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IN VITRO DESIGNING OF LORATIDINE-GELUCIRE SOLID DISPERSIONS

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ABSRACT

The aim of present work to improve solubility and bioavailability of Loratidine by preparing solid dispersion with the combination of gelucire 44/14 and 50/13 as a hydrophilic carrier by using solvent evaporation method. In present work 9 formulations of Loratidine solid dispersion were prepared by solvent evaporation method by using different ratios of carriers. All the formulations were subjected to solubility studies, powder characteristics and drug release studies out of 9 formulations F3 and F6 containing Gelucire 44/14(1:3) and Gelucire 50/13 (1:1) showed complete drug release with in 15 minutes. The optimized solid dispersions were punched to fast dissolving tablets and evaluated for various physico chemical properties. The percentage drug release in 15min(Q15) and initial dissolution rate (IDR) for optimized formulation was 94.22 ±1.08%,copared to pure drug (23.87±1.13%) solubility is improved. The improvement in the dissolution characteristics of drug described in terms of dissolution efficiency (DE) and relative dissolution rate (RDR). The RDR was found to be 2.14 and DE 67.52 and it is increased by 4 folds with optimized formulation compared to conventional tablets.

KEYWORDS: Solid dispersion, solubility studies, powder characteristics, drug release studies, IDR, DE, RDR.

INTRODUCTION[1-4]

Oral drug delivery is the simplest and easiest route of administrating drugs because of smaller bulk, accurate dosage and easy production. Solid dosage forms have many advantages over other types of oral dosage forms. New chemical entities (NCE) under development these days are intended to be used in a solid dosage form that originate an

effective and reproducible *in vivo* plasma concentration after oral administration. However, the formulation of poorly water-soluble drugs has always been a challenging problem faced by pharmaceutical scientists and it is expected to increase because approximately 40% or more of the NCE being generated through drug discovery programs have problem in water-solubility.

Drug release is a crucial and limiting step for drug bioavailability particularly for drugs with low gastrointestinal solubility and high permeability. By improving the drug release profile of these drugs, it is possible to enhance their bioavailability and reduce side effects.

Loratadine is a tricyclic antihistamine, which acts as a selective inverse agonist of peripheral histamine H_1 receptors. Which is a BCS class II drug low solubility more permeable.

Strategies to Improve Oral Bioavailability

The solubility problems of BCS class II drugs and methods for overcoming the solubility limitations are to be identified and applied commercially so that potential therapeutic benefits of these active ingredients can be realized. The increase in the amount of drug dissolved at the absorption site usually results in improvement in bioavailability.[1]

Two strategies are employed to achieve this;

i) Improvement in solubility
ii) Enhancement in dissolution rate.

SOLID DISPERSIONS

Solid dispersion technique is one of the promising strategies to formulate poorly soluble compounds that show dissolution-rate-limited absorption. This technique was most successful in improving the dissolution and bioavailability of poorly soluble drugs because it is simple and economic. The term solid dispersion refers to a group of solid products consisting of at least two different components, generally a hydrophilic matrix and a hydrophobic drug. The matrix can be either crystalline or amorphous. The drug can be dispersed molecularly, in amorphous particles (clusters) or in crystalline particles. The carrier used has traditionally been a water-soluble or water-miscible polymer such as polyethylene glycol (PEG) or polyvinylpyrrolidone (PVP), low molecular weight materials such as urea, citric acid and mannitol or more recently, carriers with surface activity such as

Gelucire ®.[6]

SOLVENT METHOD

In this method the physical mixture of the drug and carrier is dissolved in a common solvent, which is evaporated until a clear film formed. The film is further dried to constant weight.

