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Physicochemical characterization and dissolution enhancement of loratadine by solid dispersion technique

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Abstract−The purpose of this investigation was to enhance the dissolution rate of loratadine using polyethylene glycol 6000 (PEG) solid dispersions (SDs). The solubility behavior of loratadine in the presence of polyethylene glycol 4000 and polyethylene glycol 6000 in water showed linear increase with increasing concentrations of PEG, indicating A_L type solubility diagrams. SDs of loratadine with PEG 6000 were prepared at 1 : 1, 1 : 3, 1 : 5, 1 : 7 and 1 : 9 ratios by the solvent evaporation method. Solid dispersions were characterized for drug content, dissolution behavior and for physicochemical characteristics. The dissolution rate of loratadine was enhanced rapidly with increasing concentrations of PEG 6000 in SDs. Fourier transform infrared (FTIR) studies showed the stability of loratadine and the absence of a well-defined loratadine - PEG 6000 interaction. Differential scanning calorimetry (DSC) and X-ray powder diffractometry (XRD) studies revealed the amorphous state of loratadine in SDs of loratadine with PEG 6000 which was further confirmed from scanning electron microscopy (SEM) studies. The flow properties of the blend, physical characteristics and disintegration time of the tablets formulated indicated that PEG 6000 SD can be used to formulate fast release loratadine tablets.

Key words: Loratadine, Phase Solubility, Polyethylene Glycol, Solid Dispersion

INTRODUCTION

Solubility and dissolution of drugs in water are important properties that influence the release, transport and rate of absorption in the gastrointestinal tract [1]. The various strategies reported for enhancement of solubility are solid dispersions [2], cyclodextrin complexation [3], liquisolid compacts [4], self emulsion systems [5] and nanosization [6]. Among the various strategies reported, solid dispersions (SDs) have been effective in improving the dissolution properties and bioavailability of poorly water-soluble drugs [7,8]. The advantages of SDs such as improved wettability, reduction of particle size, avoidance of drug recrystallization and amorphous forms of the drug made it a widely used strategy to improve solubility or dissolution rate of poorly water-soluble drugs [9].

Various carriers that have been employed in preparing solid dispersions are polyethylene glycols (PEGs) [10], cellulose derivatives [8], polyvinyl pyrrolidone [11], Gelucires [12] mannitol and urea [13]. In this study polyethylene glycols are used as a carrier because of low toxicity, low melting point, rapid solidification rate, high aqueous solubility, economic cost and physiological tolerance. The above properties make PEGs a suitable excipient for formulation into dosage forms [2,14].

Loratadine (1-Piperidine carboxylic acid, 4-(8-chloro-5,6-dihydro-11H-benzo[5,6] cyclohepta[1,2-b] pyridin-11-ylidene)-ethyl ester) (Fig. 1) is a long-acting antihistamine [15,16] that is poorly soluble in water. It is widely used to treat seasonal and perennial allergic rhinitis, allergic dermatitis. A recent patent reported a pharmaceutical preparation of loratadine that is nasally administrable and bioavailable for the treatment of allergic rhinitis [17]. Earlier studies reported for enhancement of the aqueous solubility and dissolution rate of loratadine include complexation with cyclodextrins [18,19]. The objective of the present study was to investigate the solubility behavior of loratadine, to prepare SDs in the presence of polyethylene glycol 6000 by solvent evaporation method to enhance dissolution rate and characterize SDs by various analytical tools such as FTIR, DSC, XRD, SEM and dissolution study. The optimized SD is to formulate into fast release tablets.

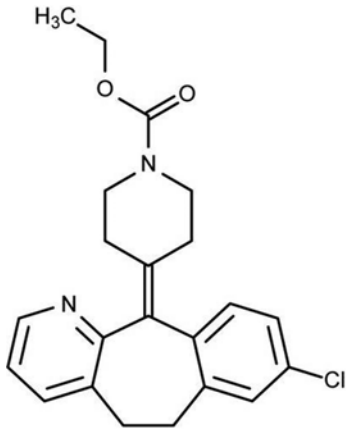

Fig. 1. Structure of loratadine.

EXPERIMENTAL

1. Materials

Loratadine was a gift sample from Vasudha Pharmaceuticals,

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Hyderabad, India. Polyethylene glycol 4000 and polyethylene glycol 6000 were purchased from Merck India Ltd., Mumbai, India. Sodium lauryl sulfate was purchased from S.D. Fine chemicals, Mumbai, India. All other chemicals used were of analytical grade and fresh distilled water was used throughout the study.

