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FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS OF DILTIAZEM HYDROCHLORIDE

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ABSTRACT

The objective of this study was to develop and evaluate fast-dissolving tablets (FDTs) of Diltiazem Hydrochloride to enhance patient compliance, particularly in populations with swallowing difficulties such as pediatric and geriatric patients. Diltiazem, a calcium channel blocker used in the treatment of hypertension and angina, suffers from first-pass metabolism and relatively low oral bioavailability. Fast-dissolving tablets were prepared using direct compression techniques with various superdisintegrants such as Crospovidone, Sodium Starch Glycolate, and Croscarmellose Sodium in different concentrations. The prepared tablets were evaluated for pre-compression parameters (bulk density, tapped density, angle of repose) and post-compression parameters including hardness, friability, weight variation, disintegration time, wetting time, and in vitro drug release. Among the formulations, the batch containing 4.5 % Crospovidone showed the fastest disintegration time (under 30 seconds) and optimal drug release profile (over 90% within 10 minutes). The results suggest that Diltiazem fast-dissolving tablets can be a promising alternative to conventional dosage forms, providing rapid onset of action and improved patient adherence.

INTRODUCTION

A **Fast Dissolving Tablet (FDT)** is a solid dosage form that disintegrates or dissolves rapidly in the mouth, typically within **30 seconds to 3 minutes**, without the need for water. FDTs are designed to improve patient compliance by offering ease of administration, especially for pediatric, geriatric, and dysphagic (difficulty in swallowing) patients. They release the drug

quickly in the saliva, leading to rapid absorption either through the oral mucosa or in the gastrointestinal tract.

Advantages of Fast Dissolving Tablets (FDTs)

- Improved Patient Compliance:
- No Need for Water:
- Rapid Onset of Action:
- Better Bioavailability:
- Convenient for On-the-Go Dosing:
- Reduced Risk of Choking:
- Enhanced Taste Masking:
- Improved Stability

Limitations of Fast Dissolving Tablets (FDTs)

- Limited Drug Load:
- Taste Masking Challenges:
- Moisture Sensitivity:
- Mechanical Strength:
- Cost of Production:
- Stability Issues:
- Not Suitable for All Drugs:
- Short Shelf-Life:

MATERIAL AND METHOD

Diltiazem HCl, Microcrystalline cellulose, Sodium starch glycolate Crosscarmellose sodium Crospovidone, Talc Magnesium stearate Aspartame Raspberry flavor Potassium dihydrogen orthophosphate Sodium hydroxide.

UV visible spectrophotometer FTIR spectrophotometer, Electronic balance Digital pH meter Bulk density apparatus, Tablet punching machine, Roche friabilator, Tablet hardness tester.

METHODOLOGY

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.

In this work, direct compression method with the aid of super disintegrants 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.

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

Diltiazem HCl fast disintegrating tablets were manufactured in nine formulations DF1 to DF9 using the ingredients mentioned in the Table 4.3 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.

Drug–polymer compatibility studies

In the preparation of tablets formulation, drug and polymer may interact as they are in close contact with each other, which could lead to the instability of drug. Preformulation studies regarding the drug-polymer interaction are therefore very critical in selecting appropriate polymers. FT-IR spectroscopy was employed to ascertain the compatibility between Diltiazem hydrochloride and the selected polymers. Potassium bromide, pure drug and the polymers were heated to 105ºC for one hour to remove the moisture content if present in a hot air oven. Then in presence of IR lamp, potassium bromide was mixed with drug and/or polymer in 9:1 ratio and the spectra were taken. FT-IR spectrum of Diltiazem HCl was compared with FT-IR spectra of polymer.

Pre-compression parameters

Angle of Repose (θ)

The frictional force in a loose powder or granules can be measured by angle of repose. Angle of repose is defined as the maximum angle possible between the surface of a pile of the powder and horizontal plane.

$$\square = \tan^{-1} (h/r)$$

Where, $\square$ is the angle of repose h is height of pile

r is radius of the base of pile

Different ranges of flowability in terms of angle of repose are given in below table.

Angle of Repose (ɵ)	Flow
>25	Excellent
25-30	Good
30-40	Passable
<40	Very poor

Method: A funnel was filled to the brim and the test sample was allowed to flow smoothly through the orifice under gravity. From the cone formed on a graph sheet was taken to measure the area of pile, thereby evaluating the flowability of the granules. Height of the pile was also measured.

Bulk Density

Loose bulk density (LBD) and tapped bulk density (TBD) of Diltiazem HCl and the tablet blends were determined using bulk density apparatus. The pure drug was passed through #18 sieve to break the clumps, if any. Accurately weighed 5 g of the drug or 25 g of polymers was placed in a 100 ml graduated measuring cylinder. Initial volume was observed. The cylinder was tapped initially 200 times from a distance of 14 ± 2 mm. The tapped volume was measured to the nearest graduated unit. The tapping was repeated additional 200 times. Again, the tapped volume was measured to the nearest graduated unit. The same thing was done for powder blends of the tablets. The LBD and TBD were calculated in g per ml using following formula.

