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DESIGN AND *IN-VITRO* EVALUATION OF FAST DISINTEGRATING TABLETS OF AN ANTIHYPERTENSIVE DRUG

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Abstract:
Aim:The aim of the work was an attempt to make the formulation of fast disintegrating tablets of Diltiazem HCl by direct compression method with the aid of superdisintegrants addition.
Method: Fast disintegrating tablets of Diltiazem HCl were prepared by direct compression method. Nine formulations were developed by using three different superdisintegrants in varying concentrations in such a way that total weight of the tablet remains same. The drug-polymer incompatibility was ruled out by FTIR studies. All the formulated tablets were subjected for pre and post-compression evaluation parameters. A comparison of in vitro drug release of optimized formulation (DF9) was compared with marketed product (Dilzem).
Result: From the FTIR studies, the drug-polymers compatibilities were confirmed. All the formulated tablets were showing satisfactory results which comply with the official limits.
Conclusion: Among the nine formulations, the formulation containing 4.5% crospovidone (DF9) showed highest drug release of 95.72% as compared to other formulations. A comparison of in vitro drug release was made with marketed product of Diltiazem HCl (Dilzem) which shows 92.53% drug release in 1 hour. From this study we can make the conclusion that the formulated tablets of Diltiazem HCl containing crospovidone are better and effective than conventional tablets to meet patient compliance along with fast relief from hypertention and angina.
Keywords: *Formulation; FTIR studies; In vitro drug release; Diltiazem HCl; Fast disintegrating tablets; Superdisintegrant etc.*

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INTRODUCTION:

Oral drug delivery system is the most convenient form of drug delivery, having the largest degree of patient compliance. Tablet is the most preferred dosage form of oral drug delivery system among all dosage forms existing today because of its convenience of self-administration, compactness and easy manufacturing [1]. Many patients find it inconvenience to swallow tablets and capsules and do not take their medication as prescribed. It is estimated that 50% of the population is affected by this problem which result in a high incidence of non-compliance and ineffective therapy. The difficulty is occurred individually by pediatric and geriatric patients, but it also applies to people who are bedridden and to those active working patients [2].

A FDT is a tablet that dissolves or disintegrates in the oral cavity without requirement of water as well as chewing. The active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients [3]. These are also called melt-in-mouth tablets; repi melts, porous tablets, orodispersible, quick dissolving or rapid disintegrating tablets [4].

One important drawback of this conventional dosage forms for some patients, is the difficulty to swallow, drinking water plays an important role in the swallowing of oral dosage forms. Often sometimes people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (Kinetosiss) and sudden episodes of coughing during the common cold, allergic condition and bronchitis [5].

Antihypertensive drugs like Propranolol, Metoprolol, Oxprenolol, Diltiazem hydrochloride have the oral problems like difficulty in swallowing, less oral bioavailability, first pass metabolism in conventional tablet dosage forms. To overcome such problems the antihypertensive drugs can be formulated in the form of fast disintegrating tablets where the drug is rapidly disintegrated in mouth within fraction of seconds and improves the oral drug bioavailability. Fast disintegrating tablets can be prepared by methods like direct compression, wet granulation, sublimation, effervescent methods along with superdisintegrants to increase in vitro dispersion time. Some of the newer methods to formulate quick release dosage forms include Zydis, Orasolv, Flashtab, Wowtab, oraquick, Ziplet, etc.

Diltiazem hydrochloride is a Antihypertensive drug, which undergoes extensive hepatic degradation, which have poor bioavailability (40%) for overcoming this problem fast disintegrating tablets of Diltiazem hydrochloride can be formulated which avoids extensive first pass metabolism and improvement in dissolution efficacy, disintegration time which results in improvement in bioavailability. This formulation can be effectively used in case of hypertensive patients as it can be administered without the intake of water. Therefore the main objective of the present work is to develop fast disintegrating tablets for Diltiazem hydrochloride to improve bioavailability, disintegration time, dissolution efficacy and patient compliance. [6-9]

Hence, in the present study an attempt has been made to formulate fast disintegrating tablets of Diltiazem HCl by direct compression method using three superdisintegrants sodium starch glycolate, (SSG) crosscarmellose sodium and crospovidone, microcrystalline cellulose (MCC) as diluent with other excipients like sweetener and flavour with a view to develop a convenient means of administration to those patients suffering from difficulties in swallowing.

MATERIAL AND METHODS:

Materials: Diltiazem Hydrochloride procured from Srushti Pharmaceutical, Bangalore, India. Crospovidone from Shreeji chemicals, Mumbai. Sodium starch glycolate, Mannitol, Magnesium stearate, Ammonium bicarbonate are from S.D. Fine Chemicals Limited, Mumbai. Microcrystalline Cellulose, Croscarmellose Sodium from S.D. Fine Chemicals Limited, Mumbai. The materials used in the present investigation were either AR/ LR grade or the best possible pharma grade.

METHODS

Preformulation studies

Preformulation testing is the first step in the rationale development of dosage forms of a drug substance. It can be defined as an investigation of physical and chemical properties of a drug substance alone and when combined with excipients. It gives extensive information to bring out good quality at high standard at which optimal dosage desired. Preformulation studies were performed on the drug (API), which included melting point determination, solubility and compatibility studies.

The following preformulation studies were performed for Diltiazem HCl and polymers;

Determination of solubility: Solubility of Diltiazem HCl was performed in solvents water and methanol.

Determination of melting point: Melting point of pure Diltiazem HCl was determined by open capillary method. The capillary tube was closed at one end by fusion and was filled with Diltiazem hydrochloride by repeated tapings. The capillary tube was placed in a digital melting point apparatus. The instrument was set to automatically increase the temperature of the heating bath at a rate of 100ºC min rise of temperature per minute. The rise in temperature was viewed through magnifying lens. The temperature at which the drug started melting was recorded. This was performed thrice and the average value was calculated.

Determination of λ_{max}: A solution of Diltiazem HCl containing conc. 10µg/ml was prepared in phosphate buffer pH 6.8 and UV spectrum was taken using Shimadzu (UV-1800) spectrophotometer. The solution was scanned in the range of 200-400nm.

