World Journal of Biology Pharmacy and Health Sciences
eISSN: 2582-5542
Cross Ref DOI: 10.30574/wjbphs
Journal homepage: https://wjbphs.com/

(RESEARCH ARTICLE)

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Exploring the super-disintegrating properties of fenugreek seed mucilage for fast-dissolving amlodipine tablets

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World Journal of Biology Pharmacy and Health Sciences, 2023, 16(01), 186–197

Publication history: Received on 05 September 2023; revised on 14 October 2023; accepted on 17 October 2023

Article DOI: https://doi.org/10.30574/wjbphs.2023.16.1.0438

Abstract

Fast dissolving tablets of amlodipine besylate were developed to improve patient compliance for hypertension treatment. Trigonella foenum-graecum (fenugreek) seed mucilage was used as a superdisintegrant in the formulation of fast dissolving tablets by direct compression method. Eight formulations with varying concentrations of fenugreek mucilage, microcrystalline cellulose, lactose and other excipients were prepared and evaluated for physicomechanical properties, drug-excipient compatibility, disintegration time, wetting time, water absorption ratio and in-vitro dissolution. The optimized formulation F6 containing 5% fenugreek mucilage, 75mg microcrystalline cellulose, 90mg lactose showed a disintegration time of 14 seconds, wetting time of 22 seconds and 90% water absorption. *In-vitro* drug release of 63% was observed within 15 minutes from F6 formulation. Physical and chemical stability studies showed the optimized F6 formulation was stable for 3 months at 40 °C/75%RH. Hence, fenugreek seed mucilage can be effectively used for developing amlodipine besylate fast dissolving tablets with improved patient compliance.

Keywords: Amlodipine besylate; Fenugreek mucilage; Fast dissolving tablets; Superdisintegrant; Formulation optimization

1. Introduction

Oral drug delivery is the most popular route of drug administration due to its advantages of convenience and patient acceptability. Among oral solid dosage forms, tablets are the most widely used due to their ease of production, stability, and portability [1]. However, difficulties swallowing tablets and capsules can reduce patient compliance, especially in elderly populations [2]. To address this issue, fast dissolving drug delivery systems have been developed that dissolve rapidly in the oral cavity without need for water.

Hypertension, or high blood pressure, is a chronic condition affecting over 1 billion people worldwide. Left uncontrolled, it increases the risks of heart attack, stroke, and other serious health issues. Amlodipine is an oral calcium channel blocker commonly prescribed for hypertension and related conditions like angina. However, swallowing tablets can pose challenges for some patients. This study aimed to develop a fast dissolving tablet formulation of amlodipine besylate using Trigonella foenum-graecum (fenugreek) seed mucilage as a natural superdisintegrant [3]. Rapid dispersion in saliva could enhance patient convenience and compliance with antihypertensive therapy [4].

The aim of this study was to develop fast-dissolving tablets of amlodipine besylate using the mucilage of Trigonella foenum-graecum (fenugreek) seeds as a natural superdisintegrant. Fenugreek mucilage was selected for its fast disintegrating properties with the goals of rapidly achieving a therapeutic plasma concentration of amlodipine, decreasing tablet disintegration time through improved water uptake, and reducing wetting time. Tablets were prepared by a simple and cost-effective direct compression method.

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2. Material and methods

2.1. Materials

The active pharmaceutical ingredient, amlodipine besylate, was obtained from Lara Drug Private Limited located in Hyderabad. Microcrystalline cellulose was sourced from Sigachi Industries private Ltd also based in Hyderabad. Talc was procured from Fine chemicals, an organization located in Mumbai, India. Magnesium stearate was obtained from Vijlak Pharma Limited situated in Hyderabad. Fenugreek seeds were acquired from the local domestic market. All other excipient materials used were of high purity.

