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## Research Article

### Extraction and Evaluation of *Mangifera indica* Gum as a Sustained Release Polymer in Gliclazide Matrix Tablets

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Extraction, *Mangifera indica* gum, Sustained release polymer, Gliclazide, Matrix tablets, Diabetes mellitus.

#### ABSTRACT

The aim of this present work extraction and evaluation of *Mangifera indica* gum as sustained release polymer in Gliclazide matrix tablets. *Mangifera indica* gum are economic, easily available and useful as tablet excipient, by using formal processes the gum of MI was tested for physicochemical and phytochemical properties and the results turned out favorable. The Gliclazide matrix tablets were prepared by the wet granulation method using *Mangifera indica* gum as a tablet excipient. Gliclazide is an oral hypoglycemic drug and is classified as a Sulfonylurea. Gliclazide is used in the treatment of patient with Non-insulin dependent diabetes mellitus (NIDDM) and give in the insulin resistance conditions. The formulations were intended and evaluated for the various parameters like hardness, friability, weight uniformity, content percent and *in-vitro* dissolution studies. Moreover, all the matrix tablets formulations were within limits of the pharmacopoeial standards. After a period of 24 h. *in-vitro* release studies, the findings of F1, F2, F3 and F4 were 63.38%, 64.48%, 65.03% and 63.38%, respectively, the best sustained drug release among those formulation (of 65.03%) was been achieved with formulation F3 at the end of 24 h, which indicated that the drug release from the matrix tablets was dependent on gum concentration, also MI gum give effective results even with every low concentrations (below 1%).

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## INTRODUCTION

Diabetes mellitus is a complex metabolic disease in which a person has hyperglycemia (high blood sugar), either condition in which pancreatic  $\beta$ -cells does not produce insulin or impaired release of insulin due to insufficient or defective insulin receptors, and it also developed if insulin is not utilized by the body cells. Diabetes mellitus is mainly classified into two type, insulin dependent diabetes mellitus (type-I) and non-insulin dependent diabetes mellitus (type-II). Type-I diabetes occurs due to the cellular mediated autoimmune destruction of the  $\beta$ -cells of the pancreas. Type-II occurs at past middle age and common disease, in this there is no perdition of  $\beta$ -cells. Type-II is 95% expansion and Type-I is 5% expansion among diabetes.

Polyuria (frequent urination), polydipsia (increased thirst), polyphagia (increased hunger), blurred vision, diabetic dermadromes (skin rashes) are the symptoms of the diabetes mellitus<sup>1</sup>.

A medicinal product releases the drug and delivers it to the site in the body are called drug delivery system (DDS). These delivery systems can be categorized according to physical state of drug, route of administration of drug and mechanism of drug release<sup>2-5</sup>. Basically, depending on the mechanism of drug release DDS are classified into immediate and modified release delivery systems.

Natural polymers are easily available, cheap and biocompatible also they are non toxic, non irritant and have soothing affect. Natural polymers significantly used in pharmaceutical industries as binders, diluents, disintegrant and many other applications. Demand for these substances is increasing and new sources are being developed<sup>6</sup>.

*Mangifera indica* (MI) tree belong to the genus *Mangifera* and the family *Anacardiaceae*. In demotic medicine MI tree has been used as a therapy against chronic dysentery also in the prevention of diabetes, diuretic, diarrhea, cancer, asthma and parasitic skin disease. The bark exudates yield resin, gum, ash and tannins<sup>7-9</sup>.

MI gum resins spurt outside the mango trees trunk by the act of the wind, fire or small injury on the trunk surface, after that those gum resin is collected and then purified to be used in pharmaceutical manufacturing to retard the release<sup>10</sup>.

*Mangifera indica* gum (MIG) is dried gummy exudates polysaccharide obtained from the bark of *Mangifera indica* plant, studies were performed on this gum for its binding, sustained release, disintegrating properties and tablets containing this gum showed good appearance and better drug release<sup>11</sup>.

MIG was incorporated as a binder in Paracetamol tablets formulation. The results disclose that Paracetamol tablets prepared by using MIG as a binder are more effective than the standard (5% w/w gum acacia). Therefore, it is concluded that the mango gum could be used well as a binding agent in the formulation of tablet dosage form<sup>12</sup>. MIG was isolated, characterized and evaluated for its release retardant properties employing Lornoxicam as a model drug<sup>13</sup>.

