AMERICAN JOURNAL OF PHARMTECH RESEARCH
Journal home page: http://www.ajptr.com/

Design Development and Evaluation of Fast Dissolving Tablets of Loratadine by Direct Compression Method

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ABSTRACT

Fast dissolving tablets are the tablets which dissolves rapidly and shows higher bioavailability than conventional tablets. The concept of formulating Fast dissolving tablets of Loratadine (antiallergic drug) offer suitable and practical approach in serving the desired objective of faster disintegration and dissolution characteristic with increase bioavailability and to know the effects of three synthetic superdisintegrants (Crosscarmeloss sodium, Sodium starch glycolate and Crospovidone). In the present work two methods of solid dispersion were compared for improving the bioavailability i.e Solvent Evaporation and Fusion method with beta cyclodextrin as a carrier to increase the solubility of the drug. Comparison between these three synthetic superdisintegrants was done by taking different ratios individually and in combination. Combination of these three superdisintegrants shows synergistic effect when it is compared to individually. Prepared tablets were subjected to different evaluation parameters such as hardness, thickness, friability, weight variation, drug content uniformity, *in vitro* disintegration time, wetting time, *in vitro* dissolution studies and stability studies are carried out by using the best formulation. From all the formulations prepared and evaluated F11 was found to the best formulation.

Key words: Fast dissolving tablets, Solid dispersion, Crosscarmeloss sodium, Sodium starch glycolate, Crospovidone, Evaluation parameters.

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Received 29 July 2013, Accepted 10 August 2013

Please cite this article in press as: Pandya AS. *et al.*, Design Development and Evaluation of Fast Dissolving Tablets of Loratadine by Direct Compression Method. American Journal of PharmTech Research 2013.

INTRODUCTION

Among the pharmaceutical dosage forms, the conventional tablet seems to be most popular because of its ease of transportability and lower manufacturing cost. The rapidly disintegrating tablets are synonymous with Fast dissolving tablets; Melt in mouth tablets**,** Rapid-melts, Quick dissolving tablets, Mouth dissolving tablets, Orodispersible tablets. Their characteristic benefits in terms of patient compliance, rapid on-set of action, increase bio-availability and good stability make these tablets popular as a dosage form of choice.[1,2]

The solubility of a drug is a key determinant of its oral bioavailability and permeability. There have always been certain drugs for which solubility has presented a challenge to the development of a suitable formulation for oral administration. Examples such as griseofulvin, digoxin, phenytoin, sulphathiazole and chloramphenicol come immediately to mind. With the recent advent of high throughput screening of potential therapeutic agents, the number of poorly soluble drug candidates has risen sharply and the formulation of poorly soluble compounds for oral delivery now presents one of the most frequent and greatest challenges to formulation scientists in the pharmaceutical industry.[3]

Loratadine is used for the symptomatic relief of allergic conditions such as runny nose, itchy or watery eyes, sneezing, and nasal or throat itching and chronic urticaria. Loratadine is practically insoluble in water (BCS Class II) drug.[4]

Hence in the present study fast dissolving tablets of Loratadine were prepared by direct compression method with solid dispersion technique to increase the surface area of the drug and also superdisintegrant has been utilized for faster disintegration. Main advantages of direct compression are low manufacturing cost and high mechanical integrity of the tablets.

Advantages of Fast Dissolving Tablets[11-14]

Accurate dosing*:*

Being unit solid dosage forms, provide luxury of accurate dosing, easy portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients.

Enhanced bioavailability:

Bioavailability of drugs is enhanced due to absorption from mouth, pharynx and esophagus.

Rapid action:

Fast onset of therapeutic action as tablet gets disintegrated rapidly along with quick dissolution and absorption in oral cavity.

Patient compliance:

Due to faster action it is showing better patient compliance.

Enhanced palatability:

Good mouth feel, especially for pediatric patients as taste masking technique is used to avoid the bitter taste of drug.

Simple packaging:

No specific packaging required. It can be packaged in push through blisters.

Business avenue:

Provide new business opportunities in the form of product differentiation, line extension, uniqueness and life cycle management.

Cost effective:

Conventional processing and packaging equipments allow the manufacturing of tablets at low cost.