2.2. Separation of Mucilage from Fenugreek Seeds

Fenugreek seeds weighing 250 grams were first thoroughly washed and soaked overnight at room temperature in double distilled water. Subsequently, these seeds were crushed using a mortar and pestle and then heated in a water bath with sufficient double distilled water while continuously stirring until a slurry consistency was achieved. After reaching room temperature, the slurry was refrigerated overnight to allow any undissolved materials to settle[5]. The upper clear solution was separated after decantation and then subjected to centrifugation at 1000 rpm for 30 minutes. The supernatant, obtained by heating on a water bath at 50-55 ^{o}C, was isolated and concentrated to one-third of its original volume. After cooling to room temperature, the solution was mixed with three times its volume of acetone and agitated consistently. Acetone was used to repeatedly wash the precipitate. The resulting gum product was then dried using a freeze dryer. The dried galactomannan gum is white, lacks odor, and has a neutral taste[6]

2.3. Direct Compression Method

All amlodipine besylate dosage form batches were produced through a direct compression method. All ingredients, except for the lubricants, were accurately measured and then sifted through a 60-mesh sieve before being placed into polybags for a 5-minute blending process. The combination of magnesium stearate and talc was also sifted into this mixture using a 60-mesh sieve. The resulting blend was then compressed into 200mg tablets using an eight-station tablet press [7].

2.4. Preformulation Studies

Preformulation studies represent the first stage in the development of dosage forms. In these studies, the physical and chemical properties of a therapeutic compound, either on its own or when combined with excipients, are examined[8]. The goal is to create a medication that is effective, dependable, and safe. These investigations aim to assess how both the drug and excipient molecules impact the formulation, the manufacturing process, as well as the pharmaceutical and pharmacokinetic characteristics of the final product. Parameters such as sensory attributes, drug solubility, melting point, and hygroscopicity were assessed for the drug. Prior to tablet compression, a range of physico-mechanical tests and compatibility assessments were carried out[9]

2.5. Drug-Excipient Compatibility studies (FTIR)

In order to investigate any potential chemical interactions among the drug as well as the excipient, an FTIR spectrophotometer (FT/IR-4600 Type A) was employed [10]. Amlodipine alone and in conjunction with mucilage produced spectra in the frequency range 4000-600 cm^{-1}.

2.6. Measurement of λ max for Amlodipine Besylate

2.6.1. Preparation of 0.01N HCl Dissolution Medium

In a 1000ml volumetric flask, a solution was prepared by combining 0.85 ml of HCl and 40 ml of distilled water, which was then topped up to the mark with additional distilled water[11]**.**

2.6.2. Preparation of Amlodipine Standard Solution

A precisely weighed 10 mg of Amlodipine was placed in a 10-ml volumetric flask, and the flask was filled to its volume with 0.01M HCl. The maximum wavelength (λ max) for the stock solution of Amlodipine was determined using a UV spectrophotometer, specifically in the wavelength range of 200–400 nm, where the maximum absorbance peak was observed at 365 nm [12]**.**

2.6.3. Preparation of Amlodipine Working Solution:

A series of concentrations, ranging from 0 to 12 µg/ml, were prepared from the standard stock solution of Amlodipine. These solutions were analyzed using a UV spectrophotometer at the λ max of 365 nm, and the resulting absorbance values were recorded. A calibration graph was constructed by plotting the concentration on the x-axis and the corresponding absorbance on the y-axis [13]

2.7. Formulation of Amlodipine Besylate Fast Dissolving Tablets

All components except magnesium stearate and talc were accurately weighed and transferred to a polybag. They were blended for 5 min in a closed polyethylene bag. Magnesium stearate and talc were thereafter added to the blend and mixed for another 2 min. The final blend was compressed into tablets using an 8-station rotary tableting machine fitted with 8.0mm flat punches. A compression force of 5 kg was employed. A total of 50 tablets were produced for each batch where each tablet weighs 200 mg [14].

Eight formulations were prepared by varying the concentration of fenugreek mucilage and other excipients as shown in Table 1. The direct compression method involved simple blending of drug and excipients followed by compression with no intermediate wet granulation step. Compressed tablets were evaluated for uniformity of weight, hardness, friability, thickness, drug content, water absorption ratio, wetting time, *In vitro* disintegration and dissolution characteristics. The optimized batch was identified based on tablet properties meeting predetermined specifications [15].