The choice of solvent and its removal rate are critical parameters affecting the quality of the solid dispersion. Since the chosen carriers are generally hydrophilic and the drugs are hydrophobic, the selection of a common solvent is difficult and its complete removal, necessitated by its toxic nature is imperative. Vacuum evaporation may be used for solvent removal at low temperature and also at a controlled rate. More rapid removal of the solvent may be accomplished by freeze-drying or spray drying. The difficulties in selecting a common solvent to both drug and carrier may be overcome by using an azeotropic mixture of solvent in water.[7]

Melting Solvent Method (Melt Evaporation)

It involves preparation of solid dispersions by dissolving the drug in a suitable liquid solvent and then incorporating the solution directly into the melt of polyethylene glycol, which is then evaporated until a clear, solvent free film is left. The film is further dried to constant weight. The 5–10% (w/w) of liquid compounds can be incorporated into polyethylene glycol 6000 without significant loss of its solid property. It is possible that the selected solvent or dissolved drug may not be miscible with the melt of the polyethylene glycol. Also the liquid solvent used may affect the polymorphic form of the drug, which precipitates as the solid dispersion. This technique possesses unique advantages of both the fusion and solvent evaporation methods. From a practical standpoint, it is only limited to drugs with a low therapeutic dose e.g. below 50 mg.[9]

Selection of Carrier

One of the most important steps in the formulation and development of solid dispersion for various applications is selection of carrier.

i) Freely water-soluble with intrinsic rapid dissolution properties.

ii) Non-toxic nature and pharmacologically inertness.

iii) Thermal stability preferably with low melting point especially for melt method.

iv) Solubility in a variety of solvents and should pass through a vitreous state upon solvent evaporation for the solvent method.

v) Ability to increase the aqueous solubility of the drug.

vi) Chemical compatibility and not forming a strongly bonded complex with drug.

Characterization of Solid Dispersions[4]

Several methods have been used to characterize solid dispersions such as Fourier transform infrared spectroscopy (FTIR), Differential scanning calorimetry (DSC), X-ray diffraction (XRD), hot stage and electron microscopy. Among these, thermal and spectral methods (i.e. FTIR, DSC and XRD) are of special interest. The main purpose of using these methods is to differentiate between crystalline and non- crystalline structure of solid dispersions.

MATERIALS AND METHOD

Materials: loratidine, Gelucire 44/14 & Gelucire 50/13 was purchased from B.M.R chemicals, remaining all chemicals are laboratory reagents.

Solubility studies of Loratidine

An excess amount of Loratidine was weighed and transferred into conical flasks which contain 10 ml of media. The content in conical flask were sonicated for 2 h at room temperature, there after the samples were placed on a shaker, agitated at room temperature for 48 h. Subsequently, the suspensions were filtered through a Whatman filter paper. The filtrate was suitably diluted and analyzed by UV-Visible spectrophotometer at a wavelength of 247 nm using a double beam. Results were shown in table no &figure no.

Calibration curve of loratidine

Accurately weighed amount of 100 mg of loratidine was dissolved in 5 ml of 0.1N Hcl and the volume was made up to 100 ml with 0.1N Hcl this is primary stock solution. From this primary stock solution 10 ml was transferred to another volumetric flask made up to 100 ml with 0.1N Hcl this is secondary stock solution, from this secondary stock solution different concentrations respectively 10, 20, 30, 40, 50, 60 mcg/ml prepared. The absorbance was measured at 247 nm by using a UV-Visible spectrophotometer. Results were shown in table no & figure no

Drug –excipient compatibility test

FTIR spectra were recorded using an FT-IR spectrophotometer (Shimadzu). The samples (drug, carrier, solid dispersions) were previously ground and mixed thoroughly with

potassium bromide. Scans were obtained at a resolution of 4 cm–1 from 4000 to 400 cm–1. Results were shown in figure no.

Differential scanning calorimetry

The DSC Thermograms were recorded for drug, carrier and solid dispersions were recorded using differential scanning calorimeter (Shimadzu, Japan). About 2–4 mg of sample in an open aluminium standard pan was heated at a scanning rate of 5°C /min from a temperature 0 to 450°C under a nitrogen gas flow. The heat of fusion of pure drug, carriers, and solid dispersions were measured in a separate experiment. Results were shown in figure no.

Preparation of Solid Dispersions

Accurately weighed amount of drug and polymers in various ratios dissolved in ethanol in a round bottom flask and the solvent was evaporated at 45°C temperature. Solid dispersions were subsequently stored in a vacuum oven at room temperature for 48 h to remove the residual solvent. The dried solid dispersions were grinded in a mortar and pestle and passed through sieve # 60. The samples were stored in desiccators until use.

