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DEVELOPMENT AND EVALUATION OF CAPTOPRIL FAST DISINTEGRATING OR DISSOLVING TABLETS BY COMPLEXATION TECHNIQUES USING *PSYLLIUM* HUSK AS A SUPERDISINTEGRANT

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ABSTRACT

The aim of the present study was an attempt to formulate and evaluate taste masked fast disintegrating tablets of Captopril to increase the palatability and bioavailability of the drug. Fast disintegrating tablets of Captopril were prepared by direct compression method using β-cyclodextrin as a complexing agent to mask the bitter taste of Captopril. *Psyllium* husk as natural superdisintegrants was used in different concentration 2.5 mg, 5 mg, 7.5 mg, 10 mg respectively. The Captopril - β-cyclodextrin complex were characterized by FT-IR, DSC and XRD. Compatibility studies by FT-IR showed no significant interactions between drug and excipients. DSC and XRD analysis confirmed the formation of complex for taste masking. The developed tablet formulations were evaluated for pre compression and post compression parameters which complied official limits. Among all the formulations, formulation F4 containing *psyllium* husk 10 mg gives best disintegration and dissolution profile compared with other formulations. The formulation F4 showed drug release of 99.84±0.18 % with very less time (4 min) and disintegration time 41.33±1.21 (sec). From this study we concluded that the formulated tablets of Captopril containing *psyllium* husk of concentration 10 mg was better and effective than conventional tablets to meet patient compliance along with fast relief from hypertension.

KEYWORDS

Captopril, β-cyclodextrin, Fast disintegrating tablets and Superdisintegrants.

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INTRODUCTION

The major problem faced by the patients with conventional tablet dosage form is difficult in taking medicine; hence patients may not comply with prescription, which results in high incidence of ineffective therapy. With the advancement in technology and experience, pharmaceuticals are prepared and administered to patients in more compliant and efficient manner. Rapid disintegrating

tablets are the new improved dosage form developed especially for the young and elderly patients who find inability to swallow tablets and capsules due to under developed muscular, nervous system and dysphagia. This solid dosage forms dissolves or disintegrate rapidly in oral cavity, resulting in solution and suspension that can be swallowed without need of water .When this type of tablet is placed in mouth, the saliva serves to rapidly dissolve the tablet usually in about 30 sec.

The critical formulation problem in making such type of dosage form is the taste masking of bitter taste associated with most of the drugs and this can be overcome by taste masking technique such as polymer coating, complex formation, granulation, microencapsulation and use of ion exchange resins[1].

Captopril is widely used antihypertensive drug but it is very bitter. Captopril is poorly absorbed followed an oral dose leads to poor bioavailability. Therefore, to provide this drug in a more accessible and patient compliant form and to overcome such problems, in the present study we plan to mask the bitter taste by complexation technique and formulate into a rapid disintegrating tablet using natural superdisintegrant. The physicochemical properties of Captopril are water soluble drug having plasma half-life of 2 hrs, make it suitable candidate to formulate buccal disintegrating tablets[2].

On the basis of these considerations, in this study, we aim to formulate rapidly disintegrating tablets of Captopril using natural superdisintegrant, since synthetic superdisintegrants are expensive, have environment related issues, need long development time for synthesis. However, the use of natural superdisintegrants in pharmaceutical application is attractive because they are economic, readily available, non-toxic and potentially degradable[3].

MATERIALS AND METHODS

Materials

Captopril (Micro labs, Bangalore), β-cyclodextrin (Rolex chemical industries, Mumbai), *Psyllium* husk (Abbott Pvt, Ltd), guar gum (Merck specialities Pvt, Mumbai), microcrystalline cellulose, magnesium stearate, mannitol (S D fine chemical Ltd, Mumbai), aspartame (Shreeji chemicals, Mumbai), talc (Loba chemical Pvt. Ltd. Mumbai). All the other solvents, reagents and chemicals used were of either pharamcopoeial or analytical grade.

Methods

Compatibility studies[4]

Compatibility studies by Fourier transformer infra-red spectroscopy (FTIR)

Infra-red spectra of drug and inclusion complexes were recorded by KBr method using Fourier transformer infra-red spectrophotometer (IR-Affinity-1, Shimadzu, Japan). A base line correction was made using dried potassium bromide and then spectra of dried mixtures of drug and inclusion complexes with potassium bromide were recorded.

Preparation of inclusion complexes by physical mixture method[5,6]

Inclusion complexes were prepared by physical mixture method, in this method Captopril and β-Cyclodextrin were accurately weighed in different molar ratios *viz.* 1:1 and 1:3 separately and blended thoroughly by triturating in a mortar at 20 °C for about 30 min. The powder mixtures were then pulverized through sieve no.80 and stored in desiccator till further use.

Characterization of Captopril inclusion complexes[7]

Inclusion complexes of Captopril were characterized by following analytical techniques.

Estimation of drug content

The quantities of inclusion complexes equivalent to 25 mg of Captopril were dissolved in water. Appropriate dilutions were made and filtered. The drug content of each complex was calculated.

Differential Scanning Calorimetric analysis (DSC)

The study was performed using DSC model (Mettler DSC 823, Germany). For this study, the samples were placed in a platinum crucible and the thermograms were recorded at a heating rate of 10 °C/min in the range of 20 °C to 310 °C. Inert atmosphere was maintained by purging nitrogen gas at a flow rate of 10 ml/min.

X-Ray diffraction (XRD) study

The X-Ray diffraction pattern of the selected inclusion complexes was compared with that of the pure Captopril. This was done by measuring 2ϕ in the range

of 4 to 50° with reproducibility of ±0.001° on a diffractometer (Rigaku Co. Tokyo, Japan). The XRD patterns were recorded automatically using rate meter with constant of 2×10^2 pulse /sec and with the scanning speed of 2° (2ϕ)/min.

Dissolution studies of Captopril and its inclusion complexes

The Dissolution study of inclusion complex (equivalent to 25 mg Captopril) and pure drug was performed using USP dissolution test apparatus type II with 900 ml of phosphate buffer pH 7.4. The stirring speed employed was 50 rpm, and the temperature was maintained at 37 ± 0.5 °C. 5 ml aliquots of dissolution medium was withdrawn at predetermined time intervals and replaced by same volume of fresh dissolution medium. The filtrates of the samples were analyzed for the content of drug by UV spectrophotometer at 205 nm. Cumulative percent drug released was determined at each time point.

