Formulation And Evaluation Of Immediate Release Tablets Of Anti-Hypertensive Drug Using Natural Gum

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ABSTRACT

The objective of designing animmediate release tablet to provide a convenient and user-friendly alternative to traditional oral dosage forms such as tablets using natural gum. Immediate release tablets, also known as orally disintegrating tablets (ODTs) or quick-dissolving tablets, are formulated to disintegrate rapidly in the mouth without the need for water or chewing, allowing for easy administration and improved patient compliance. The tablets were prepared by direct compression method using natural gum such as Plantago ovate gum (PG), Fenugreek seed gum (FG) were used in tablet formulation. The prepared formulation were evaluated for various physical parameters, in-vitro drug release profile and stability study. The formulation PGNF4 gives faster dissolution 98.53%, within 20 minutes whereas the FGNF4 fenugreek mucilage as superdisintegrant was showed highest dissolution 81.91%, within 20 minutes. The optimized PGNF4 immediate release tablet batch showed no change in physical appearance, drug content or in dissolution pattern for 90 days under the stability study. Finally it was concluded that batch PGNF4 containing formulation showed highest drug release in lesser time and both of selected natural gum successfully can be used for the development of immediate release tablet in future. It can be used as super disintegrating agent.

Keywords: Nifedipine, immediate release tablet, superdisintegrants, fenugreek seed gum, Plantago ovate gum**.**

INTRODUCTION:

The oral route is the most popular method for administering many medications since it is thought to be the safest, most practical, easy handling and least expensive method. Fast dissolving pills are highly popular right now because they dissolve or easily dissolve in the mouth after administration without the need for water. Fast dissolving tablets have been developed to address the drawbacks of conventional doses form, particularly dysphagia (difficulty swallowing), in pediatric and geriatric patients. Natural materials offer an advantage

over synthetic ones since they are more readily available, less expensive, non-toxic, and chemically inert [1]. Immediate release drug delivery system are based on single or multiple-unit reservoir or matrix system, Which are devised to obtain instant required drug levels in small duration of time. Immediate release drug delivery is craved for drug having prolonged biological half-life, large bioavailability, lower clearance and reduced elimination half-life, fast dissolution, disintegrate in stomach within a brief duration time. Immediate release drug delivery is beneficial in the aspects of improved compliance, improved stability, allows high drug loading and cost effective for the patients [2-5].

In the treatment of antihypertension, Nifedipine drug is proved one of the most effective and widely used drugs. It is administered at a dose of 20-90mg daily and availability subjected to only conventional released tablets [6]. It is a poorly tolerated medicament and usually administered with food to decrease gastrointestinal intolerance [7]. The reduced oral bioavailability of Nifedipine is due to first pass metabolism [8]. In the attempt of improve tolerability enteric-coated Nifedipine tablets were developed but improvement if gastrointestinal intolerance was not been found [9, 10]. Nifedipine is a pharmacological agent derived from 3, 5-pyridinedicarboxylic acid, specifically known as 1, 4-dihydro-2, 6-dimethyl-4-(2 nitrophenyl)-dimethyl ester, with a molecular weight of 346.34. It belongs to the Biopharmaceutics Classification System (BCS) Class-II, which is a classification system for drugs based on their solubility and permeability characteristics. Nifedipine is widely utilized in the treatment of various medical conditions. The absorption of Nifedipine has been determined to be approximately 50% ±13. It exhibits a volume of distribution of 0.75 l/kg, indicating its distribution throughout the body. Nifedipine has a high affinity for plasma proteins, with over 90% of the drug binding to them. Approximately 80% of the drug is excreted through renal elimination, while its plasma half-life is approximately 4 hours. In the current research, immediate release tablets of Nifedipine were formulated using a combination of natural superdisintegrants and synthetic disintegrants. These excipients are commonly included in immediate release solid dosage forms as they facilitate the disintegration and disaggregation of the tablets, promoting rapid drug release upon administration. [11-14].

METHODOLOGY:

Method for Isolation of natural gum:

A. Isolation of Plantago ovata gum (PG):

Imported plantago ovata seeds were mixed with 10 to 30 times their weight of water and allowed to stand for 10 to 30 hours. The solution was the pressed through cloth and the gum were obtained by addition of three volumes of 95% ethanol. In other cases the gum were isolated by extracting the seed for hour with hot water. The yield of gum obtained by thorough extraction approximately 20% of the weight of the seeds used, and then it was dried in hot air oven or by using vacuum oven at 40^0C. The dried mucilage was ground by a mechanical grinder and passed through # 60 mesh sieve and kept in desiccators [14-18].