Nicorandil sustained release matrix tablets were formulated by using MIG rate controlling factor and to evaluate drug release parameters as per various release kinetic models. Hence use of natural gum *Mangifera indica* was successful in the formulation of matrix tablets and it is effective in retarding the drug release at the same time<sup>14</sup>.

Gliclazide is an oral hypoglycemic agent used in the treatment of patient with Non-insulin dependent diabetes mellitus (NIDDM) and give in the insulin resistance conditions. The binding of Gliclazide to sulfonylurea receptor on pancreatic  $\beta$ -cells is very rapidly reversible<sup>15</sup>.

Gliclazide (GZ) usually begin with 80 mg given once daily due to its high bioavailability and rapid oral absorption, but because GZ has short elimination half life (5-8 hrs.) it is given two or three times per day. Also there is a variation in the drug release and person to person variability<sup>16</sup>. These complains certainly can be overcome by the sustained release multiunit dosage form. These reasons account for the

choice of Gliclazide to formulate a matrix tablets using purified natural gum extracted from MI plant.

Hence the aim of this research was to extract and evaluate a pharmaceutical grade *Mangifera indica* gum as excipient in sustain release oral dosage formulations using Gliclazide as a drug.

### Materials and Methods

#### Material

Gliclazide was purchased from Dr. Reddy's Laboratories Ltd. Hyderabad, India. *Mangifera indica* gum obtained from the stem bark of the mango plant from local mango farm Varanasi. Acetone from Merck Specialities Private Limited. Mumbai, Magnesium stearate from Central drug house (P) Ltd. New Delhi, Microcrystalline cellulose from Qualikems Fine Chem Pvt. Ltd. Vadodara and Isopropyl alcohol from Thomas Baker (Chemicals) Pvt. Ltd. Mumbai.

#### Methods

##### Extraction of *Mangifera indica* gum

The *Mangifera indica* gum resin was collected from *Mangifera indica* tress (by injuring trunk site). It was dried, ground and passed through sieve no 80. Dried gum (85g) was stirred in distilled water (500ml) for 6-8 hrs at room temperature. The supernatant was obtained by centrifugation.

The residue was washed with water and the washings were added to separate a supernatant. The procedure was repeated four more times. Finally, the supernatant was made up to 500 ml and treated with twice the volume of acetone by continuous stirring. The precipitated material

was washed with distilled water and dried at 50-60°C under vacuum. The dried gum was pulverized and stored in tightly closed container<sup>17, 18</sup>.

##### Physicochemical properties of gum

The physicochemical properties such as organoleptic properties, solubility, swelling index, pH determination, bulk density, tapped density and angle of repose were determined according to official procedures<sup>19, 20</sup>.

##### Phytochemical examination of gum

Elementary tests were performed to confirm the nature of gum obtained. The chemical tests that were conducted are, test for mucilage (Ruthenium red test), test for carbohydrates (Molisch test), test for reducing sugars (Fehling test) and test for alkaloids (Wagner test)<sup>21</sup>.

##### Preparation of the sustained release matrix tablets

Matrix tablets were prepared by wet granulation method, Gliclazide, MIG and MCC were mixed together and the mixture was passed through mesh (No. 60). Granulation was done using a sufficient isopropyl alcohol. The wet mass passed through mesh (No. 30). The wet granules were air dried in the oven. The granules were then sized by mesh (No. 35) and mixed with magnesium stearate.

Tablets were compressed using single rotary tablet press. Four different formulas, having different concentration of MIG (1, 20, 30 and 40% w/w), were developed, the composition of the designed formulations were showed in table 1.

Table 1: Composition of *Mangifera indica* gum Matrix Tablet Formulation

Ingredients (mg)	F1	F2	F3	F4
Gliclazide	80	80	80	80
MIG	2	40	60	80
MS	3	3	3	3
MCC	115	77	57	37
TTW	200	200	200	200

MIG: *Mangifera indica* gum; MS: Magnesium stearate; MCC: Microcrystalline cellulose; TTW: Total tablet weight

### Evaluation of the matrix tablets blend

All the matrix tablets blend evaluated by the following different parameters which includes<sup>19, 20</sup>.