2. Methods

2-1. Phase Solubility Studies

Phase solubility studies were carried out by adding an excess amount of drug (30 mg) in screw capped vials containing 20 ml of aqueous solution of polyethylene glycol 4000 (PEG 4000) and polyethylene glycol 6000 (PEG 6000) in 5, 10, 15, 20, 25 and 30% concentrations. The PEG suspensions were continuously agitated on electromagnetic stirrer (Remi, India) for 72 h. The resultant suspensions were filtered through a 0.45 μm membrane filter. The filtrates were suitably diluted and analyzed UV spectrophotometrically for the dissolved drug at 280 nm. All experiments were performed in triplicate.

The Gibbs free energy of transfer ($\Delta G^{o}tr$) value provides information about whether the treatment is favorable or unfavorable for drug solubilization in an aqueous medium. Negative Gibbs-free energy values indicate improved dissolution. The $\Delta G^{o}tr$ of loratadine from pure water to the aqueous solutions of PEGs was calculated by using following Equation [20]:

$$(\Delta G^{o}tr) = -2.303\ RT \log So/Ss$$

Where So/Ss is the ratio of molar solubility of loratadine in aqueous solutions of PEGs to that in pure water.

The apparent stability constant (Kc) of loratadine was calculated from the slope of the phase-solubility curve and So (water solubility of loratadine) using the equation

$$Kc = Slope/So\ (1 - Slope)$$

2-2. Preparation of Physical Mixture

Physical mixture (PM) of loratadine with PEG 6000 at 1 : 9 ratio was prepared by thorough blending of appropriate amounts in a mortar by trituration for 15 minutes followed by sieving (250 μm). The powder sample was stored in a desiccator until use.

2-3. Preparation of Solid Dispersions

Solid dispersions of loratadine in PEG 6000 at various weight ratios (1 : 1, 1 : 3, 1 : 5, 1 : 7 and 1 : 9) were prepared by the solvent evaporation method. An appropriate amount of PEG 6000 was added to a 15 ml ethanolic solution of loratadine. The solution was evaporated with a rotary flash evaporator (Heidolph, Germany) rotated at 60 rpm and temperature maintained at 40 °C for 2 hours. The obtained solid residue was dried in a vacuum oven for 24 hours at room temperature, then pulverized and sieved through 250 μm mesh. The powder samples were stored in a desiccator until use.

2-4. Drug Content

Solid dispersions equivalent to 10 mg of loratadine were weighed accurately and dissolved in 100 ml of 0.1 N hydrochloric acid. The solutions were centrifuged and filtered through a 0.45 μm membrane filter. The filtrates were suitably diluted and analyzed for drug content with UV spectrophotometer at 280 nm.

3. Solid State Characterization of Loratadine - PEG 6000 Systems

3-1. Differential Scanning Calorimetry

DSC thermograms were recorded for pure loratadine, pure PEG 6000, SD5 (1 : 9 ratio) and corresponding physical mixture using a differential scanning calorimeter (Perkin-Elmer, Shelton, CT). Approximately 2-5 mg of each sample was heated in an open aluminum pan from 0-350 °C at a scanning rate of 10 °C/min under stream of nitrogen.

3-2. Fourier Transform Infrared Spectroscopy

FTIR spectra of pure loratadine, pure PEG 6000, SD5 (1 : 9 ratio) and corresponding physical mixture were obtained with a JASCO V 5300 FTIR (Japan). Samples were prepared by KBr disk method and examined under absorbance mode (2 mg sample in 200 mg KBr) and scanned over the range of 4,000 to 400 cm^{-1}.

3-3. X-ray Diffraction Analysis (XRD)

Powder X-ray diffraction patterns of pure loratadine, pure PEG 6000, SD5 (1 : 9 ratio) and corresponding physical mixture were recorded by a powder X-ray diffractometer (Philips PW 3719, Netherlands). The samples were analyzed in the 2θ angle range of 0-80°.

3-4. Scanning Electron Microscopy

The surface morphology of loratadine, pure PEG 6000 and SD5 (1 : 9 ratio) were examined by means of scanning electron microscope Joel, (Japan). The powders were fixed on a brass stub using double-sided adhesive tape and made electrically conductive by coating in a vacuum with a thin layer of platinum (approximately 3-5 nm) at room temperature. The pictures were taken at an excitation voltage of 10 Kv.