Formulation development: In this work, direct compression method with the aid of superdisintegrants was attempted for the formulation development of fast disintegrating tablets of Diltiazem HCl. The Diltiazem HCl tablets are available in 30mg, 60mg and 120mg doses in the market. Dose of 30 mg is selected for the present study.

Development of the formulation in the present study was mainly based on the type and concentration of polymers and the properties of the drug. Various polymers in different concentrations (1.5%, 3% and 4.5%) were used so as to get tablets with good physical properties. The formulation design of fast disintegrating tablets of Diltiazem HCl is shown in Table 1

Table 1: Formulation design of Diltiazem HCl fast disintegrating tablets

Ingredients(mg)	**DF1**	**DF2**	**DF3**	**DF4**	**DF5**	**DF6**	**DF7**	**DF8**	**DF9**
Diltiazem HCl	30	30	30	30	30	30	30	30	30
SSG	3	6	9	-	-	-	-	-	-
Crosscarmellose	-	-	-	3	6	9	-	-	-
Crospovidone	-	-	-	-	-	-	3	6	9
Aspartame	10	10	10	10	10	10	10	10	10
Raspberry flavour	3	3	3	3	3	3	3	3	3
Talc	10	10	10	10	10	10	10	10	10
Magnesium stearate	2	2	2	2	2	2	2	2	2
MCC	50	50	50	50	50	50	50	50	50
Lactose	92	89	86	92	89	86	92	89	86
Total weight	200	200	200	200	200	200	200	200	200

Manufacture of Diltiazem HCl fast disintegrating Tablets

Diltiazem HCl fast disintegrating tablets were manufactured in nine formulations DF1 to DF9 using the ingredients mentioned in the Table keeping the total weight (200 mg) of the tablet constant in all the formulations. The drug and the excipients were passed through #60-sieve. Weighed amount of drug and excipients except magnesium stearate were mixed in a polybag by geometric addition method for 20 minutes manually. The blend was then lubricated by further mixing with magnesium sterate (#60-sieve). The mixture blend was subjected for drying to remove the moisture content at 40 to 45ºC, the mixture was blended with flavor and the powder blend was then compressed on 10-station rotary punching machine using flat faced punches. Round punches measuring 8 mm diameter were used for compression of tablets.

RESULTS:

PREFORMULATION STUDIES

Determination of solubility

Diltiazem HCl was found to be freely soluble in water and methanol.

Determination of melting point

The melting point of Diltiazem HCl was found to be in the range of 215ºC.

Determination of λ_{max}

Table 2: Wavelength of maximum absorption of Diltiazem HCl in phosphate bufferpH6.8

