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FORMULATION AND EVALUATION OF FAST DISINTEGRATING TABLETS OF VALSARTAN BY USING BANANA POWDER AS DISINTEGRATING AGENT

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ABSTRACT

The aim is to formulate various batches of Fast disintegrating tablets of Valsartan by using Banana powder and SSG with different concentrations 2%, 4%, 6%, individually by using different diluents like Mannitol and Microcrystalline cellulose by direct compression method. The tablets were evaluated for the precompression parameters such as bulk density, compressibility, angle of repose etc and post compression parameters like hardness, weight variation, friability, disintegration time and in-vitro dissolution profiles. Tablets containing banana powder as disintegrating agent were dispersed rapidly within 35 sec and showed 98.5% drug release in 30 min.

KEYWORDS: Fast disintegrating Tablet, Valsartan, Banana powder.

INTRODUCTION

Pediatric and geriatric patients may have difficulties in swallowing or chewing pharmaceutical dosage forms for oral administration[1]. Tablets that rapidly dissolve upon contact with saliva in the buccal cavity could present a solution to those problems and so there is an increased interest in fast dissolving dosage forms for buccal, sublingual and oral administration. Fast dissolving/ disintegrating tablet are perfect fit for these patients as these immediately release the active drug when placed on tongue by rapid disintegration/ dispersion, followed by dissolution of drug[2]. Fast disintegrating tablet technology, which makes tablets dissolve or disintegrate in the mouth without additional water intake.

The FDT formulation is defined by the Food and Drug Administration (FDA) as "a solid dosage form containing medical substances whish disintegrates rapidly, usually within a seconds, when placed upon the tongue.[3] According to European Pharmacopoeia, "the FDT should disperse/disintegrate in less than three minutes. Fast dissolving tablets are also called as mouth-dissolving tablets, melt-in mouth tablets, Oro-dispersible tablets, porous tablets, quick dissolving etc.[4] The basic approach in development of FDT is the use of superdisintegrants, which provide instantaneous disintegration of tablet after putting on tongue and release the drug in saliva. The fast dissolving tablets are rapidly dissolved or disintegrate by the use of superdisintegrants.[5] The faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form. The advantage of mouth dissolving dosage forms are increasingly being recognized in both, industry and academics. The basic approach in development of FDT is the use of superdisintegrant like cross linked carboxy methyl cellulose (croscarmellose), sodium starch glycolate (primogel, explotab), polyvinylpyrollidone (polyplasdone) etc, which provide instantaneous disintegration of tablet after putting on tongue, thereby release the drug in saliva.[6]

MATERIALS AND METHODS

Valsartan were obtained as a gift sample from Startech Labs, Hyderabad, Telangana. Banana powder was purchased from IndiaMart. Microcrystalline cellulose, Mannitol & Talc were purchased from Loba Chemie. Sodium starch glycolate was purchased from Meckloides. Magnesium stearate was purchased from Pure chem & Sodium saccharin was purchased from Fine chem industries.

METHODOLOGY

Direct compression method is the easiest way to manufacture tablets. Required amount of drug is taken into a mortar and the remaining ingredients are added are tabulated in Table No.1, according to their quantities in ascending order and then mixed thoroughly.

Then the resulting mixture in powder form is evaluated for its flow properties. The powder is then flown through the hopper of the punching machine (8mm) and the resulting tablets were evaluated accordingly.

Calibration Curve of Valsartan

Maximum absorbance (λmax) of Valsartan were measured at 212 nm by using P^H 1.2 0.1N hydrochloric acid buffer. Calibration curves were constructed by preparing stock solution of 1000 µg/ml from the above stock, concentrations of 10µg, 20µg, 30µg, 40µg, and50µg per ml were prepared and the above obtained concentrations are observed for absorbance in UV spectrophotometer at a λmax of 212 nm. The calibration curve will be plotted by taking concentration on x-axis and absorbance on y-axis shown in fig.1 & tabulated in Table No.2.

FT-IR Studies

The IR absorption spectra of the pure drug and with different excipients were taken in the range of 4000-450 cm-1 using KBr disc method, 1-2 mg of the substance to be examined was triturated with 300-400 mg, specified quantity, of finely powered and dried potassium bromide. These quantities are usually sufficient to give a disc of 10-15 mm diameter and pellet of suitable intensity by a hydraulic press. The scans were evaluated for presence of principle peaks of drug, shifting and masking of drug peaks due to presence of excipients shown in fig.2, 3 & tabulated in Table No.3 & 4.

