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Research Article

Development and Evaluation of Repaglinide Solid Dispersion Tablets using Natural Superdisintegrants

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Abstract

The present study was undertaken to enhance the dissolution characteristics of Repaglinide, a poorly water-soluble antidiabetic drug, by employing the solid dispersion technique combined with natural superdisintegrants. The λmax of Repaglinide in phosphate buffer pH 6.8 was found to be 243 nm. Fourier Transform Infrared (FTIR) spectroscopy was carried out for the pure drug and optimized formulations, confirming the absence of any significant drug–excipient interactions.

Solid dispersions were prepared using PEG 4000 as a hydrophilic carrier and further formulated into tablets incorporating natural superdisintegrants such as Ocimum mucilage and Gellan gum. Pre-compression evaluation of the solid dispersion blends indicated good to fair flow properties, with angle of repose below 26.20°, Carr's index ranging from 11.08 to 18.40, and Hausner's ratio less than 1.22.

Post-compression evaluation revealed that all tablet formulations complied with pharmacopeial limits for weight variation, hardness, friability, thickness, and drug content uniformity. In vitro dissolution studies conducted in phosphate buffer pH 6.8 demonstrated a significant enhancement in drug release from the solid dispersion tablets when compared among formulations. Among all batches, formulation F6 exhibited rapid disintegration and the highest drug release of 99.16% within 45 minutes.

The study concludes that the combined approach of solid dispersion and natural superdisintegrants effectively improves the dissolution performance of Repaglinide tablets. Natural superdisintegrants such as Ocimum mucilage and Gellan gum may serve as promising, economical, and biocompatible alternatives to synthetic disintegrants in solid oral dosage forms.

Keywords: Repaglinide, Solid dispersion tablets, Natural superdisintegrants, In vitro dissolution, Dissolution enhancement.

INTRODUCTION

Oral drug delivery remains the most preferred route of administration due to patient compliance, convenience, and cost-effectiveness. However, the oral bioavailability of many drugs is limited by poor aqueous solubility and dissolution rate, leading to low and erratic absorption. Drugs that exhibit dissolution rate-limited gastrointestinal absorption often demonstrate poor bioavailability, which can be improved by enhancing their dissolution characteristics[1].

Various approaches such as salt formation, particle size reduction, complexation with cyclodextrins, and use of cosolvents have been explored to improve the dissolution of poorly water-soluble drugs. However, each of these techniques presents limitations, including stability issues, aggregation of fine particles, and formulation challenges. Solid dispersion technology has emerged as an effective and practical strategy to overcome these drawbacks by dispersing the drug in a hydrophilic carrier matrix, thereby improving wettability, reducing particle size, and increasing surface area[2,3].

Solid dispersions may exist as eutectic mixtures, solid solutions, or molecular dispersions, where the drug is dispersed at the molecular or colloidal level within the carrier. Upon contact with aqueous media, the carrier dissolves rapidly, releasing the drug as fine particles that exhibit enhanced dissolution rates[4]. The concept of solid dispersion was first introduced by Sekiguchi and Obi, who demonstrated improved absorption of poorly water-soluble drugs through eutectic mixtures with water-soluble carriers[5].

In recent years, there has been increasing interest in the use of natural excipients in pharmaceutical formulations due to their biocompatibility, non-toxicity, cost-effectiveness, and environmental sustainability. Natural superdisintegrants such as plant-derived mucilages and polysaccharides have shown promising disintegration and dissolution-enhancing properties through mechanisms such as swelling, wicking, and hydration.

Repaglinide, an oral antidiabetic agent belonging to the meglitinide class, exhibits poor aqueous solubility, which limits its dissolution rate and oral bioavailability. Although several formulation strategies have been reported to enhance its dissolution, limited studies have explored the combined use of solid dispersion technology and natural superdisintegrants for its tablet formulation.

Therefore, the present study aims to develop and evaluate Repaglinide solid dispersion tablets using PEG 4000 as a hydrophilic carrier and natural superdisintegrants such as Ocimum mucilage and Gellan gum, with the objective of enhancing dissolution performance and providing a viable alternative to synthetic excipients.

METHODOLOGY

Determination of Lambda Max:

10 mg of pure drug was dissolved in 10 ml methanol (primary stock solution - 1000 µg/ml). From this primary stock solution 1 ml was pipette out into 10 ml volumetric flask and made it up to 10ml with the 6.8 Phosphate Buffer (Secondary stock solution – 100µg/ml). From secondary stock solution again 1ml was taken it in to another volumetric flask and made it up to 10 ml with 6.8 Phosphate Buffer (working solution - 10µg/ml). The working solution was taken for determining the wavelength.