SR. No.	Solvent	λ_{max}
1	Phosphate buffer pH 6.8	236

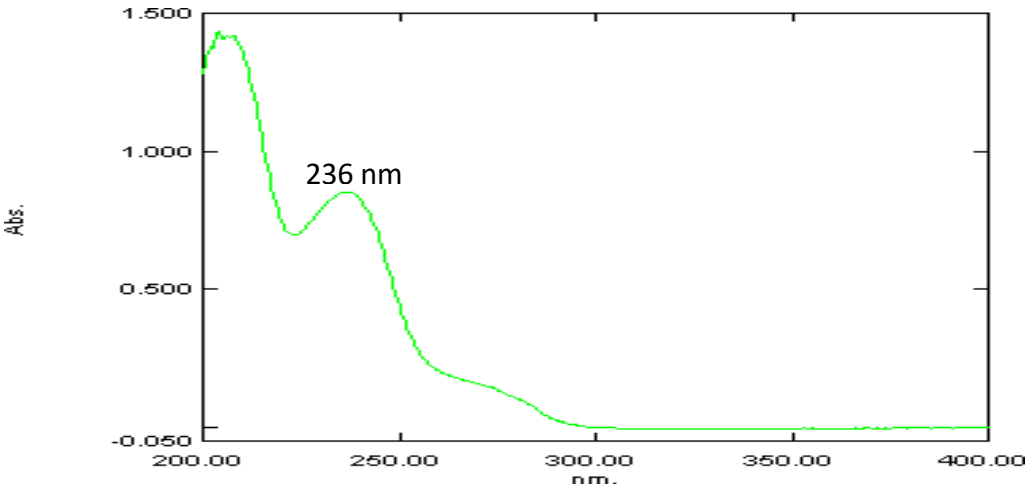

Fig. 1 UV spectra of Diltiazem HCl in phosphate buffer pH 6.8

EVALUATION PARAMETERS OF DILTIAZEM HCL TABLETS

❖ **Drug–polymer compatibility by FTIR studies**

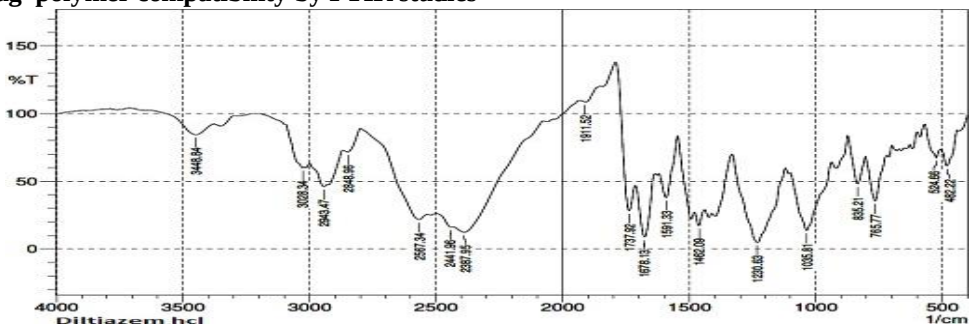

Fig. 2 IR spectra of Diltiazem HCl

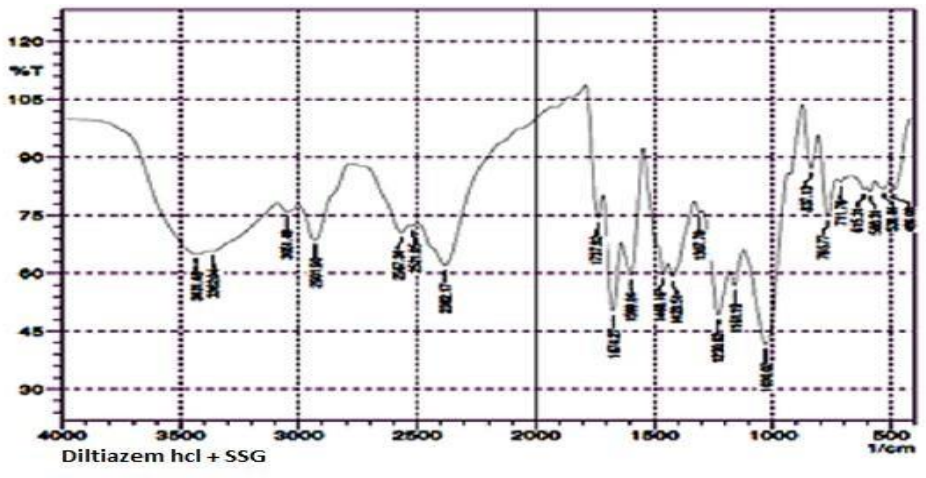

Fig 3 IR spectra of physical mixture of Diltiazem HCl and SSG

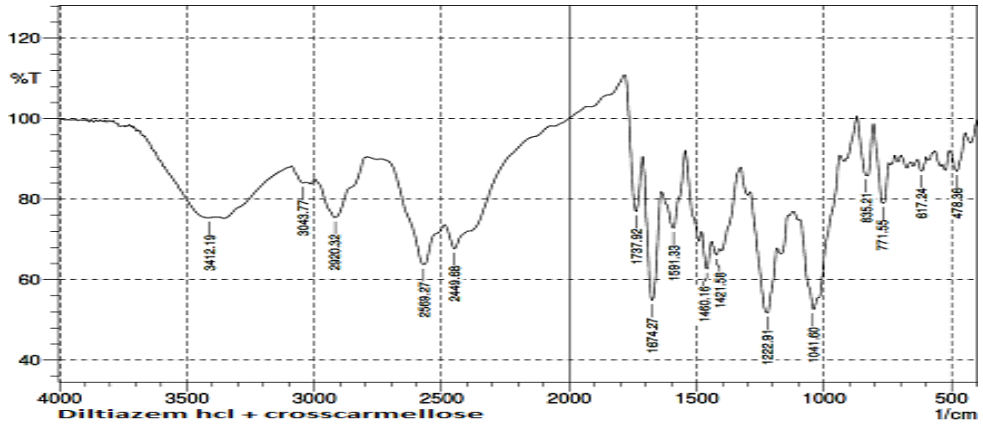

Fig. 4 IR spectra of physical mixture of Diltiazem HCl andCrosscarmellose sodium

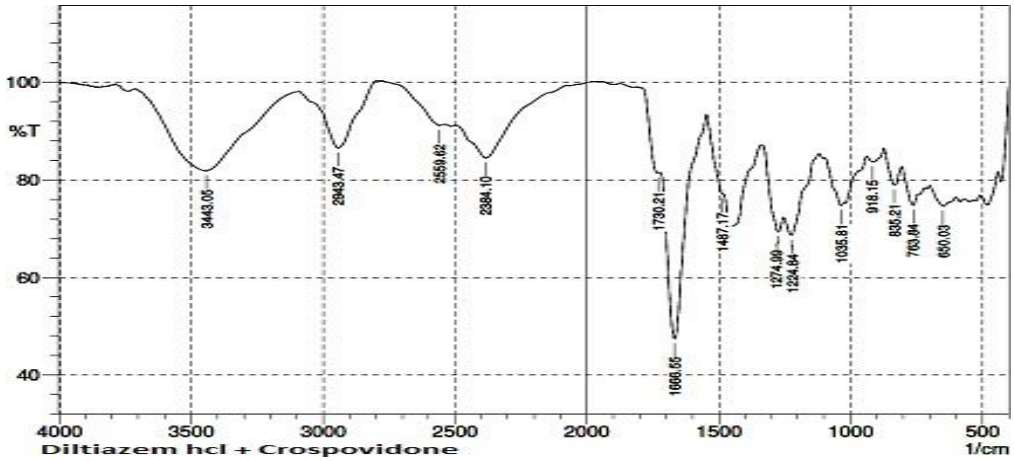

Fig. 5 IR spectra of physical mixture of Diltiazem HCl and Crospovidone

Table 3: FTIR Spectra data of drug and polymers

SR. No.	IR Spectrum	Peaks cm^{-1}	Groups	Stretching / Deformation
1	Diltiazem HCl	3448.84	N-H	Stretching
		3028.34	C-H Aromatic	Stretching
		2567.34	S-H	Stretching
		1230.63	C-N	Stretching
2	Physical mixture of Diltizem HCl and SSG	3051.49	C-H Aromatic	Stretching
		2567.34	S-H	Stretching
		1737.92	C=O	Stretching
		1674.27	C=C	Stretching
3	Physical mixture of Diltiazem HCl and Crosscarmellose sodium	3043.77	C-H Aromatic	Stretching
		2569.27	S-H	Stretching
		1737.92	C=O	Stretching
		1674.27	C=C	Stretching
4	Physical mixture of Diltiazem HCl and Crospovidone	3443.05	N-H	Stretching
		2943.47	C-H Aromatic	Stretching
		2559.62	S-H	Stretching
		1666.55	C=C	Stretching

❖ **Physical parameters of drug and superdisintegrants**

Table 4: Physical parameters of drug and polymers

Drug/Polymer	Bulk density(g/cc)	Tapped density(g/cc)	Angle of repose(ɵ)	Carr's index	Haunser ratio
Diltiazem HCl	0.52	0.43	22º 70'	18.85	1.19
SSG	0.54	0.41	25º 22'	17.28	1.24
Croscarmellose	0.55	0.43	24º 65'	19.51	1.13
Crospovidone	0.51	0.45	20º 58'	18.17	1.28