3-5. Formulation of Tablets

All formulations were prepared by direct compression method. The composition of Loratadine : PEG 6000 (1 : 9) solid dispersion tablets and the conventional tablet (CT) is given in Table 1. The solid dispersion powder equivalent to 10 mg of Loratadine, spray dried mannitol, cross-linked polyvinyl pyrrolidine were blended in a mortar for 10 minutes and passed through 40 mesh screen. The obtained powder was suitably blended with talc and magnesium stearate for 3 minutes. A loratadine CT formulation without PEG 6000 was also prepared in a similar manner using the same excipients. Tablets were compressed using flat faced 8-mm punches on rotary compression machine (Cadmach, Ahmedabad, India).

3-6. Micromeritic Properties of Blend

The flow properties of powder are vital in the manufacture of tablets. The flow properties were studied through measuring the angle of repose, Carr's index and Hausner's ratio. The angle of repose was determined by using conventional fixed funnel method [21]. Carr's index and Hausner's ratio were calculated from the bulk and tapped density of the blend [22].

3-7. Characterization of Tablets

Compressed tablets were characterized for weight variation (n=

Table 1. Composition of loratadine 10 mg plain and solid dispersion tablets

Ingredients mg/Tablet	F1	F2	CT
Solid dispersion (1 : 9)	100	100	10
Cross povidone	8	12	12
Pearlitol SD 200	86	82	172
Talc	4	4	4
Magnesium stearate	2	2	2
Total tablet weight	200	200	200

Table 2. Phase solubility and thermodynamic parameters of loratadine in different concentrations of PEG 4000 and PEG 6000-water systems

Concentration of carriers (% w/v)	Concentration of loratadine (mg/ml)	$\Delta G^{o}tr$ (KJ/mole)	Concentration of loratadine (mg/ml)	$\Delta G^{o}tr$ (KJ/mole)
	PEG 4000		PEG 6000	
5	0.00842	−2.4	0.00742	−2.04
10	0.01781	−4.2	0.01548	−3.86
15	0.02853	−5.4	0.02633	−5.18
20	0.0351	−5.9	0.0321	−5.67
25	0.04026	−6.2	0.03608	−5.96
30	0.04559	−6.5	0.03972	−6.20
Stability constant (ml/g)	453.86		393.43	
R^2	0.9849		0.9739	
Type of curve	A_L		A_L	

20), Crushing strength (n=6), friability (n=6), using Shimadzu analytical balance, Monsanto tester and with Roche type friabilator respectively. Disintegration time of the different tablet formulations was determined with disintegration apparatus (Electrolab, Mumbai, India) according to USP testing standards. The disintegration medium was distilled water at 37 ºC. The drug content in each formulation was determined by taking twenty tablets and powdering in mortar; powder equivalent to one tablet was taken and was allowed to dissolve in 100 ml of 0.1 N hydrochloric acid (HCl) by shaking for 30 minutes on a rotary shaker. The solution was filtered through 0.45 μm membrane filter, diluted suitably and analyzed using UV/visible spectrophotometer at 280 nm.

3-8. Dissolution Studies

In-vitro dissolution studies of pure loratadine, physical mixture, solid dispersions and tablets were done by using USP XXIV type II apparatus (Electrolab, Mumbai, India). Samples equivalent to 10 mg of loratadine were added to the 900 ml distilled water containing 0.1% w/v sodium lauryl sulfate at 37±0.5 ºC and stirred at 50 rpm. An aliquot of 5 ml was withdrawn at predetermined time intervals and filtered through 0.45 μm filter using a syringe filter. The withdrawn volume was replenished immediately with the same volume of fresh dissolution medium in order to keep the total volume constant. The filtered samples were diluted suitably and assayed for loratadine content with a UV spectrophotometer at 280 nm. The mean of at least three determinations was used to calculate the drug release.

3-9. Dissolution Parameters

The dissolution profiles of solid dispersions and physical mixture were evaluated for various parameters like amount of drug released in initial 15 min ($Q_{15\,min}$), time taken to release 50% of the drug ($T_{50\%}$), dissolution efficiency (DE)% [23] after 60 minutes and mean dissolution time (MDT) min [24].

RESULTS AND DISCUSSION

1. Drug Content

The drug content of the prepared solid dispersions was found to be in the range of 97.7-101.2%, indicating the application of the present method for the preparation of SDs with high content uniformity.

2. Phase Solubility Studies

The solubility of loratadine in distilled water at room temperature was found to be 3.27 μg/ml, indicating it as practically insoluble in water. The phase solubility data of PEG 4000 and PEG 6000 are shown in Table 2. There is a systematic increase in the solubility of loratadine with increasing amount of PEGs in the solution. At 30% concentration of PEG 4000 and PEG 6000, the increase in solubility at room temperature compared with pure drug was 14-fold and 12-fold, respectively. The solubility behavior of loratadine in the presence of PEG 6000 and PEG 4000 in water showed linear increase with increasing concentrations of PEG indicating A_L type solubility diagram. The increase in solubility in the presence of PEGs can probably be explained by increased wettability of loratadine. These results are in accordance with the established formation of soluble complex between water soluble carriers and poorly soluble drugs [25].