Formulation development of fast dissolving tablets by direct compression method[8]

Fast disintegrating tablets were prepared using β-CD inclusion complex of Captopril by direct compression method. Captopril: β-CD were taken and mixed with directly compressible diluent, super-disintegrants and other excipients in a plastic container. The formula included variable amount of superdisintegrants and other excipients. The resulting powder blends were evaluated for flow parameters. The powder blends equivalent to 25 mg of drug were directly compressed into tablets using 8 mm flat- faced round punches of 8 station compression machine. The natural superdisintegrant used was *psyllium* husk powder in concentration range of 2.5 mg, 5.0 mg, 7.5 mg and 10 mg. Table No.1 gives composition of these tablet formulation. Final weight of each tablet was kept constant (200 mg) by varying the weight of MCC. The prepared tablets were evaluated for various parameters.

Pre-compression parameters[9-11]

The flow properties of the powder are vital for the performance of the tablet. Hence, the flow properties of the powder were analyzed before compression to tablets. The powder mixture of different formulation were evaluated for angle of repose, bulk density, tapped density, compressibility index, hausner's ratio, and obtained values were within the prescribed limits of IP.

Post-compression parameters[12-15]

After tablet compression, all the tablets were evaluated for different parameters as follows.

Hardness and Thickness

Hardness is a force required to break a tablet across the diameter. The tablet should be stable to mechanical stress during handling and transportation. The hardness was tested using Monsanto hardness tester. The force was measured in kilograms per centimeter square (kg/cm^2). Thickness of tablets indicates the strength to withstand compression force applied during manufacturing process. Thickness of tablets was measured by digital caliper.

Friability Test

The friability of the tablets was determined using Roche friabilator. It is expressed in percentage. The % friability was then calculated using the formula:

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{final weight}}{\text{Initial weight}} \times 100$$

Weight variation test

Twenty tablets were randomly selected from each formulation, individually weighed, the average weight and standard deviation was calculated. The percentage difference in the weight variation should be within the permissible limits (±7.5%). The total weight of tablets formulated was 200 mg.

% Drug content determination

Twenty tablets were powdered; 25 mg equivalent weight of Captopril in tablet powder was accurately weighed and transferred into a 100 ml volumetric flask. Initially, 50 ml of phosphate buffer (pH 7.4) was added and shaken for 10 min. Then, the volume was made up to 100 ml with phosphate buffer. The solution in the volumetric flask was filtered, diluted suitably and analyzed spectrophotometrically at 205 nm. The drug content in each tablet was calculated using the standard calibration curve of Captopril in phosphate buffer pH 7.4 solution.

***In-vitro* dispersion time**

Tablet was added to 10 ml of phosphate buffer solution pH 7.4 (pH of saliva) in a petridish at 37±0.5°C. Time

required for complete dispersion of tablet was measured.

Wetting time and Water absorption ratio

Wetting time of dosage form is related to the contact angle. It needs to be assessed to give an insight into the disintegration properties of the tablets; a lower wetting time implies a quicker disintegration of the tablet. For this purpose, a piece of tissue paper folded twice is placed in a small petridish containing 6 ml of water. Eosin, a water soluble dye, is added to petridish. A tablet is kept on the paper and the time for complete wetting is measured. Water absorption ratio, R is then determined according to the following equation.

$$R = 100 \times (wa - wb) / wb$$

Where,

wb and wa are tablet weights before and after water absorption.

***In-vitro* drug release**

The *in-vitro* dissolution study was carried out using USP dissolution test apparatus type II. The dissolution medium consisted of 900 ml of pH 7.4 phosphate buffer solution maintained at 37 ± 0.5 °C and stirred at 50 rpm. Aliquot samples (5 ml) were withdrawn every minute, filtered through a 0.45 μm membrane filter and replaced by an equivalent volume of fresh dissolution medium. The samples were suitably diluted with phosphate buffer pH (7.4) and the amount of the drug dissolved was analyzed spectrophotometrically at 205 nm. The cumulative percentage drug release was calculated.

Stability studies[16,17]

Accelerated stability studies were performed for 6 months as per ICH guidelines. The optimized formulation (F4) was kept at 40 ± 2 °C and 75 ± 5 % RH. Physical appearance, hardness, % drug content, *In-vitro* dispersion time and *In-vitro* drug release were fixed as parameters for stability testing.

RESULTS AND DISCUSSION

Drug -polymer compatibility by FTIR studies

The IR spectral analysis of Captopril and the physical mixture of Captopril and other excipients are presented in Figure No.1 to 2 respectively. Pure Captopril spectra showed principal peaks at different wave numbers corresponding to its functional groups, confirming the purity of the drug as per established standards. The IR spectra of Captopril exhibited peak at 3000 cm^{-1} 1747 cm^{-1}, 1041 cm^{-1}, 2877 cm^{-1} (O-H Stretching, C=O Stretching, C−N Stretching, C−H Stretching). The IR spectra of β-CD showed prominent absorption bands at 3377 cm^{-1} (O-H stretching). The FTIR spectra of inclusion complexes seemed to be only summation of drug and β-CD spectra. This result suggested that there was no chemical interaction between drug and β-CD in their combination. All the above characteristic peaks appear in the spectra of physical mixture of inclusion complex of Captopril and other excipients, indicating no modification or interaction between the drug and excipients.

Characterization of Captopril inclusion complexes

Estimation of drug content:

The drug content of Captopril inclusion complex with different ratio (1:1, 1:3) was found to be 99.54 ± 0.56 % to 99.97 ± 1.09 % respectively. The drug content of Captopril inclusion complexes was shown in Table No.2.

Differential Scanning Calorimetric analysis (DSC)

The DSC thermogram of pure Captopril showed sharp endothermic peaks at 109°C (Figure No.3). The absence of sharp endothermic peak in Captopril-β-CD inclusion complexes (Figure No.4) suggesting complete complex formation.

