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**Research Article**

# Formulation and Evaluation of Miglitol Sustained Release Matrix Tablets Using Moringa Oleifera Gum

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**Abstract**

Our aim with this study was to develop and evaluate a sustained-release matrix tablet formulation for Miglitol, and to assess its effectiveness. The pre-formulation studies were carried out and the results were found to be favorable. The appropriate excipients were selected for formulation development. In accordance with the flow characteristics of the API, the experiment was carried out utilizing simultaneously dry and wet granulation procedures. Wet granulation was used to enhance the formulation in order to increase the flow quality of the tablets and turned out to be effective. During the formula's development, the beginning evaluations which included the bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose were reviewed for granules and hardness, friability, weight fluctuation, and thickness. In-vitro dissolution trials on Miglitol sustained release matrix tablets exhibited drug release in the range of 22.15% to 98.65% at the end of the 10th hour. In view of extended drug release, formulation F9 was picked as the most effective formulation. All hardness, friability, weight fluctuation, thickness, assay, drug content, and dissolution properties of the finished goods were examined. The kinetic release technique proved that the drug is released by zero-order kinetics (R2 value of 0.9491), and the Korsmeyer equations provided a value that was close to one and indicated that the drug had been released by zero-order kinetics (R2= 0.8449). Three months of testing for stability at 45°C/75% RH. Stability samples were examined at both the beginning and after three months. The resulting results were assessed in relation to the predefined requirements. All of the results have been deemed effective.

**Keywords**: Miglitol, assay, drug content, Korsmeyer equations, Carr's index

**Article Info**

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## 1. Introduction

Multiple significant aspects influence the layout of sustained-release systems for delivery. Some of these include the drug's method of administration, the form of delivery system, the medical condition being treated by the patient, the duration of treatment, and the drug's qualities. Each of these factors is interconnected, which limits the options regarding the mode of distribution, the structure of the distribution system, and the total duration of treatment. For developing a sustained release dosage form, pharmacological characteristics, particularly physicochemical and physiological features, are critical.

**Miglitol**

**Description: Miglitol** is an oral alpha-glucosidase inhibitor used to improve glycemic control by delaying the digestion of carbohydrates.

**Chemical name:** $C_8H_{17}NO_5$

**Molecular weight:** 207.224

**Structure formula:**

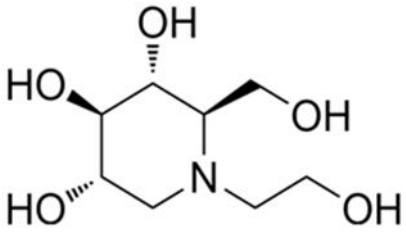


Figure 1: Structure of Miglitol

**Solubility:** It is soluble in water, alcohol, and Other Organic Solvents.

**Appearance:** white, crystalline powder

**IUPAC:**(2R,3R,4R,5S)-1-(2-hydroxyethyl)-2-(hydroxymethyl) piperidine-3,4,5-triol

**Pharmacodynamics:**

Miglitol, an oral alpha-glucosidase inhibitor, is a desoxynojirimycin derivative that delays the digestion of ingested carbohydrates, thereby resulting in a smaller rise in blood glucose concentration following meals. As a consequence of plasma glucose reduction, miglitol reduce levels of glycosylated hemoglobin in patients with Type II (non-insulin-dependent) diabetes mellitus. Systemic nonenzymatic protein glycosylation, as reflected by levels of glycosylated hemoglobin, is a function of average blood glucose concentration over time. Because its mechanism of action is different, the effect of miglitol to enhance glycemic control is additive to that of sulfonylureas when used in combination. In addition, miglitol diminishes the insulin tropic & weight-increasing effects of sulfonylureas. Miglitol has minor inhibitory activity against lactase and consequently, at the recommended doses, would not be expected to induce lactose intolerance.

**Pharmacokinetics:**

**Absorption:**

Absorption of miglitol is saturable at high doses with 25 mg being completely absorbed while a 100-mg dose is only 50-70% absorbed. No evidence exists to show that systemic absorption of miglitol adds to its therapeutic effect.

**Half-life:**

The elimination half-life of miglitol from plasma is approximately 2 hours.

**Metabolism:**

Miglitol is not metabolized in man or in any animal species studied

**Protein binding:** The protein binding of miglitol is negligible (<4.0%).

**Route of elimination:**

Miglitol is not metabolized in man or in any animal species studied. It is eliminated by renal excretion as an unchanged drug

## 2. Methodology

**Organoleptic characters:**

The pre-formulation studies such as the color, odor, and taste can be done visually.

**Solubility studies:**

The solubility studies are done by using various solvents such as ethanol, methanol, acetone, and other organic solvents.