LBD = weight of the powder / volume of the packing

TBD = weight of the powder / tapped volume of the packing

Compressibility Index (Carr's Index)

The compressibility index of the granules was determined by carr's compressibility index. Grading of the powders for their flow properties according to Carr's Index is shown in below table

Carr's Index is shown in below

% Compressibility	Flow ability
5 – 12	Excellent
12 – 16	Good
18 – 21	Fair Passable
23 – 35	Poor
33 – 38	Very Poor
< 40	Very Very Poor

Hausner ratio

The hausner's ratio of the powder was determined by the following equation.

Hausner ratio = TBD / LBD

Lower hausner's ratio (<1.25) indicates better flow properties than higher ones (>1.25).

Post-compression parameters

The tablets after punching of every batch were evaluated for in-process and finished product quality control tests i.e. thickness, weight uniformity test, hardness, friability, drug content, *in vitro* dispersion time, water absorption ratio, wetting time and *in vitro* drug release studies.

Thickness

Thickness of tablets indicates the strength to withstand compression force applied during manufacturing process. Thickness of tablets was measured by digital caliper.

Hardness Test

Hardness (diametric crushing strength) is a force required to break a tablet across the diameter. The hardness of a tablet is an indication of its strength.

The tablet should be stable to mechanical stress during handling and transportation. The degree of hardness varies with the different manufactures and with the different types of tablets. The hardness was tested using Monsanto tester. "Hardness factor", the average of the six determinations, was determined and reported. The force was measured in kilograms per centimeter square.

Friability Test

Friability is the loss of weight of tablet in the container/package, due to removal of fine particles from the surface. This in process quality control test is performed to ensure the ability of tablets to withstand the shocks during processing, handling, transportation, and

shipment. Permitted friability limit is 1.0 %. Roche friabilator (Electrolab, Mumbai) was used to measure the friability of the tablets. Ten tablets were weighed collectively and placed in the chamber of the friabilator. In the friabilator, the tablets were exposed to rolling, resulting free fall of tablets (6 inches) within the chamber of the friabilator. It was rotated at a rate of 25 rpm. After 100 rotations (4 minutes), the tablets were taken out from the friabilator and intact tablets were again weighed collectively.

Weight Uniformity Test

Twenty tablets were weighed individually and all together. Average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight. The percentage difference in the weight variation should be within the permissible limits (±7.5%). The total weight of tablets formulated was 200 mg.

The percentage deviation for weight uniformity of tablets as per IP limits is shown in below table.

Average weight of tablet	Percentage deviation
80 mg or less	±10
More than 80 mg and less than 250 mg	±7.5
250 mg or more	±5

Any variation in the weight of tablet (for any reason) leads to either under medication or over medication. So, every tablet in each batch should have a uniform weight. Deviation within the IP permissible limit of 7.5% is allowed as the tablet weight 200 mg.

***In vitro* dispersion Time**

In vitro dispersion time was measured by dropping a tablet into a Petri dish containing 10 ml of phosphate buffer pH 6.8 solution (simulated saliva fluid). Three tablets from each formulation were randomly selected and tested. *In vitro* dispersion time was found and expressed in seconds.

Wetting time and Water absorption ratio

Wetting time of dosage form is related with the contact angle. Wetting time of the fast-disintegrating tablets is another important parameter, which 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. The wetting time of the tablet can be measured using a simple procedure. Two circular tissue papers of 10 cm diameter are placed in a Petri dish having the

same inner diameter. Ten ml of phosphate buffer solution, 6.8 pH containing Eosin, a water-soluble dye, is added to Petri dish. A tablet is carefully placed on the surface of the tissue paper so that complete tablet was not immersed in the solution. Then, the time required for buffer to reach upper surface of the tablet is noted as wetting time.

❖ **Drug content determination**

Calibration of Diltiazem HCl in phosphate buffer (pH6.8) solution at λ_{max} 236

Preparation of Buffers and Reagents

Sodium hydroxide solution (0.2 M): Eight grams of sodium hydroxide was taken in 1000 ml volumetric flask containing about 700 ml distilled water and volume was made up to the mark with distilled water.

Potassium dihydrogen phosphate solution (0.2 M): 27.218 g of Potassium dihydrogen phosphate was added in 1000 ml volumetric flask containing about700 ml distilled water and volume was made up to the mark with distilled water.

Procedure for Calibration of Diltiazem HCl in phosphate buffer (pH6.8) solution: From stock solution, appropriate aliquots were pipetted into different volumetric flasks and volumes were made up to 10 ml with phosphate buffer (pH 6.8) solution, so as to get drug concentrations of 2, 4, 6, 8 and 10 µg/ml.

The data are given in the Table 5.7 and calibration curve constructed is shown in the Fig.5.8.

Procedure of determining drug content

Three uncoated tablets were selected randomly and average weight was calculated. Tablets were crushed in a mortar and accurately weighed amount of tablet powder was taken from the crushed blend. Then the samples were transferred to three 100 ml volumetric flasks and were diluted up to the mark with phosphate buffer (pH 6.8) solution. The contents were shaken periodically and kept for 24 hours for solvation of drug completely. The mixtures were filtered, appropriately diluted, and absorbances were measured at λmax 236 nm against blank reference. The drug content in each tablet was calculated using the standard calibration curve of Diltiazem HCl in phosphate buffer pH 6.8 solution.