B. Isolation of Fenugreek Seeds Gum (FG):

The seeds were washed with double distilled water to remove any adherent material. The seeds were pulverized and about three times its volume of water was added and kept aside with occasional stirring using mechanical stirrer. The process continued for about 5 hours until the slurry was prepared. The viscous solution was then filtered through eight fold muslin cloth. The process was repeated 4 times with the residue on the muslin cloth. All the filtrate was added together. Then the filtrate was precipitated in about three times its volume of ethanol with mechanical stirrer. The precipitate was washed for three times with ethanol and dried at 40°C. The dried gum was ground by a mechanical grinder and passed through # 60 mesh sieve and kept in desiccators [15-16].

2. Characterization of Gum [15-16]:

A. Physical Characterization:

Organoleptic Evaluation:

The organoleptic evaluation refers to the evaluation of color, odor, shape, taste and special features which include touch and texture. The majority of information on the identity, purity and quality of the material can be drawn from these observations.

B. Phytochemical Characterization:

Determination of Gum Purity:

To determine the purity of gum tests for alkaloids, carbohydrates, flavonoids, steroids, saponins, tannins and phenols were carried out.

C. Physicochemical Characterization:

1. Swelling Index:

Swelling index of gum was determined by using reported method. One gram of powder (#100 meshes) was accurately weighed and transferred to a 100 ml stopper measuring cylinder. The initial volume of the powder in the measuring cylinder was noted. The volume was made up to 100 ml with distilled water. The cylinder was stoppered, shaken gently and set aside for 24 hours. The volume occupied by the gum sediment was noted after 24 hours. Swelling index (SI) is expressed as a percentage and calculated according to the following equation.

$$\%\ Swelling\ index = \frac{w2 - w1}{w1} x\ 100$$

w1= weight of the polymer (Before swelling)

w2= weight of the polymer (After swelling)

2. Solubility:

Solubility of powder was checked in different solvents such as water, hot water, ethanol, methanol, ether, acetone, chloroform etc.

3. Moisture Absorption:

The dried gum powder was accurately weighed and kept in a desiccator. After 3 days, the sample was taken out and weighed. The percentage of moisture uptake was calculated as the difference between final weight and initial weight with respect to initial weight.

4. Loss on Drying (LOD):

Moisture content of gum was determined by loss on drying method. Accurately weighed 1g gum sample was heated at 105°C to get a constant weight in a hot air oven and percent loss of moisture on drying was calculated using following formula,

$$\% \, LOD = \frac{w2 - w3}{w2 - w1} x \, 100$$

w1 = Empty LOD bottle weight
w2 = Sample + Empty LOD bottle weight
w3 = Weight after drying

5. pH of Gum:

The pH of 1% w/v dispersion of the gum was determined using a digital pH meter.

1. Standard calibration curve of Nifedipine:

A solution of Nifedipine was prepared in phosphate buffer pH 6.8 and recorded UV spectrum using UV/VIS Spectrophotometer.

Procedure:

Preparation of standard solution:

100 mg of Nifedipine was accurately weighed and added into 100 ml volumetric flask and dissolve in small quantity of methanol, and the volume was made up with the phosphate buffer pH 6.8 to get the concentration of 1000µg/ml. From this 1 ml was withdrawn and diluted to 100 ml to get concentration of 100µg/ml. From those aliquots of 0.5, 1, 1.5, 2, 2.5, 3ml were pipetted out into 10ml volumetric flasks. The volume was made up with phosphate buffer pH 6.8 to get the final concentrations of 5, 10, 15, 20, 25, 30 mg/ml respectively. The absorbance of each concentration was measured at 234 nm.

UV Spectrophotometer:

The UV spectrum of Nifedipine solution was scanned at 400nm to 200nm and was determined using pH 6.8 buffer. The λ-max of Nifedipine was determined for drug estimation.

2. Differential Scanning Calorimetry Study:

DSC analysis of pure drug was performed with Shimadzu DSC 60 thermal analyser at the heating flow rates of 10^0 C per min between 10 and 300^0 C under static air using aluminium pans.

3. Preformulation studies:

***Drug Polymer Compatibility Studies**:*

The drug, polymer and physical mixtures were subjected to Fourier transform infrared studies by ATIR technique to check drug polymer interaction, using Aglient Cary 630 FTIR spectrophotometer. The selected samples was scanned and was infrared spectra of FTIR was obtained. The following samples were used such as Nifedipine, plantago ovata seeds dried gum, and fenugreek seeds dried gum and polymer + drug respectively. Then these spectrums were compared and were used for the analysis of drug compatibility with blends mixture.