**Drug and excipient compatibility studies:**

The drug and excipient compatibility studies are done by FTIR Studies using KBr pellet method. First the 1 gm of the drug powder is taken under kept for the FTIR studies. The 1gm of drug and polymer taken and kept under FTIR studies the peaks which are came for drug product the nearer to the drug the polymer peaks will come. If they are not coming the drug and excipients are in compatible with each other.

**Preparation of Standard Solution:**

Miglitol (10 mg) was dissolved in pH 7.5 P.B in a 10 ml volumetric flask and diluted quantitatively with pH 7.5 P.B to obtain a solution having a known concentration of 1000 µg/ml.

**Procedure:**

The standard solution of miglitol was subsequently diluted with pH 7.5 phosphate Buffer to obtain a series of dilutions containing 1, 2,3,4,5 µg of miglitol per ml of solution. The absorbance of these substances was measured in Analytical Technologies Limited, UV-Visible Spectrophotometer at 229 nm using pH 7.5 P.B as blank. The concentration of miglitol and the corresponding absorbances are presented. The absorbances were plotted against the concentration of miglitol.

**Construction of calibration curve in 7.5 buffer:**

To take 10mg of Miglitol active substance it is going to disperse in 10ml of 7.5 buffer in a volumetric flask which is 1000ppm. From 1000ppm to take 1 ml and it is dispersed in 10ml of volumetric flask it is 100ppm. Take 1 ml and make up to 10 ml in a volumetric flask it is 10ppm.To check absorbance at 10ppm if the absorbance is high undergo

serial dilutions like 1,2,3,4,5, ml and check the absorbance at 229 nm by using U.V visible spectroscopy.

**Construction of calibration curve in methanol:**

To take 10mg of Miglitol active substance it is going to disperse in 10ml of Methanol in volumetric it is 1000ppm. From 1000ppm to take 1 ml and it is dispersing in 10ml of volumetric flask it is 100ppm. From that take 1 ml and make up to 10 ml in a volumetric flask it is 10ppm.To check absorbance at 10ppm if the absorbance is high undergoing serial dilutions like 1,2,3,4,5, ml and check the absorbance at 315nm by using U.V visible spectroscopy.

**Precompression parameters:**

**Bulk Density**

The pre-formulation studies such as the bulk density. The bulk density is defined as a certain amount powder taken into the measuring cylinder. The Bulk density is the ratio of the weight of a powder to the volume it occupies.

It is expressed as gm/ml.

$$\text{Bulk density} = W / Vo$$

Where,

W = weight of the powder

VO = initial volume

**Tapped Density**

The tap density is defined as the amount of powder will take in the measuring cylinder the measuring cylinder is closed with lid. The tap density apparatus under kept and set for 500 tapings. The powder particles will settle down in the measuring cylinder the powder will decrease. The process is continued for the both consecutive readings were equal.

$$\text{Tapped density} = W / VF$$

Where,

W = weight of the powder

VF = final volume

**Angle of Repose**

The angle of repose is defined as the maximum angle possible between the surface of a pile of the powder and the horizontal plane. For determining of the angle of repose the funnel method is used. The certain amount of powder taken in to the glass funnel by closing the funnel orifice. The glass funnel is fixed at 2cm from horizontal plan. The finally the closed orifice will open the powder flows through the funnel and farm a pile. The height of the pile is noted. A Circumference was drawn with a pencil on a graph paper and the radius of base of a pile was measured at 5 different points and average was taken for calculation.

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

Where h = height of pile.

r = radius of the base of the pile.

θ = angle of repose.

Angle of repose below 25 indicates an excellent powder flow.