#### Angle of repose

The angle of repose of powder was determined by funnel method. The accurately weight of blend was taken in a funnel. The height of funnel was adjusted in such a manner that the tip of the funnel just touched the apex of the heap of the powder. The diameter of the powder cone measured and angle of repose was calculated using the following equation.

$$\tan \theta = (h/r)$$

Where, (h) are the height of the powder cone and (r) are the radius of the powder cone.

#### Bulk density

An accurately weight of the powder blend and lightly shaken to break any agglomerates formed and it was introduced into a measuring cylinder. The volume occupied by the powder was measured which gives bulk volume. The bulk density of powder blend was determined by the formula.

Bulk density = Total weight of powder / Total volume of powder

#### Tapped density

An accurately weight of the powder blend and lightly shaken to break any agglomerates formed and it was introduced into a measuring cylinder. The measuring cylinder was tapped 100 times and the volume was noted which gives the tapped volume. The tapped density of powder blend was determined by the formula.

Tapped density = Total weight of powder / Total volume of tapped powder

#### Compressibility index (Carr's index)

It is simple index determine on small quantities of powder. The less compressible material than the more flowable. The compressibility index of powder blend was determined by the formula.

Compressibility index (%) = [(Tapped density – Bulk density) / Tapped density] × 100

#### Hausner's ratio

It is ratio of the tapped density and bulk density. Hausner found that this ratio was related to interparticulate fraction and used to determine flow properties of powder. Hausner's ratio was determined by the equation.

Hausner's ratio = Tapped density / Bulk density

### Evaluation of the matrix tablets

All the tablets were evaluated for the following different parameters which includes<sup>19, 20</sup>.

#### General appearance of tablets

Five tablets from different batches were randomly selected and organoleptic properties such as color, odor, taste and shape were evaluated.

#### Hardness test

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of tablets was determined using Pfizer hardness tester. It is expressed in kg/cm<sup>2</sup>. Ten tablets were randomly picked from each formula and the hardness of tablets was determined. The hardness of tablets depends on the nature and quality of excipients used during formulation.

#### Friability

Friability of the tablets was determined by Roche Friabilator. This device subjects the tablets to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a distance of 6 inches in each revolution.

Pre weight sample of 10 tablets was placed in the friabilator for 4 minute. Tablets were de dusted using a soft wiper and re weighed. Compress tablets than 1% of the weight are consider acceptable.

The friability (f) was determined by the formula. Friability (%) = [(Initial weight–Final weight) / Initial weight] × 100

#### Weight variation test

Randomly twenty tablets were selected after compression, weighed individually and average weight was determined. Not more than two of the individual weights deviate from the average weight by more than the percentage given in the pharmacopoeia and none deviates by more than twice the percentage.

Percentage deviation = [(Individual weight–Average weight) / Average weight] × 100

#### Drug content test

Ten tablets were weighed individually and powdered. The powder equivalent to average weight of one tablet was weighed and drug was

extracted in Phosphate buffer pH 7.4, the drug content was determined using double beam UV-Visible spectrophotometer. The absorbance was measured at wavelength 226nm.

#### Swelling index

The extent of swelling was measured in terms of % weight gain by the tablet. The swelling of formulations F1, F2, F3 and F4 were studied. One tablet from each formulation was kept in a Petri dish containing pH 7.4 phosphate buffer. At the end of 2 h, 4 h and 6 h, kept on tissue paper and weighed the process was continued till the end of 24 h. The % weight gain by the tablet was calculated by formula:

Swelling index = [(Weight of the swollen tablet – Initial weight of the tablet) / Initial weight of the tablet] × 100

#### In vitro drug release studies

Release of Gliclazide from the formulated matrix tablets was studied in Phosphate buffer of pH 7.4 (900 ml) using a United State Pharmacopoeia (USP), Paddle Dissolution Apparatus with a rotating paddle stirrer at 50 rpm at the 37±0.5 °C temperature. Sample was done by taken 5 ml dissolution medium and addition of 5 ml of phosphate buffer solution pH 7.4 was necessary in order to maintain sink

conditions for the release of Gliclazide. Taken sample was diluted 10 times in volumetric flask and Gliclazide concentration was determined spectrophotometrically at 276 nm.

#### Results and Discussions

##### Physicochemical properties of gum

The average yield of dried gum obtained from *Mangifera indica* trees was 34% w/w. The extracted gum was brown color powder. The powder was slightly soluble in water insoluble in ethanol and acetone.