Determination of Calibration Curve:

10mg of pure drug was dissolved in 10ml methanol (primary stock solution - 1000 µg/ml). From this primary stock solution 1 ml was pipette out into 10 ml volumetric flask and made it up to 10ml with the 6.8 Phosphate Buffer (Secondary stock solution – 100µg/ml). From secondary stock solution required concentrations were prepared (shown in Table) and those concentrations absorbance were found out at required Lambda max wavelength.

Formulation Development:

Solvent Evaporation Method[11]

1. Dissolve repaglinide and carrier PEG 4000 in a common solvent at the selected ratio (drug: carrier = 1:1and 1:2 w/w).
2. Mix thoroughly to obtain a clear solution/suspension.
3. Remove solvent under reduced pressure using a rotary evaporator at controlled temperature (not exceeding the thermal stability limits of repaglinide and carrier), or by gentle heating and continuous stirring until dry.
4. Dry the residue in a vacuum oven at 40–45 °C to constant weight.
5. Pulverize and sieve 20 mesh to obtain uniform powder.

Formulation development for solid dispersion:

Solid dispersions were prepared by solvent evaporation method. Methanol was used as solvent. Repaglinide and Water-soluble polymers such as PEG 4000 is selected as carrier. Drug and polymers were taken in 1:1 and 1:2 ratio stated in the formulation chart (Table 1). The prepared solid dispersions were passed through the sieve no 20 to get uniform sized particles. The solid dispersions were mixed with required quantities of super disintegrants, Lactose, Aerosil and Sodium Stearyl fumarate (Table 2).

Table 1: Formulation of solid dispersion showing various compositions

FORMULATION (Quantities in Ratio)		
INGREDIENTS	**SD1**	**SD2**
Repaglinide	**1**	**1**
PEG 4000	**1**	**2**

Table 2: Formulation of tablet by using solid dispersion

INGREDIENTS	FORMULATION CHART											
Ingredients (mg)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
Repaglinide Equivalent to 50mg	SD1 (100)	SD1 (100)	SD1 (100	SD2 (150)	SD2 (150)	SD2 (150)	SD1 (100	SD1 (100)	SD1 (100)	SD2 (150)	SD2 (150)	SD2 (150)
Ocimum Mucilage	20	30	40	20	30	40	-	-	-	-	-	-
Gellan Gum	-	-	-	-	-	-	20	30	40	20	30	40
Lactose	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Aerosil	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
SSF	25	25	25	25	25	25	25	25	25	25	25	25
Total Weight	300	300	300	300	300	300	300	300	300	300	300	300

RESULTS AND DISCUSSION

Analytical Method Development

The analytical method employed for the estimation of Repaglinide in phosphate buffer pH 6.8 was found to be suitable and reliable. The λmax of Repaglinide was observed at 243 nm, which is consistent with previously reported literature values. The calibration curve exhibited good linearity in the concentration range studied, with a correlation coefficient (R^2) of 0.998, indicating compliance with Beer–Lambert's law and confirming the accuracy of the analytical method for quantitative estimation.

Table 3: Calibration curve of Repaglinide in phosphate buffer pH 6.8

Concentration(µg/mL)	Absorbance
0	0
5	0.121 ±0.11
10	0.214±0.23
15	0.321±0.46
20	0.449±0.33
25	0.555±0.83

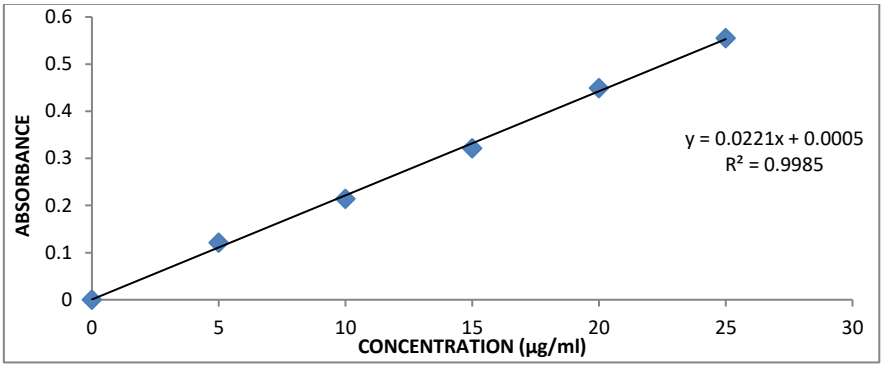

Figure 1: Calibration curve of Repaglinide in phosphate buffer pH 6.8

Micrometric properties:

The micromeritic properties of the Repaglinide solid dispersion blends were evaluated to assess their suitability for direct compression. The angle of repose values for all formulations were below 26.20°, indicating good flow characteristics. Bulk density and tapped density values were within acceptable ranges, reflecting uniform packing behavior of the powder blends.

