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DESIGN AND CHARACTERIZATION OF NATEGLINIDE ORAL DISPERSIBLE TABLETS BY SOLID DISPERSION TECHNIQUE

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ABSTRACT

An ideal dosage regimen in the drug therapy of any disease is the one which immediately attains the desired therapeutic concentration of drug in plasma and maintains it constant for the entire duration of treatment. The main objective of the present work is to investigate the possibility of obtaining an immediate release tablet of Nateglinide with improved dissolution using the Solid dispersion technique. Solid dispersions preparations containing different weight ratios of Nateglinide in PEG6000 (1:1, 1:3, 1:5) were prepared by the melting method and characterized for drug content, phase solubility study, and dissolution study. Immediate release tablets were prepared using various polymers, and the prepared tablets were evaluated for weight variation, friability, assay, hardness, thickness, disintegration test and dissolution test. The Nateglinide immediate release tablet (F2) showed 58.72% drug release within the first 5 min. and 99.50% drug release within 30 min. The results showed that the formulation satisfied the objective of fast disintegration, dissolution, % friability, hardness, wetting time, water absorption ratio, ease of administration and safety. The success of the present study recommends a detailed investigation into *in-vivo* studies for its effective use in clinical practice.

Keywords: Nateglinide, PEG6000, immediate-release tablets

INTRODUCTION

An ideal dosage regimen in the drug therapy of any disease is the one which immediately attains the desired therapeutic concentration of drug in plasma (or at the site of action) and maintains it constant for the entire duration of treatment. The drug may be administered by a variety of routes in a variety of dosage forms. Drugs are morefrequently taken by oral administration. The solid dosage forms are primarily available in unit dosage forms such as tablets, capsules, lozenges, etc[1]. When drugs are administered orally in a dry state, tablets and capsules are the most convenient dosage form[2]. For all practical purposes, only compression tablets are almost universally used, while moulded tablets are a rare commodity. Drugs are more frequently taken by oral administration[3].

Although a few drugs taken orally are intended to be dissolved within the mouth, most drugs taken orally are swallowed[4]. Compared with alternate routes, the oral route of drug administration is the most popular and has been successfully used for the conventional delivery of drug[5]. It is considered the most natural, uncomplicated, convenient, and safe means of administering drugs[6]. Some advantages are greater flexibility in dosage design, ease of production and low cost[7].

Many patients find it difficult to swallow tablets and hard gelatin capsules and thus do not comply with prescriptions, which results in a high incidence of non-compliance and ineffective therapy. Recent advances in novel drug delivery systems (NDDS) aim to enhance the safety and efficacy of drug molecules by formulating a convent dosage form for administration and to achieve better patient compliance[8].

Nearly 35 - 50% of the general population, especially the elderly and children, suffer from dysphasia or difficulty swallowing, resulting in a high incidence of non-compliance and ineffective therapy[9]. Swallowing problems also are widespread in young individuals because of their poorly developed muscular and nervous systems. Other groups who may experience difficulties swallowing conventional oraldosage forms are the patients with tremors of extremities, mentally ill, developed mentally disabled, non-cooperative and patients with reduced liquid intake or patients suffering from nausea, and patients travelling or who do not have easy access to water. Swallowing problems are also common in some cases, such as patients with motion sickness, sudden episodes of allergic attack or coughing, and lack of water.

To overcome this problem, scientists have developed an innovative drug delivery system called "Immediate release tablets" [10]. Immediate release tablets are designed to disintegrate and release their medication without any special rate-controlling features such as special coating and other techniques[11].

The main objective of the present work is to investigate the possibility of obtaining an immediate release tablet of Nateglinide with improved dissolution using the Solid dispersion technique.

MATERIALS AND METHODS

Nateglinide was gifted from Microlabs Ltd., India. Microcrystalline cellulose, sodium alginate, aerosil and talc were obtained from Loba Chemie, India. Sodium starch glycolate was obtained from Research Lab fine Chem, India.

Preparation of Solid dispersions by melting the carrier

Solid dispersions (SDs) preparations containing different weight ratios of Nateglinide in PEG6000 (1:1, 1:3, 1:5) were prepared by the melting method. Nateglinide was added to the melted PEG 6000 at 75 ºC, and the resulting homogenous preparation was rapidly cooled in a freezing mixture of ice and sodium chloride and stored in desiccators for 24 hours. Subsequently, the dispersion was ground in a mortar and sieved through 100#.