The swelling properties of MIG were studied in Phosphate buffer (pH 7.4) and water. The swelling ratio was determined as 20 for water and 15 for Phosphate buffer. Generally, the results show that MIG has been high swelling index suggesting that the gum may perform well as binder/disintegrant/matrix agent. The reading of the pH was (7.40).

The compressibility index, Hausner ratio and angle of repose of MIG were 29.82%, 1.42 and 26.85° respectively, implying that the MIG has an excellent flow with moderate compressibility. The gum obtained from *Mangifera indica* trees was subjected to physicochemical properties and the results are in table 2.

*Table 2: Physicochemical properties of Mangifera indica gum*

Parameters	Observation
Yield (%)	34%
Odor	characteristic odor
Taste	Tasteless
Colour	Brown colour
State	Amorphous powder
Solubility	Slightly soluble in water, practically insoluble in ethanol and acetone. Forms thick gel in water.
pH (1% w/v solution)	7.40
Swelling ratio, in water	20
Swelling ratio, in phosphate buffer 7.4	15
Bulk density (gm/ml)	0.40±0.05
Tapped density (gm/ml)	0.57±0.07
Compressibility index (%)	29.82
Hausner ratio	1.42
Angle of repose (θ)	26.85±0.20

### Phytochemical screening of the gum

Phytochemical tests that done on MIG assured that the gum lacks alkaloids and tannins and when the mucilage was mixed with ruthenium red it gives red color, which affirm the presence of the mucilage. Also on reaction with Molisch's

reagent a violet ring was formed confirming the presence of carbohydrates. There are no reducing sugars because the mucilage did not reduce Fehling's solution. The results of phytochemical screening of the gum are in table 3.

*Table 3: Phytochemical screening of Mangifera indica gum*

Test	Observation
Test for Carbohydrate (Molisch's test)	+
Test for Tannins (Ferric chloride test)	-
Test for Alkaloids (Wagner's test)	-
Test for mucilage (Ruthenium red test)	+
Mounting in the Iodine	No blue color (Starch absence)
Test for reducing sugar (Fehling's test)	-

### Evaluation of the matrix tablets blend

The various flow parameters like the angle of repose, bulk density, tapped density; compressibility index and Hausner ratio of the powder blends intended for compression were

estimated. The angle of repose results indicating excellent flowability, the compressibility index range was found to be 21 to 25 and the Hausner ratio range was 1.26 to 1.34 indicating good flowability. The results were shown in table 4.

*Table 4: Results of flow properties of the matrix tablet blend*

Formulations	F1	F2	F3	F4
Angle of repose ( $\theta$ )	29.18±0.20	28.51±0.24	27.14±0.40	27.14±0.20
Bulk density (gm/ml)	0.60±0.04	0.60±0.02	0.58±0.03	0.57±0.04
Tapped density (gm/ml)	0.67±0.02	0.67±0.03	0.65±0.01	0.64±0.04
Compressibility index	22.75	22.66	22.68	22.40
Hausner ratio	1.28	1.27	1.27	1.28

### Evaluation of the matrix tablets

The Gliclazide matrix tablets were dark brown in color, smooth and flat shaped in appearance. The hardness of the matrix tablets was found to be 4.40, 3.80, 3.51 and 3.45 kg/cm<sup>2</sup> for F<sub>1</sub>, F<sub>2</sub>, F<sub>3</sub> and F<sub>4</sub> respectively and the friability values were founded below 1% for all the formulations, these results indicating that as the percent of the polymer increases, there is a decrease in the

hardness values accordingly. So taking in account that the proper die size and the maximum force of compression were used in the process those hardness results may be because of the absence of the binding agents from the matrix formulations. The weight variation and drug assay were found within limits. The results of physical properties of Gliclazide matrix tablets formulations are in table 5.

