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RESEARCH ARTICLE

Development and Evaluation of Fast-Dissolving Glimepiride Tablets Using Natural Superdisintegrants

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Abstract: Fast-dissolving tablets (FDTs) of glimepiride were formulated using natural superdisintegrants - *Arachis hypogaea* shell powder (AHSP), fenugreek seed powder (FSP), and mango peel pectin powder (MPP) - and compared with synthetic alternatives sodium starch glycolate (SSG), crospovidone (CRSPVD), and croscarmellose sodium (CCS). The natural superdisintegrants were extracted, characterized, and incorporated into tablet formulations at concentrations of 5%, 10%, and 15% w/w. Direct compression method was used for preparation of tablets, and the formulations were evaluated for physicochemical parameters including weight variation, hardness, friability, drug content uniformity, disintegration time, and *in vitro* dissolution. FTIR studies confirmed the absence of drug-excipient interactions. Among the natural superdisintegrants, AHSP at 15% concentration exhibited optimal performance with a disintegration time of 24 seconds and 98.20% drug release within 20 minutes. The dissolution efficiency of the natural superdisintegrants at 15% concentration followed the order: FSP > AHSP > MPP. All formulations demonstrated acceptable physical parameters within pharmacopoeial limits. The results of this work show the potential of these natural alternatives as effective superdisintegrants for developing fast-dissolving glimepiride tablets, offering advantages of biocompatibility and cost-effectiveness over synthetic excipients.

Keywords: Glimepiride; Natural superdisintegrants; Fast-dissolving tablets; *Arachis hypogaea* shell powder; Dissolution.

1. Introduction

Oral drug delivery remains the preferred route of administration due to patient compliance and ease of use. Fast-dissolving tablets (FDTs) represent an innovative dosage form designed to disintegrate rapidly in the oral cavity, eliminating the need for water and addressing swallowing difficulties [1]. The rapid disintegration of FDTs is achieved through the incorporation of superdisintegrants, which facilitate tablet break-up by swelling, wicking, or deformation mechanisms [2].

Glimepiride, a third-generation sulfonylurea antidiabetic agent, exhibits poor aqueous solubility despite high permeability (BCS Class II drug). The drug's low solubility often results in variable bioavailability and delayed onset of action [3]. Development of fast-dissolving formulations of glimepiride can enhance its dissolution rate and potentially improve its therapeutic efficacy in managing type 2 diabetes mellitus [4]. Conventional synthetic superdisintegrants like crospovidone, croscarmellose sodium, and sodium starch glycolate have been extensively used in FDT formulations. However, these synthetic agents may present challenges related to cost, regulatory requirements, and potential adverse effects [5]. Natural polymers derived from plant sources offer several advantages including biodegradability, biocompatibility, low toxicity, and local availability [6].

The current investigation focuses on three novel natural superdisintegrants: *Arachis hypogaea* shell powder (AHSP), fenugreek seed powder (FSP), and mango peel pectin powder (MPP). *Arachis hypogaea* (groundnut) shells, typically considered agricultural waste, contain cellulose and hemicellulose that can facilitate rapid water uptake [7]. Fenugreek seeds contain galactomannans that exhibit significant swelling properties [8]. Mango peel pectin possesses both swelling and wicking properties, making it a potential candidate for use as a superdisintegrant [9].

The rationale behind selecting these natural polymers extends beyond their disintegration properties. Fenugreek seeds have demonstrated antidiabetic effects [10], while mango peel pectin exhibits antioxidant properties [11]. Therefore, these excipients may contribute additional therapeutic benefits to the formulation.

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2. Materials and Methods

2.1. Materials

Glimepiride was obtained as a gift sample from Dr. Reddy's Laboratories, Hyderabad, India. Sodium starch glycolate, crospovidone, and croscarmellose sodium were procured from Sigma-Aldrich, USA. Fresh groundnut shells, fenugreek seeds, and mango peels were sourced locally. All other chemicals and reagents used were of analytical grade.

2.2. Extraction and Processing

2.2.1. Preparation of Arachis hypogaea Shell Powder

Fresh groundnut shells were cleaned thoroughly with distilled water to remove dirt and dried under sunlight for 48 hours. The shells are dried controlled heating at 60°C for 30 minutes to reduce moisture content. The processed shells were ground using a laboratory mill and passed through a #60 mesh sieve. The resulting powder was stored in an airtight container until further use [12].