EVALUATION OF DILTIAZEM HCL TABLETS

Table 5: Precompression parameters of Diltiazem HCl tablets

Formulation Code	*Angle of repose (ɵ)	*Bulk density(g/cc)	*Tapped density (g/cc)	*Carr's index	*Haunser ratio
DF1	22.50±0.14	0.53±0.01	0.64±0.17	13.72±0.10	1.14±0.02
DF2	19.86±0.19	0.51±0.12	0.67±0.02	15.26±0.14	1.27±0.15
DF3	21.43±0.24	0.56±0.26	0.69±0.25	19.35±0.27	1.12±0.08
DF4	18.27±0.32	0.52±0.09	0.65±0.01	14.61±0.12	1.23±0.11
DF5	20.18±0.10	0.55±0.11	0.68±0.38	18.51±0.02	1.15±0.05
DF6	15.34±0.16	0.54±0.03	0.66±0.41	14.63±0.15	1.24±0.19
DF7	19.59±0.18	0.57±0.22	0.63±0.08	17.81±0.07	1.16±0.01
DF8	18.45±0.11	0.54±0.35	0.61±0.52	15.65±0.59	1.18±0.03
DF9	16.25±0.31	0.56±0.18	0.66±0.19	12.48±0.16	1.13±0.18

*Value expressed as mean ±SD, n=3

Table 6: Results of thickness, hardness, friability and weight variation of DiltiazemHCl tablets

Formulationcode	*Thickness (mm)	*Hardness (kg/cm^2)	Friability(%)	Weight variation
DF1	2.59±0.03	3.2±0.22	0.32	201.68±0.12
DF2	2.67±0.10	3.4±0.56	0.27	199.25±0.35
DF3	2.56±0.02	3.1±0.89	0.31	200.72±0.41
DF4	2.74±0.15	3.3±0.45	0.38	202.36±0.76
DF5	2.65±0.01	3.5±0.01	0.21	200.83±0.89
DF6	2.68±0.05	3.1±0.76	0.39	199.55±0.11
DF7	2.70±0.11	3.2±0.51	0.31	201.21±0.57
DF8	2.76± 0.07	3.1±0.30	0.28	200.47±0.71
DF9	2.73 ±0.13	3.3±0.19	0.35	200.67±0.14

*Value expressed as mean ±SD, n=3

Table 7: Results of *In vitro* dispersion time, wetting time and water absorption ratioof Diltiazem HCl tablets

Formulationcode	**In vitro* dispersiontime (sec)	*Wetting time(sec)	*Water absorptionratio
DF1	49±0.54	61±0.02	75.83 ±0.42
DF2	55±0.82	70±0.76	79.18±0.33
DF3	58±0.06	68±0.91	85.96±0.52
DF4	40±0.33	59±0.45	77.31±0.89
DF5	38±0.71	62±0.88	89.50±0.22
DF6	43±0.89	55±0.30	93.82±0.10
DF7	35±0.64	49±0.37	80.70±0.21
DF8	29±0.37	50±0.09	91.63±0.04
DF9	25±0.18	48±0.63	97.38±0.20

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

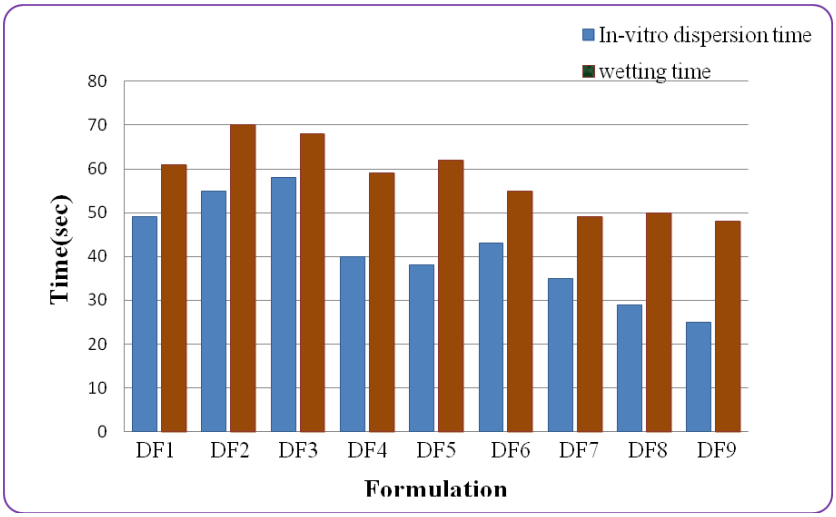

Fig. 6 Comparison between *in vitro* dispersion time and wetting time of DiltiazemHCl tablets

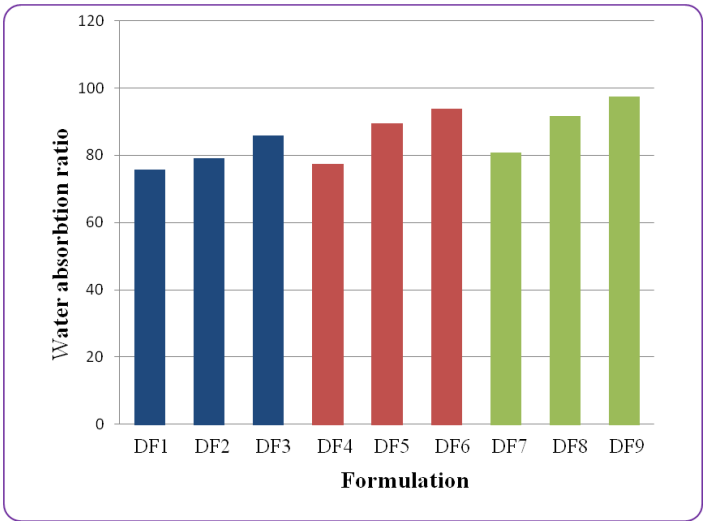

Fig. 7 Water absorption ratio of Diltiazem HCl tablets

❖ **Determination of drug content of Diltiazem HCl tablets**

Table 8: Data for calibration curve of Diltiazem HCl at 236 nm

SR. No.	Concentration(µg/ml)	Absorbance at236 nm
1	2	0.128
2	4	0.235
3	6	0.347
4	8	0.473
5	10	0.574