Carr's index values ranged from 11.08 to 18.40, while Hausner's ratio remained below 1.22 for all formulations, suggesting good to fair compressibility and flowability. These favorable micromeritic properties may be attributed to the presence of PEG 4000, which improves powder flow, and the uniform distribution of solid dispersion particles within the blend. Overall, the pre-compression parameters indicated that the blends were suitable for tablet formulation without additional flow enhancers.

Table 4: Evaluation of pre compression parameters of solid dispersion blend

Formulation Code	Angle of repose(θ)	Bulk density (gm/cc)	Tapped density (gm/cc)	Carr's index	Hausner ratio
F1	26.20±0.32	0.465±0.026	0.523±0.034	11.08±0.44	1.12±0.05
F2	21.77±0.34	0.492±0.038	0.585±0.042	15.89±0.36	1.18±0.06
F3	20.81±0.41	0.437±0.015	0.534±0.034	18.16±0.57	1.22±0.04
F4	23.25±0.53	0.435±0.042	0.526±0.021	17.30±0.46	1.20±0.11
F5	21.46±0.34	0.423±0.010	0.515±0.025	17.86±0.49	1.21±0.07
F6	25.78±0.32	0.474±0.042	0.554±0.041	14.44±0.65	1.16±0.08
F7	24.86±0.44	0.456±0.019	0.543±0.037	16.02±0.64	1.19±0.14
F8	25.60±0.32	0.461±0.026	0.565±0.023	18.40±0.76	1.22±0.004
F9	22.45±0.38	0.459±0.017	0.545±0.027	15.77±0.47	1.18±0.02
F10	22.95±0.48	0.441±0.008	0.525±0.031	16.00±0.56	1.19±0.04
F11	23.78±0.26	0.424±0.014	0.510±0.045	16.86±0.69	1.21±0.03
F12	20.12±0.18	0.426±0.016	0.515±0.039	16.69±0.75	1.20±0.01

Post compression evaluation:

Post-compression evaluation of the prepared tablets demonstrated compliance with pharmacopeial standards. All formulations passed the weight variation test, indicating uniform die fill during compression. Tablet hardness values ranged from 3.2 to 3.9 kg/cm^2, providing sufficient mechanical strength, while friability values were less than 1%, confirming adequate resistance to abrasion during handling.

Tablet thickness values were consistent across formulations, indicating uniform compression. Drug content analysis showed that all formulations contained 96.10% to 99.72% of Repaglinide, demonstrating good content uniformity and effective mixing of the solid dispersion within the tablet matrix. These results confirm that the formulation components and manufacturing process were suitable for producing tablets of acceptable quality.

Table 5: Evaluation of post compression parameters of solid dispersion tablet

Formulation code	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm^2)	Friability (%loss)	Disintegration time (sec)	Content uniformity (%)
F1	298.25±1.38	4.32±0.24	3.6±0.46	0.21±0.88	62±0.38	96.42±0.08
F2	297.65±0.34	4.15±0.36	3.5±0.37	0.64±0.32	17±0.61	98.63±0.37
F3	299.42±0.88	4.64±0.49	3.2±0.51	0.59±64	29±0.49	99.72±0.86
F4	298.29±0.64	4.58±0.54	3.9±0.37	0.76±0.35	55±0.26	98.25±0.47
F5	299.64±0.39	4.75±0.76	3.5±0.89	0.28±0.27	19±0.73	97.89±0.33
F6	300.02±0.53	4.26±0.22	3.2±0.72	0.95±0.16	12±0.83	98.97±0.57
F7	299.76±0.72	4.62±0.31	3.8±0.36	0.71±0.77	15±0.15	99.42±0.36
F8	298.24±0.29	4.44±0.21	3.4±0.44	0.89±0.53	39±0.24	96.10±0.43
F9	299.82±0.48	4.18±0.12	3.2±0.11	0.48±0.69	62±0.08	99.58±0.83
F10	297.91±0.67	4.24±0.08	3.6±0.27	0.57±0.25	18±0.19	98.72±0.71
F11	299.11±0.33	4.62±0.33	3.8±0.66	0.38±0.13	33±0.22	97.52±0.66
F12	298.34±0.62	4.37±0.68	3.7±0.48	0.53±0.22	48±0.31	99.31±0.79

