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Research Article

FORMULATION OF METFORMIN HYDROCHLORIDE TABLET USING FENUGREEK SEED MUCILAGE

Sudishna Das*, Subham Paul, Subhankar Ghosh, Subrata Ghosh, Subham Kumar Gupta, Soutik Sarkar

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Abstract
This research work aims to develop Metformin Hydrochloride tablet using fenugreek seed mucilage. Fenugreek seed has antidiabetic activity. It also contains a major proportion of mucilage. The mucilage was extracted by soaking the powdered seed into water for 12-14 hours then, after filtration the filtrate was mixed with ethanol and the precipitated mucilage was dried and grounded into powder. The tablet utilizing the mucilage as excipient was prepared by wet granulation method. The tablets were subjected to various tests. The evaluatory parameters of tablets were found to be within the limits as per Indian Pharmacopoeia.

INTRODUCTION

Various types of excipients are used in the formulation of any drug substance. Excipients can be obtaned from synthetic, semi-synthetic and natural sources. Synthetic or semi-synthetic excipients has many disadvantages. Synthetic or semi-synthetic excipient may have more side effect and may not be as effective as natural excipient. Nowadays, natural gums and mucilages have gained popularity over synthetic and semi-synthetic excipient due to their low cost, safety, and availability. Natural gums and mucilages have been used for the preparation of tablets[1].

Fenugreek seeds are obtained from *Trigonella foenum graecum L.* belonging to Leguminosae or Fabaceae family. Fenugreek seeds are easily available in Indian market, it is mainly used as spice. Fenugreek has been shown to lower blood sugar levels and cholesterol. It has also been shown to improve milk production in lactating mothers and to increase libido. Fenugreek is also used as a digestive aid and to treat stomach and intestinal disorders. Metformin is the main first-line medication for the treatment of type 2 diabetes.
Metformin is a biguanide antihyperglycemic agent. It works by decreasing glucose production by the liver, by increasing the insulin sensitivity of body tissues and by increasing GDF15 secretion, which reduces appetite and caloric intake.

MATERIALS AND METHODS

Chemical and reagent: Metformin HCL, Fenugreek seed, Starch, Ethyl Cellulose, Starch Paste, Talc, Magnesium Stearate

Extraction of mucilage: First we powdered the Fenugreek seeds using Mixer Grinder. Then we Soaked it into water for 12-14 hours. Next, we had to filtered the content using muslin cloth. After that we collected the filtrate. Then we mixed ethanol slowly to the filtrate using mechanical stirrer. Extracted mucilage was collected. Then we powder the mucilage using mortar pestle after drying.

Preparation of tablet: First we weighed the required quantity of API & excipient for preparing 50 tablets accurately. Then 10% concentration of starch paste was prepared by boiling 10gm of insoluble potato starch in 100ml of distilled water until a transparent gel like consistency is observed. After that the acquired quantity of metformin hydrochloride, mucilage, starch, ethyl cellulose is mixed.

The mixture is then transferred into mortar pestle and starch paste is added until a dough is formed. Then the dough is passed from sieve no.20 and we get the granules. After that the granules were dried in hot air oven for one and half hour at 550 C. After that Talc & Magnesium stearate was mixed with the dried granules. Finally, the granules are compressed in Rotary tablet punching machine (4) to form the tablet.

Table 1: Formulation Table

Ingredient	Quantity (mg) For 1 tablet	Quantity (gm) For 50 tablets
Metformin hydrochloride	150	7.5
Mucilage	50	2.5
Starch	246	12.3
Ethyl Cellulose	50	2.5
Starch Paste	Q.S.	Q.S.
Talc	2	0.1
Magnesium Stearate	2	0.1

*Department of Pharmaceutics, Himalayan Pharmacy Institute, Majhitar, East Sikkim, India 737136

For correspondence: dasenterapd36@gmail.com

Evaluation of prepared tablets

i. **Weight variation:** 20 tablets were selected randomly from the lot and weighed individually & the weight variation was checked.

ii. **Thickness:** Tablet thickness was measured by vernier caliper for six tablets

iii. **Hardness:** Hardness or tablet crushing strength (fc), the force required to break a tablet in a diametric compression was measured using Monsanto tablet hardness tester. It is expressed in kg/cm^2.

iv. **Friability (F)**: Friability of the tablet was determined by using Roche friabilator. This device subjected the tablet for the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at a height of 6 inches in each revolution. Pre weighed sample of 20 tablets were placed in the friabilator and were subjected to the 100 revolutions for 4 min. Tablets were dusted using a soft muslin cloth and reweighed. The friability (F) is given by the formula.