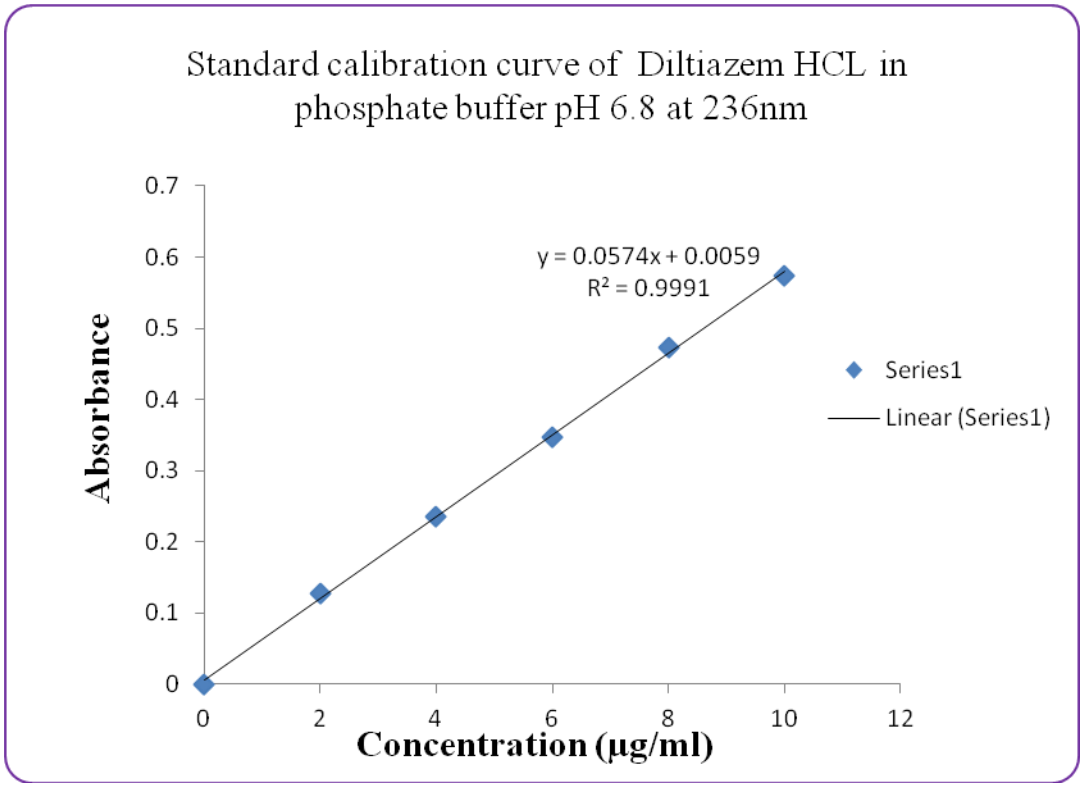

Fig. 8 Standard calibration curve of Diltiazem HCl in phosphate buffer pH 6.8 at236nm

Table 9: Data for % drug content of Diltiazem HCl tablets

Formulationcode	**%Drug content**
DF1	96.35±0.21
DF2	98.69±0.82
DF3	97.48±0.36
DF4	98.44±0.12
DF5	98.52±0.87
DF6	98.29±0.35
DF7	99.86±0.28
DF8	98.19±0.31
DF9	99.67±0.18

❖ ***In vitro* drug release profile of Diltiazem HCl tablets**

Table 10: *In vitro* drug release data of Diltiazem HCl tablets containing SSG

SR. No.	Time(min)	% Cumulative drug release		
		DF1	DF2	DF3
1	0	0	0	0
2	2	25.18±0.65	31.52±0.21	38.24±0.96
3	4	36.92±0.12	45.92±0.12	51.98±0.54
4	6	55.86±0.23	63.62±0.76	68.56±0.43
5	8	67.04±0.76	70.55±0.76	73.89±0.54
6	10	75.19±0.98	78.61±0.75	82.66±0.10

Table 11: *In vitro* drug release data of Diltiazem HCl tablets containingCrosscarmellose sodium

SR. No.	Time(min)	% Cumulative drug release		
		DF4	DF5	DF6
1	0	0	0	0
2	2	35.04±0.23	39.17±0.34	34.98±0.87
3	4	42.81±0.67	50.38±0.45	56.27±0.15
4	6	60.29±0.65	65.89±0.00	69.13±0.37
5	8	65.43±0.78	70.16±0.32	78.50±0.62
6	10	72.10±0.15	84.93±0.78	90.85±0.47

Table 12: *In vitro* drug release data of Diltiazem HCl tablets containingCrospovidone

SR. No.	Time(min)	% Cumulative drug release		
		DF7	DF8	DF9
1	0	0	0	0
2	2	32.63±0.76	38.72±0.73	40.18±0.01
3	4	48.21±0.43	53.86±0.54	58.40±0.62
4	6	65.84±0.32	70.45±0.32	75.38±0.91
5	8	71.33±0.12	78.61±0.65	81.66±0.47
6	10	87.46±0.63	91.58±0.34	95.72±0.26