Table 1 Formulation of Amlodipine Besylate Fast Dissolving Tablets

Ingredients	**Quantity per one tablet (mg)**							
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**
Amlodipine	10	10	10	10	10	10	10	10
Mucilage (FenugreekExtract)	3	5	3	5	5	5	5	5
Lactose	-		169	165	100	90	65	-
Micro crystalline Cellulose(MCC)	169	165	-	-	65	75	100	167
Talc	5	5	5	5	5	5	5	5
Sodium Saccharide	8	10	8	10	10	10	10	8
Magnesium Stearate	5	5	5	5	5	5	5	5
Net weight (mg)	200	200	200	200	200	200	200	200

2.8. Evaluation studies

The tablets were visually examined to assess their overall appearance and aesthetics, which includes factors like size, shape, and color. Other aspects considered were the presence or absence of odors, tastes, surface smoothness, and the prevention of sticking together [5].

2.8.1. Tablet Hardness

Tablets need to possess a certain level of strength or hardness to withstand handling during manufacturing, packaging, and transportation to prevent breakage. The Monsanto hardness tester, a commonly used device, was employed to measure the tablet hardness (also known as crushing strength) [16]. For each batch, a random selection of tablets was tested for hardness using a Monsanto hardness tester, and the results were expressed in kilograms per square centimeter.

2.8.2. Tablet Thickness

The thickness of tablets was determined by measuring 10 randomly selected tablets from each formulation using a Vernier caliper scale, which allows for precise measurements [17]

2.8.3. In vitro Disintegration Test

The *In vitro* disintegration test was performed using a disintegration testing apparatus. A single tablet from each batch was randomly selected and placed in one of the compartments in the disintegration test basket. The basket, along with its tablets, was then immersed in a water bath containing 900 ml of distilled water, maintained at a temperature of 37±0.5 °C. The time it took for the tablets to completely disintegrate was recorded using a stopwatch [18].

2.8.4. Friability Test

The friability test was conducted using a Roche Friabilator. Tablets with pre-determined weights were loaded into the friabilator. The friabilator was operated at a speed of 25 revolutions per minute for a duration of 4 minutes or until it completed 100 revolutions. The friability was calculated using the formula provided, utilizing the initial and final weights of the tablets [19]

$$\%Friability = \frac{Initial\ weight - Final\ weight}{Initial\ weight} * 100$$

2.8.5. Wetting Time

To determine the wetting time of the tablet, a straightforward method was employed. In a Petri dish, five circular tissue papers measuring 10 cm in diameter were arranged. Amaranth dye was dissolved in 10 ml of water and added to the Petri dish. A tablet was gently placed on the surface of the tissue. The time taken for a red hue to develop on the tablet's upper surface was recorded as the wetting time [20].

2.8.6. Water Absorption index

A folded piece of tissue paper that held a tablet on its surface was positioned in a small Petri dish containing 6 ml of water. The tablet was left to fully absorb the moisture, after which its weight was measured. The water absorption ratio (R) was calculated using the following formula:

$$R = \frac{Wa - Wb}{Wb} * 100$$

Here, Wa and Wb represent the tablet's weight after and before water absorption, respectively.

2.8.7. Weight Variation

For each batch, twenty tablets were randomly selected and individually weighed using a digital balance. The average weight of the tablets was also calculated. Each tablet's weight was compared to the average tablet weight, and any variation was documented [21]. Tablet Weight variations according to USP& IP are shown in Table 2.

Table 2 Weight variation limits as per USP and IP

As per USP (mg)	% Deviation	As per IP (mg)
≤130	± 10	80 or less
130 – 324	± 7.5	From 80 -250
≥324	± 5	More than 250

2.8.8. Drug Content

Twenty tablets were accurately weighed and then crushed. An amount of powder equivalent to 100 mg of amlodipine besylate was measured and placed in a 100 ml volumetric flask, where it was mixed with 100 ml of distilled water. From this mixture, 10 ml was extracted using a pipette and then diluted with distilled water to reach a final volume of 100 ml. Subsequently, 10 ml of this solution was withdrawn and diluted to a final volume of 100 ml in another 100 ml volumetric flask. The resulting solution was subjected to filtration, and its absorbance was measured at 365 nm. The concentration of amlodipine besylate was determined, using distilled water as a blank for reference [22].