❖ ***In vitro*** **drug release**

Calibration of Diltiazem HCl in phosphate buffer (pH6.8) solution at λ_{max} 236 nm

The procedure for the calibration curve of Diltiazem HCl is same as mentioned under Drug

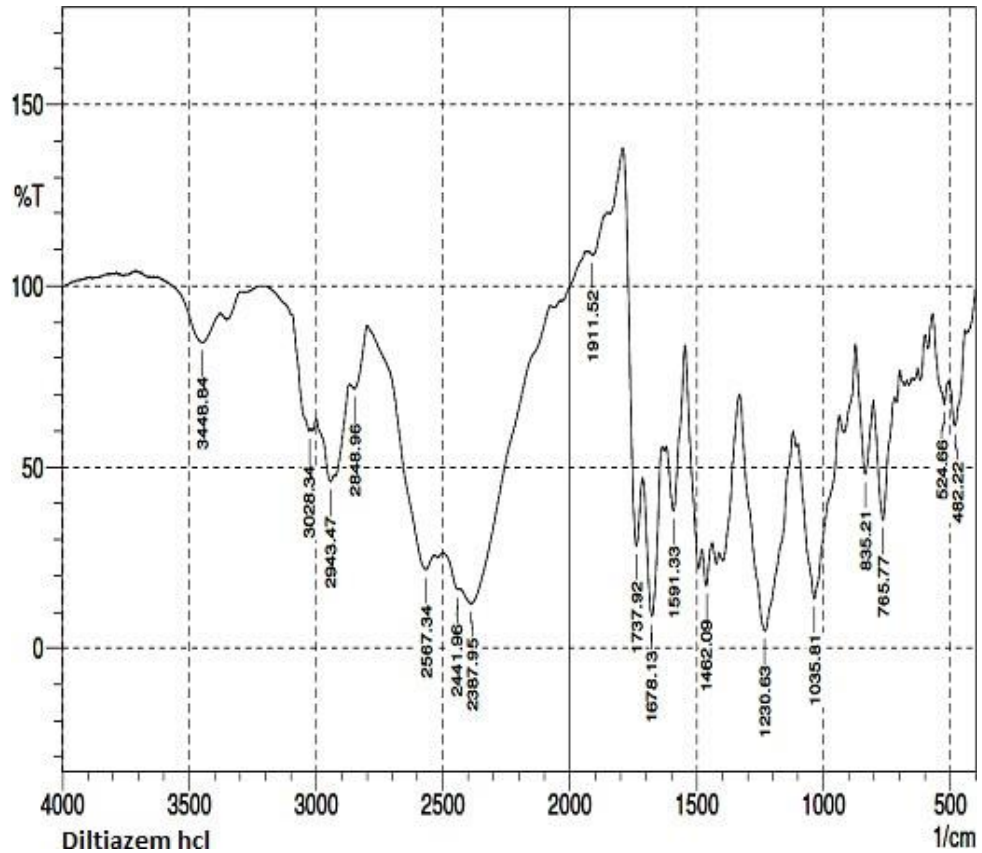
content determination section.

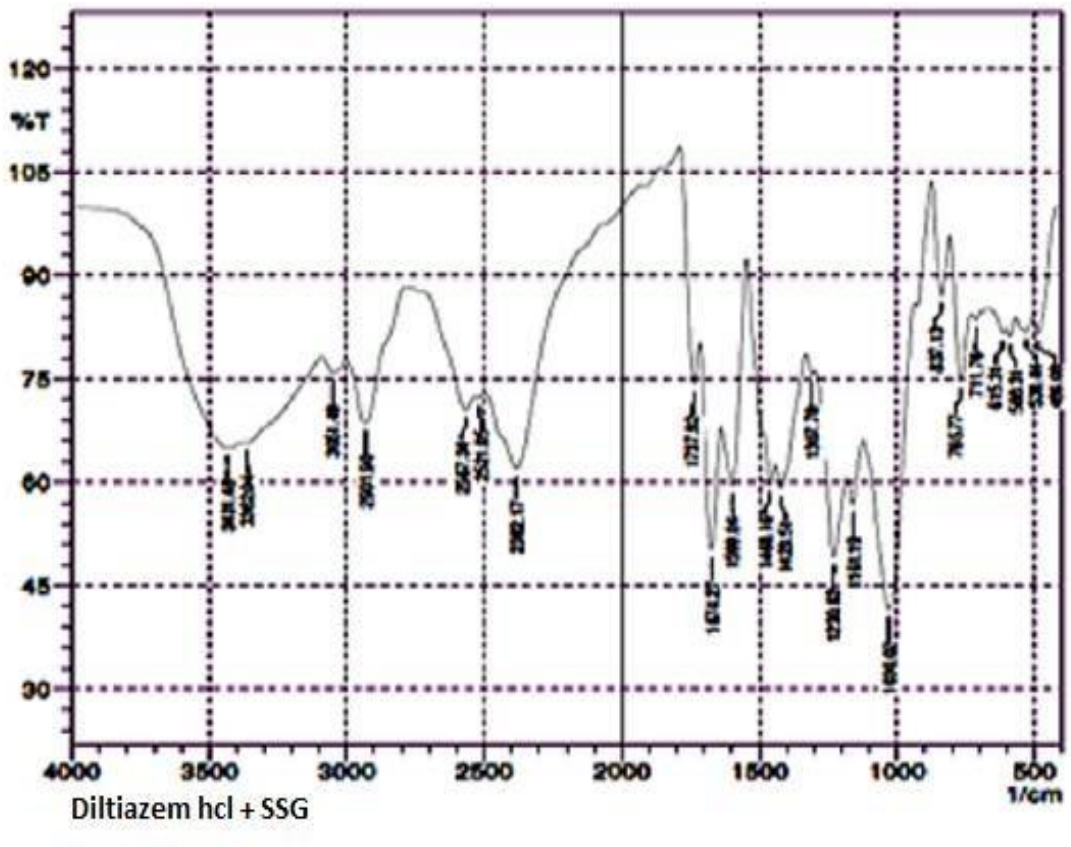
Procedure for determining In vitro drug release studies