2.2.2. Preparation of Fenugreek Seed Powder

Fenugreek seeds were cleaned and dried under controlled conditions at 40°C for 24 hours. The seeds were dried and placed in mechanical grinder for size reduction, followed by sieving through #80 mesh. The powder was stored in a desiccator to prevent moisture absorption [13].

2.2.3. Extraction of Mango Peel Pectin

Fresh mango peels were washed, chopped into small pieces, and subjected to acid hydrolysis using citric acid (pH 2.5) at 80°C for 2 hours with continuous stirring. The extracted pectin was precipitated using ethanol (95% v/v), filtered, and dried at 45°C. The dried pectin was pulverized and passed through #100 mesh sieve [14]

2.3. Preformulation Studies

2.3.1. Physicochemical Characterization of Drug

Glimepiride was characterized for organoleptic properties, melting point (using digital melting point apparatus), and solubility according to pharmacopoeial methods [15]. UV spectrophotometric analysis was performed to determine the wavelength of maximum absorption (λmax) using phosphate buffer pH 6.8.

2.3.2. Flow Properties of Drug and Excipients

The micromeritic properties including bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose were determined for both drug and excipients. The angle of repose was measured using the fixed funnel method, while bulk and tapped densities were determined using a tap density apparatus [16].

2.3.3. Drug-Excipient Compatibility Studies

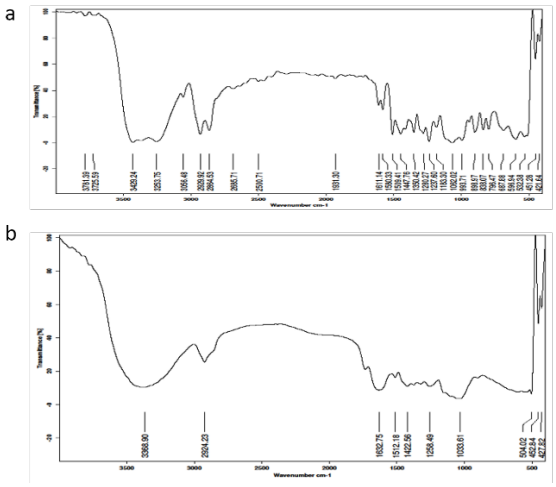

Figure 1. FTIR Spectrum of a. Pure drug b. Drug + Excipients

Fourier Transform Infrared (FTIR) spectroscopy was performed to assess potential interactions between glimepiride and the selected excipients. Samples were prepared using the KBr pellet technique and scanned over the range of 4000-400 cm^{-1} using a Jasco FTIR spectrophotometer [17].

2.4. Formulation of Fast-Dissolving Tablets

2.4.1. Preparation of Tablet Blend

Eighteen formulations (F1-F18) were designed using different concentrations (5%, 10%, and 15% w/w) of natural and synthetic superdisintegrants. The composition of tablet formulations is presented in Table 8. All ingredients were accurately weighed, passed through #60 mesh sieve, and mixed thoroughly in a geometric progression. Magnesium stearate and talc were added last and blended for an additional 3 minutes [18].

2.4.2. Tablet Compression

Tablets containing 2 mg glimepiride were compressed using a 10-station rotary tablet press (Rimek, India) equipped with 6.5 mm round flat punches. The compression force was adjusted to maintain consistent tablet hardness across all formulations [19].

Table 1. Formulation of Glimepiride Fast Dissolving Tablets

Ingredients	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9	F_{10}	F_{11}	F_{12}	F_{13}	F_{14}	F_{15}	F_{16}	F_{17}	F_{18}
Glimepiride	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
AHSP (%)	5	10	15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
FSP (%)	-	-	-	5	10	15	-	-	-	-	-	-	-	-	-	-	-	-
MPP (%)	-	-	-	-	-	-	5	10	15	-	-	-	-	-	-	-	-	-
SSG (%)	-	-	-	-	-	-	-	-	-	5	10	15	-	-	-	-	-	-
CRSPVD (%)	-	-	-	-	-	-	-	-	-	-	-	-	5	10	15	-	-	-
CCS (%)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	5	10	15
MCC	130	120	110	130	120	110	130	120	110	130	120	110	130	120	110	130	120	110
Mg. Stearate (%)	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Talc (%)	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Total tablet weight	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150

2.5. Evaluation of Prepared Tablets

2.5.1. Physical Parameters

The compressed tablets were evaluated for:

- Weight variation using 20 tablets randomly selected from each batch
- Hardness using Pfizer hardness tester (n=6)
- Friability using Roche friabilator at 25 rpm for 4 minutes
- Drug content uniformity by UV spectrophotometric method at 226 nm [20]

2.5.2. Disintegration Time

Disintegration time was determined using USP disintegration apparatus. Six tablets from each formulation were placed in the apparatus containing phosphate buffer pH 6.8 maintained at 37±2°C. The time taken for complete disintegration of tablets with no palpable mass remaining was recorded [21].