MATERIALS AND METHODS

Preparation of Solid Dispersions of Loratadine with Betacyclodextrine[5]

Solid dispersions of Loratadine were prepared by solvent evaporation method and Fusion method.

Solvent evaporation method:

Drug was weighed and taken in a china dish, dissolved in Ethanol and then carrier (beta cyclodextrine) was added in ratio of 1:1, 1:2, 1:3 and 1:4. The solvent was evaporated at room temperature and dried in hot air oven at 65°C for 4 hr. The resultant mass was passed through sieve no. 85 and stored in desiccator. The solid dispersion obtained was evaluated for drug content and dissolution studies.

Fusion Method

Solid dispersions (SD) were prepared by melting the accurately weighed amounts of beta cyclodextrine in a water bath and the drug was dispersed in the molten solution. Drug and carrier was taken in different ratios (1:1 to 1:5). The mixtures were stirred repeatedly, after 10 min cooled either at room temperature or by placing the closed container for 15 min in an ice bath. Solid mass obtained was passed through the # 80 and stored in vacuum desiccators. The solid dispersion obtained was evaluated for drug content and dissolution studies.

EVALUATION OF SOLID DISPERSION

Drug content of solid dispersion

Accurately weigh solid dispersions equivalent to 10 mg of Loratadine were weighed and transfer to 100 ml volumetric flask. Dissolve in 0.1N HCL buffer and the volume was made up with the same. An aliquot of the filtrate was analyzed spectrophotometrically at 280 nm. The drug content has been mentioned in Table 1

***In-vitro* release studies of solid dispersion and pure drug (Loratadine)**

The *in vitro* dissolution study was carried out in the USP dissolution test apparatus (Electro lab Dissolution tester USP) type 2 (paddle). 900 ml of the dissolution medium (0.1N HCL) was taken in vessel and the temperature was maintained at 37 ± 0.5°C. The speed of the paddle was set at 50 rpm. 5ml of the dissolution medium was withdrawn and the same amount of fresh medium was replenished to the dissolution medium. The sample withdrawn was filtered and analysis in the UV Spectrophotometer (UV-1700 Shimadzu Corporation, Japan) at 280 nm. The *in vitro* release has been given in Table 2 [5]

Table 1 Drug content of solid dispersion

Formulation	*Drug Content (%)
SM1	98.817±0.352
SM2	98.340±0.569
SM3	100.197±0.160
SM4	99.277±0.509
FM1	98.300±0.245
FM2	98.600±0.163
FM3	98.887±0.851
FM4	99.953±0.401
FM5	100.320±0.475

* Average of 3 determinations ± SD

Table 2- *In-vitro* release of Loratadine Pure Drug and Solid dispersion SM1 & SM4

Time (min)	Cumulative Drug Release (%)				
	Pure Drug	SM1	SM2	SM3	SM4
1	15.689	25.447	32.807	38.180	34.353
2	18.331	36.747	45.183	50.376	43.333
3	21.350	46.412	53.207	65.749	50.095
4	23.553	58.736	65.577	78.499	60.167
5	26.341	66.279	72.722	87.425	66.895
6	28.549	70.655	79.569	97.927	74.376
7	30.351	74.342	86.208	-	81.817

PREFORMULATION STUDIES OF POWDER BLEND[6,7]

Angle of Repose (θ):

The friction forces in a loose powder can be measured by the angle of repose (θ). It is an indicative of the flow properties of the powder. It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane.

$$\tan(\theta) = h / r$$

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

Where, θ is the angle of repose

h is the height in cm.

r is the radius in cm.

Bulk Density (D_b):

It is the ratio of total mass of powder to the bulk volume of powder. It was measured by pouring the weight powder (passed through standard sieve # 20) into a measuring cylinder and initial weight was noted. This initial volume is called the bulk volume. From this the bulk density is calculated according to the formula mentioned below. It is expressed in g/ml and is given by

$$D_b = M / V_b$$

Where, M is the mass of powder

V_b is the bulk volume of the powder.

Tapped Density (D_t):

It is the ratio of total mass of the powder to the tapped volume of the powder.

$$D_t = M / V_t$$

Where, M is the mass of powder

V_t is the tapped volume of the powder.

Hauser's ratio:

Hauser's ratio is an indirect index of ease of powder flow.

$$\text{Hauser's ratio} = D_t / D_b$$

Where, Dt is the tapped density.