2.8.9. In vitro dissolution studies

The dissolution testing apparatus II (paddle apparatus) of the United States Pharmacopoeia (USP) was used to assess the rate of release of formulated dosage forms. The test was conducted with 900 ml of 0.01 M HCl at 37± 0.5 °C and 50 rpm. 5ml of samples were removed from the basket at every 5-minutes time period and add the same quantity of fresh dissolution medium in to the basket. The samples were then filtered and their concentration was evaluated by Shimadzu UV/Vis double beam spectrophotometer at 365 nm. A standard curve equation was used to compute the cumulative percentage of medication release[23].

2.8.10. Stability Test

The stability test was carried out in accordance with ICH recommendations. For a period of three months, the chemical and physical stability of fast dissolving tablets was tested at 40°C±2°C, 75%±2% RH [24].

3. Results and discussion

3.1. Pre-Formulation Studies

3.1.1. Physicochemical characteristics

- In the preformulation studies of Amlodipine API, a comprehensive analysis of key parameters was undertaken to understand the physicochemical properties of the drug substance. These results provide valuable insights into the drug's characteristics and its potential suitability for formulation into pharmaceutical dosage forms [8].
- Color: The Amlodipine API appeared as a white powder, indicating a high level of purity and a lack of visible impurities. This is particularly important in pharmaceutical applications, as it suggests a clean and uncontaminated starting material.
- Taste: The taste of Amlodipine API was observed to be bitter. Bitterness can be a challenge in drug formulation, as it may affect patient compliance and acceptability. Efforts may be required to mask or mitigate this taste to enhance patient adherence.
- Odor: Amlodipine API was found to be odorless. This is advantageous in pharmaceutical products, as it ensures that the drug does not have any unpleasant or potentially harmful smells. An odorless characteristic enhances the overall user experience.
- Solubility (ml/gm): The drug demonstrated varying solubility in different media, with the highest solubility in 0.01N hydrochloric acid. These solubility values are critical for understanding the drug's dissolution behavior in different environments, which is vital for formulation design.
- Melting Point: The melting point of Amlodipine API was observed within the range of 178-179 °C. This data is significant for the drug's thermal stability and processing during manufacturing.
- Hygroscopicity: The drug was found to be non-hygroscopic, indicating that it does not readily absorb moisture from the environment. This characteristic is advantageous for drug stability and shelf-life.
- Sieve Analysis: The results of the sieve analysis indicated that the Amlodipine API is in the form of fine powder. This is desirable for uniform mixing and dosing in pharmaceutical formulations. The results are shown in Table 3.

Table 3 Physicochemical properties of Amlodipine

Parameters	**Results**
Color	White
Taste	Bitter
Odor	Odorless
Solubility (ml/gm)	Purified water-726.24 0.01N Hydrochloric acid- 1729.9 Acetate Buffer pH 1.2- 1659.5 Acetate Buffer pH 4.5- 1162.8 Phosphate Buffer pH 6.8- 1845.6

Melting Point	178-179 ^{o}C
Hygroscopicity	Non hygroscopic
Sieve analysis	Fine Powder

3.1.2. Physical Properties of mucilage

The results obtained from the analysis of Fenugreek mucilage present valuable insights into its physical and chemical characteristics. These findings (shown in Table 4) are crucial for understanding the properties and potential applications of this natural substance [6].

- Color: Fenugreek mucilage was observed to be light brown in color. This characteristic is typical of natural plant-derived mucilages and suggests that it retains some of the color inherent to fenugreek seeds. The color could be significant in various applications, such as food or pharmaceutical formulations, where the natural origin is preferred.
- Odor: The mucilage exhibited a faint smell of fenugreek. This is an expected and desirable attribute, as it indicates that the mucilage retains some of the aromatic properties of the source plant. The fenugreek odor may have applications in flavoring or scent enhancement.
- Taste: The taste of the fenugreek mucilage was determined to be bitter. Bitterness can be a common characteristic of natural plant-based compounds, and it's important to note this attribute, especially when considering its use in edible products or medicinal formulations. Efforts may be required to mask or mitigate this taste for better consumer acceptability.
- Water Dispersibility: The mucilage demonstrated good water dispersibility. This characteristic is favorable, particularly if the mucilage is intended for use in food products or pharmaceutical formulations. Good water dispersibility ensures that it can be easily incorporated into various formulations.
- pH: The pH level of the fenugreek mucilage was measured at 7.4, indicating a nearly neutral pH. This pH range is typically suitable for a wide range of applications, making it compatible with various formulation conditions.
- Solubility: The mucilage was found to be soluble in hot water but insoluble in organic solvents. This solubility profile aligns with the behavior expected from plant-derived mucilages. The hot water solubility suggests its potential use in water-based formulations, while its insolubility in organic solvents makes it suitable for specific applications that require water-based solutions [25].

