

Isolation, Purification Of *Carica Papaya* And *Ocimum Basilicum* Seed Mucilages & Preparation Of Valsartan Oro Dispersable Tablets By Using Natural Superdisintegrants

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Abstract: Orodispersible tablets (ODTs), have the unique property of disintegrating in the mouth in seconds without chewing and the need of water. The purpose of this investigation was to develop mouth dissolving tablets of Valsartan using *Carica Papaya* seed mucilage and *Ocimum bacillum* seed mucilage as a novel superdisintegrant. The present study demonstrated potentials for rapid absorption, improved bioavailability, effective therapy and patient compliance. The rationale of the study was to formulate orodispersible tablets of Valsartan for improving its poor oral bioavailability and with the aim of alleviating administration to patients facing problems with swallowing. Formulation F5 & F11 was selected as optimized batch containing *Ocimum basilicum* seed mucilage & *Carica papaya* seed mucilage as the superdisintegrant in 10% concentration. The mechanism involved in tablet disintegration is swelling action helps in the faster disintegration of tablets. It has less disintegration time of around 2'36". The dissolution study was carried out and 99.2% & 99.0 of drug release was occurring within 10min. The stability study of optimized batch was carried out at 40°C/75%RH. The tablets were found to be stable at such condition and there is slight increase in the moisture content. The promising formulations were found to be stable during the stability studies conducted as per ICH guidelines, as it showed no significant changes in the physicochemical properties, disintegration time and in-vitro drug release.

Index Terms: Novel superdisintegrant, *Ocimum basilicum* seed mucilage, *Carica papaya*, ODTs.

I. INTRODUCTION:

The oral route of administration¹⁻⁹ still continues to be the most preferred route due to its manifold advantages including ease of ingestion, pain avoidance, versatility and most importantly patient compliance. The most popular dosage forms are tablets and capsules. Drugs with poor wetting, slow dissolution properties, intermediate to large dosage, and optimum absorption in the gastrointestinal tract or any combination of these features may be difficult or impossible to formulate and manufacture as a tablet that will still provide adequate or full drug bioavailability. The most important role of drug delivery system is to get the drug delivered to the site of action in sufficient amount & at the appropriate rate. However it should meet other important criteria such as physical & chemical stability, ability to be mass-produced in a manner that assures content uniformity.

Oral route of drug administration has wide acceptance and of the drugs administered orally in solid dosage forms represents the preferred class of products. The reasons are, Tablets and capsules represent unit dosage form in which one usual dose of drug has been accurately placed.

By comparison liquid oral dosage forms such as syrups, suspensions, emulsions, solutions, and elixirs are usually designed to contain one dose medication in 5-30ml. Such dosage measurements are typically error by a factor ranging from 20-50% when the drug is self-administered by patient. Liquid oral dosage forms have other disadvantages and limitations.

Disintegrants are substances or mixture of substances added to the drug formulation that facilitates the breakup or disintegration of tablet or capsule content into smaller particles that dissolve more rapidly than in the absence of disintegrants.

Super Disintegrants are substituted and cross linked polymers. Here swelling is inversely proportional to the level of substitution.

II. MATERIALS & METHODS

1. STANDARD CURVE OF VALSARTAN: An accurately weighed 10 mg of Valsartan was dissolved in methanol and made up to 100 ml in volumetric flask (Stock solution- I) (100 µg/ml). From this 10 ml of solution were pipetted out and made up to 100 ml in an 100 ml volumetric flask (Stock solution- II) (10 µg/ml). From this the aliquots were prepared whose concentration ranging from 2 to 10 µg/ml and the absorbance were measured at 249 nm against the reagent blank

2. ISOLATION OF MUCILAGE FROM OCIMUM BASILICUM SEEDS: Basil seeds were rinsed with water to remove foreign particles. Seeds were soaked in water (seed: water = 1:10) for 20 minutes. The swollen seeds subjected to high agitation using homogenizer at 1500 rpm to separate gel layer from seeds. The separated gel layer was passed through muslin cloth to remove unwanted particles and then precipitated using acetone. The precipitate was washed with ethanol and dried in Hot air Oven at 50°C. The dried mucilage was powdered and stored in airtight containers.