D_b is the bulk density.

Carr's index (or) % compressibility:

It indicates powder flow properties. Result It is expressed in percentage and is given by

$$I = (D_t - D_b / D_t) \times 100$$

Where, D_t is the tapped density of the powder and D_b is the bulk density of the powder. It has been mentioned in table 5.

Preparation of Tablets Containing Solid Dispersions of Loratadine by Direct Compression Method[6]

The solid dispersions equivalent to 10 mg of drug was taken. Then it mixed with directly compressible diluents and superdisintegrant in a plastic container. Magnesium stearate and talc

were passed through sieve no. 60, mixed and blended with initial mixture in the plastic container followed by compression of the blend.

Table 3. Formulation chart for fast dissolving tablets of Loratadine

Ingredients (mg)	Formulation code												
	F0	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Solid dispersion equivalent to 10mg of drug	40	40	40	40	40	40	40	40	40	40	40	40	40
Ac-Di-Sol	-	3	5	7	-	-	-	-	-	-	3	-	3
SSG	-				3	5	7				3	3	-
Crospovidone	-							3	5	7	-	3	3
MCC	100	97	95	93	97	95	93	97	95	93	94	94	94
Aspartame	4	4	4	4	4	4	4	4	4	4	4	4	4
Talc	4	4	4	4	4	4	4	4	4	4	4	4	4
Magnesium stearate	2	2	2	2	2	2	2	2	2	2	2	2	2
Total(mg)	150	150	150	150	150	150	150	150	150	150	150	150	150

Tablet compression

The tablets were compressed by using single-station tableting machine. The compressible weight of each tablet was 150 mg. The tablet was compressed using 6 mm flat-faced punches. The hardness was adjusted to 2.5 to 3.0 kg/cm^2.

EVALUATION OF FAST DISSOLVING TABLETS

Weight variation: [8,9,10]

The procedure described in Indian Pharmacopoeia (IP, 1996) was employed to determine the weight variation of the tablets. Ten tablets were randomly selected from each batch and weighed on an electronic balance and mean weight was taken. Each tablet was then weighed individually and standard deviation in weight was calculated for each batch.

Hardness: [9, 10]

Five tablets were randomly selected from each batch and hardness of tablets was determined by using Monsanto hardness tester. The mean values and standard deviation for each batch were calculated.

Thickness: [8, 9]

Dimension of the tablets was measured by using a calibrated dial caliper. Five tablets of each formulation were picked out randomly and its thickness was measured individually

Friability (F):[9,10]

Friability of the tablet determined using Roche friabilator. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at a height of 6 inches in each revolution. Pre weighed sample of tablets was placed in the

friabilator and were subjected to the 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. The friability (F) is given by the formula.

$$F = (W_{initial} - W_{final} / W_{initial}) \times 100$$

***In-vitro* Disintegration time:** [8]

The *in-vitro* disintegration time was determined using disintegration test apparatus. A tablet was placed in each of the six tubes of the apparatus and one disc was added to each tube. The time in seconds taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds.

Wetting time: [8]

Wetting is the important step for disintegration process to take place. A piece of tissue paper folded double was placed in a Petri plate (internal diameter is 6.5 cm) containing 6ml of water. The tablet was placed on the paper and the time for complete wetting of the tablet was measured in seconds. The method was slightly modified by maintaining water at 37^{o}C. Wetting time corresponds to the time taken for the tablet to disintegrate when kept motionless on the tongue.

***In-vitro* drug release:** [9]

USP II Paddle apparatus was used and paddle was allowed to rotate at 50 rpm. 0.1N HCL (900 ml) was used as a dissolution medium at 37±0.5°C temperature. Determination of amount of drug dissolved form tablets was carried by UV spectrophotometer at 280 nm. In this test, single tablet from each formulation was used for the studies. At specified time intervals, 5 ml samples were collected and immediately replaced with an equal volume of fresh medium. Samples were analyzed by using UV spectrophotometer (Shimadzu 1700, Japan) at 280 nm.