**3. Results and discussion**

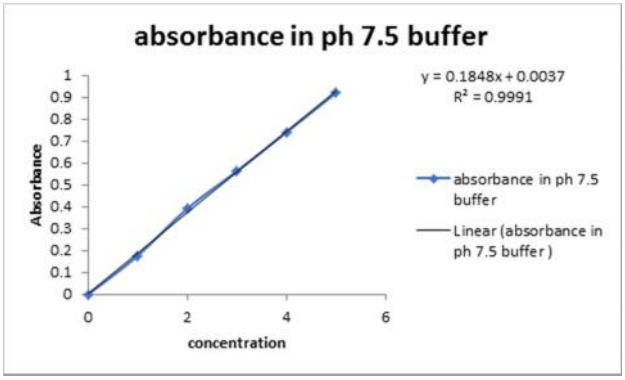


Fig.No:2 showing picture of the calibration plot in 7.5 buffer

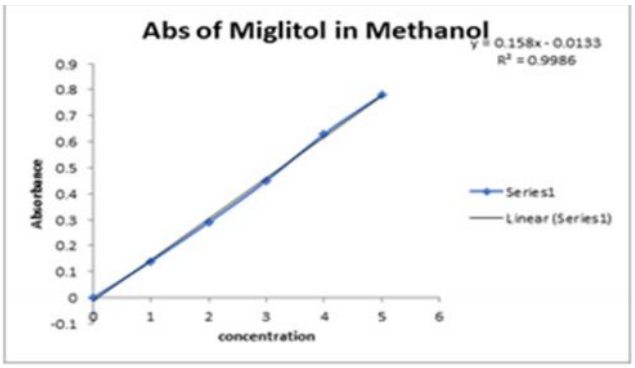


Fig.No: 3 showing calibration plot in methanol

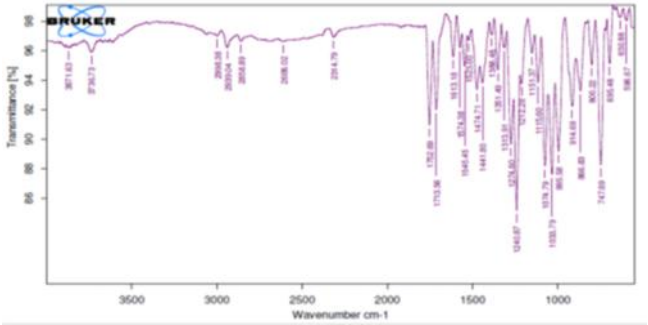


Fig.No: 4 pure spectra of the Miglitol

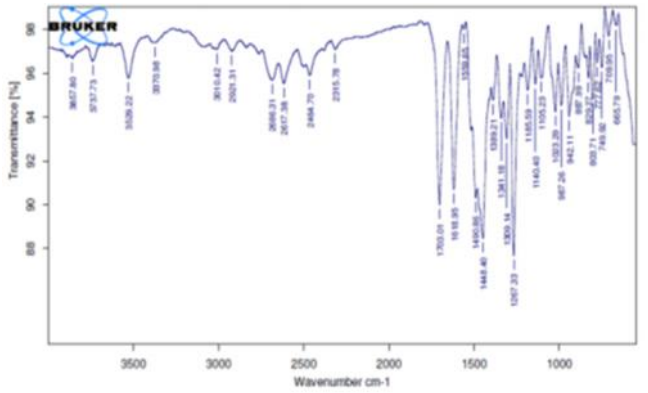


Fig. No: 5 The fig shows the FTIR spectra of the drug and polymer blend

Table. No 1: showing values of the pre compression parameters

| Formulatic | Angle of repose (θ) | Bulk density (gm/ml) | Tapped density (gm/ml) | Carr's index (%) | Hausner's rati |
|---|---|---|---|---|---|
| F1 | 25.38±0.13 | 0.40±0.02 | 0.50±0.02 | 20±0.13 | 1.25±0.01 |
| F2 | 22.52±0.28 | 0.44 ±0.02 | 0.56±0.04 | 20±0.04 | 1.27±0.01 |
| F3 | 27.19±0.19 | 0.44±0.00 | 0.54±0.01 | 18.61±0.11 | 1.22±0.02 |
| F4 | 28.51±0.16 | 0.45±0.01 | 0.55±0.01 | 18.33±0.15 | 1.22±0.01 |
| F5 | 23.60±0.21 | 0.41±0.01 | 0.50±0.00 | 18±0.05 | 1.21±0.02 |

| Formulatic | Angle of repose (θ) | Bulk density (gm/ml) | Tapped density (gm/ml) | Carr's index (%) | Hausner's rati |
|---|---|---|---|---|---|
| F6 | 24.38±0.13 | 0.38±0.02 | 0.48±0.02 | 20.83±0.13 | 1.26±0.01 |
| F7 | 23.52±0.28 | 0.39 ±0.02 | 0.47±0.04 | 17.02±0.04 | 1.20±0.01 |
| F8 | 24.19±0.19 | 0.39±0.00 | 0.45±0.01 | 13.33±0.11 | 1.15±0.02 |
| F9 | 22.51±0.16 | 0.40±0.01 | 0.44±0.01 | 9.09±0.15 | 1.1±0.01 |
| F10 | 23.60±0.21 | 0.40±0.01 | 0.46±0.00 | 13.04±0.05 | 1.15±0.02 |