Evaluation parameters

1. General appearance

The general appearance of tablets, its visual identity and overall ‘elegance’ is essential for consumer acceptance.

2. Bulk Density

Apparent bulk density was determined by pouring blend into a graduated cylinder shown in Table No.5.

3. Tapped Density

The measuring cylinder containing known mass of blend was tapped for a fixed time measured shown in Table No.5.

4. Carr’s compressibility index

It is an indication of the ease with which a material can be induced to flow is given by compressibility index of the granules was determined by Carr’s compressibility index shown in Table No.5.

5. Hausner ratio

It is an indirect index of ease of powder flow shown in Table No.5.

6. Angle of Repose

It is an indicative of the flow properties of the powder. It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane shown in Table No.5.

7. Uniformity of Thickness

The thickness of individual tablets may be measured with a vernier caliper, which permits accurate measurements and provides information of the variation between tablets. Tablet thickness should be controlled within a ± 5% variation of a standard value shown in Table No.6.

8. Weight variation

Twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity shown in Table No.6.

9. Friability

Roche friabilator is used to determine the friability by following procedure. Pre weighed tablets are placed in the friabilator.

Friabilator consist of a plastic chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets are rotated in the friabilator for at least 4 minutes. At the end of test tablets are dusted and reweighed; the loss in the weight of tablet is the measure of friability and is expressed in percentage as shown in Table No.6.

10. Hardness

Tablet hardness is measured with hardness testers like Monsanto hards tester. A tablet is placed in the hardness tester and load required to crush the tablet is measured shown in Table No.6.

11. Wetting time

A petri dish containing 6 ml of distilled water is taken and a tissue paper folded twice is placed in it. A tablet containing a small quantity of amaranth color is placed on this. Time

required for the upper surface of the tablet to become complete red is the wetting time shown in Table No.6.

12. Disintegration Time

A cylindrical vessel was used in which 10-mesh screen was placed in such way that only 4 ml of disintegrating medium would be placed below the sieve. To determine disintegration time, 6ml of phosphate buffer (pH 7.4), was placed inside the vessel in such way that 4ml of the media was below the sieve and 2ml above the sieve. Tablet was placed on the sieve and the whole assembly was then placed on a shaker. The time at which all the particles pass through the sieve was taken as a disintegration time of the tablet. Six tablets were chosen randomly from the composite samples and the average value was determined shown in Table No.6.

13. Dissolution studies

The dissolution study was carried out using USP Type I (Basket type) dissolution apparatus. The dissolution was carried out in 900 ml of pH6.8 phosphate buffer maintained at 37°C at 50 rpm.

10 ml aliquots of samples were taken at various time intervals which were replaced with same volume of fresh pH 6.8 phosphate buffer maintained at 37°C. Valsartan in the samples was then determined spectrophotometrically at λ max of 212 nm shown in Table No.7 & Fig.4.

RESULTS AND DISCUSSION

Table No.1 –Formulation Of Valsartan.

Ingredients	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8
Valsartan (mg)	40	40	40	40	40	40	40	40
Banana powder(mg)	2	4	6	_	_	_	2	2
Sodium Starch Glycolate(mg)	_	_	_	2	4	6	1	2
Mannitol	70	70	70	70	70	70	70	70
Micro crystalline cellulose(mg)	85	83	81	85	83	81	84	83
Magnesium stearate (mg)	1	1	1	1	1	1	1	1
Sodium saccharine	1	1	1	1	1	1	1	1
Talc (mg)	1	1	1	1	1	1	1	1
Total weight (mg)	200	200	200	200	200	200	200	200