Formulation of Loratidine Solid Dispersion

Table no 1: Formulation of Loratidine Solid dispersions.

Formulation Code	Ingredients in (mg)			
	Loratidine	Gelucire 44/14	Gelucire 50/13	Drug, carrier Ratio
F1	10	10	-	1:1
F2	10	20	-	1:2
F3	10	30	-	1:3
F4	10	40	-	1:4
F5	10	50	-	1:5
F6	10	-	10	1:1
F7	10	-	20	1:2
F8	10	-	30	1:3
F9	10	-	40	1:4
F10	10	-	50	1:5

Solubility of studies of LTD Solid Dispersions in Various Solvents (mg/ml)

The solubility studies were conducted in different media for all the prepared solid dispersions and compared with pure drug. The aqueous solubility of the solid dispersion formulations of different carriers was determined in different media i.e., 0.1 N HCl, distilled water and phosphate buffer pH 7.4. From the solubility studies, it was found that as the increase in pH of the media increased the solubility i.e. LTD showed greater solubility in 7.4 pH phosphate

buffer when compared others. The solubility data of different formulations using different carriers showed in Table 5. From the results given in above tables, solid dispersions with both Gelucires showed grater solubility and as the carrier concentration increases, the solubility increased proportionally up to 1:3 ratio, but after that there was no proportional increase.

Pre-Compression Parameters

Angle of repose

The angle of repose physical mixtures of liquisolid compacts were determined by fixed funnel method.

$$\mathbf{Tan\ \theta = h/r}$$

Bulk Density

The loose bulk density and tapped density were determined by using bulk density apparatus. Apparent bulk density was determined by pouring the blend into a graduated cylinder. The bulk volume (V_b) and weight of the powder (M) was determined. The bulk density was calculated using the formula

$$\mathbf{Bulk\ Density = M/V_b}$$

Where, M is the mass of powder and V_b is bulk volume of powder.

Tapped Density

The measuring cylinder containing a known mass of blend was tapped for a fixed time. The minimum volume (V_t) occupied in the cylinder and the weight (M) of the blend was measured. The tapped density was calculated using the formula

$$\mathbf{Tapped\ Density = M/V_t}$$

Where, M is the mass of powder and V_t is tapped volume of powder

Carr's Index (%)

The compressibility index has been proposed as an indirect measure of bulk density, size and shape, surface area, moisture content and cohesiveness of material because all of these ca influence the observed compressibility index.

$$\mathbf{CI\ (\%) = [(Tapped\ density - Bulk\ density) / Tapped\ density] \times 100}$$

Hausner's Ratio

It is the ratio of tapped density and bulk density. Hausner found that this ratio was related to interparticle friction and, as such, could be used to predict powder flow properties. Generally a value less than 1.25 indicates good flow properties.

Dissolution studies of prepared solid dispersions

In vitro dissolution studies of prepared solid dispersions were carried out by using USP XXIV type II paddle method. Samples equivalent to 10 mg of loratidine was added to the 900 ml of 0.1N HCl at 37±0.5°C and stirred at 50 rpm. An aliquot of 5 ml was withdrawn at different time intervals with a syringe filter. The withdrawn volume was replaced immediately with same volume of dissolution medium in order to keep total volume constant. The filtered samples were assayed spectrophotometrically at 247 nm. The mean of at least three determinations were used to calculate the drug release.

Tablet Preparation

From the results of dissolution studies, tablets were prepared for optimized solid dispersion preparations. All excipients were weighed as per the below table and mixed well. The blend was compressed to 100 mg tablets, using 6mm punch on a 8-station rotary tablet compression machine

Composition of Loratidine (LTD) Tablets using Optimized Solid Dispersions

Table no 2: Composition of Loratidine Tablets using optimized solid dispersions.

Formulation Code	Ingredients in mg	
	F3	F6
LTD Solid dispersion equivalent to 10 mg LTD	40	40
Crosspovidone	6	6
Avicel pH 102	51	51
Magnesium stearate	1	1
Talc	2	2
Total Tablet weight	100	100

Evaluation of Fast Dissolving Tablets

The prepared tablets were evaluated for weight variation, hardness, friability, content uniformity, disintegration time and *in vitro* dissolution.