4. Formulation of Tablet [17-19]:

Table 1: Formulation of Nifedipine mouth dissolving tablet by direct compression method

S/N	Ingredients	BATCHES							
		PGNF				FGNF			
		PGNF1	PGNF2	PGNF3	PGNF4	FGNF1	FGNF2	FGNF3	FGNF4
1	Nifedipine	20	20	20	20	20	20	20	20
2	PVP-K40	100	100	100	100	100	100	100	100
3	Avicel PH102	116.25	113.75	111.25	108.75	116.25	113.75	111.25	108.75
4	Aspartame	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
5	PO gum dried powder	5	7.5	10	12.5	-	-	-	-
6	Fenugreek gum dried powder	-	-	-	-	5	7.5	10	12.5
7	Pippermintflavour	0.250	0.250	0.250	0.250	0.250	0.250	0.250	0.250
8	Magnesium stearate	1.21	1.21	1.21	1.21	1.21	1.21	1.21	1.21
9	Talc	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
10	Aerosil	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25
Average Weight		250	250	250	250	250	250	250	250

*All values are in mg

Procedure:

1. Accurately weigh all the components.
2. The remaining ingredients Avicel PH102, PVP, aspartame, plantago ovata dried gum, and fenugreek seeds dried gum were manually combined in a polybag for five minutes after being processed through sieve #60.
3. After that, for two minutes, they were lubricated with talc, aerosil and magnesium stearate.
4. Precompression settings for the lubricated granules were assessed.
5. Compression of tablets and was compressed using hand operated single 8mm punch tablet machine.
6. Post compression parameters for compressed tablets were assessed.

5. Pre compression parameter

Bulk density and Tapped density:

Loose bulk density and tapped density were determined. A quantity of 10 gm of powder from each formula, previously lightly shaken to break any agglomerates formed, was introduced into a 10 ml measuring cylinder and after the initial volume was observed, and the allowed cylinder allowed falling on its own weight onto a hard surface from the height of 2.5 cm at 2 second intervals. The tapping was continued until no further change in volume was noted. BD and TD were calculated using the following formula,

BD = Mass/ volume

TD = Mass/ Tapped volume

Hausner's ratio:

Hausner's ratio gives an idea regarding the flow of the blend. It is the ratio of tapped density to the bulk density. Hausner's ratio is calculated as:

$$\text{Hausner's Ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Compressibility Index:

The compressibility index measures the propensity of powder to be compressed. The packing ability of drug was evaluated from change in volume, which is due to rearrangement of packing occurring during tapping. It is indicated as Carr's index (CI) and can be calculated as follow,

$$\%\ CI = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Bulk density}} \times 100$$

Angle of Repose:

A funnel was held with a clamp such that the stem of the funnel is 2 cm above the graph paper is Weighed amount of blend 5 gm was taken and poured into the funnel keeping the orifice of funnel blocked. The powder was allowed to flow by removing the blockage until the apex of the conical pile just touches the tip of the funnel. Height of pile and average of six diameters formed by the pile of the powder was measured with the help of a ruler and the angle of repose was determined.

$$\theta = \tan^{-1}(h/r)$$

Where;

h - Height of powder pile

r - Radius of powder pile

θ - Angle of repose

5. Post Compression Parameter

Weight Variation:

Twenty tablets were randomly selected from each formulation and weighed individually to check for weight variation. The following percentage deviation in weight variation according to IP was allowed.

Thickness:

Twenty tablets were randomly selected and thickness was measured individually using vernier caliper. It was expressed in millimeter. The difference in tablet thickness should not exceed 5%.

Hardness:

Hardness indicates the ability of tablet to withstand mechanical shocks while handling. The hardness of the tablets was measured using Monsanto hardness tester, It was expressed in (kg/cm^2).

Friability:

Friability is the loss of tablet weight in the container or package caused by the removal of surface particles. To verify that tablets can endure shocks throughout processing (coating and stripping, packaging), handling, transportation, and shipment, a quality control test is conducted as part of the manufacturing process. Chipping, capping, and breaking of tablets are indicators of their friability. Friability is only 1% of the total. The friability of tablets was determined using Roche friabilator. Tablets were transferred in the friabilator. The friabilator was operated at 25 rpm for 4 minutes. The tablets were dedusted and weighed again. The percentage friability was calculated following formula:

$$\% F = \frac{W_{initial} - W_{final}}{W_{final}} \times 100$$

% Friability of tablets less than 1% is acceptable.

Disintegration time:

The test was carried out on 6 tablets using the disintegration test apparatus. Hydrochloric Acid Solution (0.1 M) at 37ºC ± 2ºC was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds.

Uniformity of Dispersion:

Two randomly selected tablets were kept in 100 ml water and stirred for two minutes. The dispersion was passed through 22 meshes. The tablets were considered to pass the test if no residue remains on the screen.

Wetting time:

A piece of tissue paper (12cmx10.75cm) a petri dish (Internal diameter = 9cm) containing 9ml of buffer solution pH 6.8. A tablet was placed on the paper and the time taken for complete wetting was noted. Three tablets from each formulation were randomly selected and the average wetting time was noted.

Water absorption ratio (%):

A piece of tissue paper folded twice was placed in a small petridish containing 6 ml of water. A tablet was put on the paper & the time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio, R, was determined using followingequation,

$$\%\ water\ absorption\ ratio = \frac{wa - wb}{wb} x\ 100$$

Wa is weight of tablet after water absorption and Wb is weight of tablet before water absorption.