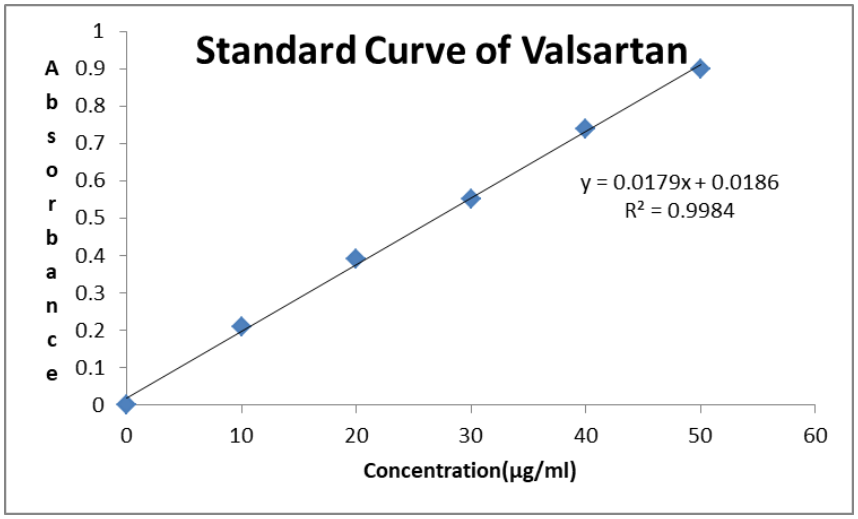

Figure 1: Standard Curve Of Valsartan.

Table No.2 – Standard Graph Of Valsartan.

Concentration (µg/ml)	Absorbance
0	0
10	0.21
20	0.39
30	0.55
40	0.74
50	0.9

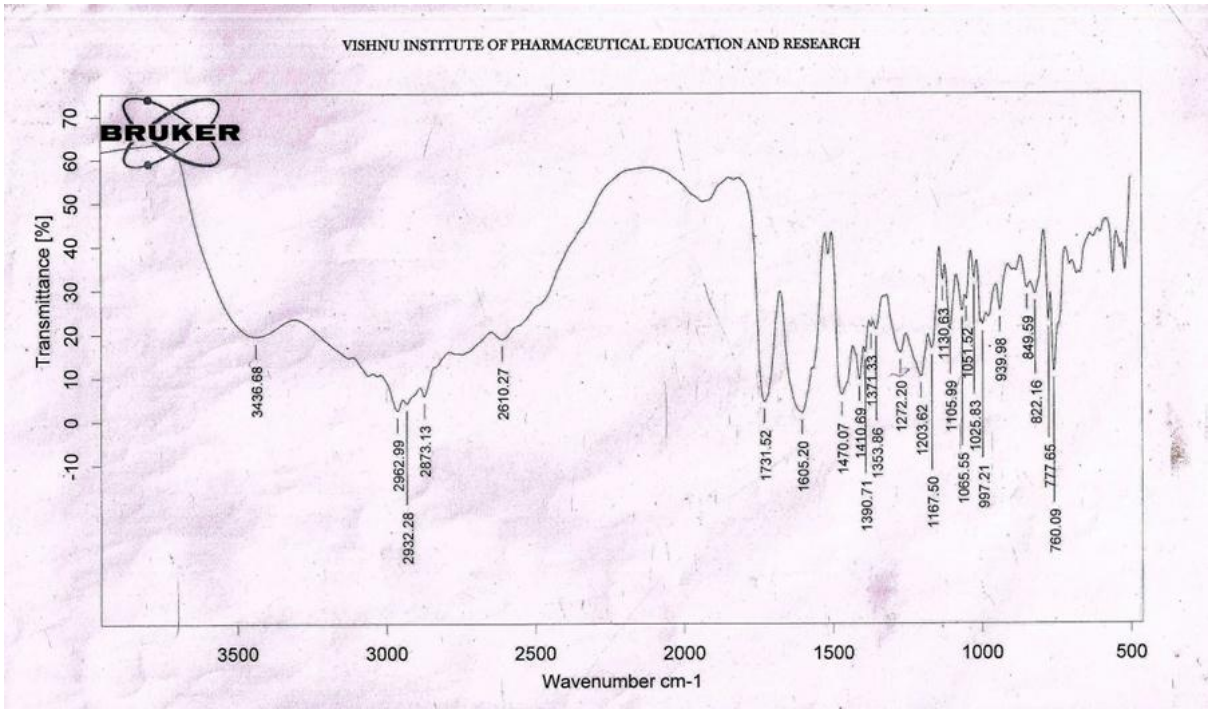

Figure 2: Ft-Ir Spectra Of Valsartan (Api).

Table No.3 – Ft-Ir Spectra Values Of Valsartan.