Weight variation

Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation three batches were calculated. It passes the test for weight variation test if not more than two of the individual tablet weights deviate from the average weight by more than the allowed percentage deviation and none deviate by more than twice the percentage shown. It was calculated on an electronic weighing balance.

Hardness

The hardness of the tablets was determined by using Pfizer hardness tester. Six individual tablets from each batch were and results averaged.

Friability

The friability values of the tablets were determined using a Roche-type friabilator. Accurately weighed six tablets were placed in Roche friabilator and rotated at 25 rpm for 4 min. Percentage friability was calculated using the following equation.

$$\textbf{Friability} = ([WO - W] / W_O) \times 100$$

Where, W_O = weight of the tablet at time zero before revolution, W = weight of the tablet after 100 revolutions.

Content of uniformity

Three randomly selected tablets were grinded in mortar to get powder; this powder was dissolved in. 0.1N HCl buffer by sonication for 30 min and filtered through filter paper. The drug content was analyzed spectrophotometrically at 247 nm using UV-Visible spectrophotometer. Each measurement was carried out in triplicate and the average drug content was calculated.

Disintegration time

Three tablets were taken randomly from each batch and placed in USP disintegration apparatus baskets Apparatus was run for 10 min and the basket was lift from the fluid, observe whether all of the tablets have disintegrated.

***In- vitro* dissolution Studies**

In- vitro dissolution studies of prepared tablets were carried out by using USP type I (Basket) apparatus. Dissolution was carried in 900 ml of 0.1N HCl at a temperature of $37^0C \pm 0.5^0C$ at speed of 50 rpm. 5ml aliquots of dissolution media were withdrawn each time at suitable time

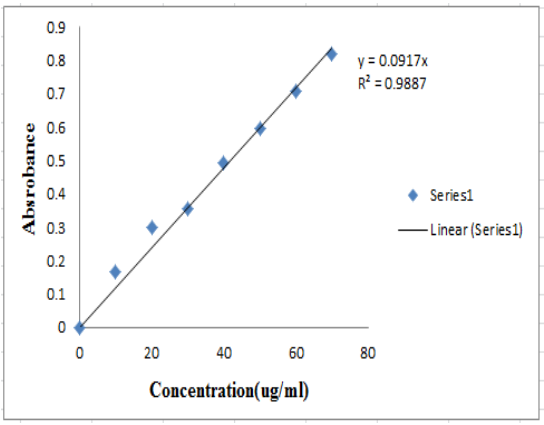
intervals and replaced with fresh medium. After withdrawing the samples they were filtered and analyzed 247 nm by UV-Visible spectrophotometer. The concentration was calculated using standard calibration curve.

RESULTS AND DISCUSSION

Calibration curve of Loratidine

From the UV spectrophotometric analysis the λ_{max} of LTD was found as 247 nm. From the standard graph of LTD in 0.1 N HCl, the r^2 value was found as 0.987, which suggest that it obeys the Beer- Lambert law (Table 4 and Figure 3). The slope calculated from the standard graph is found as 0.0917.

Table no 2: Calibration curve of LTD in 0.1N HCl.



Concentration (mcg/ml)	Absorbance
0	0
10	0.165
20	0.298
30	0.355
40	0.491
50	0.595
60	0.709
70	0.819

Figure no 2: Calibration curve of LTD in 0.1N HCl.