Drug content uniformity:

The 10 tablets were taken and powdered and the powdered tablet added in 30 mL of a mixture of acetonitrile and water (3:2), shake vigorously for 20 minutes, and then add a mixture of acetonitrile and water (3:2) to make exactly volume so that each mL contains about 40 mg of Nifedipine, centrifuge, and use the supernatant liquid as the sample solution. Separately, weigh accurately about 50 mg of Nifedipine for assay, and dissolve in aceto-nitrile to make exactly 50 ml. Pipette 4 mL of this solution, add a mixture of acetonitrile and water (3:2) to make exactly 100 mL, and use this solution as the standard solution. Determine the absorbance of the sample solution and standard solution under ultraviolet-visible spectrophotometry.

As per IP Active ingredients less than 10mg or 10%

As per BP Active ingredients less than 2mg or 2%

As per IP Active ingredients less than 25mg or 25%

In-vitro dissolution study:

Utilizing a dissolution apparatus Type-2 (USP XXVIII), in-vitro release rate measurements were performed in 900 ml of sodium phosphate buffer (pH 6.8) at 37°C. At 50 rpm, the stirring speed was set. A 5-ml sample was taken out and replaced up to 12 hours later with new dissolving media at predefined intervals. Following the proper dilutions, the samples were examined using a UV spectrophotometric technique at a wavelength of 234nm. The mean of three pills from each of three different batches was utilized in data analysis to compute the cumulative percent of medication released.

Stability study:

Prepared immediate release tablets were tested for hardness, thickness, friability, in vitro buoyancy, drug content, and in vitro drug release over a period of three months at various

temperatures, including room temperature at 30°C/60% R.H. and accelerated temperature at 40°C/75% R.H.

RESULTS AND DISCUSSION:

All of the chemical, reagents and selected model drug Nifedipine was collected and was used for the preformulation study before the formulation of immediate release tablets of Nifedipine. In this process, we were firstly collected seeds of *Plantago ovata* and fenugreek seeds were used for the isolation of natural gum.

Plantago ovata and fenugreek gum were isolated from their seeds respectively. It was used as natural super disintegrant in the formulation of Nifedipine immediate release or mouth dissolving tablet.

Isolated *Plantago ovata* and fenugreek gum was characterized by using a number of parameters like organoleptic properties using our visual organ. Result of organoleptic characterisation of plantago ovata and fenugreek gum was given in table 2.

Table 2: Result of Organoleptic Characterisation of Plantago Ovata Seeds and Fenugreek Seeds Gum

Sr. No.	Property	Plantago ovata seeds mucilage	Fenugreek seeds mucilage
1	Color	Light brown	Off-white to light brown
2	Odour	Odourless	Odourless
3	Taste	Tasteless	Mucilaginous
4	State	Amorphous	Amorphous
5	Shape	Irregular	Irregular

Result of Phytochemical parameters of plantago ovata and fenugreek gum were determined that are shown in table 3.

Table 3: Result of Physicochemical Characterisation of *Plantago Ovata* Seeds and Fenugreek Seeds gum

Sr. No.	Test	Observation	
		Plantago ovata seeds gum	Fenugreek seeds gum
1	Ruthenium test	Test present	Test present
2	Molish test	Test present	Test present
3	Iodine test	Test absent	Test absent
4	Enzyme test	Test absent	Test absent
5	Test for steroids	Test absent	Test absent
6	Test for saponins	Test absent	Test absent
7	Test for tannins	Test absent	Test absent
8	Test for alkaloids	Test absent	Test absent

Physicochemical parameters of any natural gum are the key properties which gives an idea about the natural gum. Therefore I was determined the physicochemical parameters of isolated the gum using a number of parameters such as Swelling Index, Solubility-Soluble, Solubility-Insoluble, Moisture absorption, Loss on drying and pH. The results of physicochemical characterisation of isolated plantago ovata and fenugreek seed gum were shown in table 4.

Table 4: Result of Physicochemical Characterisation of Plantago Ovata Seeds and Fenugreek Seeds gum

Sr. No.	Parameter	Observation	
		Plantago ovate seeds gum	**Fenugreek seeds gum**
1	Swelling Index	60±1.53	65±2.02
2	Solubility-Soluble Solubility-Insoluble	Cold water Ethanol, methanol, acetone.	Water Ethanol, acetone, chloroform
3	Moisture absorption	210±0.785%	196±0.522%
4	Loss on drying	1.61±0.3607	4.18±0.26%
5	pH	6.6±0.35%	6.9±0.31%

The selected Nifedipine drug was taken accurately and dissolved in Phosphate buffer having p^H 6.8 and was make solution. The prepared drug solution in proper strength and was scanned at 400 nm to 200 nm, the maxima were observed at 234 nm shown in fig. 1. This was confirmed with standard UV spectrum of Nifedipine.