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

v. **Standard preparation:** Solution of metformin hydrochloride in water was prepared having a known concentration of about 10, 20, 30, 40, 50 µg/ml. The percentage of metformin HCl release was calculated. The limit for extended-release tablet was followed for 24 hours.

vi. **In vitro dissolution studies:** Dissolution study of our tablet is carried out by using Dissolution apparatus USP of Electrolab TDT-08L. Phosphate buffer was prepared and the pH is adjusted at 6.8 as per IP. 900ml of phosphate buffer was added in dissolution apparatus and then the apparatus was switched on and the temperature was set at 37°±2°C, then the rpm was set at 100. USP Type II (Paddle type) dissolution apparatus has been used. After the dissolution apparatus is ready for experimentation, two tablets are put in one side of vessels and dissolution is started. 10ml of solution was withdrawn from the vessels at every 1.5 hour and 10ml of fresh buffer solution was added in the vessels to maintain the sink condition. This process was continued for 24 hours. Each of the withdrawn sample's absorbance was measured at 232 nm through UV spectrophotometer for estimating drug content.

RESULT AND DISCUSSION

Day by day the need of a safer dosage form with a minimal side effect is increasing. We can formulate a safer drug by replacing the synthetic or semi-synthetic excipients with the natural one. Our work has been focusing on exactly the same thing, and we have chosen one of the most important drugs for mankind that is Metformin Hydrochloride. Nowadays, diabetes is considered as endemic disease. In its 2014 global report, the World Health Organization has reported that 1.5 million people died of diabetes alone. 422 million people were suffering from diabetes in 2014 compare to 108 million in 1980 [2].

We have made an anti-diabetic drug by using Metformin hydrochloride as a main therapeutic ingredient and fenugreek seed mucilage as natural excipient. After making any drug we should measure some important parameters, which should be in required limit to make a successful dosage form. According to the Pharmacopoeial recommendation for tablets weighing more than 324 mg, ±5% deviation from the mean weight is acceptable [3]. As the results show, the average weight deviation percentage of 20 tablets was less than ±0.5%.

The hardness of tablets was in the range of 4-6 kg/cm^2, which is in an acceptable limit according to Indian Pharmacopoeia. All tablets showed less than 1% (w/w) friability, which was within the prescribed limits [4]. The result of our dissolution study shows that the cumulative drug release (%) increases by the time. It shows that our tablet is giving sustained release.

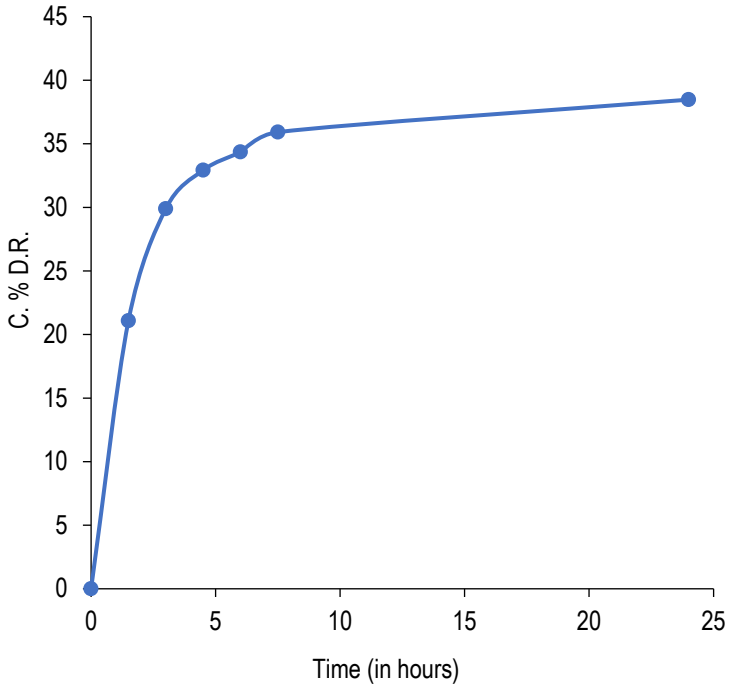

Fig 1: Drug release profile

CONCLUSION

The approach of the present study was to make Metformin HCL tablets using Fenugreek Mucilage. Metformin HCL, is the first drug of choice among all oral hypoglycemic patients as it lowers elevated blood glucose in patients. This study provides evidence for the use of Metformin tablets using fenugreek mucilage as an anti-diabetic agent.

Our research studies also shows that it passes the various evaluation test of the tablets and is under the range of Pharmacopeial standards which has a good therapeutic effect and can be used as an Anti-Diabetic agent. Our results strongly suggest that our prepared Metformin Tablets using mucilage is useful to lower the blood glucose and diabetes.

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CONSENT FOR PUBLICATION

The authors declare no conflict of interest.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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