Table 4 Physicochemical properties of fenugreek mucilage

S. No	**Parameters**	**Result**
1.	Colour	Light brown in colour
2.	Odour	Faint smell of fenugreek
3.	Taste	Bitter
4.	Water dispersibility	Good
5.	P^{H}	7.4±0.058
6.	Solubility	Soluble in hot water. Insoluble in organic solvents

3.1.3. Drug excipient incompatibility using FTIR

The FTIR spectra of pure Amlodipine and Amlodipine in the presence of excipients provide important insights into the chemical composition and functional groups within these samples. This analysis aids in understanding the chemical interactions and compatibility of Amlodipine with the excipients in the formulation [26].

Pure Amlodipine

The FTIR spectrum of pure Amlodipine (shown in Figure 1) exhibits characteristic peaks associated with its chemical structure. The presence of the benzene ring is confirmed by the peak at 2980 cm^{-1}, representing the stretching of CH bonds. This peak highlights the aromatic nature of Amlodipine. The carbonyl (C=O) groups in Amlodipine are evident from the peaks at 1671 cm^{-1} and 1614 cm^{-1}. These carbonyl functionalities play a vital role in the chemical structure of the drug. The stretching of C-S bonds, indicated by the peak at 1201 cm^{-1}, suggests the presence of a sulfonic acid group in Amlodipine. The peak at 1089 cm^{-1} corresponds to the stretching of NH bonds, signifying the existence of a secondary

amino group in the molecule. Another peak related to carbonyl groups is observed at 1031 cm^{-1}, further affirming the presence of carbonyl functionalities. The peak at 753 cm^{-1} is associated with the bending of OH groups and is linked to the sulfonic acid group [27].