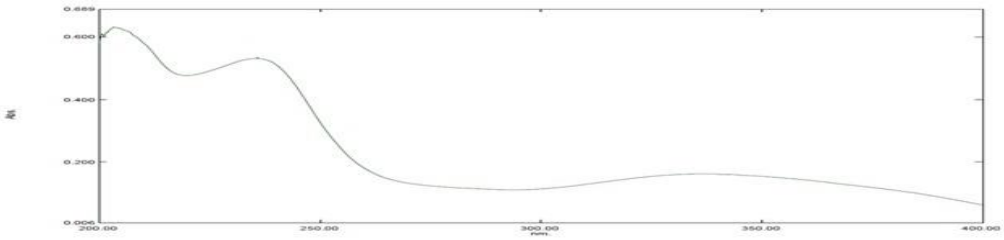

Figure 1: UV Spectra of Nifedipine in Phosphate buffer pH 6.8

The 234nm wave length was used to prepare standard curve for the drug estimation during in-vivo study. The standard curve of Nifedipine was showed that Nifedipine standard curve was followed Bears Lambert Law. The R^2 value was found to be 0.998.

Table 5: Standard curve of Nifedipine

S. No.	Concentration µg/ml	Absorbance
1	0	0
2	1	0.04

3	2	0.079
4	3	0.14
5	4	0.19
6	5	0.257
7	6	0.321

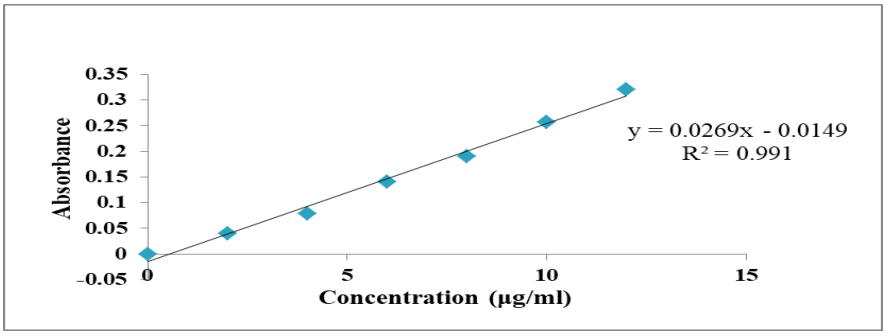

Figure 2: Standard Calibration Curve of Nifedipine in Phosphate buffer pH 6.8 at 234 nm

The melting point of Nifedipine was determined by using digital melting point apparatus. The melting point of selected model drug Nifedipine was found to be 173.16^{0}C. It is matching with the standard value 171-175^{0}C. It is indicated that selected model drug Nifedipine was showed the melting point under the limit as per Indian Pharmacopoeia and drug was pure. It is also indicated that selected drug was suitable for the research work. This experiment was performed in three times and average of melting point calculated.

Table 6: Results of melting point of Nifedipine

S. No.	Obtained melting point	Average
1	173.5℃	173.16℃
2	172.5℃	
3	173.5℃	

Drug Polymer Compatability Studies was performed with FTIR method. The FTIR spectra of pure model drug and blends mixture was showed that no any interaction present between each others. In was represented in the form of FTIR spectral peaks. Thus it reveals that Nifedipine was compatible with plantago ovata as well as fenugreek dried mucilage.