2.5.3. In Vitro Dissolution Studies

Dissolution studies were conducted using USP Type II (Paddle) apparatus at 50 rpm. The dissolution medium consisted of 900 mL phosphate buffer pH 6.8 maintained at 37±0.5°C. Samples (5 mL) were withdrawn at predetermined time intervals (5, 10, 15, 20, 25, 30, 35, 40, 45, 50, and 55 minutes) and replaced with fresh medium. The samples were filtered through 0.45 µm membrane filter and analyzed spectrophotometrically at 226 nm [22].

2.6. Stability Studies

Optimized formulations were subjected to stability studies as per ICH guidelines. Tablets were stored at 40±2°C/75±5% RH for three months. Samples were evaluated for physical appearance, drug content, disintegration time, and dissolution profile at monthly intervals [23].

3. Results and Discussion

3.1. Preformulation Studies

3.1.1. Physicochemical Characterization

Glimepiride appeared as a white to yellowish-white crystalline powder with an amorphous texture. The melting point was determined to be 207±0.5°C, which aligns with the reported literature value of 207°C, confirming the drug's identity and purity. Solubility studies revealed that glimepiride was poorly soluble in water but exhibited good solubility in ethanol, consistent with its BCS Class II classification [24].

3.1.2. Calibration Curve

The calibration curve of glimepiride was constructed by using phosphate buffer pH 6.8 which showed maximum absorption (λmax) at 226 nm. The calibration curve demonstrated linearity in the concentration range of 2-10 µg/mL with a correlation coefficient (R^2) of 0.9998, indicating compliance with Beer-Lambert's law [25].

3.2. Micromeritic Properties

The flow properties of glimepiride and excipient blends were essential determinants for successful tablet compression. The angle of repose for glimepiride was found to be 51.63°, indicating poor flow characteristics. The bulk density and tapped density values were 0.188 g/cc and 0.335 g/cc, respectively. Carr's index value of 31.62% and Hausner's ratio of 2.31 further confirmed the poor flow properties of the drug, necessitating the incorporation of flow enhancers in the formulation [26].

3.3. Drug-Excipient Compatibility

FTIR spectroscopic analysis revealed characteristic peaks for glimepiride at 3369 cm^{-1} (N-H stretching), 1674 cm^{-1} (C=O stretching), and 1345 cm^{-1} (S=O stretching). The spectra of physical mixtures containing drug and excipients showed no significant shifts in these characteristic peaks, indicating the absence of chemical interactions between glimepiride and the selected excipients [27].

3.4. Evaluation of Tablets

3.4.1. Physical Parameters

All formulations (F1-F18) exhibited uniform weight variation within ±7.5% of the average weight, complying with pharmacopoeial specifications. The tablet hardness ranged from 4.8-5.2 kg/cm^2, ensuring adequate mechanical strength while maintaining rapid disintegration potential. Friability values remained below 1% across all formulations, ranging from 0.43% to 0.87%, indicating sufficient resistance to mechanical stress during handling and transportation [28].

3.4.2. Content Uniformity

Drug content analysis showed values ranging from 93.0% to 98.78% of the labeled amount across all formulations, meeting the acceptance criteria of 90-110%. The low standard deviation values (<2%) indicated uniform drug distribution within the compressed tablets [29].

3.4.3. Disintegration Test

The disintegration time varied significantly among formulations containing different types and concentrations of superdisintegrants. Among the natural superdisintegrants, AHSP at 15% concentration (F3) exhibited the fastest disintegration time of 24 seconds, followed by FSP at 15% (F6) with 30 seconds, and MPP at 15% (F9) with 38 seconds. The rapid disintegration of AHSP-containing tablets can be attributed to its highly porous structure facilitating rapid water uptake and subsequent tablet breakdown [30].