X-Ray diffraction (XRD) study

Captopril in pure form and inclusion complex of drugs with β-CD prepared by physical mixture was subjected to XRD analysis and the results were depicted in Figure No.5 and 6. From the figure, it was evident that diffraction pattern of the pure drug shows its highly crystalline nature indicated by numerous distinctive peak. On the other hand XRD of inclusion complex showed significant decrease in degree of crystallinity as evident from disappearance of sharp distinctive peaks, suggesting probable transformation of crystalline form into an amorphous state.

Dissolution

The Captopril and inclusion complex of different ratio (1:1, 1:3) were evaluated for *in-vitro* dissolution studies in pH 7.4 buffer and the results were shown in the Table No.3. The release of Captopril was increased with increasing concentration of β-CD with pure drug as standard.

Formulation developments

Fast disintegrating tablets of Captopril were prepared by complexation technique using direct compression method and by using an 8 mm flat- faced punch of 8 station compression machine. *Psyllium* husk powder was used as superdisintegrants. MCC and mannitol was used as diluent. Magnesium stearate and talc were added to the above blend as flow promoters.

Evaluation of Captopril fast dissolving tablets

Pre-compression parameters

The powder blends were also evaluated for various pre-compression parameters. The results were shown in Table No.4. Bulk densities of powder blends were found between 0.44 ± 0.01 to 0.46 ± 0.01 gm/ml. Tapped densities of powder blends were found between 0.51 ± 0.01 to 0.53 ± 0.01 gm/ml. The angle of repose values varied from 26.39 ± 1.09 to 28.93 ± 0.59. Carr's index values were found to be in the range of 12.65 ± 1.0 to 13.82 ± 0.86 %. Haunser's ratio values were found to be in the range of 1.14 ± 0.01 to 1.15 ± 0.005. From these values it was evident that all these blends had excellent flow properties.

Post-compression parameters

The formulated tablets were evaluated for various post-compression parameters. The results were shown in Table No.5. The thickness of the batch from F1-F4 was found to be in the range of 3.63 ± 0.04 to 3.84 ± 0.09 mm. The hardness was uniformly maintained for all formulation and it was found to be 3.83 ± 0.258 to 3.91 ± 0.2 kg/cm^2. Thus, tablets were having good mechanical strength. The friability of all the formulated tablets of Captopril was found to be in the 0.39 to 0.60 %. The weight variation and percentage deviation from the average weight were found to be within (±7.5) the prescribed official limits.

% Drug content

The drug content of all the formulations of Captopril fast disintegrating tablets were found to be within the range of 99.64 ± 0.81 to 100.30 ± 1.01 % which were within the limits of IP specifications. The drug content of all the formulations of Captopril tablets was shown in Table No.6.

***In-vitro* dispersion time**

All the formulated tablets (F1-F4) were evaluated for *in-vitro* dispersion time and it was found to be 41.33 ± 1.21 to 54.83 ± 3.37 sec. The results were showed in table 6. Photographs of *in-vitro* dispersion time were shown in Figure No.7.

Wetting time

The wetting time of all the formulations (F1-F4) were found to be within 1.30 ± 2.12 to 1.55 ± 2.78 mins, which complies with the official specifications. The results were showed in Table No.6. Photographs of wetting time of formulation F4 was shown in Figure No.8.

Water absorption ratio

The water absorption ratio of all the formulated batches was found to be in the range 73.38 ± 2.00 to 91.60 ± 2.06 which was satisfactory in giving effective and better formulations of fast disintegrating tablets. The results were shown in Table No.6.

***In-vitro* dissolution study**

The tablets were evaluated for *in-vitro* dissolution studies in pH 7.4 buffer and the results were shown in the Table No.7 and in the Figure No.9. All formulations were formulated by using *psyllium* husk in varying concentration of 2.5 mg, 5.0 mg, 7.5 mg, 10 mg respectively. The *in-vitro* release of Captopril from fast disintegrating tablets was found to vary according to the type and ratio of superdisintegrants used. The release of Captopril was increased with increasing concentration of *psyllium* hush.

The percentage of the drug released from the formulations F1, F2, F3, F4 was found to be 100.21 ± 0.66 %, 99.94 ± 1.19 %, 99.66 ± 0.12 %, and 99.84 ± 0.18 % respectively. More than 90% of the drug was released from F1-F4 was found that in between 4-10 mins.

Among the different formulation the F4 10 mg *Psyllium* husk powder showed 90 % drug release within 4 min. These results suggested that *Psyllium* husk powder have faster disintegrating effect than guar gum.

Various dissolution parameters values *viz.*, Percent drug dissolved in 5 and 10 min (D_5 and D_{10}), Time taken to dissolve the 50%, 70% and 90% drug (t_{50}, t_{70}, t_{90} respectively) were given in the Table No.8. From the results it was observed that percent drug dissolves was increased by increasing the concentration of superdisintegrant and t_{50}, t_{70}, t_{90} values decreased with

increase in the concentration of *Psyllium* husk powder. From the dissolution parameter it was evident that the formulation F4 achieved maximum dissolution efficiency of 99.84 for D_5 and 100 % for D_{10} and lowest t_{50}, t_{70}, t_{90} values of 1.30 min, 3.0 min and 5.18 min respectively.

Stability studies

Accelerated Stability studies were carried out at 40 ± 2°C and 75 ± 5 % RH for the optimized formulation F4 and monitored for physical appearance, hardness, drug content, *in-vitro* dispersion time and dissolution profile study and found to stable for all the different parameters. The results are shown in Table No.9.