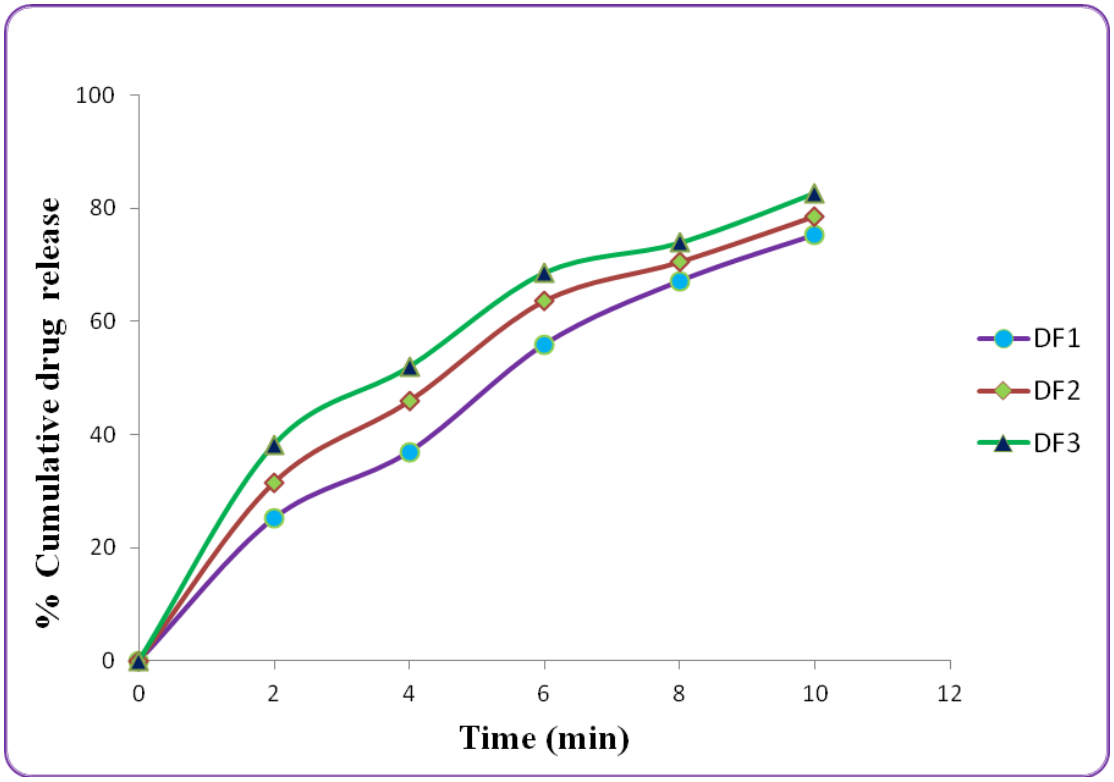

Fig .9 *In vitro* drug release profile of Diltiazem HCl tablets containing SSG

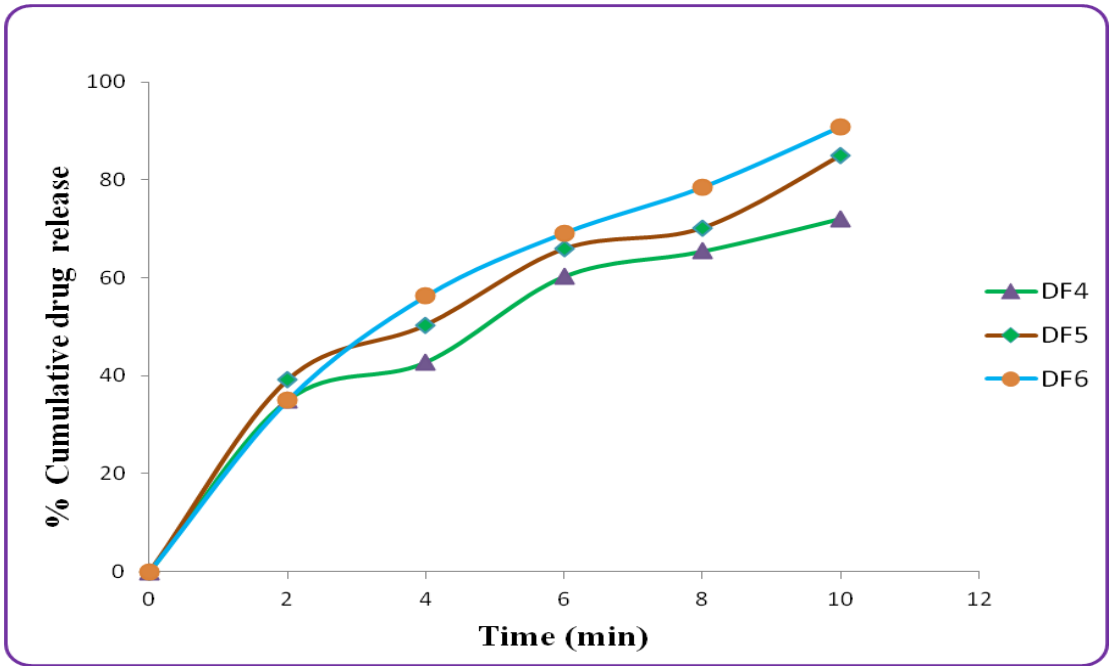

Fig.10 *In vitro* drug release profile of Diltiazem HCl tablets containingCrosscarmellose sodium