Physical Mixture

Physical mixture (PMs) having the same weight ratios were prepared by thoroughly mixing appropriate amounts of Nateglinide and PEG 6000 in a mortar until a homogenous mixture was obtained. The resulting mixture was sieved through a 100# sieve and denoted as PM.

Characterization of solid dispersions of Nateglinide with PEG 6000

Drug content: About 10 mg of drug equivalent of the physical mixture and solid dispersion were weighed accurately and transferred to a 50 ml volumetric flask to which 10 ml methanol was added and sonicated for 15 min, and the volume was made up with methanol. Further dilution was done and assayed from this stock solution using a UV spectrophotometer measured at 283 nm.

Phase-Solubility Study: Phase-solubility studies were carried out to evaluate the possible solubilizing effect of the carrier by adding an excess amount of drug to a flask containing 10 ml of aqueous solutions containing increasing concentrations of PEG6000. The flask was placed in a mechanical shaker at 75 rpm and at room temperature for 24 hours. After 24 hours, the solutions were filtered and analysed by UV-Spectrophotometer at 283 nm.

Dissolution Studies: Dissolution studies of Nateglinide in powder form, SDs, and PMs were performed using the USP type II paddle apparatus at the paddle rotation speed of 75 rpm in 900 ml of pH 5 acetate buffers as a dissolution medium at 37±0.5 °C. The SDs or PMs equivalent to 2 mg of Nateglinide were weighed using a digital balance and added to the dissolution medium. At the specified times (every 10 min for 2 hours), 10 ml samples were withdrawn using a syringe filter (0.45 µm) and then assayed for Nateglinide content by measuring the absorbance at 283 nm using a UV- Visible spectrophotometer. Fresh medium (10 ml), prewarmed at 37 °C, was added to the dissolution medium after each sampling to maintain its constant volume throughout the test.

Fourier transforms IR spectroscopy: Fourier-transform infrared (FT-IR) spectra were obtained by using BrukerGermany FTIR. The samples (Nateglinide or SDs or PMs) were previously ground and mixed thoroughly with potassium bromide, an infrared transparent matrix, at a 1:5 (Sample/KBr) ratio, respectively. The KBr discs were prepared by compressing the powders at a pressure of 5 tons for 5 min in a hydraulic press.'

Preparation of natural super disintegrants (*Plantago ovata* seed powder, mucilage, and husk powder): The powder of seeds and husk were prepared by an automatic grinder and sieved (#80). Then it is stored in a dedicator until use. For isolation of seed mucilage, thecleaned seeds of *Plantago ovata* were soaked in distilled water for 48 hours and then boiled for a few minutes so that mucilage was released entirely into the water. This material is squeezed through muslin cloth for filtering and separating the marc. Then an equal volume of acetone was added to the filtrate to precipitate the mucilage. The mucilage was dried in an oven (less than 60 ºC), powdered, sieved (# 80) and stored in desiccators until use. The natural super disintegrants were evaluated for their physicochemical properties. The swelling index is calculated; it is the volume in millilitres occupied by 1 gm of drug or any substance after it has swollen in an aqueous liquid for 4 hours. The physical mixture of the drug complex with these super disintegrants was allowed to stand for seven days, and the drug assay was performed for compatibility studies.

Preparation of the prepared natural super disintegrants was evaluated forswelling factor, bulk density, tapped density, and angle of repose. The angle of repose was calculated according to the formula procedure in 6.1.4 bulk density, and tapped density was found using the procedure given compressibility and Hausner ratio.

Formulation of immediate release tablets of Nateglinide: Different Nateglinide Immediate Release Tablets were prepared according to the proportions given in Table 1. The raw materials passed through a screen (# 60). Before mixing powdered separately, the Nateglinide Solid dispersion and weighed the amount equivalent to 10 mg Nateglinide was combined with other excipients and compressed proton mini press tablet punching machine. All formulations are prepared according to the following formulation table.