Stability study: [9]

Selected formulations were subjected to stability studies as per I.C.H. Guidelines. Following conditions were used for stability studies

- ✶ 30°C/65 % RH analyzed at a time interval of 30 days till a period of 60 days
- ✶ 40°C/75 % RH analyzed at a time interval of 30 days till a period of 60 days

RESULTS AND DISCUSSION

In this work initially solid dispersion of Loratadine were prepared by solvent evaporation and fusion method by using beta cyclodextrin, Then drug release of Solid dispersed Loratadine by solvent evaporation 1:3 and Fusion method 1:4 was compared (Figure 4). Standard graph of Loratadine was taken in 0.1N HCl pH1.2, the absorption maxima was found at 280 nm.

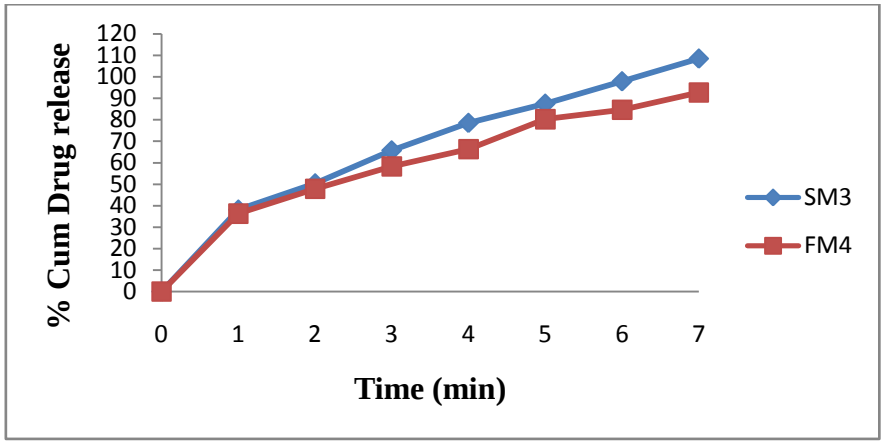

Figure 4 *In-vitro* release of SM3 & FM4(SM: Solvent evaporation method & FM: Fusion method)

The IR spectra of the formulations were compared with the standard spectrum of pure drug Loratadine and the characteristic peaks associated with specific functional groups and bonds of the molecule and their presence/absence in the exipients were noted. It has been mentioned in Figure 1 and 2 & Table 4.

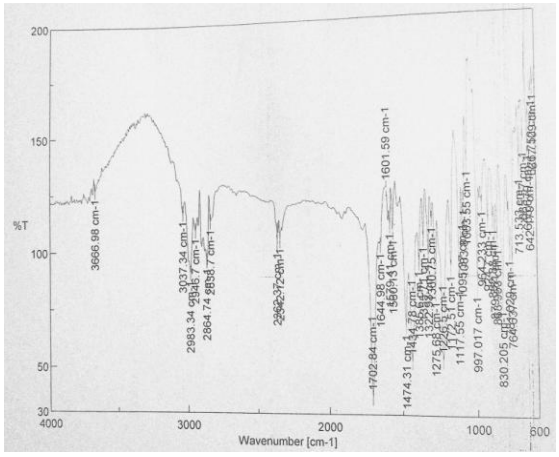

Figure 1: FTIR of Loratadine

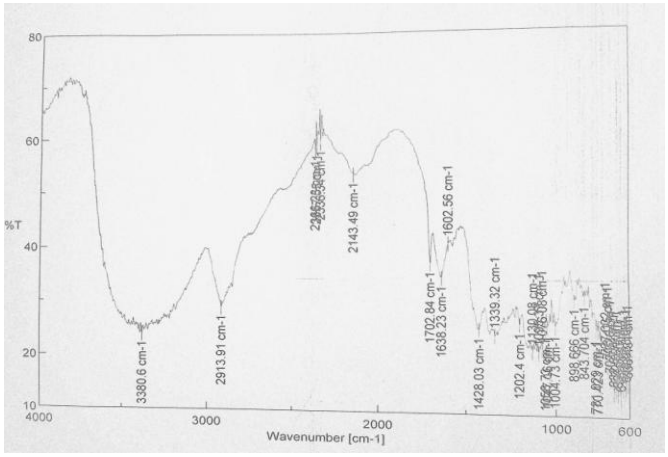

Figure 2: FTIR of F11(Optimized formula)