In vitro drug release of the samples was carried out using USP – type II dissolution apparatus (paddle type). The dissolution medium, 900 ml of phosphate buffer (pH 6.8) solution, was placed into the dissolution flask maintaining the temperature of 37±0.5ºC and rpm of 50. One tablet was placed in each flask of dissolution apparatus. The apparatus was allowed to run for 10 min. Samples measuring 5 ml were withdrawn after every 1, 2, 3, 4, 5, 6, 7-, 8-, 9- and 10-min. Samples were filtered through 10 µm filter. The fresh dissolution medium was replaced every time to maintain sink condition. The collected samples were analyzed at 236 nm using dissolution medium as blank. The cumulative percentage drug release was calculated.

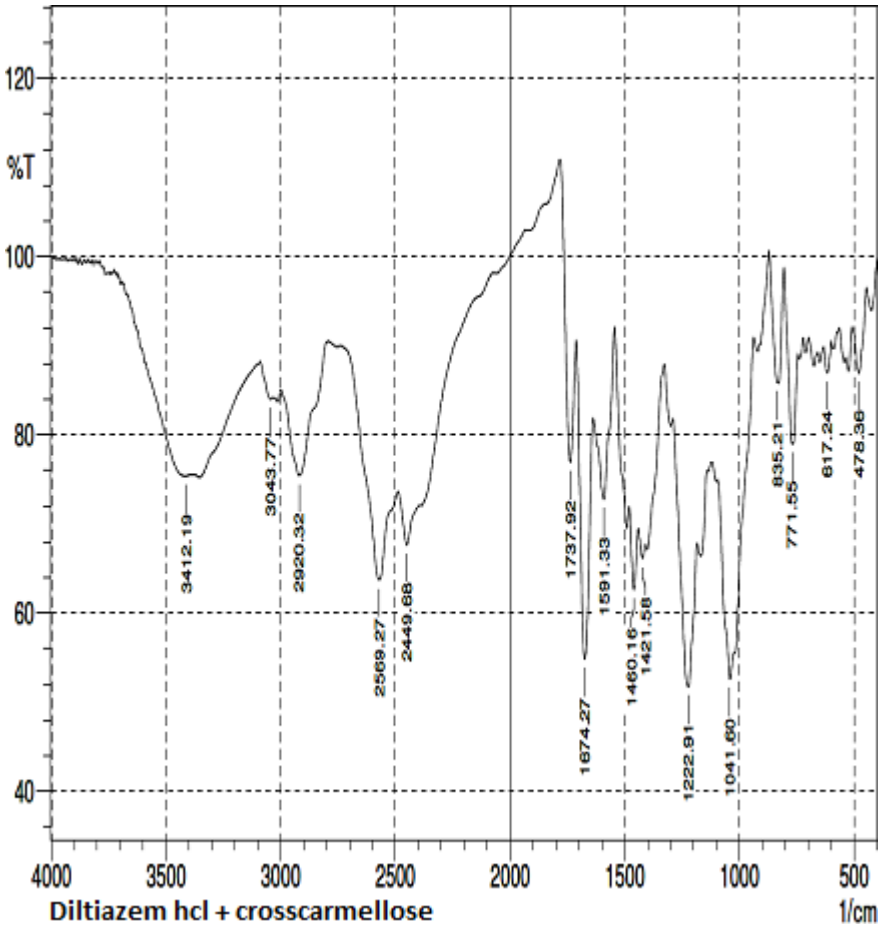
RESULTS AND DISCUSSION