Table 2. Post compression studies of Glimepiride tablets formulated with AHSP

Formulation	Weight variation (mg)	Hardness(kg/ cm^2)	Friability (%)	Disintegration (sec)	Drug content (%)
F1-AHSP 5%	150±0.79	5.0±1.02	0.79±0.1	35±0.3	96.12±0.06
F2-AHSP 10%	148±0.98	5.0±1.02	0.85±0.1	30±0.3	94.35±0.06
F3-AHSP 15%	151±0.69	5.0±1.02	0.69±0.1	24±0.3	98.27±0.06
F4-FSP 5%	149±0.80	5.0±1.02	0.76±0.1	40±0.3	95.28±0.06
F5-FSP 10%	147±0.99	5.0±1.02	0.83±0.1	35±0.3	93.24±0.06
F6-FSP 15%	150±0.71	5.0±1.02	0.68±0.1	30±0.3	9626±0.06
F7-MPP 5%	148±0.50	5.0±1.02	0.72±0.1	42±0.3	96.29±0.06
F8-MPP 10%	150±0.95	5.0±1.02	0.80±0.1	34±0.3	94.19±0.06
F9-MPP 15%	151±0.78	5.0±1.02	0.67±0.1	38±0.3	98.59±0.06
F10-SSG 5%	148±0.49	5.0±1.02	0.62±0.1	53±0.3	95.34±0.38
F11-SSG 10%	152±0.80	5.0±1.02	0.78±0.1	49±0.3	94.27±0.06
F12-SSG 15%	151±0.32	5.0±1.02	0.66±0.1	42±0.3	97.19±0.16
F13-CSPD 5%	149±0.64	5.0±1.02	0.56±0.1	79±0.3	93.76±0.56
F14-CSPD 10%	150±0.22	5.0±1.02	0.43±0.1	73±0.3	96.29±0.98
F15-CSPD 15%	151±0.57	5.0±1.02	0.75±0.1	68±0.3	95.15±0.34
F16-CSS 5%	152±0.19	5.0±1.02	0.87±0.1	110±0.3	97.24±0.74
F17-CSS 10%	149±0.10	5.0±1.02	0.77±0.1	102±0.3	98.39±0.78
F18-CSS 15%	150±0.33	5.0±1.02	0.64±0.1	96±0.3	95.41±0.54

3.5. Dissolution Studies

3.5.1. Effect of Natural Superdisintegrants

Formulations containing AHSP demonstrated superior dissolution profiles compared to other natural superdisintegrants. F3 (AHSP 15%) achieved 98.20% drug release within 20 minutes, whereas F1 (AHSP 5%) and F2 (AHSP 10%) showed 98.36% and 97.91% release at 35 and 30 minutes, respectively. The enhanced dissolution rate with AHSP can be attributed to its cellular structure, which facilitates rapid water absorption and subsequent tablet disintegration [31].

FSP-containing formulations exhibited concentration-dependent improvement in dissolution rate. F6 (FSP 15%) achieved 98.23% drug release in 20 minutes, while F4 (FSP 5%) and F5 (FSP 10%) required 35 and 30 minutes respectively for comparable release. The presence of galactomannans in FSP contributes to rapid swelling and subsequent tablet disintegration [32]. MPP-based formulations showed slightly slower dissolution profiles compared to AHSP and FSP. F9 (MPP 15%) achieved 98.12% release in 20 minutes, while F7 (MPP 5%) and F8 (MPP 10%) required 35 and 30 minutes respectively. The dissolution enhancement can be attributed to the combined effect of swelling and wicking mechanisms of pectin [33].

3.5.2. Synthetic Superdisintegrants

The synthetic superdisintegrants showed varying degrees of dissolution enhancement. SSG-based formulations (F10-F12) showed relatively slower dissolution rates, with F12 (SSG 15%) achieving 98.56% release in 45 minutes. CRSPVD formulations (F13-F15) performed better, with F15 (CRSPVD 15%) showing 97.19% release in 35 minutes. CCS-containing formulations (F16-F18) exhibited intermediate performance, with F18 (CCS 15%) achieving 98.75% release in 40 minutes [34].