FTIR studies of LTD solid dispersions

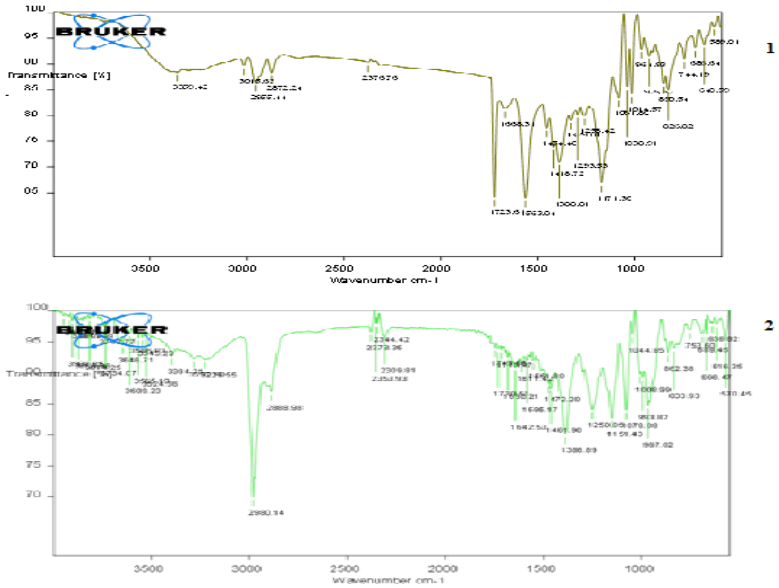


Figure no 3: FTIR spectra of LTD &F3 solid dispersion.

Solubility of studies of LTD Solid Dispersions in Various Solvents (mg/ml)

Table no 3: Solubility studies of LTD solid dispersions using various solvents.

S. No	0.1 N HCl	Distilled Water	7.4 pH Buffer
F1	0.402±0.73	1.134±0.59	1.391±0.18
F2	0.456±0.64	1.283±0.84	1.483±0.31
F3	0.509±0.87	1.416±0.37	1.612±0.58
F4	0.514±0.56	1.421±0.52	1.619±0.41
F5	0.518±0.32	0.429±0.26	1.624±0.63
F6	0.389±0.47	1.122±0.32	1.365±0.18
F7	0.436±0.78	1.262±0.47	1.447±0.31
F8	0.498±0.65	1.396±0.58	1.576±0.58
F9	0.507±0.24	1.411±0.71	1.583±0.41
F10	0.511±0.89	0.418±0.29	1.589±0.63

DSC studies of LTD solid dispersions

The thermograms of the LTD, solid dispersion of LTD with gelucire 44/14 were shown in Figure 4. The DSC thermograms of LTD exhibited a sharp endothermal peak around 134.4^{o}C corresponding to melting point. The thermogram of solid dispersions with gelucire 44/14 showed a short endothermal peak of drug at 138.4^{o}C indicating that slight shift in peak i.e., change in drug crystallinity due to solid dispersions.

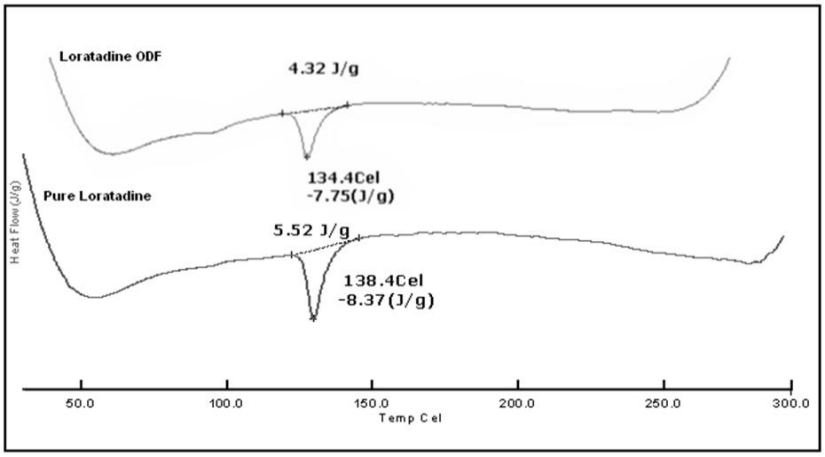


Figure no 4: DSC thermograms of 1) LTD 2) F3 solid dispersion.