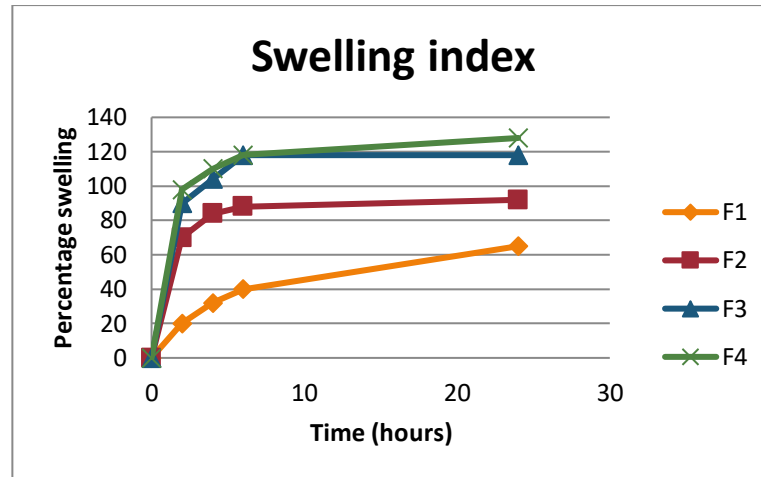
*Table 5: Results of physical properties of Gliclazide matrix tablets*

Formulations	F1	F2	F3	F4
Hardness (kg/cm <sup>2</sup> )(n=10)	4.40±0.30	3.80±0.20	3.50±0.50	3.45±0.15
Friability (%) (n=10)	0.98±0.012	0.97±0.020	0.96±0.045	0.94±0.025
Average weight (mg)(n=20)	201±0.44	198±0.25	203±0.12	201±0.24
Drug content (%) (n=10)	97.04±0.12	102.2±0.26	94.08±0.42	93.4±0.22

### Swelling behavior of matrix tablets

The % weight gain by the tablet was used to estimate the magnitude of swelling. This was applied for all the formulations in order to study their behavior. Figure 1 showed the swelling

properties of MIG containing tablets. After calculating the swelling index with respect to time, a direct proportion was found. (as the time increases, the swelling index was increased).



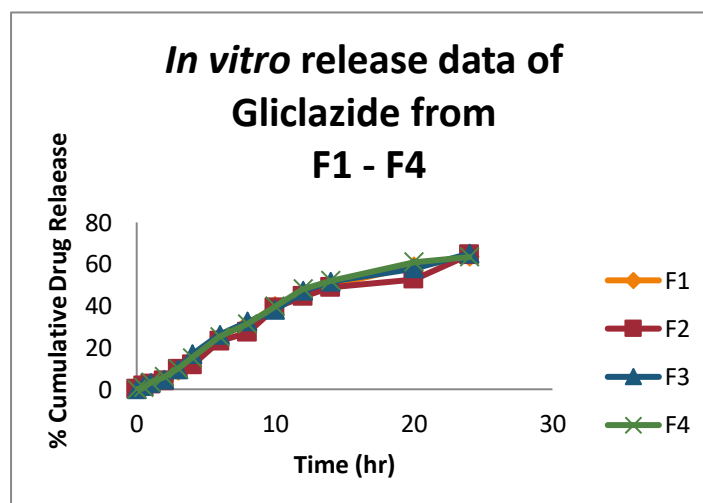
(Fig 1: Results of swelling behavior of different matrix tablet formulations)

### In vitro drug release studies

The profile of Gliclazide matrix formulations *in vitro* studies was shown in Fig 2. The results indicated release retardant property of the gum from all Gliclazide matrix formulations with an increase in the polymer concentration.

An *in-vitro* dissolution study was carried out in triplicate and the results of all formulations are

in the Fig 2. Formulation F1, F2, F3 and F4 release drug 63.48%, 64.48%, 65.03% and 63.38% respectively at 24 hours, so this is cleared that the concentration of *Mangifera indica* gum polymer due to sustaining release effect with drug formulation.



(Fig 2: Results of In-vitro dissolution profile of different matrix tablet formulations)

### CONCLUSIONS

This study provided a clue about the evaluation of MIG as a release retardant in the formulation of sustained release matrix tablets because of its

good swelling, good flow and suitability for matrix formulations. The results of this study demonstrated that MIG sustained the drug release.

The polymer obtained was of high purity, and the method of extraction and characterization is economic and gave a high yield.

There is a fit reverse between the release from MIG matrix formulations and the ratio the gum present in that formulation, as the ratio increased the release is decreased. This may be result from an increase in the path length of the diffusion layer which in turn obtained from the formulation of gel layer, resulting in reduction in a diffusion coefficient of the drug.

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