An indication of the process of transfer of loratadine from pure water to the aqueous solutions of PEG 4000 and 6000 was obtained from the values of Gibbs free energy change ($\Delta G^{o}tr$). The obtained values of Gibbs free energy are presented in Table 2. The data provide the information regarding the increased solubility of loratadine in the presence of PEG 4000 and 6000. $\Delta G^{o}tr$ values were all negative, indicating the spontaneous nature of loratadine solubilization and it decreased with increase in concentration of PEG 4000 and 6000, demonstrating that the reaction became more favorable as the concentration of PEGs increased. The apparent stability constant (Kc) of loratadine with PEG 4000 and 6000 was 453.86 and 393.43 ml/g, respectively, indicating ideal binding affinity between loratadine and PEGs. The value of the stability constant in the range of 100 to 1,000 ml/g was considered to be ideal [26]. Actually, smaller values of (Kc) indicate too weak interaction, whereas larger values are symptomatic of an incomplete release of drug from the complex.

Usually, PEGs of molecular weight (MW) 4000 and 6000 are the most frequently used for the manufacture of solid dispersions, because in this MW range the water solubility is still very high, without hygroscopic problem and stickiness in formulating acceptable pharmaceutical product [27]. The solubilizing capacity of loratadine in PEG 4000 and PEG 6000 has shown to increase with increase in PEG concentration representing A_L type curve. PEG 6000 was utilized in further studies because of relatively less sticky solid dis-

persions obtained with PEG 6000 than PEG 4000 at highest ratio studied. Thus the solid dispersions using PEG 6000 were prepared and further formulated into tablets.

3. Dissolution Studies

The dissolution of poorly soluble drugs requires dissolution media that are different from those used for water-soluble drugs. One of the techniques that have been found to be useful in dissolution of insoluble drugs is the incorporation of a small amount of surfactant in the dissolution medium [28]. The use of surfactants in the dissolution systems may be physiologically more meaningful, due to the presence of natural surfactants like bile salts in the gastrointestinal tract. The ability of surfactants to accelerate the *in vitro* dissolution of poorly water soluble drugs has been attributed to wetting, micellar solubilization and/or deflocculation. It is understood that the biorelavant medium needs similar surface activity as bio fluids; the studies on sodium lauryl sulphate have been shown to satisfy these needs [29]. Based on these facts, dissolution of pure loratadine, PM, SDs and tablets was carried out in distilled water containing 0.1% w/v sodium lauryl sulfate. Since the principal aim of this work was to improve the dissolution rate of loratadine, dissolution studies were performed for the initial 2 h.

Because of its poor solubility and wettability, pure loratadine dissolved very slowly in 0.1% w/v sodium lauryl sulfate in distilled water. After 1 h of dissolution study, the pure loratadine showed dissolution of 28.1%, and even after 2 h, the pure drug did not show 50% dissolution. Fig. 2 shows the percent of loratadine dissolved as a function of time from pure drug, PM and SDs of all formulations. The results indicate that the solid dispersions of loratadine exhibited higher, faster release profiles than pure loratadine and PM. It is very clear that the loratadine dissolution rate increased with increasing PEG 6000 content in PM and SD.

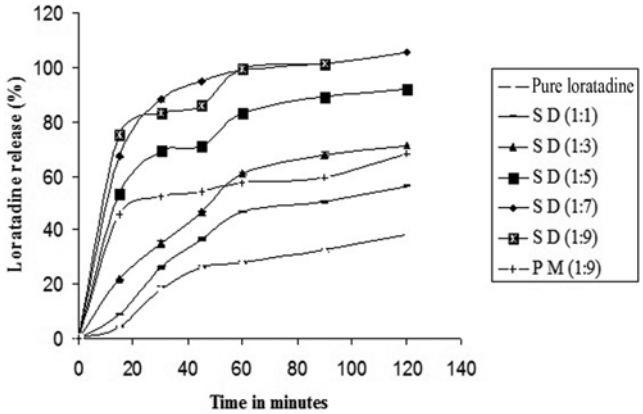

Fig. 2. *In vitro* dissolution profile of SDs (1 : 1, 1 : 3, 1 : 5, 1 : 7 and 1 : 9 ratio) and PM (1 : 9 ratio) formulations along with pure loratadine. Results are shown as mean±SD (SD - solid dispersions and PM - physical mixture).