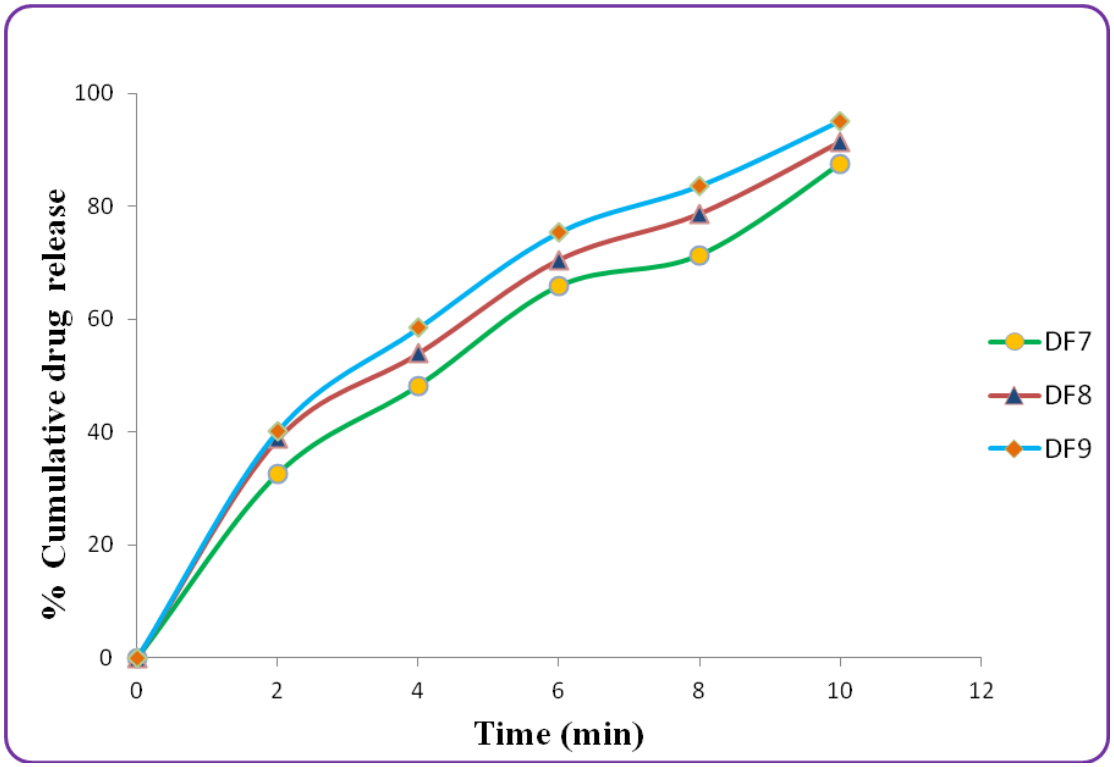

Fig. 11 *In vitro* drug release profile of Diltiazem HCl tablets containingCrospovidone

Comparison with Marketed Product

Brand name: Dilzem Company name: Torrent
Labelled claim: Diltiazem HCl 30mg, total weight of tablets 200mg.

Table 13: Characterization of the marketed tablets of Diltiazem HCl (Dilzem)

SR. No.	EvaluationParameter	Observations
1	Thickness*	2.65±0.14 mm
2	Hardness*	4.1±0.82 kg/cm^2
3	Friability*	0.37±0.05 %
4	Weight variation	201±1.38 mg
5	% Drug content*	97.81±1.07%
6	% Cumulative drugrelease	92.53 (1 hour)

*Each value is an average of three determinations

Table 14: *In vitro* dissolution profile of Diltiazem HCl tablet formulation DF9 andmarketed product (Dilzem)

Time (min)	% Cumulative drug release	
	DF9	Marketed product (Dilzem)
2	40.18±0.01	2.75±0.63
4	58.40±0.62	10.18±0.95
6	75.38±0.91	27.70±0.37
8	81.66±0.47	34.55±0.51
10	95.72±0.26	41.62±0.80
20	-	60.43±0.89
30	-	69.87±0.53
40	-	78.43±0.21
50	-	81.29±0.68
60	-	92.53±0.10

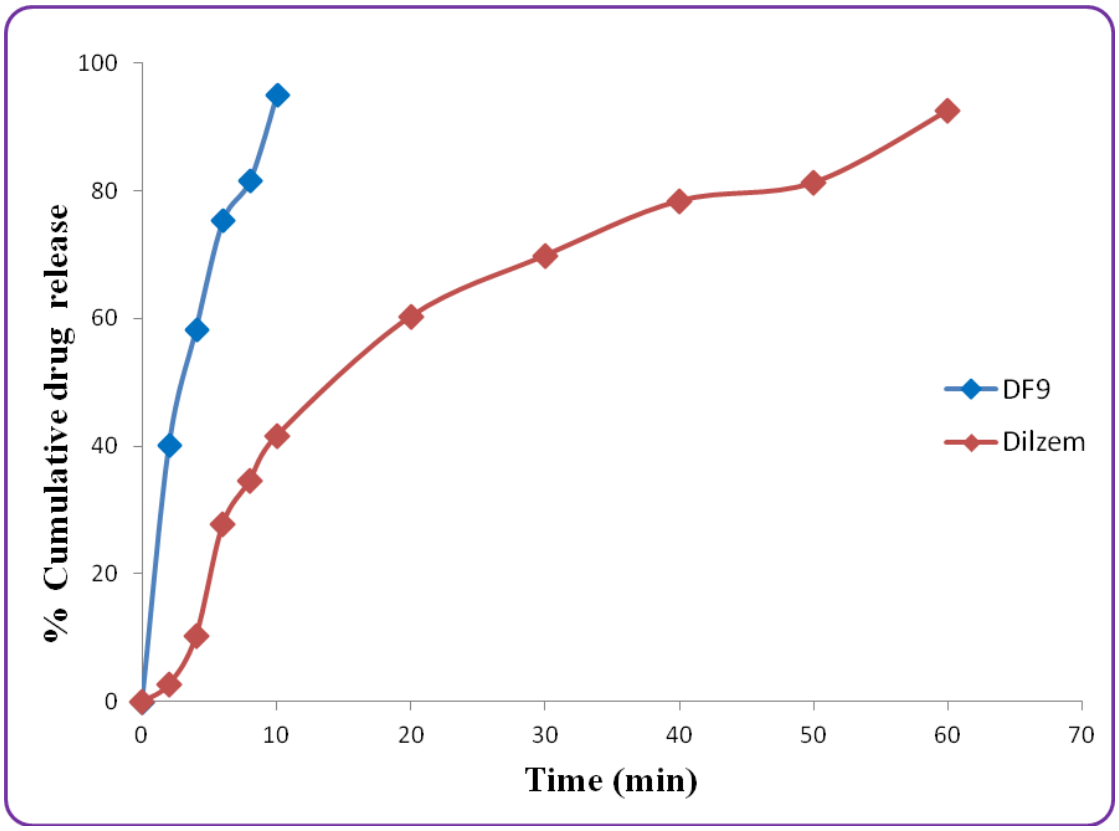

Fig. 12 Comparison of *in vitro* drug release profile of Diltiazem HCl tabletformulation DF9 with marketed product (Dilzem)

Discussion: In the present study, an attempt was made to develop and evaluate fast disintegrating tablets of Diltiazem HCl (30mg) for better treatment of hypertension especially for angina pectoris condition. In general Diltiazem HCl having only 40% oral bioavailability because of high first pass metabolism rate. Thus, formulated fast disintegrating tablets of Diltiazem HCl prevents or avoids first pass metabolism and their absorption directly takes place into the saliva which results in better oral bioavailability compared to conventional Diltiazem HCl tablets.