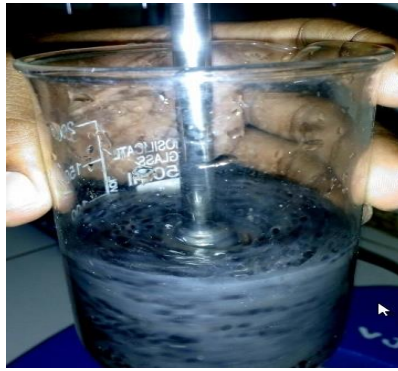


Fig: 1 SEPERATION OF OCIMUM MUCILAGE



Fig: 2 Dried Mucilage of Ocimumbasilicum

Isolation of Mucilage from Carica Papaya Seeds

The papaya seeds are taken from raw papaya then the mucilage was separated with the help of forceps. The separated mucilage was washed with acetone to remove unwanted particles then it was dried in Hot air Oven at 50°C. The dried mucilage was powdered and stored in airtight containers.



Fig: 3 SEEDS OF RAW PAPAYA

Fig 7: DRIED PAPAYA SEED MUCILAGE

III. DRUG EXCIPIENT COMPATIBILITY STUDIES:

Compatibility studies are carried out to study the possible interactions Valsartan and other inactive ingredients.

Procedure:

The compatibility studies were carried out by taking a mixture of drug and excipients. A part of mixture can be exposure to storage conditions like 40°C/75% RH. They were tested with respect to their physical and chemical aspects.

IV. FORMULATION DEVELOPMENT:

The main objective of the experimental work is to prepare Valsartan tablets using natural superdisintegrants by direct compression method. Superdisintegrant are added to oral solid dosage formulations to facilitate disintegration. Natural superdisintegrant used are Papaya seed mucilage and Ocimum basilicum seed mucilage are highly efficient at low concentration levels (2–12 W/W %) in

the tablet formulation at facilitating the rate and extent of tablet disintegration. Superdisintegrants helps in decreasing the disintegration time and increase the percentage of drug release at various concentrations.

Table : 1 Composition of formulation F1 to F6

S.No	Ingredients	F1(mg)	F2(mg)	F3(mg)	F4(mg)	F5(mg)	F6(mg)
1	Valsartan	160	160	160	160	160	160
2	Ocimum basilicum Mucilage	13 (2%)	26 (4%)	39 (6%)	59 (8%)	65 (10%)	78 (12%)
3	MCC-102	97.5	97.5	97.5	97.5	97.5	97.5
4	Mannitol	369.5	356.5	343.5	330.5	317.5	304.5
5	Talc	5	5	5	5	5	5
6	Magnesium Stearate	5	5	5	5	5	5
Total (mg)		650	650	650	650	650	650

Table: 2 Compositions for formulations F7 to F12

S.No	Ingredients	F1(mg)	F2(mg)	F3(mg)	F4(mg)	F5(mg)	F6(mg)
1	Valsartan	160	160	160	160	160	160
2	Carica papaya seed mucilage	13 (2%)	26 (4%)	39 (6%)	59 (8%)	65 (10%)	78 (12%)
3	MCC-102	97.5	97.5	97.5	97.5	97.5	97.5
4	Mannitol	369.5	356.5	343.5	330.5	317.5	304.5
5	Talc	5	5	5	5	5	5
6	Magnesium Stearate	5	5	5	5	5	5
Total (mg)		650	650	650	650	650	650

V. RESULTS & DISCUSSION:

Table: 3 Standard calibration curve

S.NO	CONCENTRATION $\mu\text{g/ml}$	ABSORBANCE
1.	2	0.089
2	4	0.150
3	6	0.226
4	8	0.303
5	10	0.339