In Vitro Dissolution Studies of Solid Dispersions

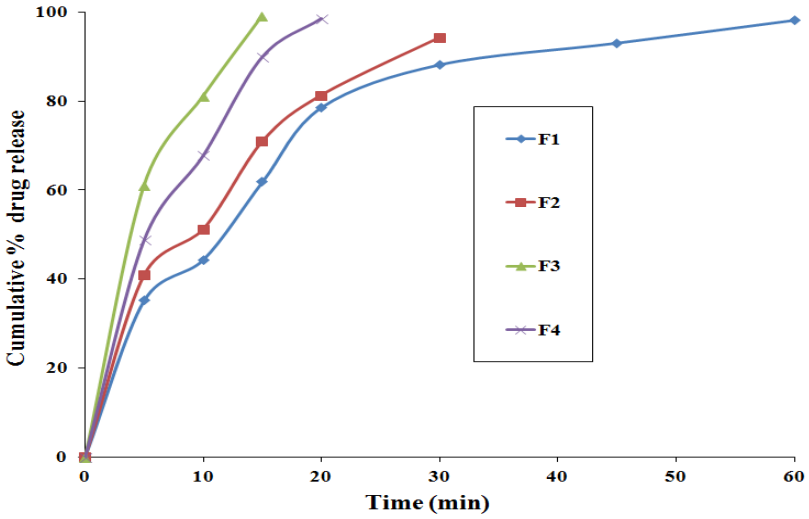
The in vitro dissolution studies, the results were shown in Table 6 & 7 and Figure 6 & 7. From all these formulations, solid dispersions containing Gelucire 44/14 in 1:3 ratio (F3 formulation) showed highest dissolution rate within 15 min i.e. 94.22±1.08%. From the dissolution studies, in case of different formulations, formulations with gelucire 44/14 were showed increased dissolution rate when compared to 50/13. From the *in vitro* dissolution

studies, LTD in the form of solid dispersion showed significant increase in dissolution rate. Many factors contributed to faster drug release rate such as decrease in particle size, decrease in agglomeration of particles, increase wettability and decrease in crystallinity of the drug.

Table Dissolution studies of LTD Solid Dispersions Gelucire 44/14

Table no 4: Dissolution studies of LTD Solid Dispersions Gelucire 44/14.

Time (min)	F1	F2	F3	F4
0	0	0	0	0
5	35.21 ± 2.01	40.96 ± 2.76	61.11 ± 1.12	48.80 ± 0.99
10	44.36 ± 1.98	51.28 ± 1.89	81.22 ± 1.98	67.77 ± 1.22
15	61.85 ± 1.56	70.96 ± 1.90	95.48 ± 1.08	89.92 ± 1.76
20	78.61 ± 2.11	81.35 ± 0.98	99.31 ± 1.78	98.56 ± 1.67
30	88.21 ± 0.33	94.28 ± 0.09	-	-
45	93.08 ± 0.45	-	-	-
60	98.21 ± 0.99	-	-	-



Dissolution studies of LTD Solid Dispersions using Gelucire 50/13

Table no 5: Dissolution studies of Loratidine solid dispersions using Gelucire 50/13.

Time (min)	F6	F7	F8	F9
0	0	0	0	0
5	17.53 ± 2.76	23.64 ± 2.21	30.54 ± 1.94	31.24 ± 2.31
10	28.63 ± 3.09	32.52 ± 2.66	40.85 ± 2.18	42.25± 3.45
15	39.12 ± 4.34	43.51± 3.01	52.31 ± 1.06	57.08 ± 2.91
20	52.66 ± 1.56	55.28 ± 1.87	79.64 ± 1.62	77.63 ± 1.34
30	61.82 ± 2.32	69.56 ± 1.18	98.97 ± 1.21	93.98 ± 1.08
45	65.23 ± 0.58	74.53 ± 2.76	-	-
60	72.65 ± 0.67	81.46 ± 0.87	-	-

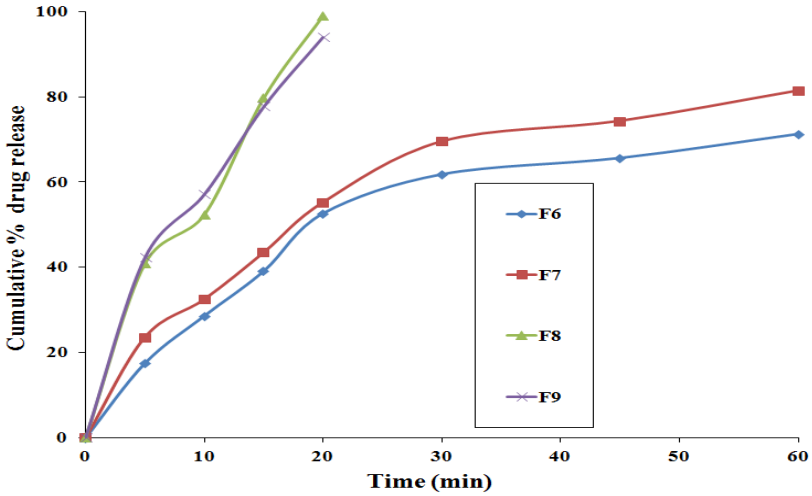


Figure no 5: Dissolution studies of Loratidine solid dispersions using Gelucire 50/13.

