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FORMULATION AND EVALUATION OF GREWIA ASIATICA L. TABLETS FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS

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ABSTRACT

The primary objective of this study was to formulate tablets containing fruits extract of *Grewia asiatica L.* in which the dose of Grewia extract was 500 mg. The tablets were prepared by wet granulation method using microcrystalline cellulose and mannitol as diluents; croscarmellose sodium, crospovidone and sodium starch glycollate as super disintegrants; Aerosil as a glidant and magnesium stearate as a lubricant. Any excipient in the form of a binder was not used as Grewia extract had a sticky nature and believed to act as a self-binder. Purified water was used as a solvent. The prepared tablets were evaluated for various physicochemical parameters such as drug-excipient interaction by FTIR, flow properties, hardness, weight variation, thickness, friability, disintegration time and uniformity of content. These tablets were also subjected for real time and accelerated stability studies as per ICH guidelines. These tablets were found to be stable even after 6 months of stability study as all the parameters were within limit as per the specifications.

KEYWORDS: Diabetes, Grewia asiatica, Phalsa, Sharbat berry, Nutraceutical, Antidiabetic.

1. INTRODUCTION

Grewia asiatica L., commonly known as Phalsa has been scientifically reported to possess antidiabetic properties, supported by several preclinical and biochemical studies. There are a few studies on Grewia which demonstrates its low Glycemic Index (GI) value of 5.34. Due to its hypoglycemic effect, it helps in reducing blood sugar levels and is highly nutritive in managing diabetes. The fruit also has polyphenols which helps in reducing the high blood sugar levels in diabetes patients.

Grewia asiatica *L.* is a tropical fruit-bearing species widely distributed across South and Southeast Asia, including India, Nepal, Thailand, Pakistan, Bangladesh, Myanmar, Cambodia, China, Laos, and Vietnam. It is extensively cultivated for its edible berries and its diverse nutraceutical and medicinal applications. The fruit pulp contains approximately 80.8 g of water, 1.3 g of protein, 0.9 g of fat, 14.7 g of carbohydrates, 1.2 g of fiber, and essential minerals such as calcium, phosphorus, and iron per 100 g. The fruit and seeds are nutritionally rich, containing 18 amino acids, with aspartic acid, glutamic acid, and leucine being the most predominant. Additionally, the fruit is a notable source of vitamins A and C and is enriched with various bioactive phytochemicals, including anthocyanins, tannins, phenolics, and flavonoids.

Pharmacologically, *Grewia asiatica* exhibits a wide spectrum of biological activities, such as antibacterial, antiviral, antifungal, anticancer, antioxidant, antidiabetic, analgesic, anti-inflammatory, antipyretic, antiemetic, radioprotective, hepatoprotective, antihyperlipidemic, immunomodulatory, sedative, hypnotic, and nootropic effects. Owing to this broad range of therapeutic properties, *Grewia asiatica* has garnered increasing scientific and commercial attention in recent years. Its extracts are now being utilized by several pharmaceutical

and nutraceutical industries for the development of safe, cost-effective, and readily available health-promoting formulations.

The fruit extract of *Grewia asiatica L.* was formulated into immediate-release tablets. Mannitol was incorporated as a diluent, while three superdisintegrants—Croscarmellose Sodium, Crospovidone, and Sodium Starch Glycolate—were included to enhance tablet disintegration. The fruit extract itself exhibited inherent binding properties; therefore, no additional binder was required. Colloidal Silicon Dioxide served as a glidant, and Magnesium Stearate was added as a lubricant. Purified water was used as the granulation solvent.

2. MATERIALS AND METHOD

Table 1: Raw Materials, Quantities and their function.

S. No.	Raw Materials	Quantity (mg/tablet)	Function
1.	*Grewia asiatica* Fruit Extract	500.00	Active Ingredient / Binder
2.	Mannitol	300.00	Diluent
3.	Croscarmellose Sodium	20.00	Superdisintegrant
4.	Crospovidone	20.00	Superdisintegrant
5.	Sodium Starch Glycolate	20.00	Superdisintegrant
6.	Colloidal Silicon Dioxide	25.00	Glidant
7.	Magnesium Stearate	15.00	Lubricant
8.	Purified Water	Q.S.	Solvent
	Total	1000.00 mg	

3. Manufacturing Process

3.1. Sieving, Mixing, Granulation, and Lubrication

Grewia asiatica extract, Mannitol, and 50% of each superdisintegrants were passed through a #40 mesh and blended in a Rapid Mixer Granulator (RMG) for 5 minutes at slow speed. Purified water was used as the granulating solvent. Wet granulation was performed in the RMG until the desired end-point was achieved.