Drug–polymer compatibility by FTIR studies

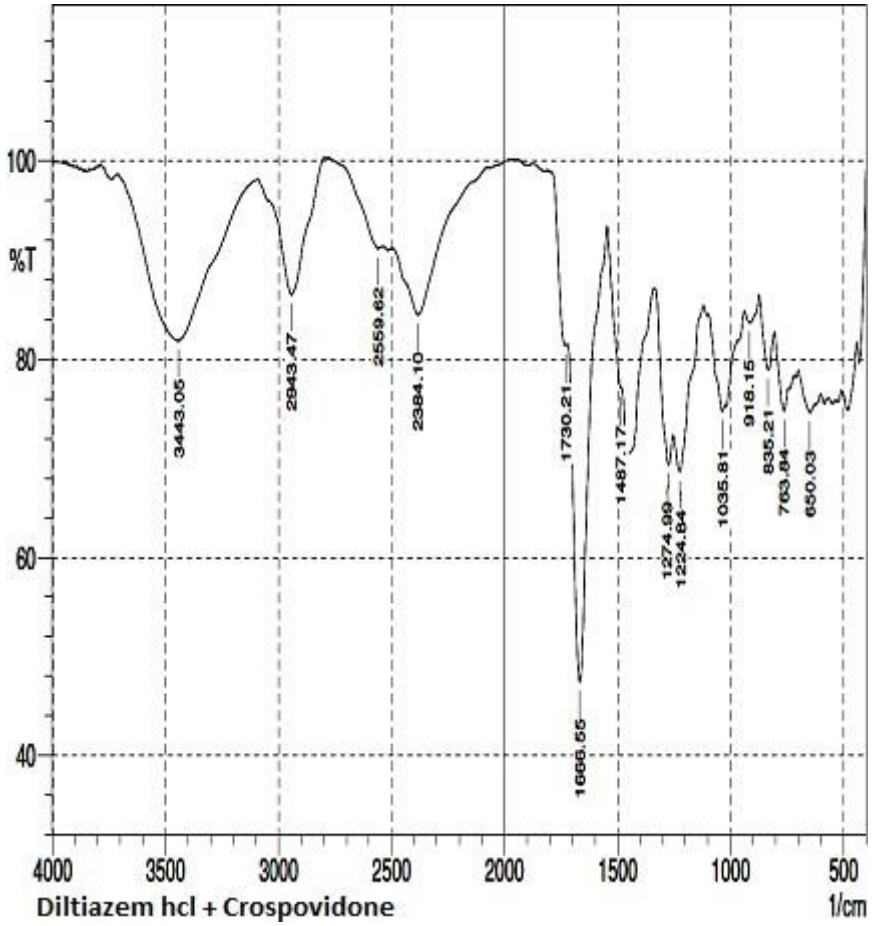




IR spectra of physical mixture of Diltiazem HCl and SSG



IR spectra of physical mixture of Diltiazem HCl and Crosscarmellose sodium



IR spectra of physical mixture of Diltiazem HCl and Crospovidone

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

Precompression parameters of Diltiazem HCl tablets

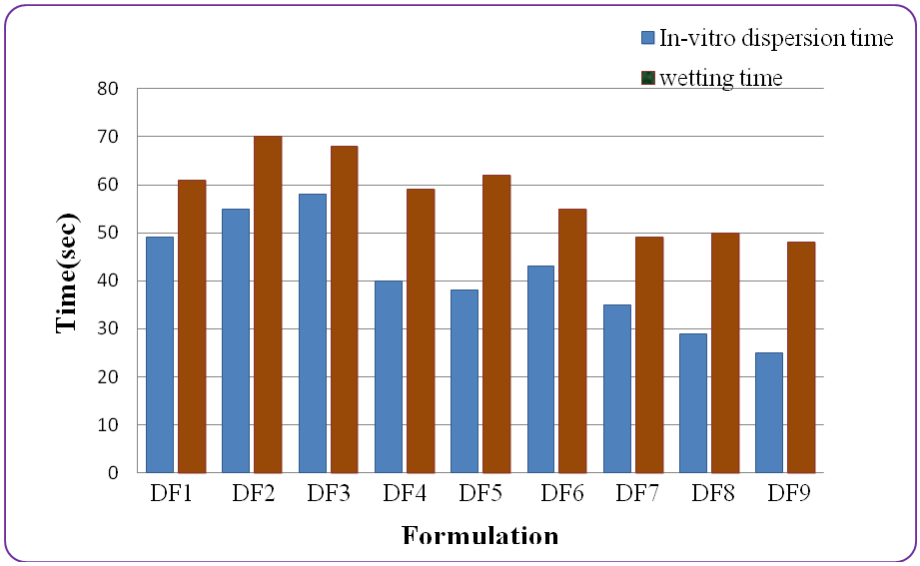
Formulation Code	*Angle of repose (ɵ)	*Bulk density (g/cc)	*Tapped density (g/cc)	*Carr's index	*Haunser ratio
DF1	22.50±0.14	0.53±0.01	0.64±0.17	13.72±0.10	1.14±0.02
DF2	19.86±0.19	0.51±0.12	0.67±0.02	15.26±0.14	1.27±0.15
DF3	21.43±0.24	0.56±0.26	0.69±0.25	19.35±0.27	1.12±0.08
DF4	18.27±0.32	0.52±0.09	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