Table No.1: Formulation design of Captopril fast disintegrating tablets

S.No	Ingredients (mg)	F1	F2	F3	F4
1	Captopril and β – cyclodextrin (1:3)equivalent to 25 mg Captopril	100	100	100	100
2	*Psyllium* husk	2.5	5.0	7.5	10
3	MCC	57.5	55	52.5	50
4	Mannitol	30	30	30	30
5	Aspartame	10	10	10	10
6	Magnesium stearate	2	2	2	2
7	Talc	2	2	2	2
8	Total weight	200	200	200	200

Table No.2: % Drug content of inclusion complex

S.No	Ratio of drug and β-cyclodextrin	% drug content
1	1:1	99.54±0.56
2	1:3	99.97±1.09

Table No.3: *In-vitro* dissolution study of inclusion complex and pure drug

S.No	Time (min)	Pure drug %	% Cumulative drug release	
			1:1	1:3
1	0	0	0	0
2	0.5	1.28±1.42	1.51±1.11	2.53±0.67
3	1	5.32±1.08	7.82±1.25	12.87±0.85
4	2	12.2±0.78	14.57±1.02	20.55±1.19
5	4	27.55±1.18	28.64±0.90	35.53±1.68
6	6	44.88±0.91	49.25±0.76	54.21±1.05
7	8	52.44±0.56	54.56±0.81	61.47±0.64
8	10	66.79±1.19	69.12±0.89	74.16±0.94

Table No.4: Pre compression parameters of Captopril tablets

S.No	Formulation Code	Bulk density (g/cc)	Tapped Density (g/cc)	Angle of repose (ɵ)	Carr's index %	Hausner's ratio
1	F1	0.45±0.00	0.53±0.01	28.15±0.85	13.82±0.86	1.15±0.01
2	F2	0.44±0.01	0.51±0.01	27.97±0.54	13.64±0.40	1.15±0.005
3	F3	0.44±0.01	0.51±0.01	27.17±0.53	13.64±0.40	1.15±0.005
4	F4	0.46±0.01	0.51±0.01	26.39±1.09	12.65±1.0	1.14±0.01

Value expressed as mean ±SD, n=3

Table No.5: Post compression parameters of Captopril tablets

S.No	Formulation Code	*Hardness (kg/cm^2)	*Thickness (mm)	Friability (%)	**Weight Variation (%)
1	F1	3.91±0.204	3.63±0.047	0.40	0.042±0.69
2	F2	3.91±0.204	3.75±0.072	0.60	0.065±0.77
3	F3	3.83±0.258	3.84±0.095	0.52	0.019±0.78
4	F4	3.91±0.204	3.74±0.127	0.39	0.062±0.92

Value expressed as mean ±SD,* n=6, **n=20

Table No.6: Results of % drug content *In vitro* dispersion time, wetting time and water absorption ratio of Captopril tablets

S.No	Formulation Code	% Drug content	*In vitro* dispersion time (sec)	Wetting time (min)	Water absorption ratio (%)
1	F1	99.64±0.81	48.0±3.21	1.55±2.78	73.38±2.00
2	F2	100.30±1.01	54.83±3.37	1.40±2.08	77.99±1.56
3	F3	100.05±1.31	43.66±1.36	1.34±1.91	83.18±2.43
4	F4	100.12±0.97	41.33±1.21	1.30±2.12	91.60±2.06

Value expressed as mean ±SD, n=3

Table No.8: *In-vitro* dissolution parameters of different formulations

S.No	Formulation	DE_5 (%)	DE_{10} (%)	T_{50} (min)	T_{70} (min)	T_{90} (min)
1	F1	45.87	95.46	5.30	7.30	9.30
2	F2	54.04	98.72	4.48	6.54	9.54
3	F3	87.4	100	2.24	3.24	7.0
4	F4	99.84	100	1.30	3.00	5.18

DE_5= Percent drug dissolved in 5 min, DE_{10}= Percent drug dissolved in 10 min
t_{50} =Time taken to dissolve 50% of the drug, t_{70} =Time taken to dissolve 70% of the drug and
t_{90} =Time taken to dissolve 90% of the drug.

Table No.9: Stability studies for the formulation F4

S.No	Specification	Parameters	Time (months)		
			0	3	6
1	40±2 °C and 75±5% RH	Hardness* (kg/cm^2)	3.91±0.204	3.91±0.35	3.94±0.28
		Drug content** (%)	100.12±1.21	100.09±0.12	100.07±0.16
		Dispersion** time(sec)	41.33±0.97	41.29±1.12	41.48±1.16
		Cumulative % drug release**	99.84±0.18	99.81±0.24	99.78±0.31