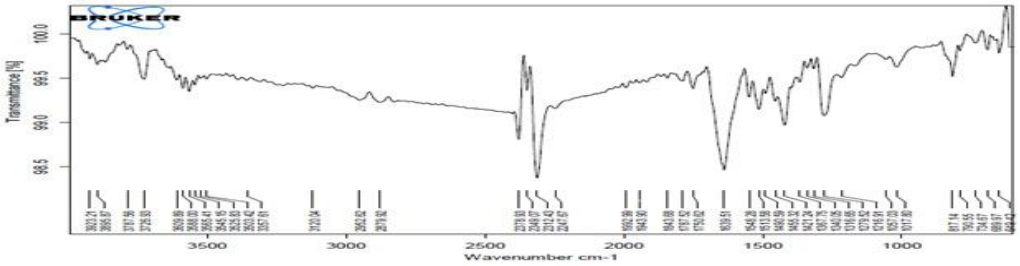

Figure 3: FTIR Spectra of Nifedipine

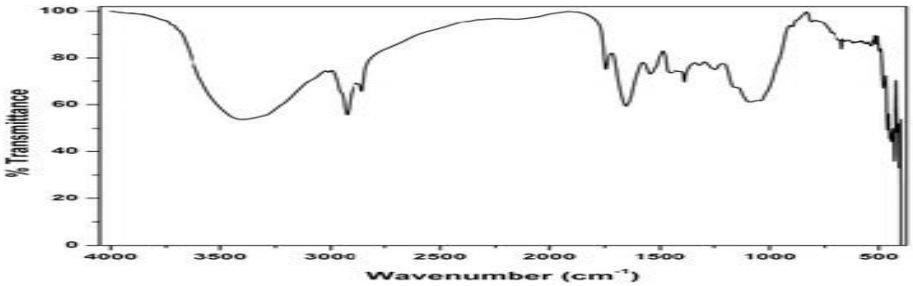

Figure 4: FTIR Spectra of Plantago Ovata Seeds Gum

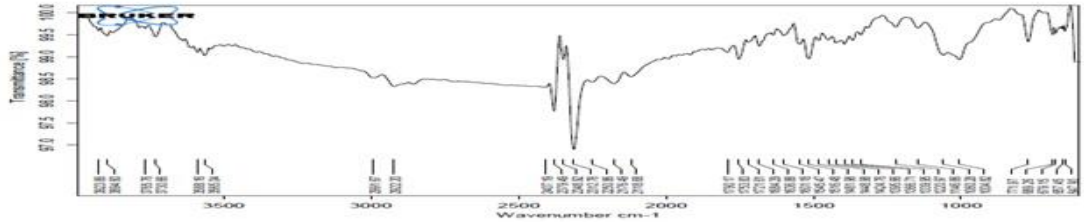

Figure 5: FTIR Spectra of Fenugreek Seeds Gum

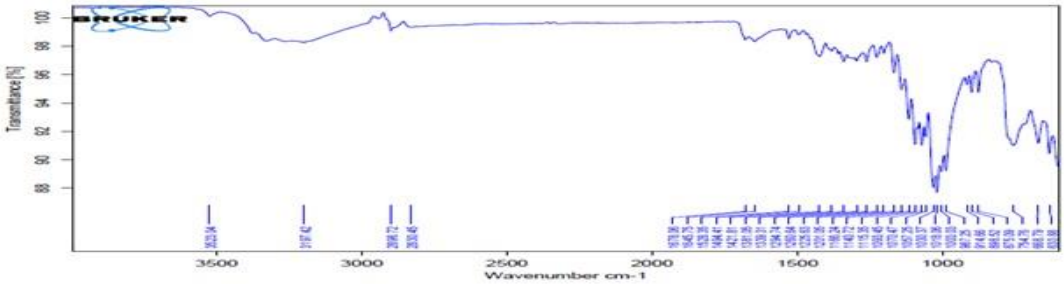

Figure 6: FTIR Spectra of Nifedipine + Plantago Ovata Seeds Gum + Fenugreek Seeds Gum

Diffrential Scanning Calorimetry Study was used for the drug purity. The spectra of DSC indicated that drug was pure and suitable. It is also indicated that drug was not showed any interation with blends mixture.

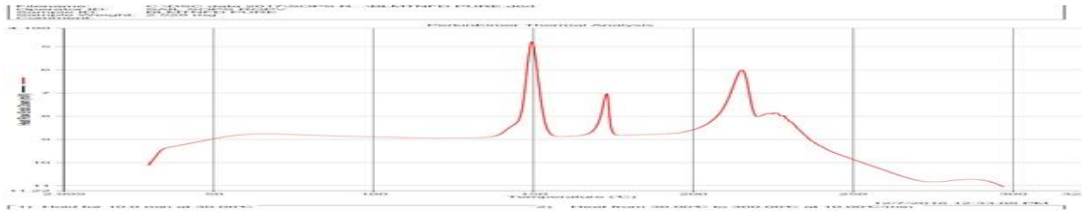

Figure 7: DSC of Nifedipine

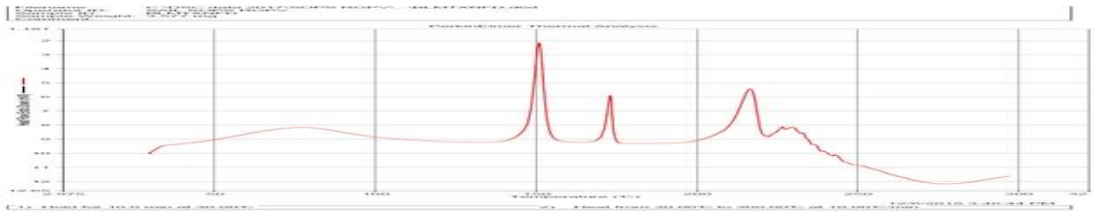

Figure 8: DSC of Nifedipine + Plantago Ovata Seeds Gum + Fenugreek Seeds Gum

The preformulation parameters such as bulk density, tapped density, carr's index, hausner's ratio and angle of repose were studied and found to be within limits, and data for the same given in the table 7.