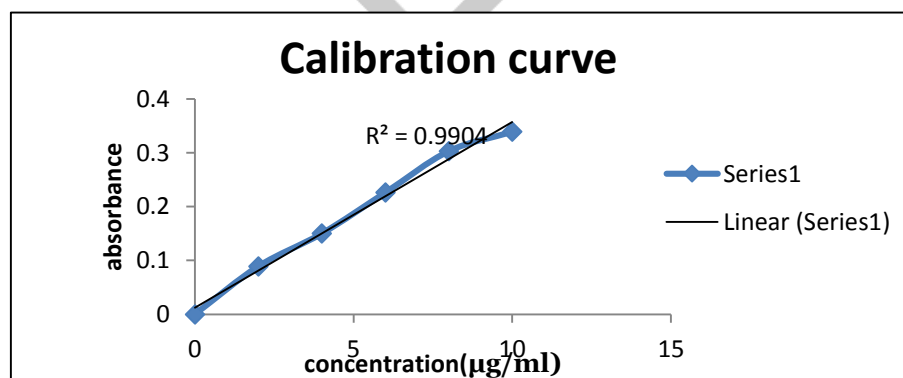
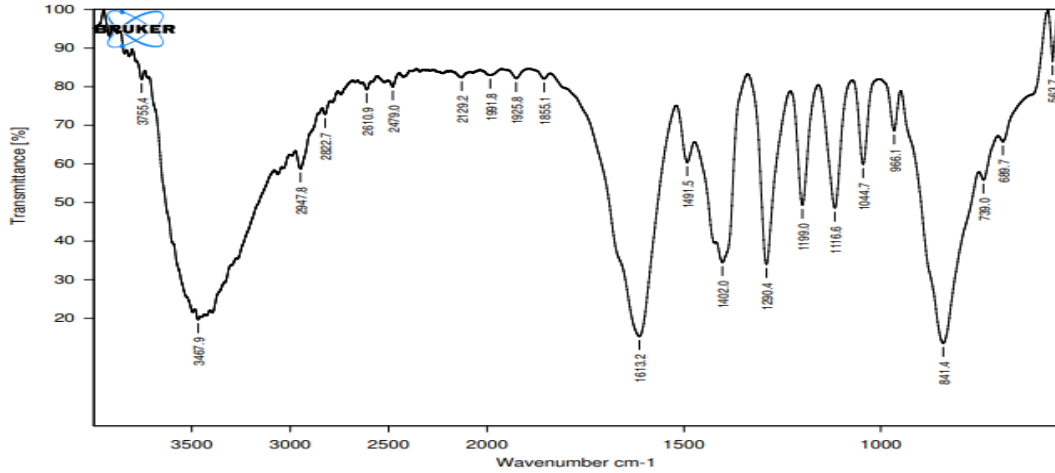


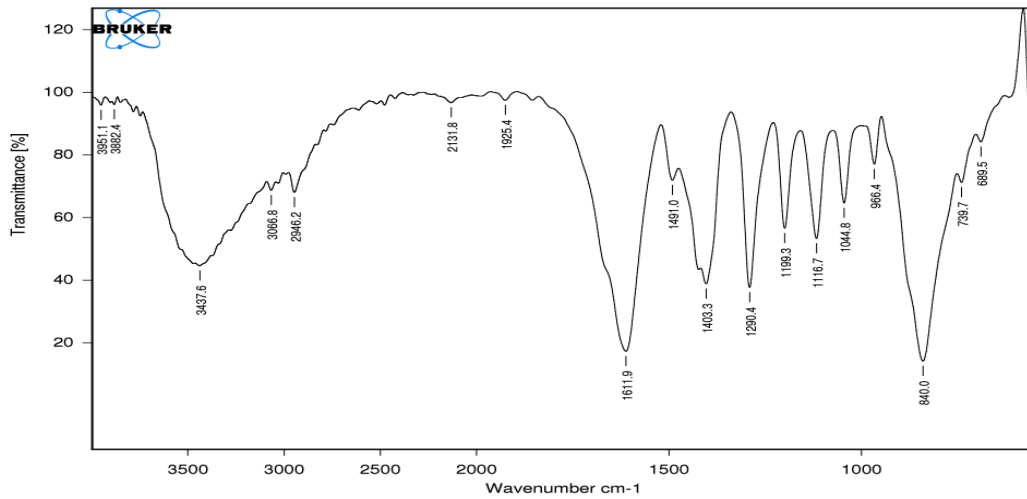
Fig: 4 standard calibration curve of Valsartan

FTIR STUDIES:



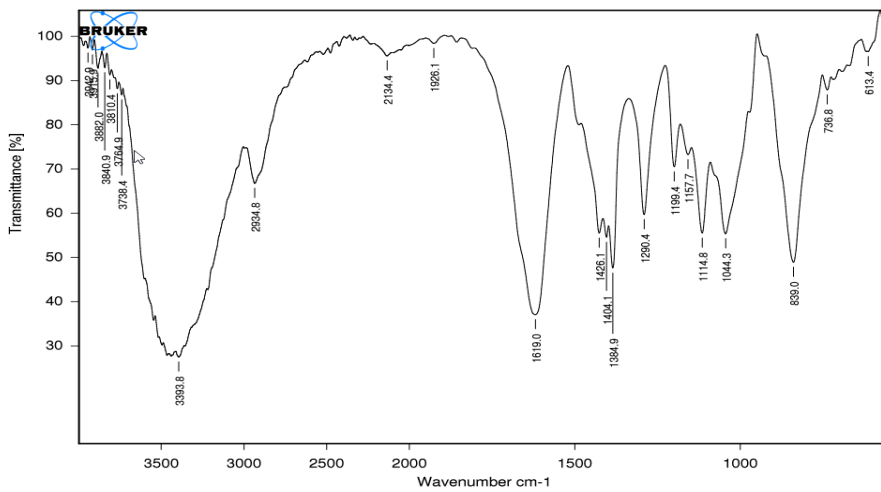
E:\NEW PROJECT: VALSARTAN: SOLID: 16/11/2017

Fig: 5 IR Spectra of Valsartan (Pure Drug)



E:\NEW PROJECT: VALSARTAN+ OCIMUM: SOLID: 16/11/2017

Fig: 6 IR Spectra of Valsartan+ Ocimum + Carica Papaya



E:\NEW PROJECT: VALSARTAN+ BLEND OCIMUM: SOLID: 16/11/2017

Fig: 7 IR Spectra of VALSARTAN & BLEND

Table: 4 Blend properties for all the formulations

<i>Formulation</i>	<i>Bulk density g/mL (untapped)</i>	<i>Tap density(g/mL)</i>	<i>Angle of repose(θ)</i>	<i>Compressibility or Carr's index</i>	<i>Hausner's ratio</i>
F1	0.39	0.44	27.410410	9.25%	1.09
F2	0.39	0.44	29.120	11.30%	1.15
F3	0.39	0.44	29.20	13.25%	1.15
F4	0.36	0.46	31.400	19.58%	1.25
F5	0.46	0.52	30.380	15.10%	1.18
F6	0.41	0.46	28.450	9.09%	1.09
F7	0.38	0.40	27.360	9.50%	1.05
F8	0.39	0.42	28.90	11.20%	1.12
F9	0.36	0.42	28.100	13.25%	1.16
F10	0.36	0.42	31.200	19.10%	1.26
F11	0.45	0.52	30.420	15.20%	1.20
F12	0.41	0.41	28.45	10.10%	1.09

Table: 5 Compression parameters for all the formulations

<i>Fomula</i>	<i>Hardness (kp)</i>	<i>Thickness (mm)</i>	<i>Friability %w/w</i>	<i>Weight variation (mg)</i>	<i>D.T (sec)</i>	<i>Assay %</i>
F1	3.61±0.28	4±0.5	0.88	645±1.7	156±0.8	96.6±0.18
F2	3.61±0.28	4±0.6	0.88	645±1.7	156±0.8	96.6±0.18
F3	3.61±0.28	4±0.9	0.88	645±1.7	156±0.8	96.6±0.18
F4	3.61±0.28	4±0.2	0.88	645±1.7	156±0.8	96.6±0.18
F5	3.61±0.28	4±0.3	0.88	645±1.7	156±0.8	96.6±0.18
F6	3.61±0.28	4±0.2	0.88	645±1.7	156±0.8	96.6±0.18
F7	3.65±0.28	4±0.3	0.90	646±1.3	143±0.4	98.2±0.20
F8	3.65±0.28	4±0.6	0.90	646±1.3	143±0.4	98.2±0.20
F9	3.65±0.28	4±0.2	0.90	646±1.3	143±0.4	98.2±0.20
F10	3.65±0.28	4±0.4	0.90	646±1.3	143±0.4	98.2±0.20
F11	3.65±0.28	4±0.5	0.90	646±1.3	143±0.4	98.2±0.20
F12	3.65±0.28	4±0.2	0.90	646±1.3	143±0.4	98.2±0.20