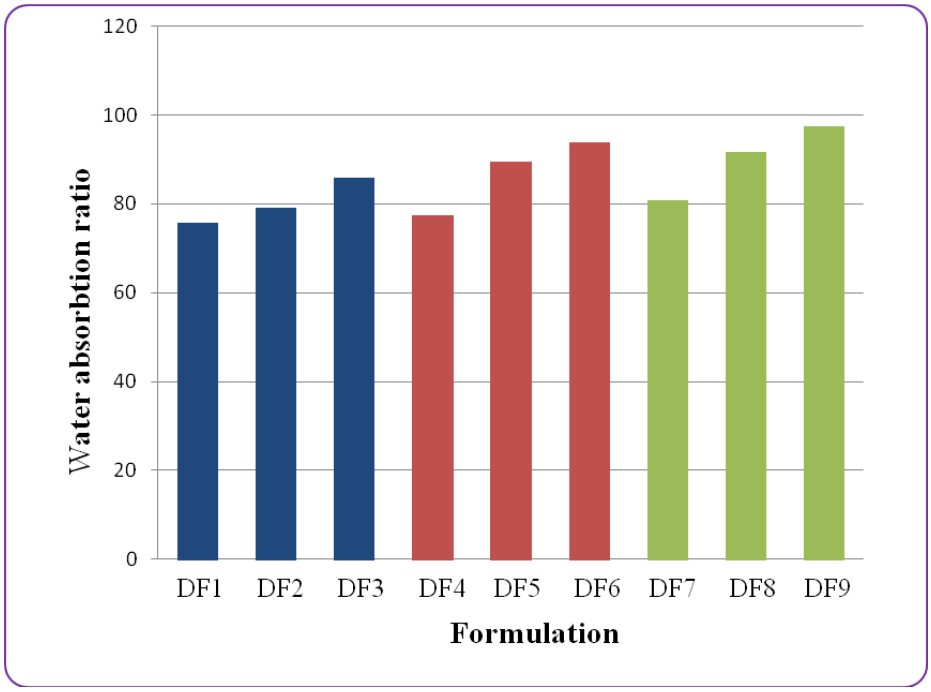
Results of thickness, hardness, friability and weight variation of Diltiazem HCl tablets

Formulation code	*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

Results of *In vitro* dispersion time, wetting time and water absorption ratio of Diltiazem HCl tablets

Formulation code	**In vitro* dispersion time (sec)	*Wetting time (sec)	*Water absorption ratio
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

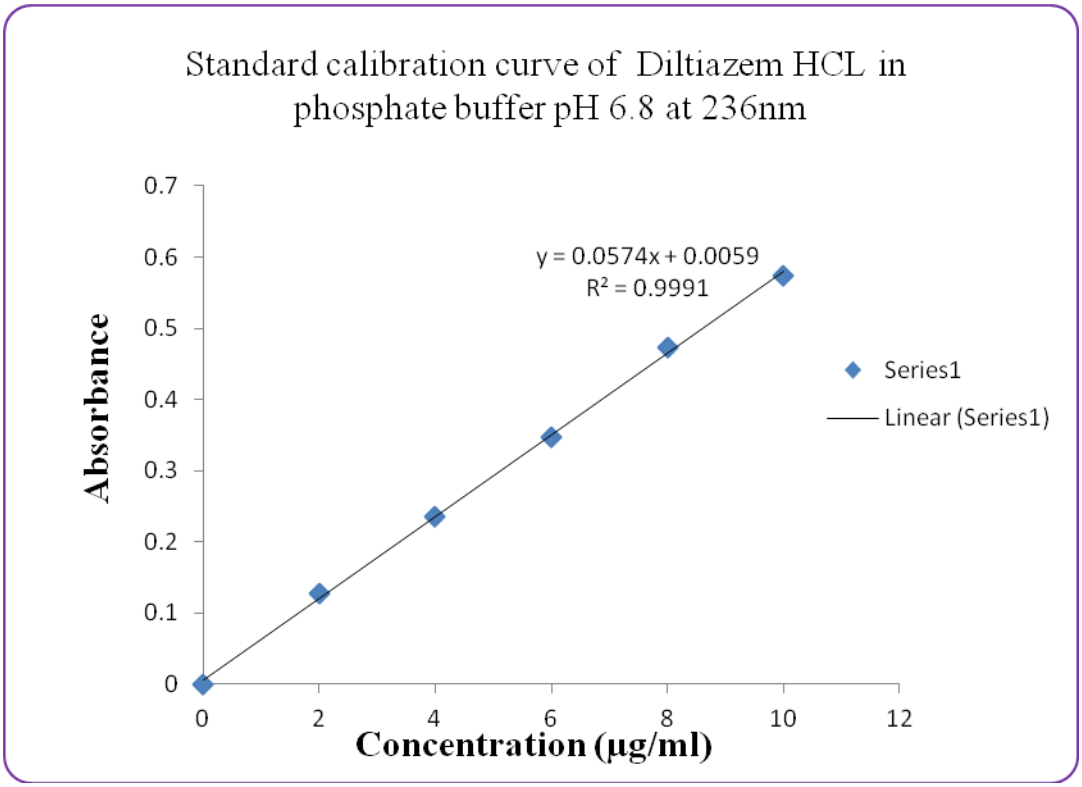




Comparison between *in vitro* dispersion time and wetting time of Diltiazem HCl tablets