Table 1: Formulation chart for immediate release tablet

SN	Ingredient Name	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
1	1:5 Solid dispersion equivalent to 2mg Nateglinide	10	10	10	10	10	10	10	10	10	10	10	10
2	Microcrystalline Cellulose	92	92	92	92	92	92	92	92	92	92	92	92
3	Mannitol	80.0	78.0	80.0	78.0	80.0	78.0	80.0	78.0	80.0	78.0	80.0	78.0
4	Isabgol Mucilage	10	12.0	-	-	-	-	-	-	-	-	-	-
5	Isabgol Powder	-	-	10.0	12.0	-	-	-	-	-	-	-	-
6	Isabgol husk powder	-	-	-	-	10.0	120	-	-	-	-	-	-
7	Cross Povidone	-	-	-	-	-	-	10.0	12.0	-	-	-	-
8	CMC		-	-	-	-	-	-	-	-	-	10.0	12.0
9	SSG	-	-	-	-	-	-	-	-	10.0	12.0	-	-
10	Talc	2	2	2	2	2	2	2	2	2	2	2	2
11	Aspartame	1	1	1	1	1	1	1	1	1	1	1	1
12	Aerosil	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
13	Orange Flavour	1	1	1	1	1	1	1	1	1	1	1	1
	The total weight (mg)	200	200	200	200	200	200	200	200	200	200	200	200

Evaluation of immediate release tablet

Physical appearance: Prepared immediate release tablets were evaluated for the smoothness and absence of cracks, chips and other undesirable characteristics**.**

Weight variation: Twenty tablets were randomly selected and weighed to determine the average weight and were compared with individual tablet weights. The percentage weightvariation was calculated. As per Indian Pharmacopoeia specification, for tablets with an average weight between 80 – 250 mg, the percentage deviation should not be more than ±0.5 %, and the tablet with an average weight of more than 250 mg should not be more than ± 10 %.

$$\% \textbf{ deviation} = \frac{\textbf{tablet wt.} - \textbf{avg. wt.}}{\textbf{tablet wt.}} \times \mathbf{100}$$

Friability: Friability of the tablets was checked by Roche friabilator. In this device, tablets are subjected to combined effects of abrasion and shock by utilizing a plastic chamber that revolves at 75 rpm, dropping the tablets at a distance of6 inches in each revolution. Pre-weighed tablets were placed in a friabilator and then operated for 100 revolutions. The tablets were dusted and reweighed.

$$\% \text{ friability} = \frac{\text{initial wt.} - \text{final wt.}}{\text{initial wt.}} \times 100$$

Thickness: The thicknesses were measured using vernier callipers, and values were tabulated. Three tablets of each batch were measured. Average and standard deviation was calculated.

Hardness: Monsanto hardness tester was used for the determination of hardness. For each formulation, three tablets were determined.

Disintegration time: A disintegration time of 6 tablets from each formulation was determined by using the USP disintegration apparatus. A disintegration test was carried out in 900 ml buffer pH 6.8 at 37 ± 2 ^{0}C and apparatus operated for 3 min, six tablets were taken, one tablet was introduced in each tube, the disc was placed and basket and the disintegration time in seconds were noted.

Wetting time: This is carried out as a measure of the hydrophilicity of tablets. Wetting time is the length of time required to wet the tablet. A piece of tissue paper (12 x 10.75) was folded twice and placed in the small Petri dish (I.D 6.5 cm) containing 6 ml of buffer pH 6.8 simulated salivary pH. Tablet was placed on the paper, and the time for complete wetting was measured. Three batch trials were performed, and the standard deviation was determined.

Uniformity of dispersion test: Two tablets from each batch were separately kept in 100 ml water and gently stirred for 2 min. The dispersion was passed through 22 mesh. The tablets were considered to pass the test if no residue remained on the screen.

Water absorption ratio: The water absorption ratio is an important criterion for understanding the capacity of disintegrants to swell in the presence of a little amount of water. Weight of the tablet after and before the test was taken. The water absorption ratio (R) is calculated using the following formula.

$$\mathbf{R} = \frac{\mathbf{Wa} - \mathbf{Wb}}{\mathbf{Wb}} \times \mathbf{100}$$

W_a = weights of the tablets after the water absorption test

W_b = weight of the tablets before the water absorption test

ASSAY

Standard preparation: Weigh 100 ml volumetric flask, dissolved in a minimum quantity of methanol. The volume made up to 100 ml with 0.1 N hydrochloric acid. Took 10 ml of that solution and diluted it to 100 ml with 0.1 N hydrochloric acid. Took 1 ml from that solution and diluted to 10 ml with 0.1 N hydrochloric acid.