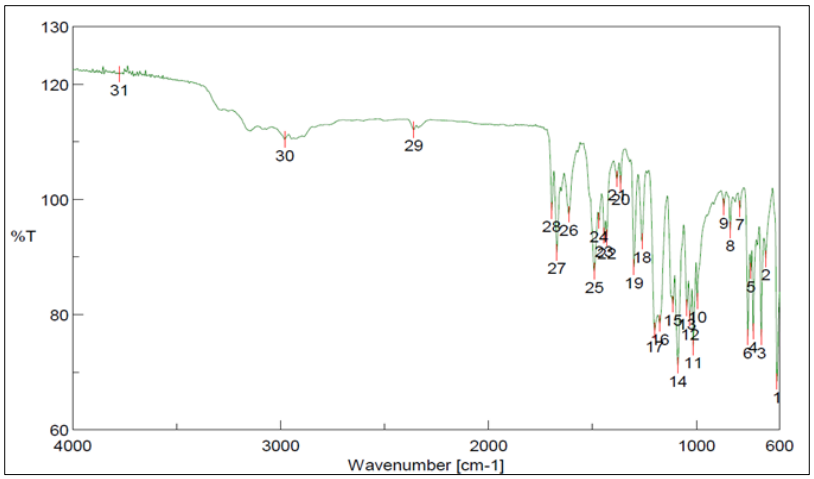

Figure 1 FTIR spectrum of Amlodipine pure drug

Amlodipine + Excipients

In the FTIR spectrum of Amlodipine with excipients (shown in Figure 2), the introduction of new functional groups is apparent. The peak at 3283 cm^{-1} indicates the presence of NH bonds, suggesting the addition of primary amino groups. This signifies the incorporation of excipients with primary amino functionalities into the formulation. The peaks at 2917 cm^{-1} and 1617 cm^{-1} correspond to the stretching of carbonyl (C=O) groups, consistent with the presence of carbonyl functionalities, possibly from Amlodipine itself. The peak at 1215 cm^{-1} suggests the stretching of C-S bonds, implying the presence of a sulfonic acid group, which may originate from Amlodipine or from the added excipients. The peak at 758 cm^{-1} is associated with the bending of OH groups, linked to the sulfonic acid group, which can be attributed to Amlodipine. These FTIR results indicate that the Amlodipine formulation with excipients introduces primary amino groups, while retaining the carbonyl functionalities, which are integral to the Amlodipine molecule. The presence of sulfonic acid groups in both cases suggests that Amlodipine's sulfonic acid group remains unchanged and that the excipients do not significantly impact this group.

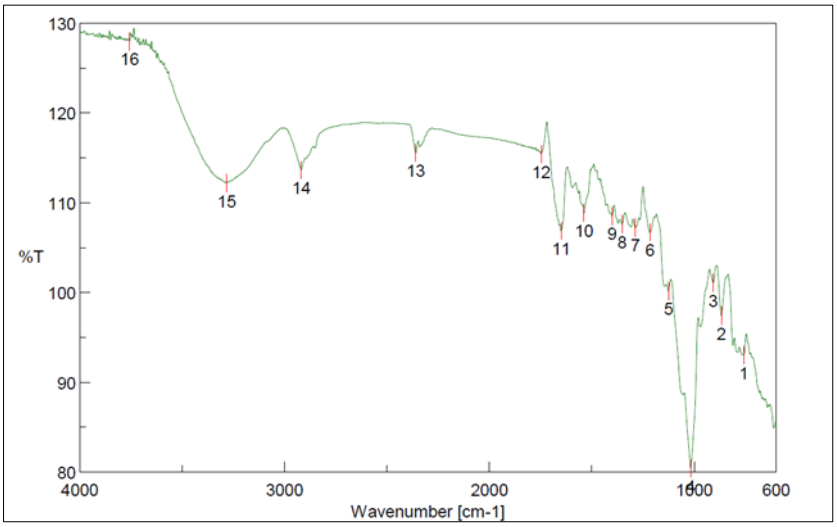

Figure 2 FTIR spectrum of pure drug (Amlodipine) + Excipients

3.2 Calibration of Amlodipine in 0.01N HCL buffer

The results of the standard calibration curve using a UV spectrophotometer at 365 nm for Amlodipine in 0.01M HCl buffer and the results offer important insights into the quantitative analysis of Amlodipine in this specific medium. The

calibration curve provides a correlation between the concentration of Amlodipine (in µg/ml) and the corresponding absorbance values at 365 nm. These results are crucial for the accurate quantification of Amlodipine in samples by UV spectrophotometry. The calibration curve follows a linear relationship, as indicated by the equation: y = 0.0292x + 0.0066, where 'y' represents the absorbance at 365 nm and 'x' represents the concentration of Amlodipine in µg/ml. The coefficient of determination (R^2) for the calibration curve is 0.999. An R^2 value close to 1.0 signifies an excellent correlation between concentration and absorbance (shown in Figure 3), indicating the reliability and accuracy of the calibration curve. As the concentration of Amlodipine increases, there is a proportional increase in absorbance at 365 nm. This relationship is clearly illustrated by the equation of the calibration curve [13].