As indicated in Table 3, solid dispersions enhanced the dissolution rate of the drug. Dissolution efficiency of SD5 was improved around five-fold compared to pure drug. The MDT of pure loratadine was 43.9 min, decreasing to a greater extent 17.6 min after preparing SDs with PEG 6000. The MDT of loratadine decreases with increasing concentrations of PEG 6000 in SDs. The percent drug released from pure drug, 1 : 9 ratio of SD (loratadine and PEG 6000) and corresponding PM, in 15 minutes ($Q_{15\,min}$) was found to be 4.34%, 75.08%, 45.53%, respectively, indicating enhanced dissolution rate. However, PM and all SDs showed improved dissolution over pure loratadine. The time taken to release 50% of loratadine ($T_{50\%}$) from SD5 and PM was found to be 8 minutes and 26 minutes, respectively.

4. Solid State Characterization

4-1. Differential Scanning Calorimetry

The thermograms of the pure loratadine, pure PEG 6000, SD5 and corresponding physical mixture (PM) are shown in Fig. 3. The thermograms of the pure products show a single endothermic peak corresponding to the melting of loratadine at 135.7 °C and PEG 6000 around 63 °C. SD5 (loratadine with PEG 6000) at 1 : 9 ratio shows no endothermic peak corresponding to loratadine, suggesting amorphous form of loratadine in the SD. Similar observations have been previously reported [30]. From the DSC study, loratadine appears to exist in an amorphous state in PEG 6000 SD. The reduction in crystallinity and improved wettability of loratadine in the SD can also be seen in the MDT of Table 3.

4-2. Fourier Transform Infrared Spectroscopy

The FTIR spectra of pure loratadine, pure PEG 6000, SD5 and corresponding PM are shown Fig. 4. Prominent drug peaks at 1,701 cm^{-1} indicating (C=O stretching), 1,473 cm^{-1} (-C-O stretching of carboxylate), 1,226 cm^{-1} (-C-N stretching of aryl N), 997 cm^{-1} (Aryl C-Cl stretching) and PEG 6000 peaks, 2887 cm^{-1} (C-H stretching), 1,465 cm^{-1}, (C-H deformation of alkyl group), 1,114 cm^{-1}, (C-O ether) stretching are observed in both solid dispersion, physical mixture. This clearly suggests no possible interaction between drug and carrier and confirms the stability of loratadine in SD prepared by solvent

Table 3. Composition and dissolution parameters of loratadine-PEG 6000 solid dispersions and physical mixture

Formulation code	Drug : Carrier ratio	$T_{50\%}$ (min)	Q_{15} (min)	(DE %)	MDT (min)
Loratadine	1 : 0	>120	4.34±0.32	15.72±0.79	43.99±0.44
SD1	1 : 1	76±0.99	8.82±0.26	23.78±0.92	39.73±0.67
SD2	1 : 3	43±0.38	29.86±0.49	37.49±0.37	35.99±0.25
SD3	1 : 5	14±0.19	53.14±0.93	58.76±0.77	24.19±0.89
SD4	1 : 7	10±0.33	67.02±0.65	73.42±0.56	19.55±0.73
SD5	1 : 9	8±0.94	75.08±0.43	74.82±0.56	17.57±0.35
PM	1 : 9	26±0.62	45.53±0.53	48.44±0.14	31.63±0.49

$T_{50\%}$- Time taken for 50% dissolution, Q_{15} (min)-Amount of drug released in 15 minutes, DE %-Dissolution Efficiency, MDT-Mean Dissolution Time, (SD - solid dispersions and PM - physical mixture)