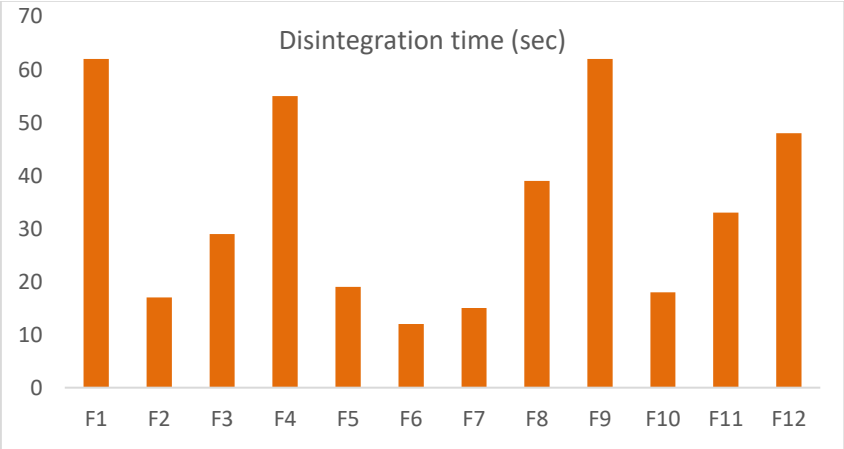

Figure 2: Disintegration Time

Disintegration time plays a crucial role in the dissolution behavior of immediate-release tablets. The disintegration times of all formulations were within acceptable limits; however, formulations containing natural superdisintegrants exhibited significantly reduced disintegration times.

Among all formulations, F6 showed the least disintegration time of 12 seconds. This rapid disintegration may be attributed to the synergistic effect of solid dispersion and the natural superdisintegrant, which promotes rapid water uptake, swelling, and wicking action. Ocimum mucilage and Gellan gum are known to form hydrophilic networks upon hydration, facilitating faster tablet breakup and subsequent drug release.

In vitro Dissolution Studies

In vitro dissolution studies were conducted in phosphate buffer pH 6.8 to evaluate the dissolution behavior of Repaglinide from the solid dispersion tablets. All formulations exhibited improved drug release compared to conventional tablet formulations, indicating the effectiveness of the solid dispersion approach.

Formulation F6 demonstrated the highest drug release of 99.18% within 45 minutes, outperforming other formulations. The enhanced dissolution observed in F6 can be attributed to several factors, including improved wettability due to PEG 4000, reduced drug crystallinity, and rapid tablet disintegration facilitated by the natural superdisintegrant. The rapid exposure of finely dispersed drug particles to the dissolution medium resulted in increased surface area and faster drug release.

Comparative analysis of formulations containing different concentrations of natural superdisintegrants indicated that an optimal concentration is essential to achieve maximum dissolution enhancement. Excessive amounts may lead to increased viscosity of the diffusion layer, while insufficient quantities may result in slower disintegration. The optimized balance achieved in F6 contributed to its superior performance.