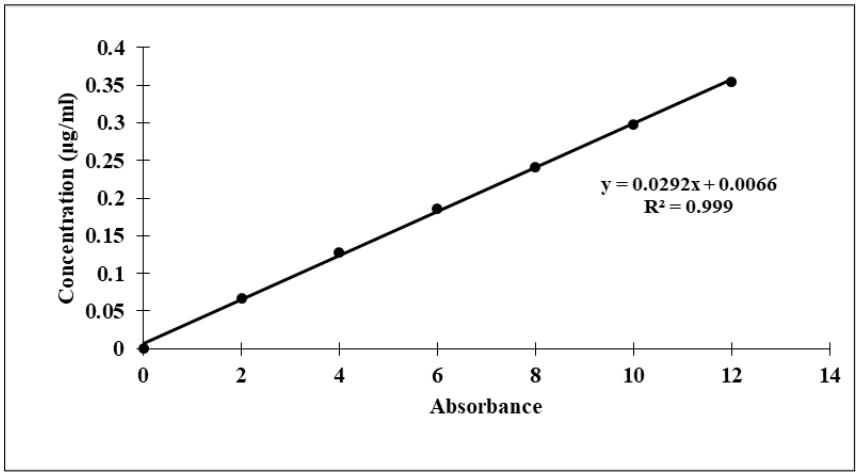

Figure 3 Calibration Curve of Amlodipine

3.3 Precompression parameters

In the assessment of precompression parameters for various formulations (F1 to F8), it is observed that there is variation in these parameters across the formulations. Formulation F6 shows the highest bulk density (0.40±0.22 g/ml) and the lowest Carr's index (15.05±0.35), indicating good flow properties. On the other hand, formulation F5 exhibits the lowest bulk density (0.43±0.25 g/ml) and the highest angle of repose (32.54±0.32°), implying comparatively poorer flow characteristics. F1, F2, and F3 have intermediate values for these parameters (Results are shown in Table 5). The variations in these precompression parameters among the formulations may have implications for their manufacturability and performance, emphasizing the importance of selecting the most appropriate formulation [9].

Table 5 Pre compression parameters of formulations

Batch	Bulk Density(g/ml)*	Tapped Density(g/ml)*	Carr's Index*	Hausner's ratio*	Angle of Repose(°)*
F1	0.39±0.42	0.56±0.19	20.0±0.15	1.251±0.17	36.61±0.22
F2	0.42±0.39	0.60±0.22	18.66±0.23	1.23±0.16	33.81±0.25
F3	0.45±0.16	0.57±0.3	23.0±0.31	1.250±0.19	36.90±0.21
F4	0.47±0.29	0.56±0.27	19.7±0.19	1.197±0.14	37.21±0.28
F5	0.43±0.25	0.50±0.15	25.0±0.27	1.211±0.16	32.54±0.32
F6	0.40±0.22	0.556±0.11	15.05±0.35	1.16±0.14	29.46±0.23
F7	0.47±0.32	0.56±0.33	22.79±0.17	1.20±0.09	38.21±0.24
F8	0.45±0.26	0.58±0.26	18.0±0.09	1.18±0.12	39.54±0.30

(* Observation ± SEM, n= 3)

3.4 Post-compression parameters

The post-compression parameters for formulations (F1 to F8) provide valuable insights into the quality and performance of these formulations. Hardness, friability, weight variation, disintegration time, wetting time, water

absorption ratio, and drug content were assessed (Results are shown in Table 6). Formulation F6 stands out with the highest hardness (2.9±0.1 kg/cm^2), indicating robust tablet strength. On the other hand, F4 displays the lowest hardness (0.5±0.2 kg/cm^2), suggesting lower tablet strength. In terms of friability, all formulations exhibit low friability percentages, indicating minimal tablet abrasion during the testing process. Formulations F3 and F6 have the lowest friability values, reflecting the ability of these formulations to resist mechanical stress during handling and transportation. Weight variation is uniform across all formulations, with each maintaining a constant weight (200 mg). Disintegration time is relatively consistent as well, with Formulation F6 showing the fastest disintegration (14 seconds). Formulation F7, however, exhibits the longest disintegration time (22 seconds). Wetting time is variable, with F1 displaying the longest wetting time (42 seconds), while F6 showcases the shortest wetting time (22 seconds). These parameters collectively reflect the formulations' consistency in terms of weight and their performance in disintegration and wetting, which can impact the rate and effectiveness of drug release [9].