Data for calibration curve of Diltiazem HCl at 236 nm

SR. No.	Concentration (µg/ml)	Absorbance at 236 nm
1	2	0.128
2	4	0.235
3	6	0.347
4	8	0.473
5	10	0.574



Standard calibration curve of Diltiazem HCl in phosphate buffer pH 6.8 at 236nm

Data for % drug content of Diltiazem HCl tablets

Formulation code	%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 data of Diltiazem HCl tablets containing SSG**

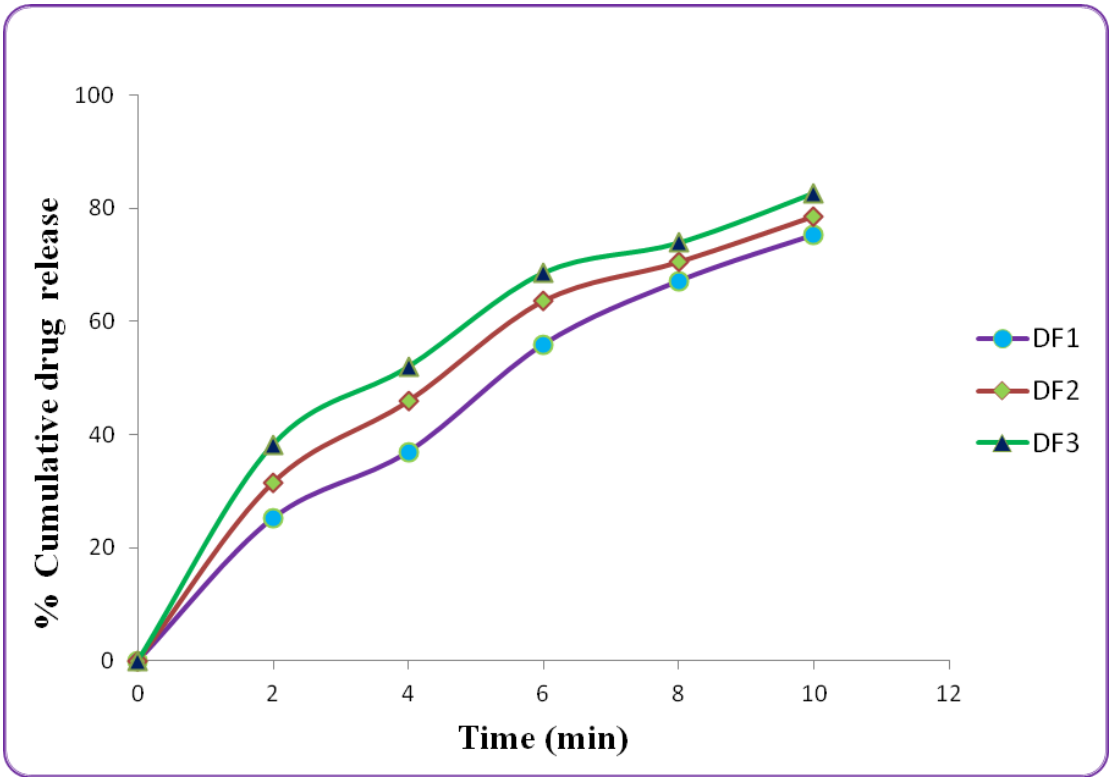
SR. No.	Time (min)	% Cumulative drug release		
		DF1	DF2	DF3
1	0	0	0	0
2	2	25.18±0.65	31.52±0.21	38.24±0.96
3	4	36.92±0.12	45.92±0.12	51.98±0.54
4	6	55.86±0.23	63.62±0.76	68.56±0.43
5	8	67.04±0.76	70.55±0.76	73.89±0.54
6	10	75.19±0.98	78.61±0.75	82.66±0.10

In vitro **drug release data of Diltiazem HCl tablets containing Crosscarmellose 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