Table : 6 % Cumulative drug release for the formulations F1 to F6

<i>Time (Min)</i>	<i>% Drug release</i>					
	F1	F2	F3	F4	F5	F6
	0	0	0	0	0	0
1	36.2±0.6	71.2±0.06	80.4±0.14	85.6±0.16	87.4±0.09	25.3±0.20
2	72.6±0.4	76.1±0.12	82.8±0.20	91.6±0.08	92.5±0.07	30.5±0.15
3	74.2±0.20	81.5±0.20	83.6±0.21	94.1±0.06	95.6±0.03	55.6±0.09
4	77.3±0.31	83.8±0.14	84.2±0.10	96.4±0.10	97.2±0.02	78.8±0.18
5	79.8±0.02	84.2±0.10	86.1±0.08	97.8±0.05	98.3±0.19	79.8±0.06
10	81.6±0.18	86.4±0.06	93.4±0.12	98.0±0.08	99.2±0.41	83.1±0.02

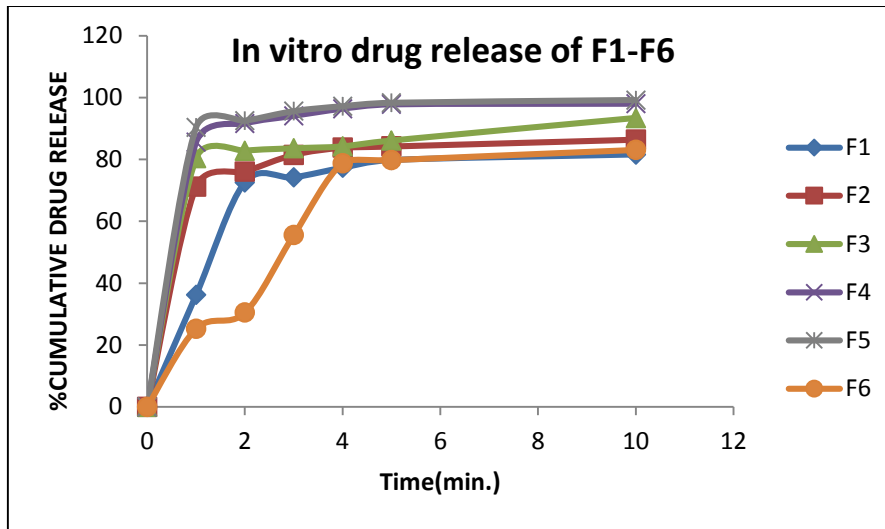


Fig :8 Dissolution profile for formulations F1 to F6 Observation:

Table: 7 % Cumulative drug release from the formulations F7 to F12

Time (min)	% Drug release					
	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0
1	35.4 ± 0.8	70.1 ± 0.08	79.2 ± 0.09	84.2 ± 0.18	85.2 ± 0.09	26 ± 0.30
2	74.6 ± 0.6	75.2 ± 0.25	82.4 ± 0.2	92.1 ± 0.30	92.8 ± 0.10	30.8 ± 0.15
3	76.2 ± 0.14	80.9 ± 0.10	83.8 ± 0.1	94.9 ± 0.01	94.2 ± 0.20	55.2 ± 0.10
4	77.1 ± 0.20	84.1 ± 0.09	84.1 ± 0.1	96.2 ± 0.10	97.5 ± 0.16	78.6 ± 0.12
5	79.9 ± 0.02	86.2 ± 0.04	86.9 ± 0.02	97.1 ± 0.20	98.1 ± 0.21	78.9 ± 0.05
10	82.2 ± 0.20	88.2 ± 0.20	94.1 ± 0.04	98.2 ± 0.02	99.0 ± 0.02	84.2 ± 0.05