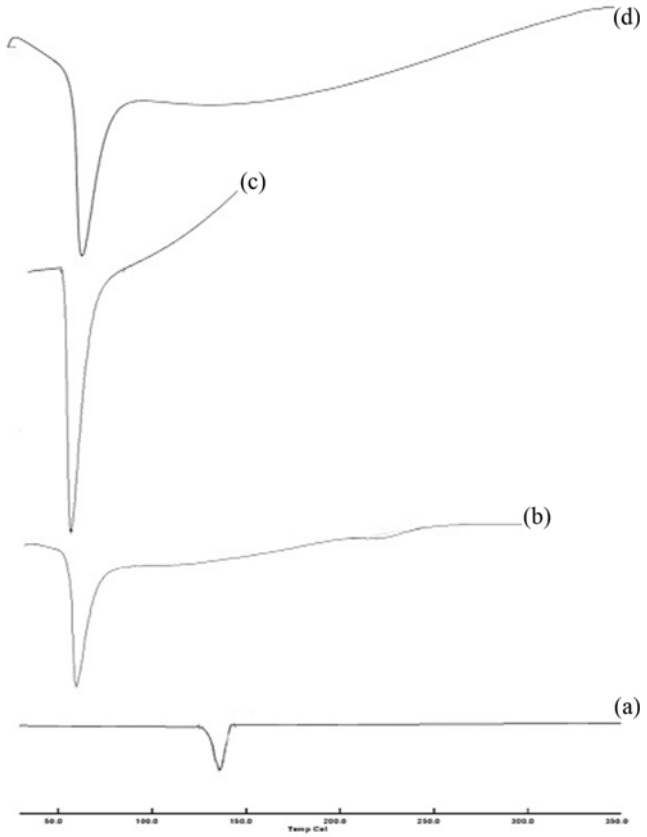

Fig. 3. Differential scanning calorimetry thermograms of pure loratadine (a), pure PEG 6000 (b), loratadine-PEG 6000 physical mixture at 1 : 9 ratio (c) and loratadine-PEG 6000 solid dispersion at 1 :9 ratio (d).

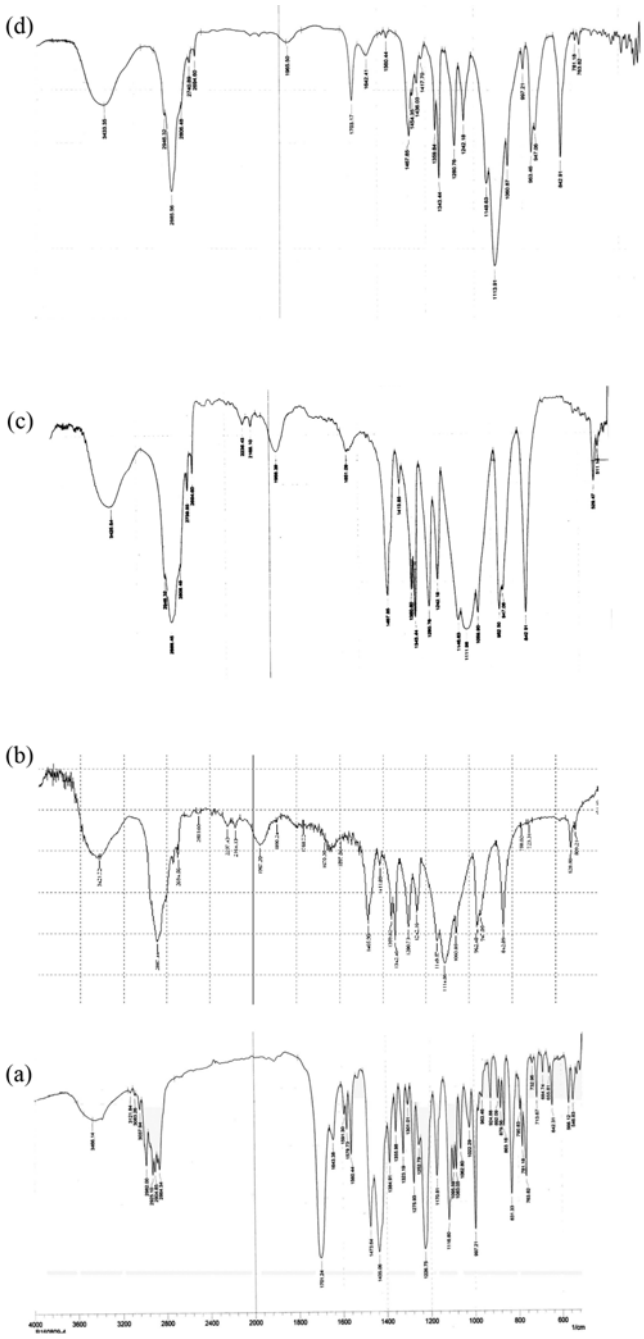

Fig. 4. Fourier transform infrared spectrograms of pure loratadine (a), pure PEG 6000 (b), loratadine-PEG 6000 physical mixture at 1 : 9 ratio (c) and loratadine-PEG 6000 solid dispersion at 1 : 9 ratio (d).

evaporation method.

4-3. X-ray Diffraction Analysis

X-ray diffractograms for pure loratadine, pure PEG 6000, SD5 and corresponding PM investigated are shown in Fig. 5. The diffraction pattern of pure loratadine shows high intensity peaks at 2 theta values of 13°, 15.1°, 16.4°, 21°, 24° and 30.5°, respectively. Sharp intense peaks may be due to presence of crystalline form of the drug. The diffraction pattern of PEG 6000 exhibits intensity peaks at 19.2°, 23.3°.

