.54	3.54	3.54	0.82
K_1 (min^{-1})	0.01±0.002	0.02±0.004	0.04±0.007	0.05±0.007	-	0.10±0.008	-	0.07±0.003

CONCLUSION

Ocimum gratissimum mucilage is an efficient superdisintegrant for fast dissolving tablets. The disintegration and dissolution efficiency of the fast dissolving tablets of valsartan was good and depended on the concentration of superdisintegrant employed i.e., Ocimum gratissimum mucilage (10%), sodium starch glycolate (10%) and croscarmellose sodium (10%). The formulated fast dissolving tablets of valsartan employing Ocimum gratissimum mucilage, sodium starch glycolate and croscarmellose sodium exhibited good dissolution efficiency in 10 min which can be used for the fast therapeutic action of valsartan. Overall, Ocimum gratissimum mucilage was found to be a super-disintegrant when combined with sodium starch glycolate and croscarmellose sodium, the dissolution efficiency of valsartan was enhanced and hence it could be used in the formulation of fast dissolving tablets to provide immediate release of the contained drug within 10 min.

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AUTHORS CONTRIBUTION STATEMENT

Dr. A.Bharathi contrived the idea and analyzed the data with regard to this work. Mr Chandra Sekhar Naik gathered the data and gave necessary inputs towards the designing of the manuscript.

CONFLICT OF INTEREST

Conflict of interest declared none.

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