Pre-Compression Parameters

The powder mixture for tablets were characterized with respect to angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio (Table 9). Angle of repose was less than 35° and Carr's index values were less than 21 for the powder mixture of all the batches indicating good to fair flowability. Hausner's ratio was less than 1.25 for all the batches indicating good flow properties.

Evaluation of pre-compression parameters (Mean ± SD, n=3)

Table no 6: Evaluationof pre-compression parameters (Mean ± SD, n=3).

Formulation	Angle of Repose (^{0})	Bulk Density (gm/cc^3)	Tapped Density (gm/cc^3)	Carr's Index (%)	Hausner's Ratio
F1	25.11±1.4	0.34	0.398	18	1.22±0.01
F2	33.52±1.9	0.309	0.402	21.5	1.25±0.01
F3	31.13±1.5	0.320	0.398	22	1.26±0.02
F4	23.31±1.6	0.32	0.354	18.2	1.15±0.01
F5	27.13±1.5	0.306	0.357	17.7	1.14±0.01
F6	33.44±1.5	0.326	0.405	18	1.14±0.01
F7	30.87±1.6	0.325	0.408	19.5	1.15±0.02
F8	31.32±1.6	0.307	0.382	20	1.21±0.02
F9	30.64±1.3	0.321	0.345	21	1.20±0.02
F10	36.35±1.5	0.325	0.408	20	1.36±0.01

Evaluation of Fast Dissolving Tablets

Based on the solubility studies, the better solid dispersions were converted into tablets. Table 10 showed all the physical parameters determined for LTD tablets. In weight variation test, the pharmacopoeial limits for the tablets of not more than 5% of the average weight and

found to be near 100 mg. The tablet hardness and friability were found to be around 3 kg/cm^2 and 0.33-0.38%, demonstrating the integrity and strength of tablets. The tablets assay was found to contain 98-99%. From the disintegration test, the prepared tablets were disintegrated rapidly and it was found in the range of 52-75 sec. The dissolution studies of prepared tablets and it showed similar results as shown in dissolution of solid dispersions. The optimized formulation F3 was compare with conventional tablet that have same dose.

Physical Properties of LTD Tablets

Table no 7: Physical properties of Loratidine Tablets.

Formulation	Weight variation* (mg)	Hardness† (Kg/cm^2)	Friability (%)	Disintegration time‡ (sec)	Drug content‡ (%)
F3	101.4±1.28	3.1±0.45	0.38	52±5	99.83±1.15
F6	100.20±3.82	3.4±0.29	0.33	75±5	98.33±1.82

*** All values represent mean ± standard deviation, n=20; † n=6; ‡ n=3**

Comparison of Dissolution profile of LTD optimized formulation (F3) and conventional tablet (n=3).

Table no 8: Comparison of Dissolution profile of LTD optimized formulation (F3) and conventional tablet (n=3).

Time(min)	Optimized Tablet (F3)	Conventional Tablet
0	0	0
5	54.34 ± 1.23	18.62±1.21
10	78.63 ± 1.76	23.87±1.13
15	94.22 ± 1.15	39.62±1.29
30	99.12 ± 1.74	47.62±0.77
45	-	51.23±0.24
60	-	58.62±0.99