Value expressed as mean ±SD, *n=6, **n=3

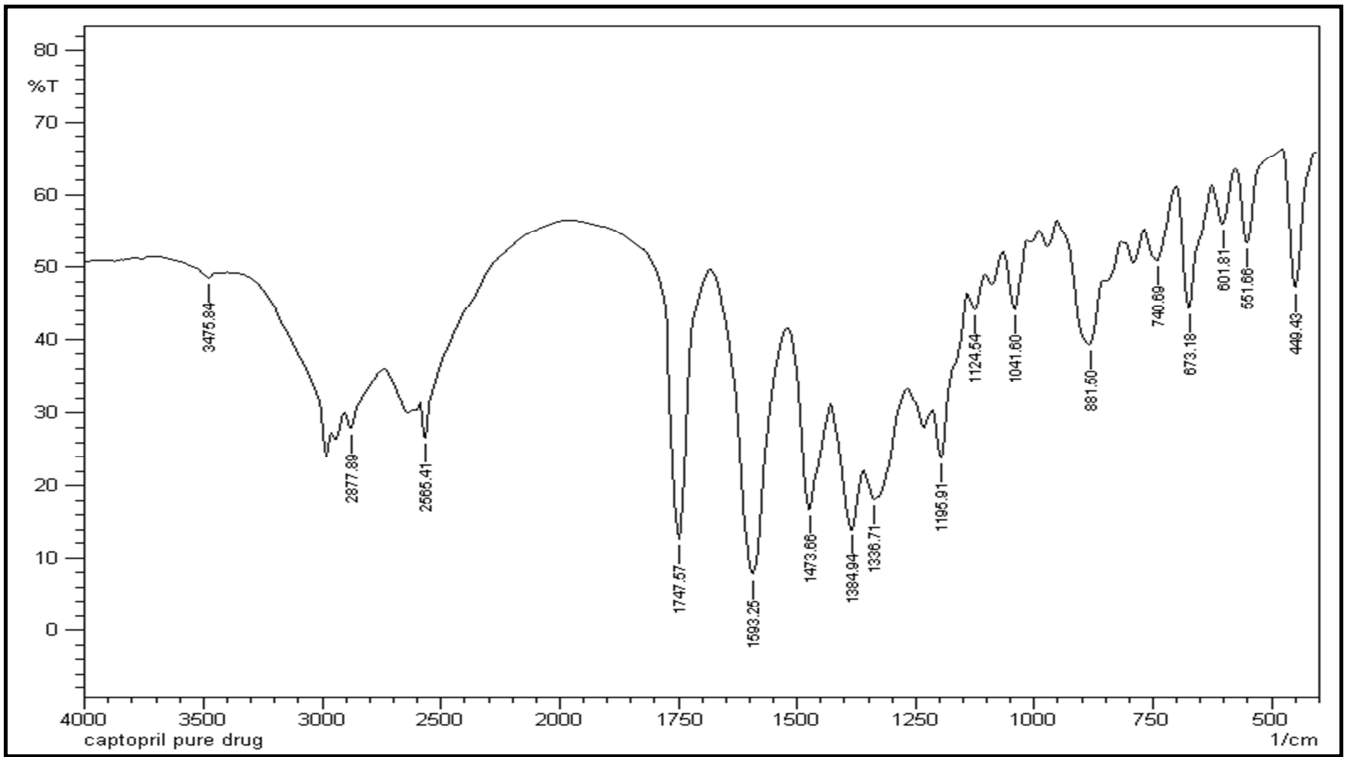


Figure No.1: IR spectra of Captopril

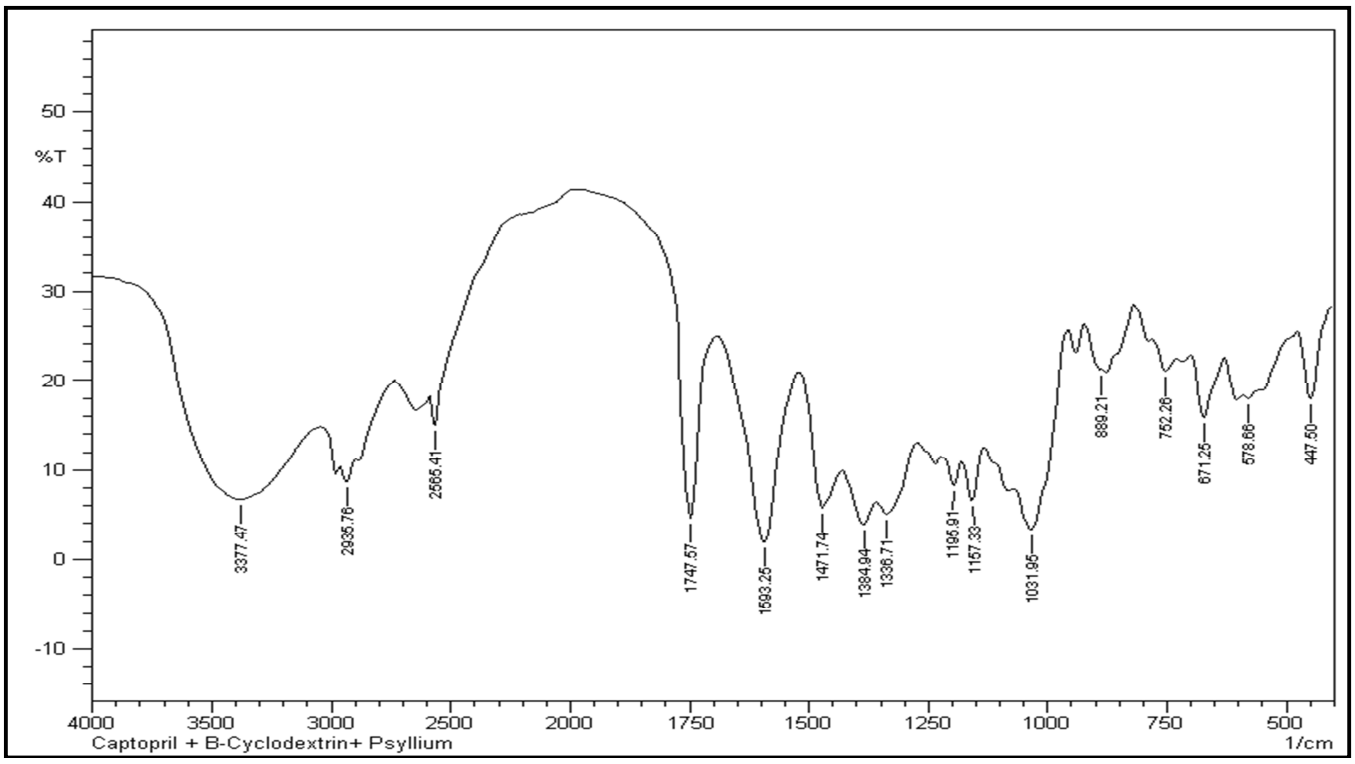


Figure No.2: IR spectra of Captopril, β-cyclodextrin and *Psyllium* husk powder