Table 4: FT-IR frequencies observed with excipients

Sr. no	Functional Group	Reported Frequency cm^{-1}	Observed Frequency cm^{-1}							
			Drug + BCD	SD + CCS	SD + SSG	SD + CP	SD + CCS+ SSG	SD + CP+ SSG	SD + CCS+ CP	F11
1	C=O	1650-1800	1701.87	1702.8	1702.8	1702.8	1702.84	1702.8	1702.8	1702.8
2	C=N	1640-1690	1641.31	1641.1	1644.0	1644.9	1641.13	1644.9	1645.8	1638.2
3	C=C	1600-1670	1601.59	1601.5	1601.5	1601.5	1601.59	1601.5	1600.0	1602.5
4	C-Cl	800-850	853.34	831.16	830.20	831.16	832.13	831.16	830.20	843.70

(BCD: Betacyclo dextrin, SD: Solid dispersion, CCS: Crosscarmellosse sodium, SSG: Sodium starch glycolate, CP: Crospovidone)

The principle IR absorption peak of Loratadine and all exipients are as follows:

1. The peak at 1702.84 cm^{-1}, 1701.87 cm^{-1}, 1702.84 cm^{-1}, 1702.84 cm^{-1} and 1702.84 cm^{-1} is observed due to C=O functional group (Reported Frequency : 1650-1800cm^{-1}).
2. The peak at 1644.98 cm^{-1}, 1641.31 cm^{-1}, 1644.13 cm^{-1}, 1644.02 cm^{-1} and 1644.98 cm^{-1} is observed due to C=N functional group (Reported Frequency : 1640-1690cm^{-1}).
3. The peak at 1601.59 cm^{-1} in all the samples is observed due to C=C functional group (Reported Frequency : 1600-1670cm^{-1}).
4. The peak at 830.250 cm^{-1}, 853.34 cm^{-1}, 831.16 cm^{-1}, 830.20 cm^{-1} and 831.16 cm^{-1} is observed due to C-Cl functional group (Reported Frequency : 800-850cm^{-1}).The range of peak values were found to be the same indicating that there were no Interaction of Loratadine with different disintegrants confirming the stability of drug in the formulations.

The angle of repose values of formulation F0 to F12 ranged from 27.68±0.22 to 29.91±0.61 which indicate the good flow properties of powder. The angle of repose values of all the formulations were depicted in Table 5.

Table 5: Micromeritic properties of pre-compressional powder blend.

Batch no.	Angle of repose (Θ)± SD	Bulk Density (gm/cc)± SD	Tapped Density (gm/cc)± SD	Hausner's Ratio± SD	Carr's Index (%)± SD
F0	27.68±0.22	0.2872±0.0047	0.3409±0.0018	1.177±0.0029	15.27±0.255
F1	29.55±0.53	0.2904±0.0066	0.3468±0.0063	1.191±0.0025	16.77±0.411
F2	29.15±0.36	0.2919±0.0041	0.3502±0.0081	1.210±0.0029	16.12±0.164
F3	29.00±0.70	0.2922±0.0082	0.3516±0.0054	1.198±0.0066	16.21±0.329
F4	28.64±0.80	0.2836±0.0102	0.3378±0.0016	1.199±0.0037	16.84±0.519
F5	29.15±0.36	0.2958±0.0033	0.3413±0.0029	1.144±0.0029	13.99±0.849
F6	29.36±0.29	0.2922±0.0059	0.3515±0.0033	1.220±0.0045	16.50±0.679
F7	29.47±0.75	0.2900±0.0071	0.3456±0.0031	1.183±0.0037	16.99±1.122
F8	29.91±0.61	0.2932±0.0016	0.3536±0.0112	1.212±0.0021	17.93±0.965
F9	29.17±0.40	0.3055±0.0109	0.3575±0.0053	1.165±0.0053	15.24±1.267
F10	27.95±0.05	0.2913±0.0073	0.3401±0.0031	1.176±0.0034	14.89±0.291
F11	28.73±0.34	0.2972±0.0060	0.3432±0.0031	1.157±0.0064	13.99±1.414
F12	29.44±0.54	0.2907±0.0076	0.3607±0.0016	1.239±0.0025	19.97±0.789

All values are expressed as mean ± SD, n=3

The Hausners ratio values for all F0 to F12 formulation ranged from 1.144±0.0029 to 1.239±0.0025. These values are less than 1.25 which indicates powder mixture of all batches exhibited good flow properties. Hausner's ratio of all the formulations was depicted in Table 5. The Carr's Index values for all F0 to F12 formulation ranged from 13.99±0.849% to 19.97±0.789% which indicates good flow properties which was depicted in Table 5

The hardness for all the formulations F0 to F12 was ranged from 2.70±0.04kg/cm^2 to 2.98±0.02 kg/cm^2 which showed that there was no significant difference in hardness of all formulation which was depicted in Table 6.