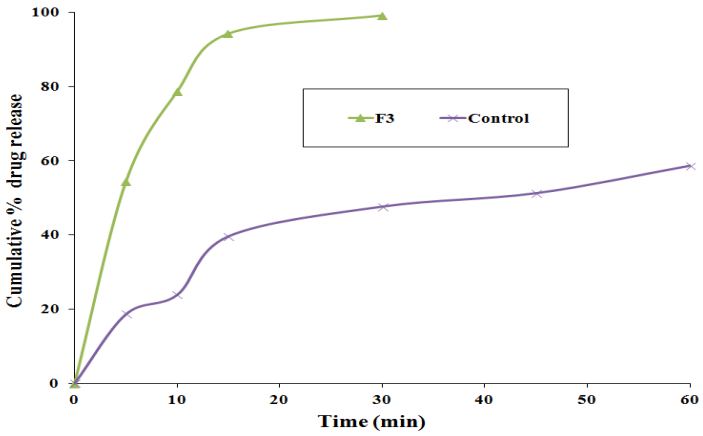


Figure no6: Comparison of dissolution of LTD conventional and optimized tablets

Calculation of Dissolution Parameters

Dissolution Parameters of LTD conventional and F3 optimized tablets (Mean ± SD n=3)

Table no 9: Dissolution Parameters of LTD conventional and F3 optimized tablets (Mean ± SD n=3).

Formulation	(Q_{15})*	IDR (%/min)	DE	RDR
Optimized (F3)	94.22±1.08	9.26	67.52	2.14
Conventional tablet	39.62±1.29	2.38	15.27	

The percent drug release in 15 min (Q_{15}) and initial dissolution rate (IDR) for optimized formulation (F3) was 94.22±1.08%, 9.26%/min. These were very much higher compared to pure drug (23.87±1.13%, 2.38%/min). The improvement in the dissolution characteristics of a drug described in terms of dissolution efficiency (DE) and relative dissolution rate (RDR). The RDR was found to be 2.14. The DE was found to be 67.52 and it is increased by 4.0 fold with optimized FDT formulation compared to conventional tablets. Overall increase in the dissolution performance of the optimized formulations described in terms of dissolution parameters (IDR, DE, RDR) compared to conventional tablets.

SUMMARY

- The design of any drug delivery system is to provide a therapeutic amount of drug to the proper site in the proper time at the desired concentration level. For poorly water soluble drugs dissolution rate is the rate limiting step.
- The solid dispersion method is one of the widely used methods to increase the dissolution rate and is confirmed by the experiment results using Loratidine as a model drug.
- In the present investigation an attempt was made to formulate fast dissolving tablets of loratidine by solid dispersion method using Gelucire 44/14 and 50/13 as hydrophilic carriers.
- All the formulations were subjected to solubility studies, powder analysis for drug-excipient interactions and for flow properties and also for drug release studies.
- All the prepared tablets were evaluated for different physical parameters of tablets and they were compared with Indian pharmacopoeial limits.
- From the *in vitro* drug release studies the optimized formulation F3 containing gelucire 44/14 showed almost complete drug release within the 15 minutes.
- The percent drug release in 15 min (Q_{15}) and initial dissolution rate (IDR) for optimized formulation (F3) was 94.22±1.08%, 9.26%/min. These were very much higher compared to pure drug (23.87±1.13%, 2.38%/min).

- The improvement in the dissolution characteristics of a drug described in terms of dissolution efficiency (DE) and relative dissolution rate (RDR). The RDR was found to be 2.14. The DE was found to be 67.52 and it is increased by 4.0 fold with optimized FDT formulation compared to conventional tablets.

CONCLUSION

In the present study, various weight ratios of Loratidine and carriers were prepared and evaluated for Physiochemical properties. Dissolution rate of all formulations were shown greater than the conventional tablets due to intermolecular interactions between the polymer and drug. The percent drug release in 15 min (Q_{15}) and initial dissolution rate (IDR) for optimized formulation (F3) was 94.22±1.08%, 9.26%/min. These were very much higher compared to pure drug (23.87±1.13%, 2.38%/min). The improvement in the dissolution characteristics of a drug described in terms of dissolution efficiency (DE) and relative dissolution rate (RDR). The RDR was found to be 2.14. The DE was found to be 67.52 and it is increased by 4.0 fold with optimized FDT formulation compared to conventional tablets. In conclusion, development of the solid dispersions can be a promising alternative method to attain the fast dissolution rate and absorption for water-insoluble drugs like loratidine and it was achieved with Gelucire 44/14 as carrier. Further the pharmacokinetic evaluation is needed to prove the capability of Gelucire 44/14 solid dispersions to improve the bioavailability of loratidine.

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