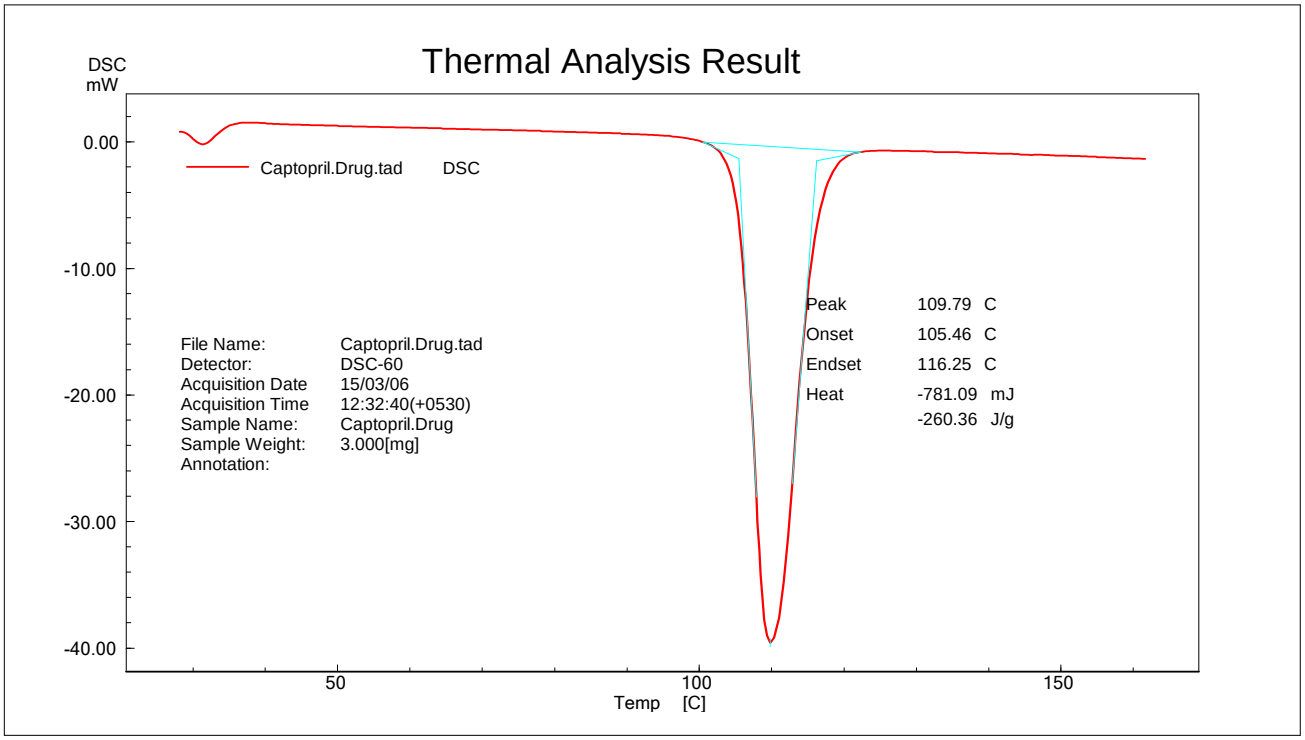


Figure No.3: DSC thermo graph of pure drug Captopril

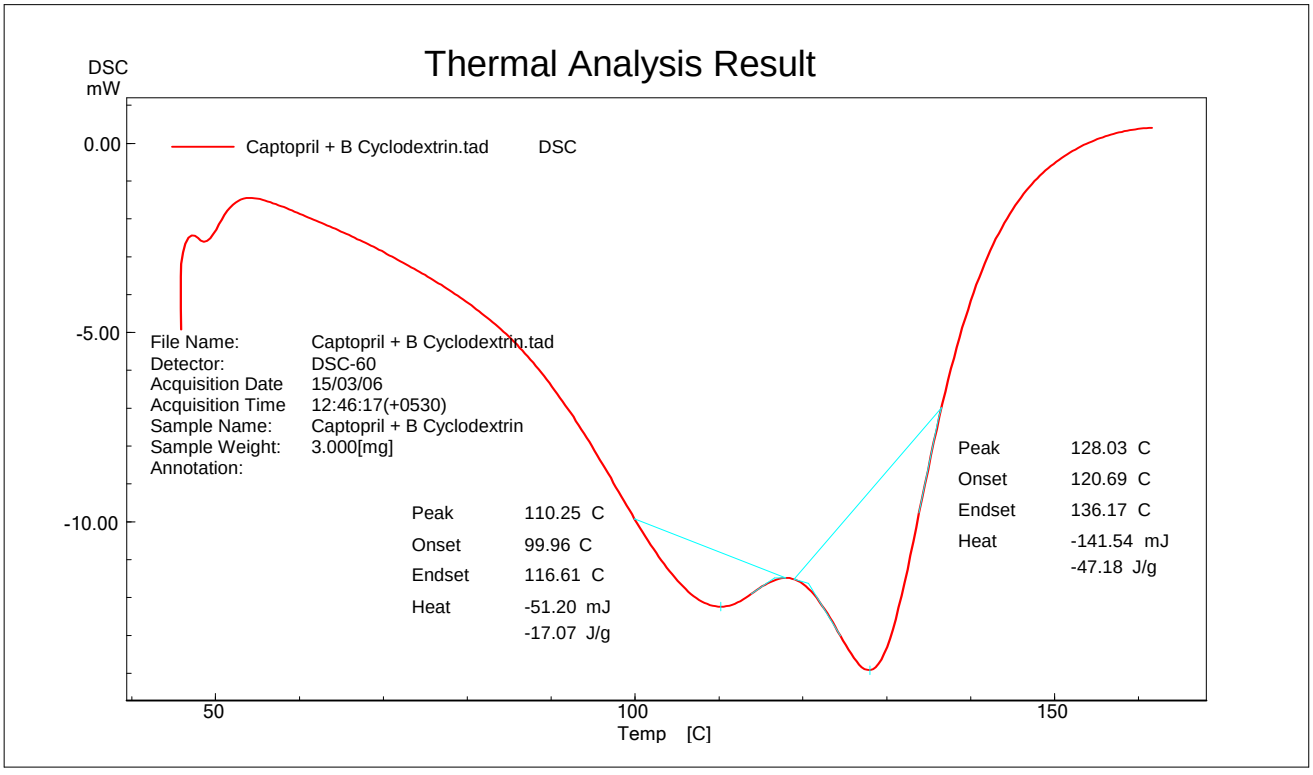


Figure No.4: DSC thermo graph of pure drug and β-cyclodextrin