Functional group	Wavelengthcm^{-1}	Range(cm^{-1})
C=O bending	1371.33	144-1390
CH_2 bending	1470.07	1430-1470
N-H bending	1500.03	1500-1560
C=C stretching	1605.20	1600-1680

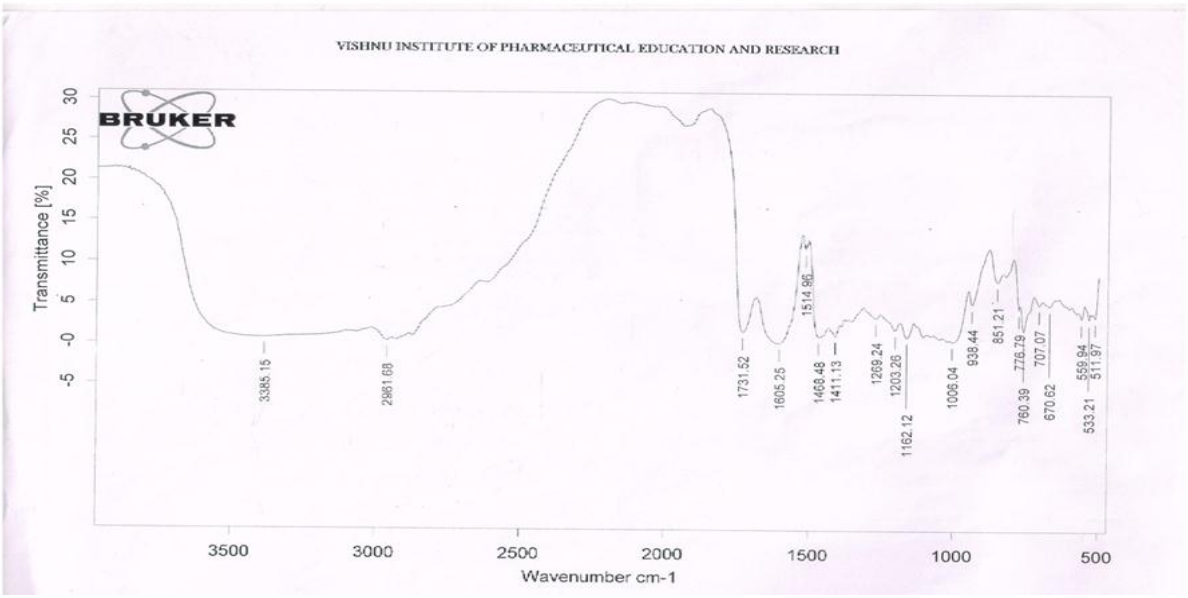

Figure 3: Ft-Ir Spectra Of Drug +Excipents.

Table No.4 – Ft-Ir Spectra Values Of Drug +Excipents.

Functional group	Wavelengthcm^{-1}	Range(cm^{-1})
C=O bending	1269.24	144-1390
CH_2 bending	1468.48	1430-1470
N-H bending	1514.96	1500-1560
C=C stretching	1605.25	1600-1680
C-H stretching	2961.68	2950-2970

Table No.5 – Evaluation Parameters.

Formulation code	Angle of repose (θ)	Bulk density (gm/ml)	Tapped density (gm/ml)	Hausner's ratio	Carr's index
F-1	25.01±0.20	0.456±0.73	0.553±0.32	1.173±0.20	12.5±0.68
F-2	25.56±0.43	0.452±0.68	0.567±0.42	1.192±0.43	13.17±0.73
F-3	26.32±0.62	0.448±0.42	0.539±0.68	1.204±0.62	12.55±0.48
F-4	26.14±0.26	0.461±0.32	0.547±0.73	1.189±0.23	13.04±0.52
F-5	23.22±0.32	0.445±0.26	0.569±0.20	1.186±0.32	14.02±0.63
F-6	24.56±0.42	0.453±0.62	0.548±0.43	1.198±0.42	12.89±0.72
F-7	25.15±0.68	0.457±0.43	0.551±0.62	1.187±0.68	1368±0.26
F-8	24.96±0.73	0.449±0.28	0.558±0.26	1.201±0.73	12.58±0.18

Table No.6 – Evaluation Parameters.