Table 7: Pre Compression Parameters of Nifedipine Directly Compressible Granules

Batch	Bulk density (gm/cc)	Tapped density (gm/cc)	Carr's Index (%)	Hausner's ratio	Angle of repose (^{0})
PGNF1	0.398±0.005	0.410±0.0003	20.28	1.18	20.15
PGNF2	0.415±0.004	0.510±0.004	18.89	1.28	20.16
PGNF3	0.420±0.003	0.515±0.003	16.34	1.21	25.47
PGNF4	0.418±0.005	0.524±0.003	22.35	1.25	24.13
FGNF1	0.420±0.005	0.540±0.003	18.79	1.23	21.24
FGNF2	0.435±0.003	0.515±0.003	17.74	1.29	23.23
FGNF3	0.401±0.004	0.525±0.003	20.38	1.18	20.08
FGNF4	0.430±0.005	0.543±0.005	22.31	1.27	24.16

Prepared tablets were evaluated for post compression parameters like, weight variation, thikness, hardness, friability, disintegration time, % drug content, wetting time and in vitro dispersion time. The related data were given in table 8 and 9.

Table 8: Post Compression Parameters Nifedipine IRT

Batch	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Weight variation (%)	Drug content uniformity (%)
PGNF1	4.74±0.013	2.47±0.06	0.316±0.002	246.66±1.033	97.71±0.255
PGNF2	4.75±0.017	2.47±0.06	0.311±0.005	246.66±1.033	98.35±0.111
PGNF3	4.71±0.057	2.12±0.05	0.331±0.034	248±0.064	98.59±0.158
PGNF4	475±0.0099	2.45±0.05	0.313±0.002	246.33±1.04	98.90±0.122
FGNF1	4.74±0.0082	2.47±0.06	0.316±0.004	246±1.16	97.77±0.352
FGNF 2	4.74±0.008	2.43±0.05	0.316±0.002	245.66±1.04	98.04±0.488
FGNF 3	4.75±0.005	2.47±0.06	0.317±0.003	246.05±0.58	98.30±0.211
FGNF 4	4.73±0.048	2.48±0.06	0.298±0.035	245.16±0.99	98.77±0.205

Table 9: Post Compression Parameters of Nifedipine IRT

Batch	Wetting Time (sec)	Water absorption ratio (%)	Uniformity of dispersion	Disintegration time (sec.)
PGNF1	46.33±2.43	36.12±0.478	32.65±0.29	18.16±0.984
PGNF2	39.61±1.84	30.47±0.392	28.59±0.64	13±0.753
PGNF3	28.33±1.033	25.07±0.596	21.96±0.28	12±01.55

PGNF4	23±1.265	20.18±0.808	16.±0.12	8.66±0.82
FGNF1	45.05±2.46	82.90±0.26	31.58±0.95	40.85±0.428
FGNF 2	45.83±2.42	87.90±0.92	31.96±0.99	32.06±0.639
FGNF 3	42.33±1.983	89.20±0.98	33.17±0.62	26.16±0.234
FGNF 4	35.42±1.052	91.48±1.99	21.88±0.29	21.32±0.179

All prepared optimized formulation were used for the in-vitro dissolution drug release (shows in Figure 9 and 10). The batch PGNF4 gives faster dissolution 98.53%, within 20 minutes whereas the FGNF4 fenugreek mucilage as superdisintegrant was showed highest dissolution 81.91%, within 20 minutes. Hence, PGNF4 was batter batch than other optimized formulations said to be good batch (16-19):