Table 6: Evaluation of different fast dissolving tablets of Loratadine

Batch	Weight variation* (mg) ±SD	Hardness$^+$ (kg/cm^2)±SD	Thickness$^+$ (mm)±SD
F0	149.67±2.055	2.79±0.05	3.64±0.0249
F1	149.33±1.700	2.82±0.08	3.70±0.0163
F2	150.67±1.247	2.76±0.06	3.71±0.0374
F3	149.00±0.816	2.72±0.01	3.73±0.0205
F4	149.67±1.700	2.82±0.02	3.70±0.0249
F5	150.00±0.816	2.79±0.06	3.69±0.0125
F6	150.33±1.886	2.71±0.01	3.76±0.0082
F7	149.00±2.160	2.70±0.04	3.68±0.0368
F8	149.33±1.247	2.90±0.05	3.70±0.0492
F9	149.67±2.055	2.93±0.04	3.75±0.0216
F10	150.67±2.055	2.98±0.02	3.70±0.0450
F11	150.00±2.160	2.95±0.01	3.72±0.0340
F12	150.67±1.247	2.93±0.08	3.67±0.0170

All values are expressed as mean ± SD, n = 6$^+$, 10*.

The percentage friability of all the formulations was found to be not more than 0.710±0.0039, which was found to be well within the maximum 1 % limit which was depicted in Table.7. The disintegration time for formulations F1 to F12 was ranged from 15.42±1.25 sec to 56.33±0.85 sec which was depicted in Table 7.

Table 7: Evaluation of different fast dissolving tablets of Loratadine

Batch no.	%Friability† ±SD	Disintegration Time*(sec)± SD	Wetting Time*(sec)± SD	Drug Content (%)±SD
F0	0.698±0.0029	140.67±1.25	182.00±0.82	99.41±0.32
F1	0.583±0.0037	39.17±0.24	47.67±0.47	100.07±0.10
F2	0.613±0.0029	28.67±1.25	40.83±0.24	98.65±0.48
F3	0.692±0.0066	21.00±0.35	33.00±0.82	99.72±0.18
F4	0.710±0.0039	50.52±0.73	57.33±1.25	100.14±0.04
F5	0.316±0.0123	43.00±1.63	51.33±1.70	98.25±0.20
F6	0.514±0.0098	29.33±0.47	43.17±0.62	98.28±0.26
F7	0.620±0.0148	34.67±1.25	38.27±1.71	99.87±0.02
F8	0.708±0.0050	25.33±0.94	31.93±0.33	99.37±0.02
F9	0.680±0.0161	19.67±1.25	27.77±0.56	100.09±0.04
F10	0.621±0.0078	27.00±0.82	41.57±0.31	98.85±0.08
F11	0.499±0.0110	15.42±1.25	23.90±1.00	100.23±0.03
F12	0.422±0.0082	56.33±0.85	60.00±1.01	98.98±0.01

All values are expressed as mean ± SD, n = 10†, 6*

The percentage of Loratadine released as a function of time for all the different formulations F1 to F12 were determined. The rapid drug dissolution was observed in F11, which releases 99.92% at the end of 2.5min. The rapid drug dissolution might be due to easy breakdown of particles due to presence of disintegrants. Among all the formulations the formulation containing 3mg crospovidone and 3mg sodium starch glycolate per tablets released maximum amount of drug, which confirms that the combination of crospovidone and sodium starch glycolate gives synergistic effect when it's compared with the individual super disintegrating agent. The dissolution profiles of all formulations were depicted in Table 9, 10 & Figure 5.