Formulations	Thickness (mm)	Weight variation (mg)	Drug content (%)	Friability (%)	Hardness (kg/cm^2) ± SD	Wetting time (sec)	Disintegration time(sec)
F-1	3.49±0.12	192±0.11	97.31±0.04	0.18	2.6 ± 0.12	10± 0.01	98±1
F-2	3.48±0.02	191±0.24	96.25±0.06	0.24	2.25±0.02	12±0.0 2	82±1
F-3	3.50±0.29	193±0.22	98.65±0.08	0.22	2.2 ± 0.29	12±0.04	74±1
F-4	3.48±0.26	198±0.19	99.88±0.12	0.28	2± 0.26	2± 0.05	68±1
F-5	3.51±0.22	198±0.12	97.30±0.07	0.21	2.1± 0.22	2± 0.09	65±1
F-6	3.49±0.12	199±0.05	97.28±0.06	0.19	2.2 ± 0.12	3± 0.08	59±1
F-7	3.50±0.02	198±0.08	97.25±0.02	0.22	2.3± 0.02	4 ± 0.09	44±1
F-8	3.52±0.02	198±0.08	99.65±0.02	0.24	2.5 ± 0.29	3 ±0.01	35±1

Table No.7 Dissolution Studies.

Time (min)	% Drug Release							
	F-1	**F-2**	**F-3**	**F-4**	**F-5**	**F-6**	**F-7**	**F-8**
0	0	0	0	0	0	0	0	0
1	11.36	18.42	24.36	17.49	22.6	24.3	12.18	26.47
3	19.48	25.48	33.65	24.33	33.46	43.65	29.35	48.65
5	24.26	36.48	49.68	32.34	48.37	61.42	37.37	67.33
10	32.48	47.36	56.24	45.34	54.63	72.37	49.24	86.49
15	39.27	53.38	61.36	52.24	63.34	78.62	56.19	89.38
20	48.46	59.47	68.68	61.37	72.41	86.31	67.23	95.46
25	59.32	68.37	79.37	69.78	78.68	92.78	77.38	98.21
30	67.42	79.12	88.4	72.5	84.1	96	89.5	98.5

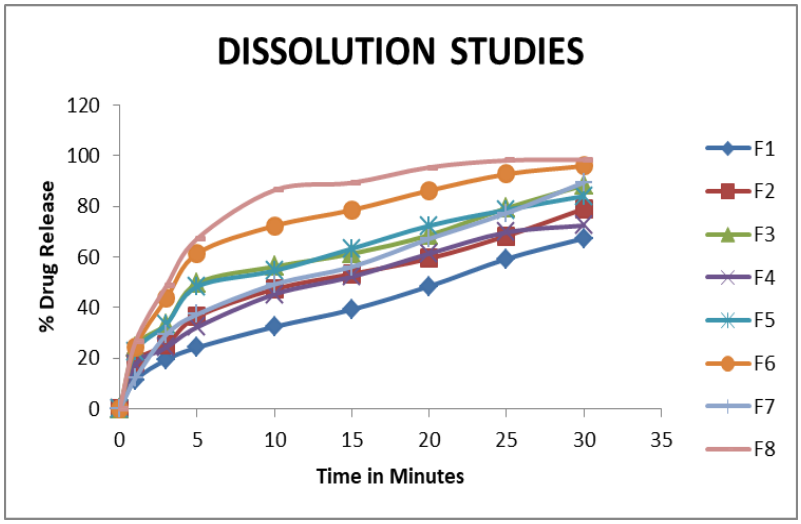

Figure 4: Dissolution Studies.

CONCLUSION

The pre-formulation studies indicated that the prepared tablets have good flow properties, uniformity of thickness, weight variation, drug content, friability, hardness, wetting time,

disintegration time and dissolution. The drug content of tablets was evaluated. The tablets have the drug within the range, 96.25±0.06 % to 99.88±0.12 %. The weight variation for all the tablets showed compliance within the limit of 191±0.24mg to 199±0.05mg. In addition, thickness of these tablets was found uniform range 3.48±0.02mm to 3.52±0.29mm, The hardness of these tablets was within the range between 2.0±0.26 kg/cm2 to 2.6±0.12 kg/cm2, friability (%) of all formulated tablets was found within the range of 0.18% to 0.28 %. wetting time was found in the range of 2±0.05-12±0.02secs. disintegration time was found to be in the range of 35±1 to 98±1. For in-vitro dissolution studies pH 6.8 phosphate buffer was used for the determination of Valsartan. The in-vitro drug release of formulations F1-F8 was found to be in the range of 67.42-98.05%. In-vitro drug release profile of F8 formulation showed the disintegration time of 98.05% for 30 minutes. From the present investigation, it may be concluded that banana powder has the disintegrating property and in combination with SSG formulation F8 showed best result among all other formulations. The results of stability studies also showed that all investigated parameters were remained same indicating the good stability of Valsartan fast disintegrating tablets in combination with banana powder.

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