Sample preparation: Mixed well and volume made up to 100ml. Filtered the solution, and 10 ml of this solution was diluted to 100 ml. From that, took 1ml and diluted to 10 ml. Absorbance was measured at 283 nm by UV/Visible spectrophotometer.

$$\frac{\text{Avg. Sample absorbance}}{\text{Avg. Sample absorbance}} \times \frac{\text{standard dilution}}{\text{sample dilution}} \times \frac{\text{avg. wt.}}{\text{std. purity}} \times 100$$

Dissolution studies were carried out using USP type II (paddle apparatus) at 75 rpm pH 5 acetate buffer as dissolution medium. The temperature was maintained at 37 ±0.5 ^{0}C. Aliquots of dissolution media were withdrawn at specific time intervals and filtered. The exact quantity of fresh media was replaced. The filtered solution was used to determine the estimation of drug content. The absorbances were measured at 283 nm by UV/Visible spectrophotometer. The test was carried out for 30 min.

Accelerated stability studies: Under ICH guidelines, selected formulations were subjected to stability studies. Following conditions were used for stability testing. 40 ºC / 75 % RH was analysed monthly as per ICH guidelines. By keeping 40 ± 2 ºC /RH, the formula was studied every month for three months.

Table 2: Drug content in physical mixtures and solid dispersions

Solid dispersion (Drug to PEG mass ratio)	Drug content (%)	Physical mixture (Drug to PEG massratio)	Drug content (%)
SD 1:1	97.54	PM 1:1	98.05
SD 1:3	96.25	PM 1:3	97.96
SD 1:5	98.42	PM 1:5	98.18

Table 3: *In-vitro* dissolution profile of Nateglinide physical mixture of Nateglinide and Solid Dispersion of Nateglinide in pH 1.2 Buffers

SN	Formulation	Percentage of drugs released after 30 min (DR)
A1	Drug	31.23 ± 2.25 %
A2	PM 1:1	41.54 ± 2.58 %
A3	PM 1:2	44.86 ± 2.69%
A4	PM 1:5	51.12 ± 2.50%
A5	SD 1;1	87.89 ± 2.25 %
A6	SD 1:2	93.46 ± 2.35 %
A7	SD 1:5	98.35 ± 2.76 %

Table 4: Preliminary evaluation of natural super disintegrants

Parameters	Mucilage	Seed Powder	Husk Powder
Bulk Density (gm/cm^3)	0.96	0.50	1.17
Tapped Density (gm/cm^3)	1.08	0.91	1.35
Hausner's Ratio	1.083	1.14	1.11
Compressibility index (%)	6.58	15.37	14.66
The angle of Repose (°)	25.20	40.36	33.15

Table 5: Pre-compression parameters for prepared formulations (F1-F12)

Parameters	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Bulk density	0.36	0.37	0.31	0.31	0.32	0.33	0.32	0.35	0.37	0.35	0.33	0.32
Tapped Density	0.45	0.44	0.43	0.42	0.43	0.44	0.41	0.44	0.44	0.45	0.43	0.41
% Compressibility	15.3	15.0	21.6	20.1	20.8	20.4	16.6	16.5	17.3	18.1	18.8	I7.6
Hausner's Ratio	1.18	1.11	1.25	1.23	1.24	1.21	1.20	1.43	1.17	1.26	1.36	1.26
Angle of Repose	21.2	20.1	24.3	24.4	23.2	23.1	20.3	20.0	21.1	21.2	25.3	24.1

Table 6: Evaluation results of immediate release tablets

SN	Parameter	Formulation Code										
		F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
1	Weight Variation Test	198.74	197.24	197.86	200.82	198.15	196.81	198.91	197.46	199.05	198.18	199.33	199.63
2	% Friability	0.26	0.20	0.21	0.30	0.28	0.20	0.23	0.21	0.24	0.32	0.25	0.23
3	Thickness (mm)	2.58± 0.01	2.59± 0.03	2.35± 0.05	2.30± 0.02	2.41± 0.05	2.42± 0.06	2.42± 0.02	2.48± 0.06	2.44± 0.04	2.43± 0.05	2.41± 0.04	2.35± 0.06
4	Hardness (Kg / cm^2)	2.06 ±0.10	2.06 ±0.09	2.84 ±0.41	3.17 ±0.15	2.91 ±0.18	2.95 ±0.14	2.74 ±0.14	2.79 ±0.31	2.84 ±0.36	2.90 ±0.37	2.91 ±0.39	2.96 ±0.40
5	Disintegration Time(sec)	23.36 ±2.6	21.05 ±1.5	27.39 ±2.5	23.69 ±2.8	25.63 ±2.4	26.05 ±3.5	22.00 ±2.8	22.05 ±2.5	28.05 ±2.6	26.63 ±3.7	34.68 ±2.9	34.69 ±2.5
6	Wetting time (sec)	50.69 ±1.6	47.69 ±1.9	63.04 ±2.9	66.339 ±2.9	63.36 ±2.6	57.63 ±2.6	54.36 ±1.6	52.69 ±2.7	52.05 ±2.6	53.36 ±2.9	65.39 ±2.5	63.06 ±2.6
7	Uniformity of Dispersion	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
8	W.A.Ratio (%)	65.46	65.36	73.85	74.07	66.07	67.35	65.34	65.39	66.15	66.93	74.19	73.69
9	Assay (%)	99.48	100.5	98.34	99.82	99.10	101.41	100.06	100.15	101.21	101.02	100.9	100.4