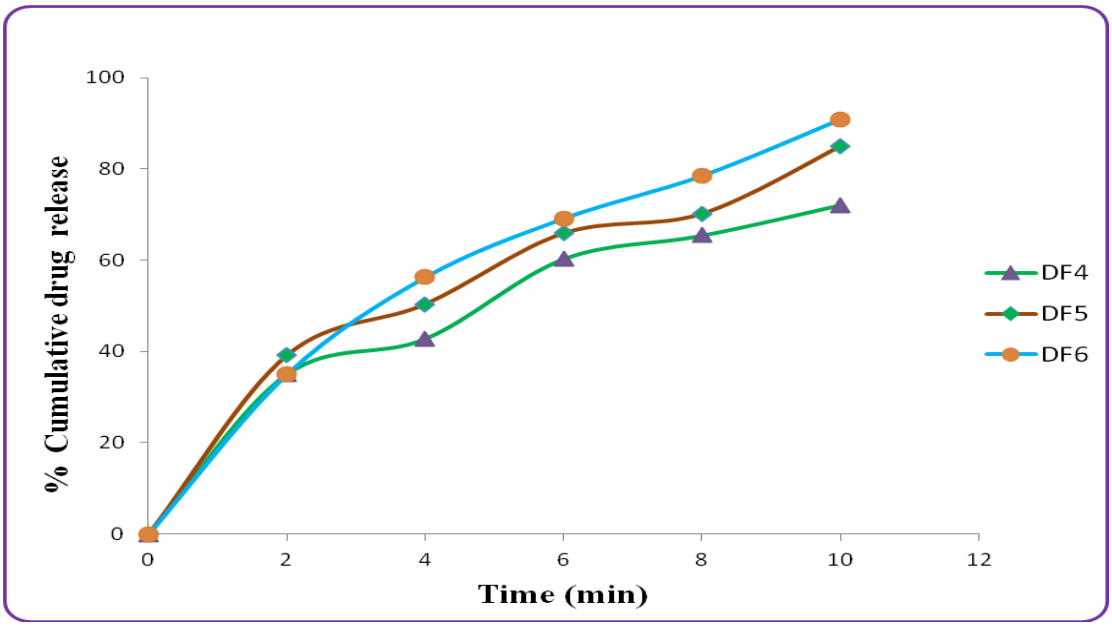
In vitro **drug release data of Diltiazem HCl tablets containing Crospovidone**

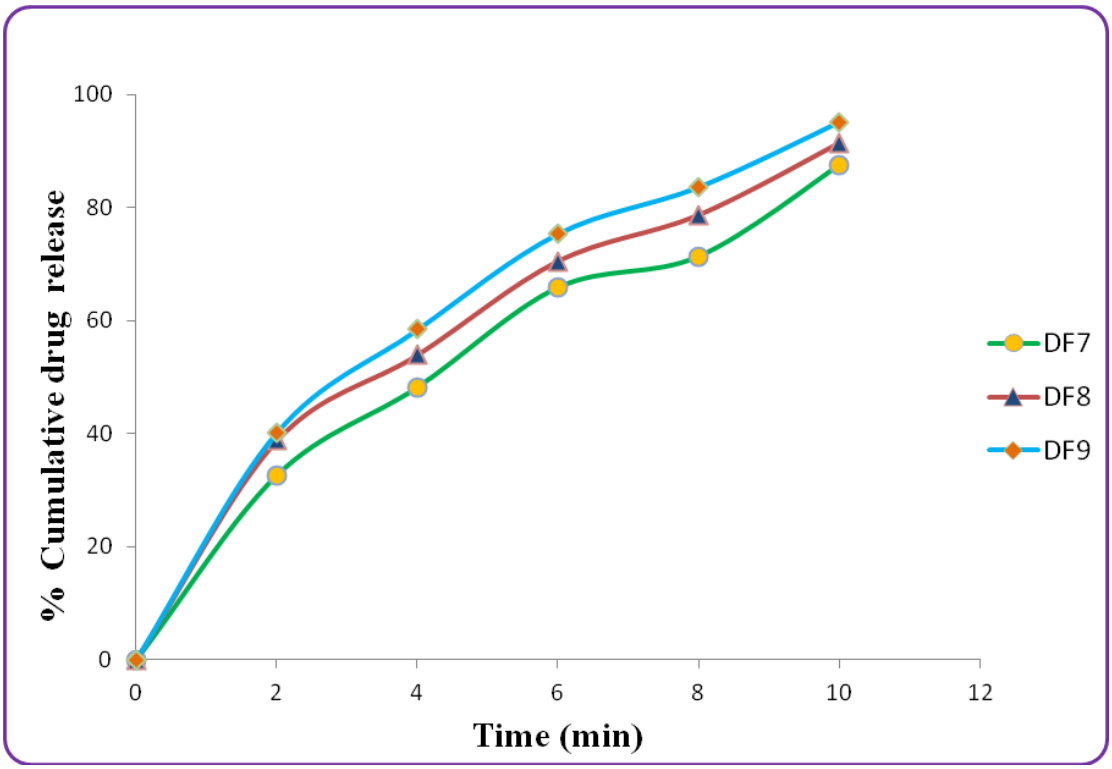
SR. No.	Time (min)	% Cumulative drug release		
		DF7	DF8	DF9
1	0	0	0	0
2	2	32.63±0.76	38.72±0.73	40.18±0.01
3	4	48.21±0.43	53.86±0.54	58.40±0.62
4	6	65.84±0.32	70.45±0.32	75.38±0.91
5	8	71.33±0.12	78.61±0.65	81.66±0.47
6	10	87.46±0.63	91.58±0.34	95.72±0.26



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

In vitro **drug release profile of Diltiazem HCl tablets containing Crosscarmellose sodium**





In vitro **drug release profile of Diltiazem HCl tablets containing Crospovidone**

Characterization of the marketed tablets of Diltiazem HCl (Dilzem)

SR.No.	Evaluation Parameter	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 drug release	92.53 (1 hour)

***In vitro* dissolution profile of Diltiazem HCl tablet formulation DF9 and marketed 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

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 studiesBased 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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