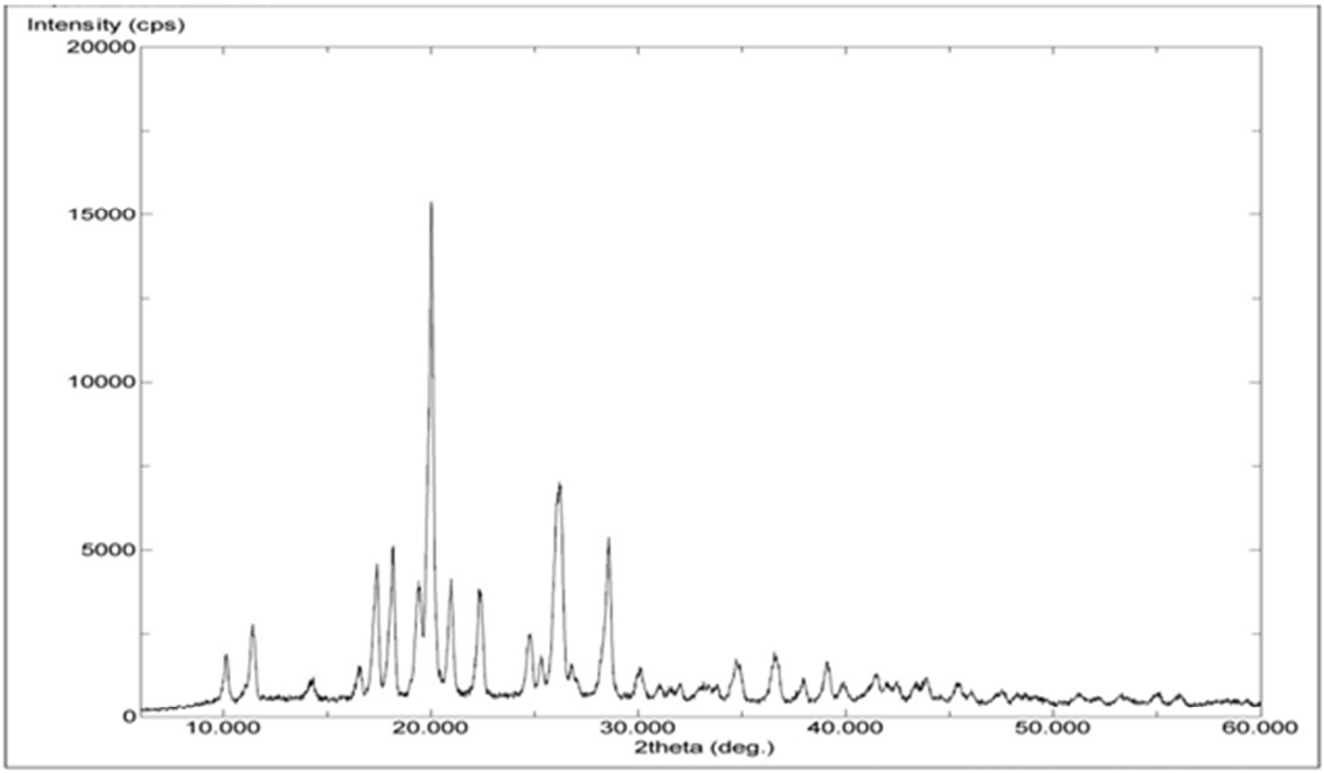


Figure No.5: X-Ray diffraction pattern study of Captopril

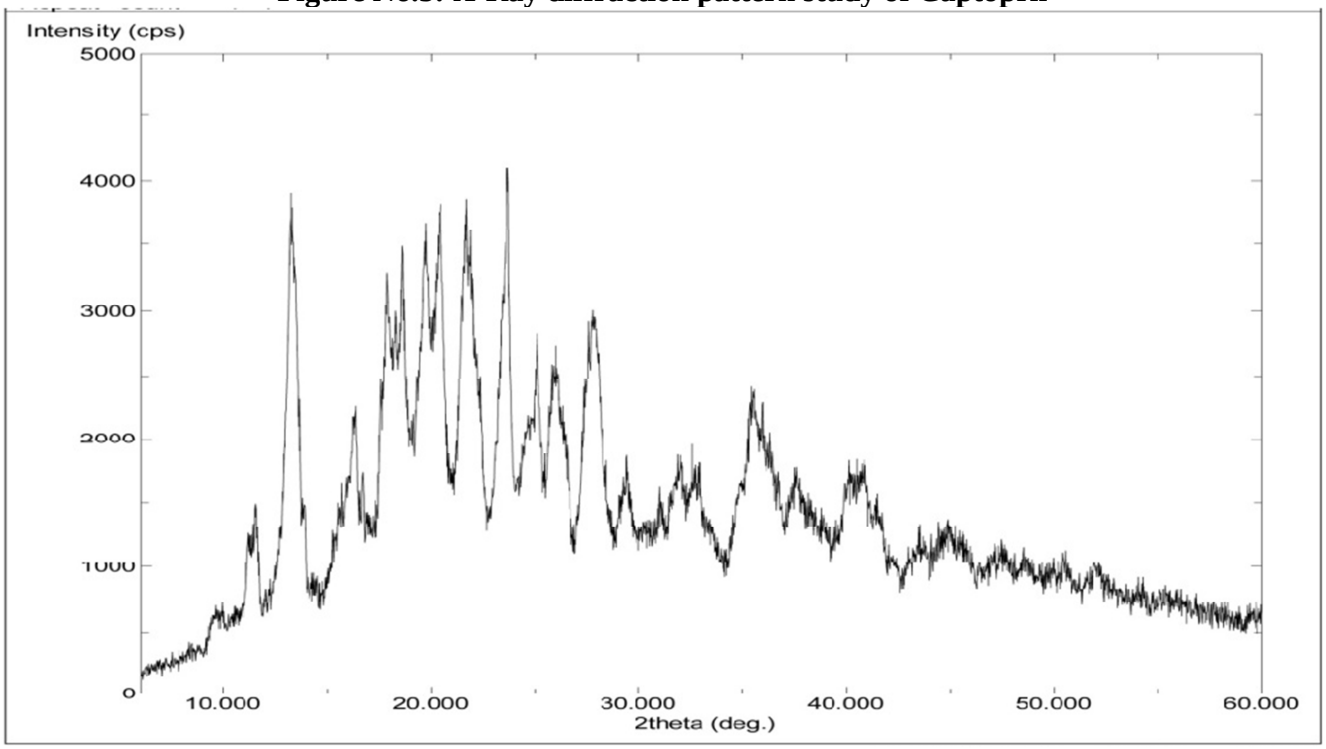
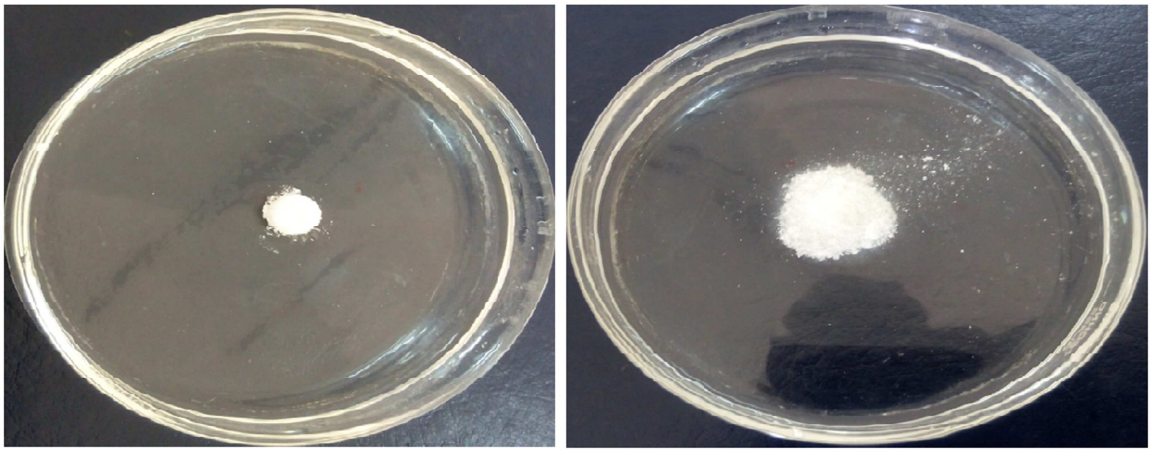
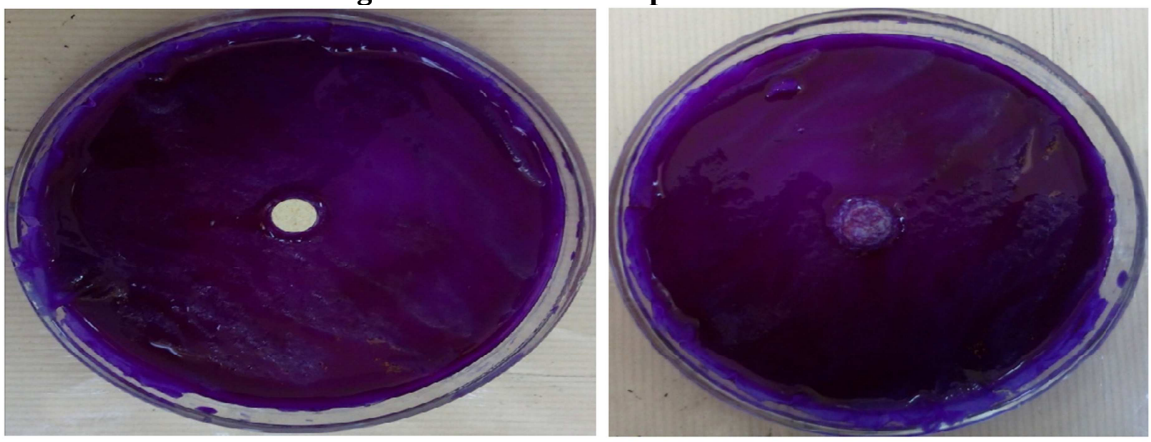