Table 7: Stability data

Storage condition	Test	Observation	Inference
RT	Descriptions	No change of colour in allstrengths	Complies with stabilitycondition
40ºC + 2ºC/75% RH	Descriptions	No change of colour in allstrengths	Complies with stabilitycondition

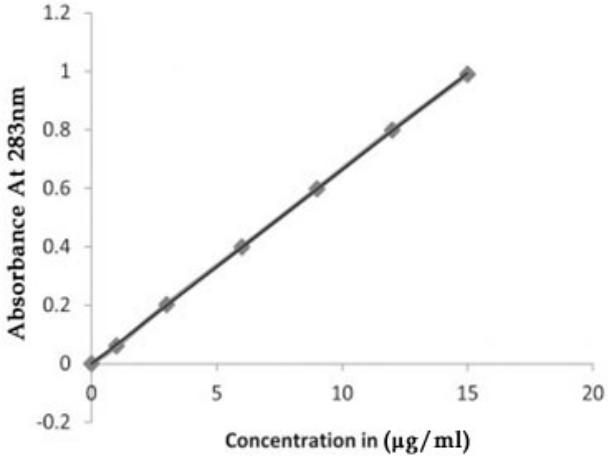

Figure 1: Solubility diagram of Nateglinide in the presence of PEG 6000

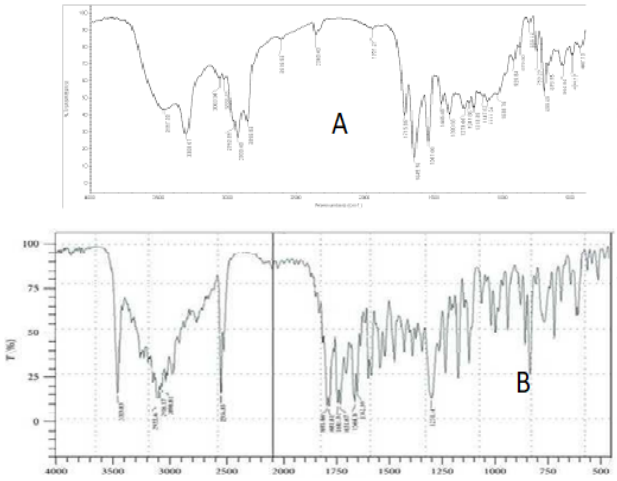

Figure 2: FTIR spectra of A. pure drug and B. drug and excipient

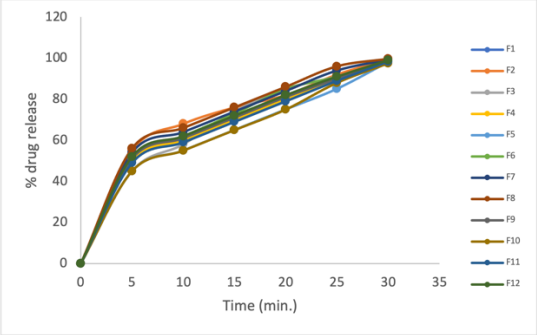

Figure 3: % drug release profile for prepared formulations (F1-F12)

RESULTS AND DISCUSSION

Nateglinide was evaluated for organoleptic characters, loss on drying, flow property, density, solubility, compressibility index, Hausner ratio, pH of the solution and assay, and the results found were Nateglinide colour observed is a white colour with odourless powder, loss on drying was 0.085%, flow property was 27.85, bulk density was 0.24 gm/ml, tap density was 0.35 gm/ml, compressibility index was 14.23%, Hausner ratio was 1.84%, it was Practically insoluble in water, freelysoluble in methylene chloride, soluble in methanol, observed pH was 5 and assay was 101.18%. The observed results were within limits.