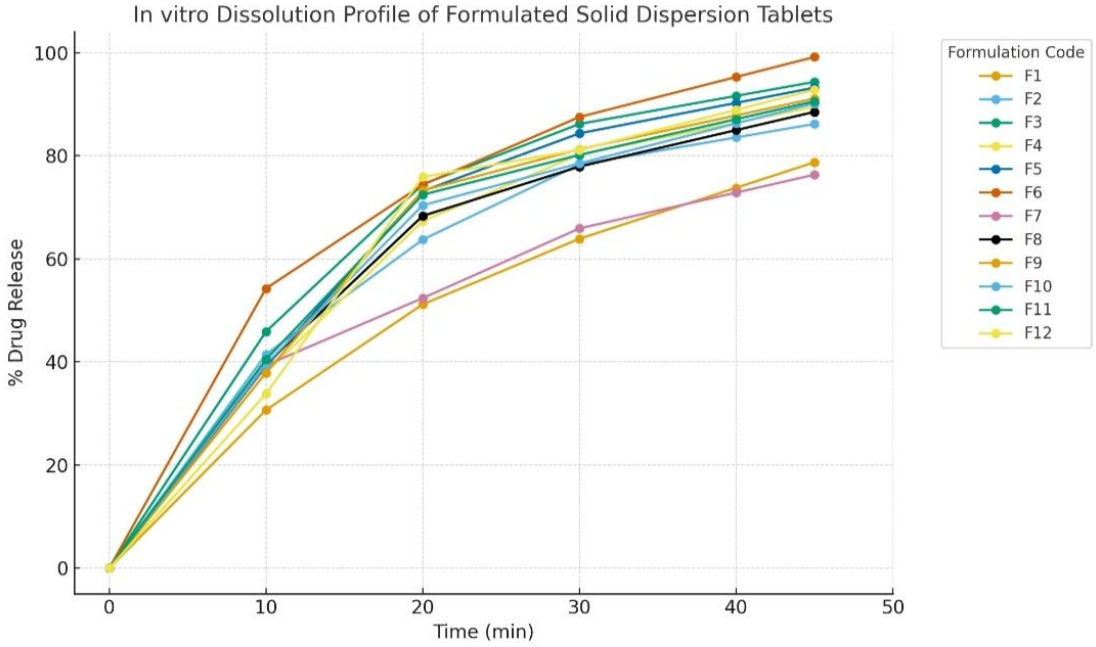

Figure 3: In vitro dissolution studies of formulated solid dispersion tablets F1-F12

Drug Excipient Interactions

Fourier transform infrared (FTIR) spectroscopy studies:

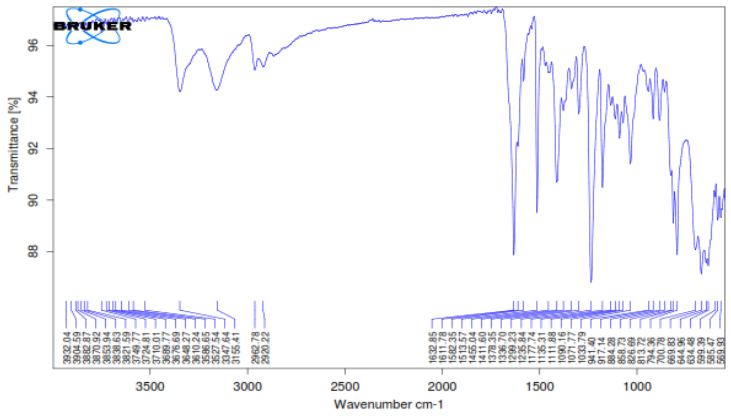

Figure 4: FTIR Spectrum of Repaglinide pure drug

Fourier Transform Infrared (FTIR) spectroscopy was employed to investigate potential interactions between Repaglinide and the formulation excipients. The characteristic peaks of Repaglinide were retained in the optimized formulation, indicating the absence of chemical interaction between the drug and excipients. This confirms the compatibility of Repaglinide with PEG 4000 and the selected natural superdisintegrants, supporting the stability of the formulation.

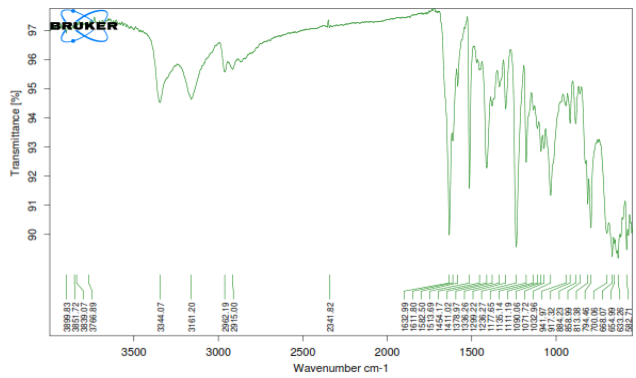

Figure 5: FTIR Spectrum of Optimized Formulation

CONCLUSION

The present study successfully demonstrated the enhancement of dissolution performance of Repaglinide through the development of solid dispersion tablets incorporating natural superdisintegrants. Solid dispersions prepared using PEG 4000 as a hydrophilic carrier exhibited satisfactory flow properties and compressibility, enabling efficient tablet formulation.

All prepared formulations complied with pharmacopeial requirements for pre-compression and post-compression parameters, indicating good mechanical strength, uniformity, and stability of the tablets. The inclusion of natural superdisintegrants significantly reduced disintegration time and improved the dissolution behavior of Repaglinide tablets. Among all formulations, F6 showed rapid disintegration and maximum drug release, highlighting the importance of optimizing the concentration of natural superdisintegrants.

FTIR studies confirmed the absence of any significant drug–excipient interactions, indicating good compatibility between Repaglinide and the selected excipients. Overall, the results suggest that natural superdisintegrants such as Ocimum mucilage and Gellan gum are effective, economical, and biocompatible alternatives to synthetic disintegrants for solid dispersion-based tablet formulations.

The study concludes that the combined approach of solid dispersion technology and natural superdisintegrants offers a promising strategy for improving the dissolution characteristics of poorly water-soluble drugs and may contribute to enhanced oral bioavailability.

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