Figure No.6: X-Ray diffraction pattern study of Captopril and β-cyclodextrin



at 5 sec at 41.33 sec

Figure No.7: *In-vitro* dispersion of F4



at 0 min at 1.3 min

Figure No.8: Wetting of formulation F4

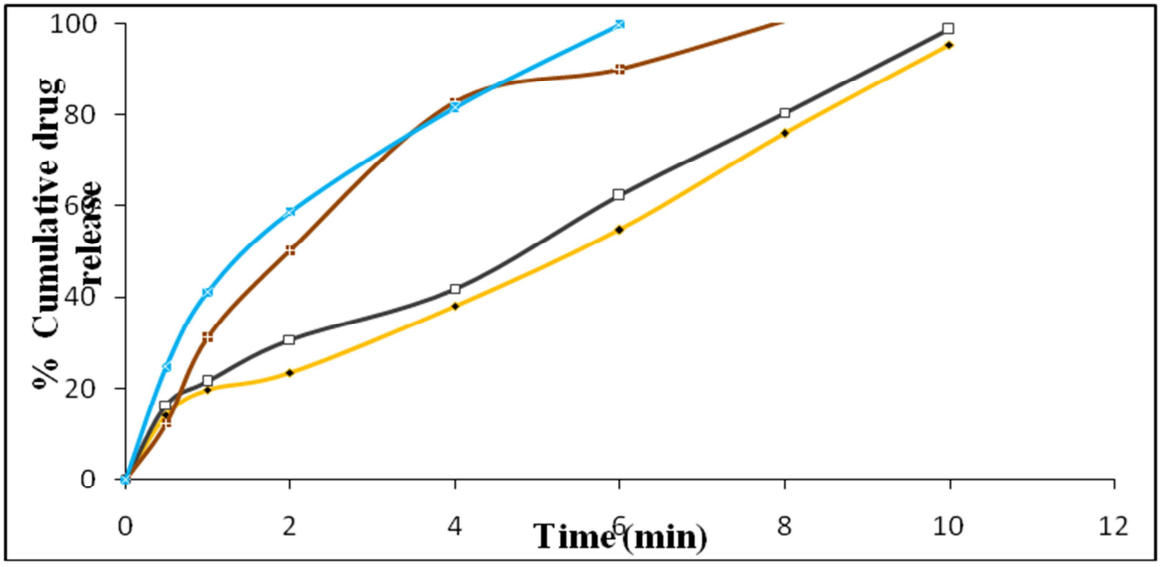


Figure No.9: *In-vitro* release profile of formulation F1-F4

CONCLUSION

The tablets were evaluated for various parameters like hardness, thickness, friability, weight variation, % of drug content, wetting time, water absorption ratio, *in-vitro* dispersion time, *in-vitro* dissolution studies confirmed that the results were within the specified limits. The *in-vitro* release of Captopril from fast disintegrating tablets was found to vary according to the type and concentration of disintegrants used. The drug release was increased with increasing disintegrants concentration. Among all the formulation, the formulation F4 was showed 99.84 ± 0.18 % drug release within 4 min and it showed dispersion time 41.33 ± 1.21 sec. Stability studies of selected formulation F4 showed that, negligible changes in hardness, % drug content, *in-vitro* dispersion time and *in-vitro* drug release revealed that the tablets were stable on storage condition. From the present study, it can be concluded that natural superdisintegrants like *psyllium* husk showed better disintegrating property.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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