Characterization of solid dispersions of Nateglinide with PEG 6000

Drug content: Drug content was characterized by physical mixture and solid dispersion with different rations, and the results are shown in Table 2.

Phase solubility Study

Figure 1 represents the effect of different polymers concentrations at different temperatures on the solubility of Nateglinide. The plots of drug solubility against the polymer concentration at the investigated temperatures indicated a linear relationship between drug solution and polymer concentration. The result showedthat in both cases, the solubility of Nateglinide increased with increasing temperature and carrier concentration.

Solubility of Nateglinide in pure water at 25 ºC was 0.01 (µg/ml). At the highest polymer concentration (10% w/w), the solubility increased approximately 4-fold for PEG 6000 at 25 ºC. The same tendency was observed for other temperatures.

Dissolution studies

The percentage release of Nateglinide at various intervals from the physical mixtures and solid dispersions made using multiple concentrations. The percentage release of Nateglinide at different time intervals from the physical mixtures and solid dispersions made by using various concentrations of PEG 6000, and it is evident that the onset of dissolution of pure Nateglinide is very low, with about 31.23% of the drug being dissolved within 30 min. In the 30 minutes, physical mixtures of PEG 6000 (1:1, 1:2 and 1:5) showed 41.54, 44.86 and 51.12% drug release, and 87.89, 93.46, and 98.35 % drug release from solid dispersions (1:1, 1:2 and 1:5). SDs of Nateglinide with PEG 6000 considerably enhanced dissolution rates within 30 min compared to pure Nateglinide and PMs. Results are depicted in Table 3.

Drug-excipients compatibility study by FTIR

The IR spectra of SDs and PMs were compared with the standard spectrum of Nateglinide. IR spectrum of Nateglinide was characterized by the absorption of the carbonyl (C-O) group at 1108.83cm $^{-1}$. In spectra of SDs and PMs, this band was shifted towards higher frequencies at 3005.14 and 2,825.87 cm^{-1}, respectively. Also, the O-H group, located at 3,103.54 cm^{-1} from the IR spectrum of Nateglinide, N-H group at1599.09, C=C group at 3005.90, and C-N group at 2825.87. It was concluded that there was no well-defined chemical interaction between Nateglinide and PEG 6000 in SDs and PMs, as no important new peaks could be observed. The spectra results are depicted in Figure 2.

Evaluation of natural super disintegrants

Natural super disintegrants, i.e., mucilage, seed powder and husk powder and prepared formulations, were preliminarily evaluated for bulk density, tap density, Hausner ration, compressibility index and angle of repose. The results for natural super disintegrants were shown in table 4, and results found for formulations were depicted in Table 5, and all the results were found within limits.

Evaluation of immediate release tablets

After compression, the tablets were evaluated for weight variation, friability, thickness, hardness, wetting time, disintegration time, uniformity dispersion, absorption ratio, and assay. The results observed are shown in Table 6, and the dissolution profile for all prepared formulations is depicted in Figure 3.

Stability study

Optimized formulation (F2) was subjected to stability studies at 40ºc± 2ºc/75% RH ±5 % for 90 days. The product was evaluated for appearance and hardness, friability, and disintegration. Drug release studies were conducted as per the planned schedule as above (Table 7).[12-19]

CONCLUSION

The solubility and dissolution rate of Nateglinide can be enhanced by formulating SDs of Nateglinide with PEG 6000. The solubilization effect of PEG 6000, reduction of particle aggregation of the drug, formation of the microcrystalline or amorphous drug, increased wettability and dispersibility, and alteration of the surface properties of the drug particles might be responsible for the enhanced solubility and dissolution rate of Nateglinide from its SD and to some extent in PMs. No endothermic peak of Nateglinide was present in SDs with PEG 6000, suggesting the absence of crystalline Nateglinide. FTIR spectroscopy concluded that there was no well-defined chemical interaction between Nateglinide and PEG 6000 in SDs and PMs, as no important new peaks could be observed. The identical composition of Superdisintegrants showed that a substantially shorter time for disintegration could be obtained, and immediate release tablets were prepared. The Nateglinide immediate release tablet (F2) showed 58.72% drug release within the first 5 min. and 99.50% drug release within 30 min. The results showed that the formulation satisfied the objective of fast disintegration, dissolution, % friability, hardness, wetting time, water absorption ratio, ease of administration and safety. The success of the present study recommends a detailed investigation into *in-vivo* studies for its effective use in clinical practice.

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