SD and physical mixture exhibited the absence of characteristic peaks of loratadine, suggesting that loratadine is present in an amorphous form. An amorphous or metastable form will dissolve at the fastest rate because of its higher internal energy and greater molecular motion, enhancing thermodynamic properties relative to crystalline materials [31]. From the present data, it is clear that the amorphous properties of loratadine in the SD and physical mixture are responsible for the enhanced dissolution. The MDT values also supported this finding as both SD and physical mixture formulations exhibited greater reduction in the MDT of loratadine. MDT is inversely related to dissolution rate. The previous researchers reported the presence of amorphous forms of poorly water soluble drugs in SDs and physical mixture [12,32].

4-4. Scanning Electron Microscopy

The scanning electron micrographs of pure loratadine, pure PEG 6000 and SD5 are shown in Fig. 6. Pure loratadine appears as rod shaped crystals (Fig. 6(a)); PEG 6000 has presented bulky particles with a comparatively smooth surface. The solid dispersion formulation is constituted by relative bulky particles and the surface nature mostly resembles that of pure PEG 6000 (see Fig. 6(b) and 6(c)), indicating that loratadine is homogeneously dispersed at the molecular level.

4-5. Characterization of Tablets

4-5-1. Flow Properties

It is very well known that poor flowing powders present several

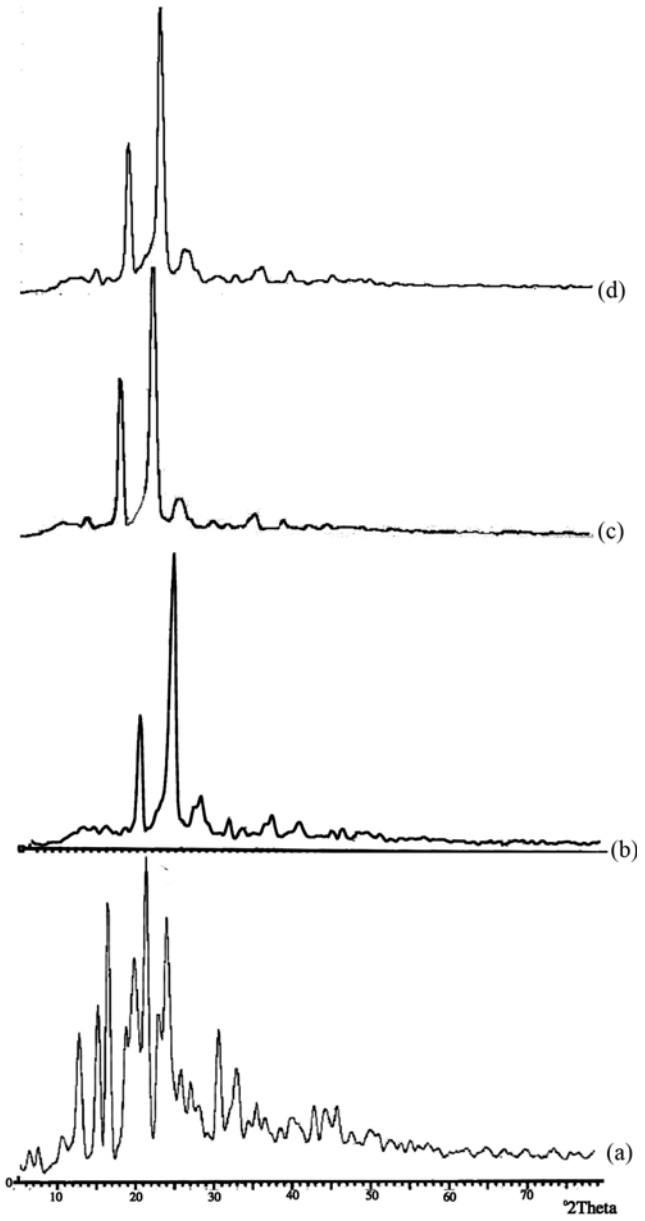

Fig. 5. X-ray diffract to grams of pure loratadine (a), pure PEG 6000 (b), loratadine-PEG 6000 physical mixture at 1 : 9 ratio (c) and loratadine-PEG 6000 solid dispersion at 1 : 9 ratio (d).

difficulties during the compression process. The flow properties were assessed by angle of repose, Carr's index and Hausner's ratio. The SD5 powder exhibited the angle of repose, Carr's index and Hausner's ratio values of 35, 20 and 1.20, respectively, indicating fair flow properties. However, the blend of formulations prepared exhibited excellent flow properties with angle of repose in the range of 23 to 24.5, Carr's index of 14.2 to 15.0 and Hausner's ratio of 0.75-0.8.