Table 6 Post compression parameters

Formulations	Hardness (kg/cm^2)*	Friability (%)	Weight variation (mg)*	Disintegration time (sec)	Wetting time (sec)*	Water absorption (%)*	Drug Content*
F1	2.1±0.5	0.9	200±1	22	42±0.36	80.21±0.35	95.67±0.65
F2	1.5 ±0.2	0.43	200±2.2	22	23±0.29	84.27±0.73	98.15±0.69
F3	1.5 ±0.3	0.1	200±1.7	18	39±0.06	76.64±1.01	97.4±0.27
F4	0.5 ±0.2	0.86	200±0.9	20	26±0.51	82.11±0.82	99.11±1.89
F5	1.5±0.6	0.86	200±15	19	34±0.18	85.71±0.29	98.72±0.56
F6	2.9±0.1	0.8	200±2.7	14	22±0.14	90.12±0.28	99.32±0.43
F7	2±0.2	0.8	200±1.6	17	36±0.25	69.46±0.39	101.82±1.34
F8	2±0.6	0.9	200±2.3	22	53±0.16	73.49±0.52	96.20±0.87

(* Absorbance ± SEM, n= 3)

3.4.1 Dissolution Studies

The results of the % cumulative drug release in 900 ml of 0.01M HCl at 50 rpm and 37±0.50°C, using USP Type II paddle apparatus, demonstrate differences in drug release profiles among formulations (F1 to F8) (results are shown in Table 7). Over a 45-minute time period, it is evident that F5 and F6 exhibit the highest cumulative drug release percentages, reaching approximately 97.44% and 99.3%, respectively. Formulation F3 also shows a relatively high drug release of around 93.14% after 45 minutes. In contrast, F1, F2, F4, F7, and F8 display lower drug release percentages, with F1 having the lowest cumulative drug release of approximately 90.2% after 45 minutes. These variations in drug release profiles suggest differences in the formulations' dissolution characteristics, which can be attributed to variations in excipients, formulation design, and manufacturing processes [23].

Table 7 *In vitro* drug dissolution study

Time (min)	% Cumulative drug release in 900 ml 0.01M HCL 50 rpm, 37±0.5^{o}C, USP type II(paddle)							
	F1	F2	F3	F4	F5	F6	F7	F8
5	21.67	24.2	26.6	29.24	27.26	**29.4**	26.2	24.83
10	35.24	39.32	39.76	40.64	38.26	**40.8**	42.36	39.16
15	53.2	55.66	58.24	55.16	59.78	**63.1**	61.22	57.42
20	68.4	73.92	78.34	75.33	76.18	**79.2**	77.16	72.19
30	79.5	83.64	86.24	87.14	86.12	**89.7**	89.2	83.17
45	90.2	92.3	93.14	93.12	97.44	**99.3**	96.29	92.84

3.4.2 Stability Studies

Table 8 Results of stability studies

S.NO	Parameters	Formulation F6 stored at 40°C±2 °C, 75%±2% RH	
		0 months	**3 months**
1.	Colour	White	White
2.	Odour	Odourless	Odourless
3.	Disintegration	14 sec	14 sec
4.	Dissolution	99.3 %	99.17%

The stability results for Formulation F6, stored at 40°C±2 °C and 75%±2% relative humidity for 0 and 3 months, reveal that the formulation remains stable in terms of color and odor, with no noticeable changes. The disintegration time remains consistent at 14 seconds, indicating that the tablets maintain their integrity even after three months of storage under accelerated conditions. In terms of dissolution, there is a slight decrease in the percentage of drug dissolution from 99.3% to 99.17% over the 3-month storage period, suggesting a minimal reduction in drug release efficiency. Overall, these results suggest that Formulation F6 exhibits good stability under these accelerated storage conditions, with only minor changes in dissolution performance. Further long-term stability studies may be warranted to confirm the formulation's robustness over an extended shelf life [24].

4. Conclusion

This study explored the super-disintegrating properties of fenugreek seed mucilage. Amlodipine fast-dissolving tablets were developed using fenugreek seed mucilage via direct compression, resulting in tablets that exhibited significant swelling, porosity, and wicking action attributed to the utilization of fenugreek seed mucilage. The dosage forms underwent a comprehensive characterization and optimization process, encompassing parameters such as weight consistency, hardness, thickness, friability, wetting time, water absorption, disintegration, and dissolution. The findings indicated that the F6 formulation met the specified optimization criteria. Consequently, it can be inferred that the F6 formulation is the optimal choice, and fenugreek seed mucilage holds promise for various applications in tablet dosage forms, offering improved therapeutic efficacy, cost-efficiency, and reduced side effects.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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