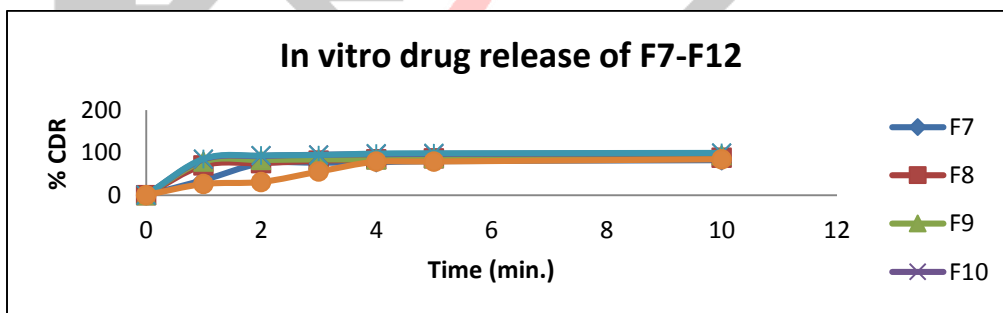


Fig :9 Dissolution profile for formulations F7 to F12 Observation

Comparative dissolution studies:

Formulation F5 and F11 containing 10% of natural superdisintegrant. *In vitro* dissolution profile of formulation F5 of Ocimum basilicum & F11 formulation of papaya seed mucilage were shown high drug release in 10 minutes. The dissolution procedure is following as per the USP conditions.

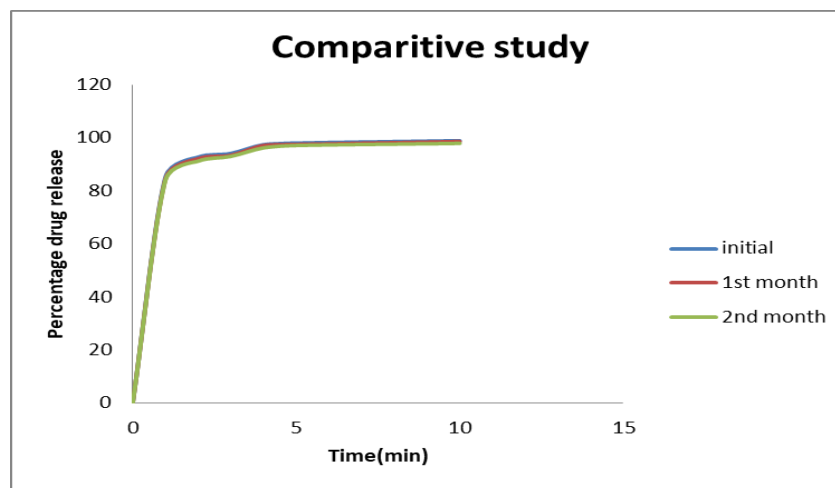


Fig: 10 Comparative Dissolution profile for F5, F11 & Innovator

VI. CONCLUSION:

The main objective of the experimental work undertaken was to formulate and evaluate Valsartan Tablets using natural superdisintegrants at various concentrations.

Tablets were prepared by using direct compression. Tablets were obtained of uniform weight due to uniform die fill, with acceptable weight variation as per pharmacopoeial specification. The drug content found in the range of 96.6-99. (Acceptable limit) and the hardness of the tablet was found between 3.61 – 3.65 kp. The tablet thickness was found to be 4mm, friability of tablet was found below 1% indicating good mechanical resistance.

The formulations F1 to F6 were prepared using Ocimum basilicum seed mucilage and Carica papaya seed mucilage as the superdisintegrant. The formulations were prepared by increasing the concentration of superdisintegrants. The percentage drug release for the two formulations is increased with the increase in concentration.

The formulations F7 to F12 were prepared using Carica papaya seed mucilage as the superdisintegrant. The formulations were prepared by increasing the concentration of superdisintegrants. The percentage drug release for the two formulations is increased with the increase in concentration.

Formulation F5 & F11 was selected as optimized batch containing Ocimum basilicum seed mucilage & Carica papaya seed mucilage as the superdisintegrant in 10% concentration. The mechanism involved in tablet disintegration is swelling action helps in the faster disintegration of tablets. It has less disintegration time of around 2'36". The dissolution study was carried out and 99.2% & 99.0% of drug release was occurring within 10min. The stability study of optimized batch was carried out at 40°C/75%RH. The tablets were found to be stable at such condition and there is slight increase in the moisture content.

Hence, Valsartan tablets were formulated and evaluated, and formulation F5 & F11 were concluded as the optimized formulation in manufacturing Valsartan tablets.

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