Table.no 2: showing in—vitro drug release studies

| Time in hrs | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 | F10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1 | 10.23 | 12.65 | 15.89 | 18.56 | 20.56 | 22.32 | 22.52 | 21.65 | 22.15 | 23.21 |
| 3 | 18.35 | 25.65 | 28.36 | 30.56 | 35.62 | 40.53 | 41.53 | 42.62 | 45.15 | 48.65 |
| 4 | 75.35 | 50.36 | 55.68 | 56.12 | 57.65 | 57.65 | 56.72 | 58.56 | 59.12 | 58.52 |
| 6 | 89.35 | 60.78 | 64.65 | 68.42 | 70.56 | 70.55 | 71.62 | 72.62 | 78.32 | 79.22 |
| 8 | 100.33 | 80.41 | 70.42 | 74.74 | 79.56 | 80.18 | 81.43 | 82.65 | 92.63 | 89.23 |
| 10 | 105.65 | 85.96 | 80.75 | 82.23 | 85.65 | 89.83 | 89.53 | 89.65 | 98.65 | 96.23 |

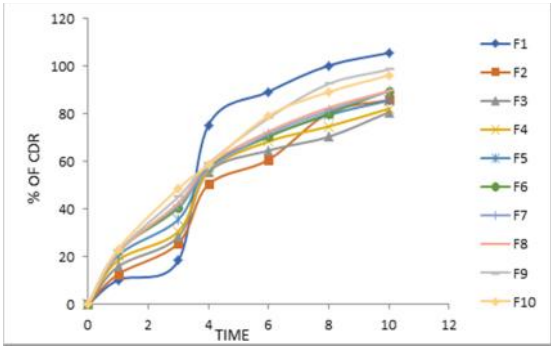


Fig.No 6: showing picture of in vitro drug release studies comparative graph

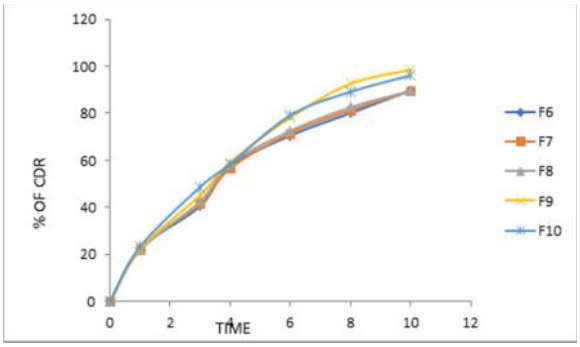


Fig.no 8: Picture showing all Comparative drug release profile for F6-F10Kinetic profile data

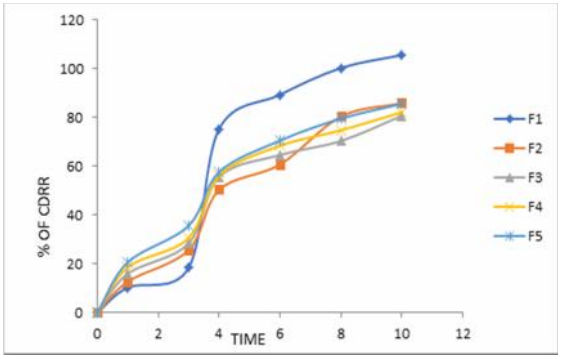


Fig.no 7: Picture showing all Comparative drug release profile F1-F5

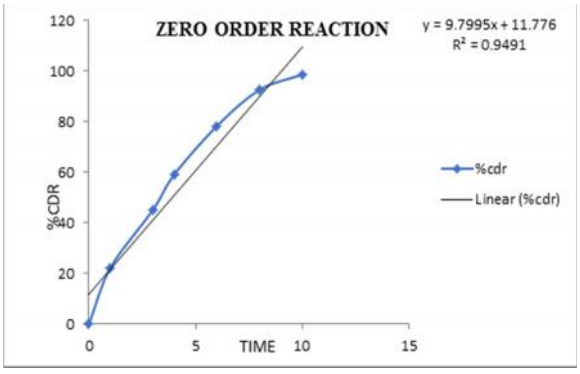


Fig.no: 9 showing picture of zero order reaction

**4. Conclusion**

Formulation and evaluation of the sustained release tablets of the Miglitol. The before going to formulate the tablets the pre formulation studies are carried out such as FTIR, calibration, organoleptic characters. The formulation is developed by using different types of the super disintegrates such as the cros povidone and moringa gum in different trails. The pre compression parameters such as angle of repose, bulk density, true density, and compressibility index, are found to be within the limits. The oral sustained release tablets of miglitol tablets are prepared by the direct compression method. The talc used as glidant and Mg. stearate used as lubricant, mcc used as filler. The after development of oral sustained release tablets are undergo for evaluation parameters. Such as weight variation, thickness, friability, drug content, and In vitro dissolution studies. They all are found in within range of limits. The in vitro drug release studies carried out by USP-II apparatus. The buffer medium 7.5pH. The optimized formulation under go for stability studies for 3 months. In stability studies the drug content and drug release studies carried out. These no degradation takes place in the drug content and drug release studies.

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