PREFORMULATION STUDIES

- The solubility of Diltiazem HCl reveals that it was soluble in water and alcohol.
- The melting point of Diltiazem HCl was found to be 215ºC, which complied with BP standards thus indicating purity of obtained drug sample.
- In Preformulation studies, it was found that, the λ_{max} of Diltiazem HCl by UV spectroscopic method was found at 236 nm in pH6.8 buffer as shown in Fig. A standard calibration curve of Diltiazem HCl was made in phosphate buffer pH

6.8 by taking absorbance V/S concentration between 2-12µg/ml ranges, the data was given in Table and calibration curve is shown in Fig . This complied with BP standards thus indicating purity of obtained drug.

Evaluation of Diltiazem HCl fast disintegrating tablets

❖ **Drug –polymer compatibility by FTIR studies**

FTIR of drug-polymers interaction studies are shown in Fig 5.2 to 5.5. It was found that Diltiazem HCl was compatible with superdisintegrants used in the formulation and there were no extra peaks observed.

Pre-compression parameters

Precompression parameters play an important role in improving the flow properties of pharmaceuticals especially in tablet formulation. These include angle of repose, bulk density, tapped density, carr's index and haunser ratio. Before formulation of tablets the drug and superdisintegrants were evaluated for all the abovesaid parameters and it was found that all the observations were within the prescribed limits of IP.

Angle of repose of all the formulations was found to be raging from 15.34- 22.50, bulk density was found to be 0.51-0.57g/cc, tapped density was in between 0.61-0.69g/cc, Carr's index was found to be within 12.48-19.35 and haunser ratio wasfound to be within 1.12-1.27 indicating compressibility of the tablet granules is good as reported in Table.

Post-compression parameters

Tablet thickness and hardness

The thickness of the tablet indicates that die fill was uniform. The thickness depends upon the size of the punch (8 mm) and the weight of the tablet (200 mg). The thickness of the batch from DF1-DF9 was found to be 2.56 - 2.76 mm and hardness was found to be 3.1 - 3.5 kg/cm^2 as reported in Table and thus tablets were having good mechanical strength.

Friability

Friability is needed for tablets to withstand force of compression applied during the manufacture of tablets. The friability of all the formulated tablets of Diltiazem HCl was found to be between 0.21 - 0.39 % are reported in Table and all the formulated tablets of Diltiazem HCl were shown the % friability within the official limits.(i.e. not more than 1%).

Weight variation

Prepared tablets were evaluated for weight variation and percentage deviation from the average weight are reported in Table and was found to be within (±7.5) the prescribed official limits.

***In vitro* dispersion time**

All the formulated tablets (DF1-DF9) have shown *in vitro* dispersion time of less than 60 seconds, showing that formulated Diltiazem HCl tablets were better and effective for the treatment of hypertension than conventional tablets. Among all the formulations, tablets prepared with crospovidone were shown less than 40 sec of dispersion time. The obtained results were showed in Table.

Wetting time

The wetting time of all the formulations (DF1-DF9) were found to be within 48- 70 seconds, which complies with the official specifications. The results were showed in Table. An comparison of *in vitro* dispersion time and wetting time was shownin Fig

Water absorption ratio

The water absorption ratio of all the formulated batches was found to be 75-97 % which was satisfactory in giving effective and better formulations of fast disintegrating tablets. The results were shown in Table. The water absorption ratio of all the formulations was represented in Fig.

Drug content

The drug content of all the nine formulations of Diltiazem HCl tablets were found to be within the

range of 96.35-99.67% which were within the limits of BP specifications. The drug content of all the formulations of Diltiazem HCl tablets is shown in Table

***In vitro* dissolution study**

Total nine formulations were formulated DF1 to DF9 by using three different superdisinegrants in varying concentrations. The formulations DF1-DF3 were formulated with the help of sodium starch glycolate in concentration 1.5%, 3%, 4.5% respectively. The formulations DF4-DF6 were formulated with the help of crosscarmellose in concentration 1.5%, 3%, 4.5% respectively and the formulations DF7-DF9 were formulated with the help of crospovidone in concentrations 1.5%, 3%, 4.5% respectively. The formulations DF7-DF9 containing crospovidone showed more than 80% drug release. Among those three the formulation DF9 showed highest drug release of 95.72%. The data for *in vitro* drug release of formulations was shown in Tables 5.9, 5.10 and 5.11, the *in vitro* drug release profiles were shownin Fig.5.9, 5.10 and 5.11. The characterization of marketed tablets of Diltiazem HCl (Dilzem) is displayed in Table . A comparision of optimized formulation (DF9) was made with marketed tablets (Dilzem) to show that formulated Diltiazem HCl tablets were effective and suitable than conventional tablets. The comparison of *in vitro* drug release profile of optimized formulation (DF9) and marketed product (Dilzem) was shown in Fig.

CONCLUSION:

- Preformulation studies of Diltiazem HCl were performed. From the FT-IR, the interference was verified and found that Diltiazem HCl did not interfere with the polymers used.
- Nine batches of fast disintegrating tablets of Diltiazem HCl were successfully prepared using sodium starch glycolate, crosscarmellose and crospovidone by direct compression method.
- The tablets were evaluated for parameters like thickness, hardness, friability, *in- vitro* dispersion time, wetting time, water absorption ratio, % drug content and *in- vitro* drug release studies.
- Based on the results, formulation containing 4.5% crospovidone (DF9) was identified as ideal and better formulation among all formulations developed for Diltiazem HCL tablets.
- *In vitro* release of optimized formulation of Diltiazem HCl fast disintegrating tablets of DF9 was found to be 95.72% drug release within 10 min. with *in vitro* dispersion time being 25 sec.
- The final optimized formulation (DF9) was compared with marketed product of Diltiazem HCl tablets (Dilzem) which shows 92.53% drug release in 1 hr. From this observation it was concluded that the formulated tablets of Diltiazem HCl (DF9) were superior and effective in achieving patient compliance.

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