4-6. Characterization of PEG 6000 Tablets

The results of the physical characteristics of compressed tablets revealed that the tablets comply with the standards. The weight of all the tablets was uniform as evidenced from low RSD values. Hardness of tablets was found to be between 3.3 to 3.5 kg/cm^2, indicating sufficient crushing strength. The friability was below 1% for all formulations, indicating good mechanical resistance of the tablet. The drug content of compressed tablets varied between 99.4 to 100.6% with low standard deviation, indicating content uniformity of the prepared batches.

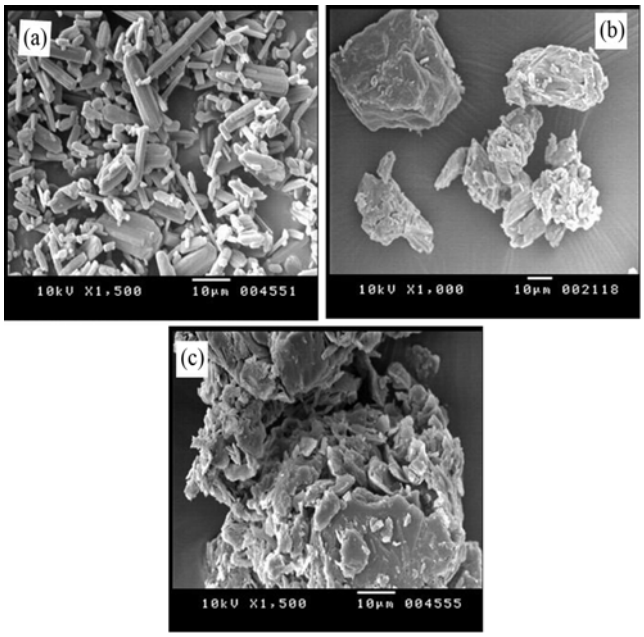

Fig. 6. SEM micrographs of pure loratadine (a), PEG 6000 (b), SD of loratadine-PEG 6000 (1 : 9) (c).

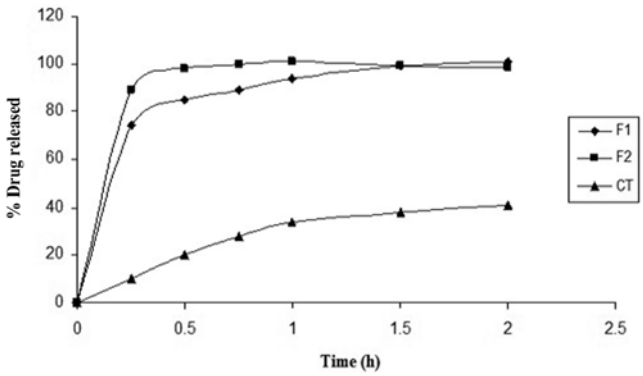

Fig. 7. *In vitro* dissolution profiles of tablets containing plain drug and solid dispersions with PEG 6000.

4-7. Disintegration Time

Previous studies indicated that PEG 6000 [33] prolongs the disintegration time of tablets. However, the observed disintegration time of 12±0.92 minutes and 9±0.56 minutes of the formulations F1 and F2 revealed that tablets disintegrated within the USP requirements (<15 minutes). However, DT of the formulations decreased with increased amounts of disintegrant used.

4-8. Dissolution Studies

The release profile of loratadine from tablets containing SD5 with varying concentrations of disintegrant and conventional tablets containing loratadine (without PEG 6000) is shown in Fig. 7. Release of loratadine from tablets containing SD with PEG 6000 at 4% and 6% concentration of disintegrant studied was faster and higher than

the conventional tablets containing plain loratadine. These results further suggest the advantage of improved aqueous solubility of Loratadine solid dispersions compared with free drug that can be formulated as tablets with enhanced dissolution characteristics.

CONCLUSIONS

The phase solubility behavior of loratadine showed linear increase in solubility with increasing concentrations of PEGs. The negative values of the Gibbs free energy from water to an aqueous solution of both PEGs indicated the spontaneity of the transfer. The results revealed that SDs of loratadine in PEG 6000 showed increased dissolution rate with decreased MDT. FTIR spectroscopy studies showed no interaction between loratadine and PEG 6000. The absence of an endothermic peak of loratadine in the DSC thermograms of SD with PEG 6000 showed the conversion of loratadine from a crystalline to an amorphous state; this was supported by XRD and SEM studies. The flow properties of the blend, physical characteristics and disintegration time of the tablets indicated that PEG 6000 SD can be used to formulate fast release loratadine tablets.

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