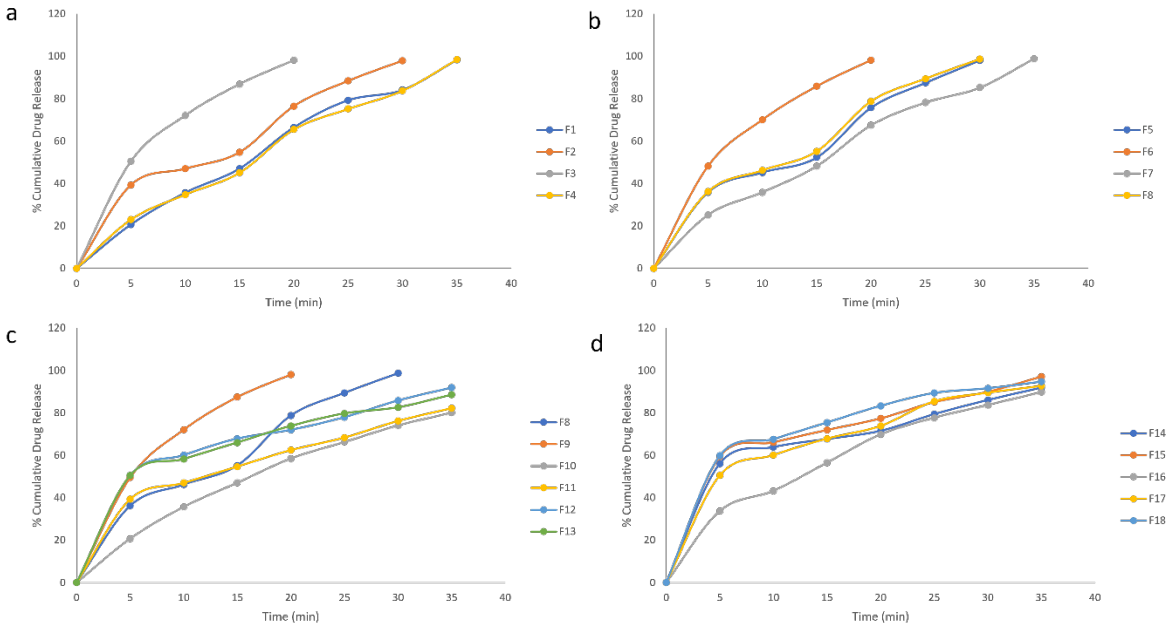

Figure 2. %Cumulative drug release from all the formulations

3.6. Statistical Analysis of Dissolution Data

Analysis of variance (ANOVA) revealed significant differences ($p < 0.05$) in dissolution profiles among formulations containing different types and concentrations of superdisintegrants. The dissolution efficiency (DE) values at 30 minutes followed the order: AHSP > FSP > MPP > CRSPVD > CCS > SSG for formulations containing 15% superdisintegrant concentration [35].

3.7. Stability Studies

The optimized formulations stored at accelerated conditions (40±2°C/75±5% RH) for three months showed no significant changes in physical appearance, drug content, or dissolution profiles. The disintegration times showed minimal variation (±2 seconds), indicating good stability of the formulations [36].

Table 3. Results of Stability Studies conducted on Optimized formulation (F3)

Parameters	Initial	After 1 month	After 2 months	After 3 months
Physical appearance	No change	No change	No change	No change
Drug content (%)	98.27±0.06	98.15±0.08	97.98±0.12	97.85±0.15
Disintegration time (s)	24±0.3	24.8±0.4	25.2±0.5	26.0±0.6
Drug release at 20 min (%)	98.20	98.05	97.85	97.65

4. Conclusion

The development of fast-dissolving tablets of glimepiride using natural superdisintegrants proved successful, with formulations demonstrating rapid disintegration and enhanced dissolution profiles. *Arachis hypogaea* shell powder at 15% concentration emerged as the most effective natural superdisintegrant, achieving complete tablet disintegration within 24 seconds and 98.20% drug release in 20 minutes. The dissolution enhancement efficiency of natural superdisintegrants at optimal concentration followed the order: FSP > AHSP > MPP, surpassing the performance of conventional synthetic alternatives. The superior performance of natural superdisintegrants, particularly AHSP and FSP, can be attributed to their unique structural and chemical characteristics. AHSP's cellular structure provides extensive capillary networks facilitating rapid water uptake. FSP's branched galactomannan structure enables rapid swelling and subsequent tablet disintegration. All formulations exhibited satisfactory physical parameters, content uniformity, and stability under accelerated conditions. The absence of drug-excipient interactions, confirmed through FTIR studies, supports the compatibility and suitability of these natural polymers in glimepiride formulations. The incorporation of these natural superdisintegrants not only enhanced the pharmaceutical performance but also aligned with principles of green pharmacy and sustainability. The results indicate the potential of these natural alternatives as effective superdisintegrants for developing fast-

dissolving formulations. Their superior performance, coupled with advantages of biocompatibility, local availability, and cost-effectiveness, presents a promising approach for improving the delivery of poorly soluble drugs like glimepiride.

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