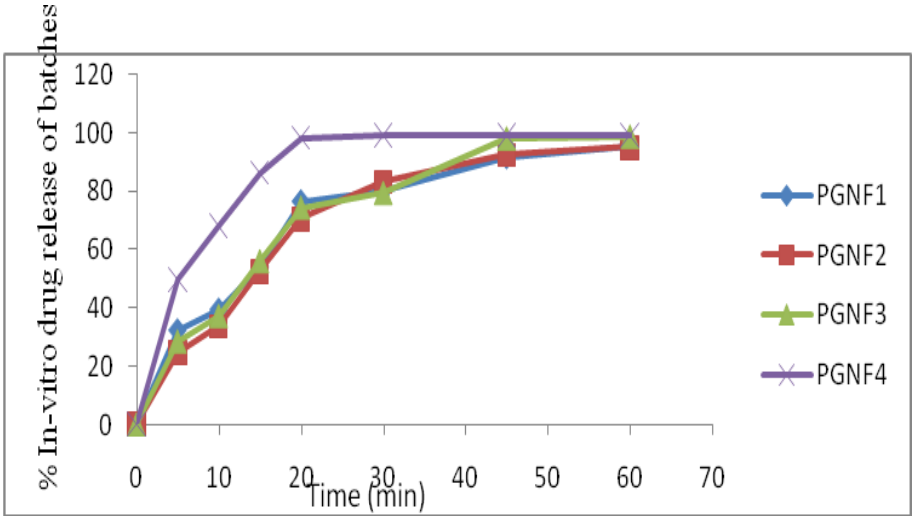

Figure 9: In-vitro Drug Release Profile of PGNF1- PGNF4

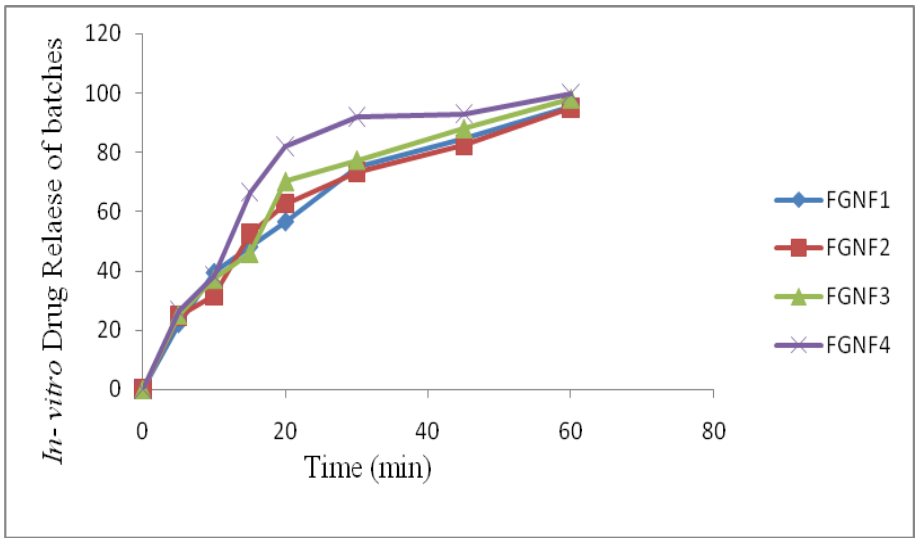

Figure 10: In-vitro Drug Release Profile of FGNF1-FGNF4

Prepared immediate release tablets were tested for hardness, thickness, friability, in vitro buoyancy, drug content, and in vitro drug release over a period of three months at various temperatures, including room temperature at $30^{o}C$/60% R.H. and accelerated temperature at $40^{o}C$/75% R.H. No changes of found in the PGNF4 batch. This study represented that selected PGNF4 batch was stable and effective.

TABLE 10: Stability test of PGNF4 at different storage and testing conditions

Storage Condition	Testing condition	Time duration (hr)				Result
		1/2	1	3	6	
Ambient	$30^{0}C$ / 60%R.H.	-	-	-	-	No change during 6 hours
Warm(30-$40^{0}C$)	$35^{0}C$ / 60%R.H.	-	-	-	-	No change during 6 hours
Accelerated	$40^{0}C$ / 75%R.H.	-	-	-	-	No change during 6 hours
Accelerated	$50^{0}C$ / 60%R.H.	-	-	-	+	Degradation starts after 4 hours
Accelerated	$55^{0}C$ / 60%R.H.	-	-	-	+	Degradation starts after 3 hours
Accelerated	$65^{0}C$ / 60%R.H.	-	-	+	+	Degradation starts after 2 hours

Note: (-) No change, (+) Degradation starts

We successfully made Nifedipine mouth dissolving tablets using two natural substances: plantago ovata seeds and fenugreek seeds dried gum. These substances act as superdisintegrants, which help the tablets dissolve quickly in the mouth. They are a better and safer alternative to synthetic superdisintegrants because they are non-toxic, inexpensive, easily available, gentle on the skin, and do not cause irritation. Among the different formulations we tested, the one containing plantago ovata gum as the superdisintegrant performed the best. The percentage release of Nifedipine was given in figure 9 and figure 10. The batch PGNF4 gives faster dissolution 98.53%, within 20 minutes whereas the FGNF4 fenugreek mucilage as superdisintegrant was showed highest dissolution 81.91%, within 20 minutes. Hence, PGNF4 was batter batch than other optimized formulations said to be good batch. Overall, we found that the tablets made with plantago ovata gum performed better than those made with fenugreek gum. We also observed that isapghulla seeds dried mucilage, another natural substance we tested, caused the tablets to disintegrate quickly and release the drug effectively compared to fenugreek seeds dried mucilage.

CONCLUSION:

The present research study aimed to evaluate the efficacy of formulated immediate release tablets of Nifedipine incorporating plantago ovata and Fenugreek seed gum as natural

gums. Both selected natural gums exhibited favorable physical parameters. The comprehensive findings indicated that the formulations PGNF4 and FGNF4, which contained plantago ovata and Fenugreek seed gum along with superdisintegrants, met all the criteria for immediate release tablets. Advancements in the development of rapid disintegrating tablets have enabled the formulation of these tablets with reduced quantities of superdisintegrants. Rapidly disintegrating dosage forms have successfully entered the commercial market by utilizing various types of superdisintegrating agents. The use of diverse superdisintegrating agents has led to improved patient compliance, commercial viability, and therapeutic benefits. Given the increasing number of poorly soluble drugs in pharmaceutical research, it is crucial to select superdisintegrating agents that maximize drug dissolution. The fast acceptance of rapidly disintegrating tablets by patients and pharmaceutical companies has resulted in a growing market for this dosage form, with a rapidly expanding product pipeline. However, the success of this field would not have been possible without the advancements in superdisintegrating agents.

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