Figure 3: Wetting time of F11

Table 8: *In-vitro* release of Loratadine Conventional (Fcon) and Solid dispersed (F0)

Time (min)	Cumulative Drug Release (%)	
	Fcon	F0
1	14.897	27.443
2	18.720	30.080
3	24.810	37.580
4	27.530	45.680
5	30.437	55.283
6	35.040	70.703

Table 9: *In-vitro* release of Loratadine Fast Dissolving Tablets from formulations F1 to F6

Time (min)	Cumulative Drug Release (%)					
	F1	F2	F3	F4	F5	F6
0.5	28.140	30.419	36.149	20.134	22.158	30.139
1	32.997	34.268	40.187	25.749	26.248	36.040
1.5	40.850	44.828	52.950	36.272	37.111	51.517
2	48.497	61.110	67.751	43.263	48.847	65.533
2.5	61.273	70.418	80.490	51.010	61.551	80.111
3	65.667	82.297	91.438	61.773	73.422	87.235
3.5	82.173	94.728	99.800	74.323	80.635	96.198
4	91.383	99.786	-	85.765	92.587	-

Table 10: *In-vitro* release of Loratadine Fast Dissolving Tablets from formulation F7 to F12

Time (min)	Cumulative Drug Release (%)					
	F7	F8	F9	F10	F11	F12
0.5	31.855	35.071	40.201	17.071	38.003	11.217
1	36.746	41.835	49.468	23.284	63.185	14.541
1.5	44.998	52.978	55.913	35.342	83.805	18.989
2	52.774	68.049	76.162	49.229	91.866	28.838
2.5	67.500	79.707	88.857	62.563	99.923	40.949
3	81.261	90.958	99.079	77.036	-	54.936
3.5	84.994	96.053	-	91.953	-	62.767
4	93.018	-	-	97.237	-	71.469

The stability studies were carried out for the best formulation (F11) at 30±2°C/65±5% RH and 40±2°C/75±5% RH for two month. The results indicated that the tablets did not show any physical changes (hardness and friability) during the study period and the drug content was found above 98% at the end of two month. There were no significant differences found in the percentage cumulative drug release after stability study.

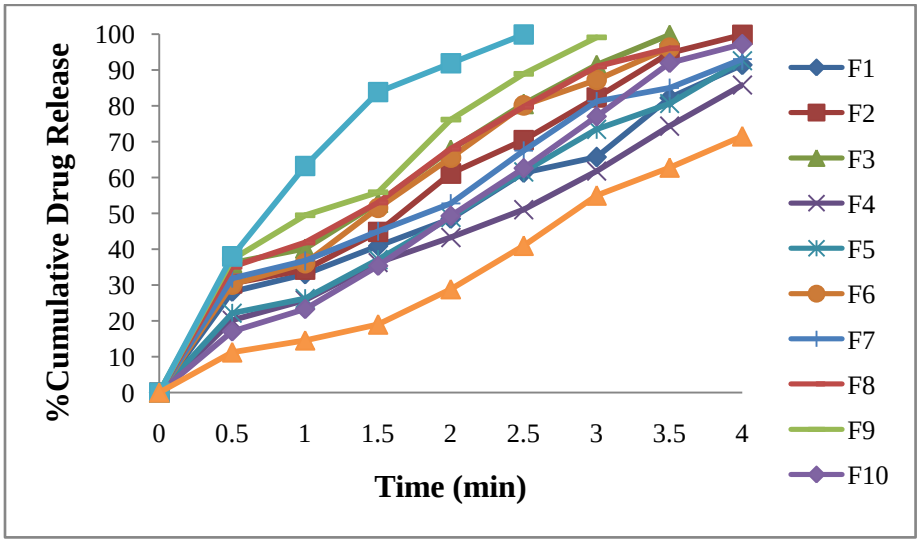

Figure 5: *In Vitro* release of Formulation F1 to F12

CONCLUSION

From the above work it was concluded that formulation F11 showed maximum drug release within 2.5 min when compared to all other formulation and the combination of crospovidone and sodium starch glycolate (3-3 mg/tab) which is used in F11 formulation was found ideal due to its synergistic effect. Hence the present formulation of fast dissolving tablet of Loratadine by direct compression method can be proved as cost effective formulation.

ACKNOWLEDGEMENTS

We are thankful to Srinivas college of Pharmacy for providing the opportunity to carry out our research work successfully.I heartly thank Prof Dr AR Shabaraya for providing us Kind support all the time throughout the work.

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