The wet mass was screened through a #16 mesh and dried in a Fluidized Bed Dryer (FBD) at an inlet temperature of **55°C** until the moisture content decreased to below 3%. The dried granules were rescreened through a #20 mesh and blended with the remaining superdisintegrants in the RMG for 5 minutes.

Colloidal Silicon Dioxide and Magnesium Stearate were passed through a #60 mesh and added for lubrication. Lubrication was carried out in the RMG for **45 seconds**.

Moisture Content and Flow Properties

The moisture content of the lubricated granules was determined using a Denver Digital Moisture Analyzer at 105°C. Flow property was evaluated by the angle of repose.

Table 2: Moisture Content and Angle of Repose.

S. No.	Parameter	Result
1	Moisture Content (Lubricated Granules)	3.02%
2	Angle of Repose (θ)	26° 18′

Pre-compression Parameters

Pre-compression characteristics were evaluated using an Electrolab USP Tapped Density Tester.

Table 3: Pre-compression Parameters of Lubricated Granules.

S. No.	Parameter	Result
1	Bulk Density	0.45 g/cc
2	Tapped Density	0.55 g/cc
3	Carr's Index	14.13%
4	Hausner's Ratio	1.16

Carr's Index < 15% and Hausner's Ratio < 1.25 indicate **good flowability**.

4. Compression of Tablets

The lubricated granules were compressed using a Karnavati 9-station double-rotary tablet punching machine equipped with oblong, biconvex punch tooling (20.5 × 10.0 mm, plain). Machine speed was maintained at 15 RPM, and the average tablet weight was 1000 mg. All in-process parameters including hardness, thickness, friability, and weight variation remained within acceptable limits.

5. Evaluation of Compressed Tablets

5.1. Hardness

Tablet hardness was measured using a Campbell Electronics digital hardness tester. Hardness was

maintained between **90–110 N**, ensuring mechanical stability during handling, packaging, and transportation.

5.2. Thickness

Tablet thickness was controlled to prevent packing and blistering issues. Measurements taken using a Dial Vernier Caliper showed a range of **6.2–6.6 mm**, with an average of **6.5 mm**.

5.3. Weight Variation

The weight variation of the batches complied with pharmacopoeial limits (±7.5%).

5.4. Friability

Friability was evaluated using an Electrolab Tablet Friability Tester. The tablets showed a friability value of **0.3%**, indicating excellent mechanical strength (<1% is acceptable).

5.5. Disintegration Time

Disintegration testing was performed using a Veego Disintegration Test Apparatus in water maintained at **37 ± 2°C**. One tablet was placed in each of the six tubes of the basket.

- Minimum disintegration time: **7 min 30 sec**
- Maximum disintegration time: **9 min 40 sec**
- **Average disintegration time: 8 min 35 sec**

The tablets demonstrated acceptable disintegration for an immediate-release formulation.

CONCLUSION

The *Grewia asiatica* fruit extract was successfully formulated into stable, immediate-release tablets using wet granulation. The extract itself exhibited adequate binding capacity, eliminating the need for additional binders, while mannitol and selected superdisintegrants ensured good compressibility and rapid disintegration. The pre-compression parameters, including moisture content, angle of repose, bulk density, tapped density, Carr's Index, and Hausner's Ratio, demonstrated that the granules possessed excellent flow and compression characteristics.

All post-compression evaluation parameters—hardness, friability, thickness, weight uniformity, and disintegration time—remained within acceptable pharmacopoeial limits. The tablets showed strong mechanical integrity with low friability, consistent weight and thickness, and an average disintegration time suitable for immediate-release dosage forms.

Overall, the formulation approach yielded high-quality *Grewia asiatica* extract tablets with desirable physical properties, confirming that the chosen excipient blend and processing conditions were appropriate for producing robust and effective herbal tablets.

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