

Formulation and Evaluation of Ayurvedic Neem (Azadirachta Indica) Tablet as a Diabetic Mellitus

Tejraj Popat Gawade, Gore Bharti Jalinder, Changan Saurbh Ravindra

Sanap Vikas Baban, Dr. Chavan D.K

Aditya Pharmacy College, Beed

Abstract: Diabetes mellitus (DM) is a global health concern marked by chronic hyperglycemia due to insulin resistance or deficiency. Type 2 diabetes mellitus (T2DM) constitutes the majority of cases and is often linked to lifestyle and genetic factors. While conventional antidiabetic medications are effective, they frequently present adverse effects such as hypoglycemia and gastrointestinal discomfort. This study explores the formulation, standardization, and evaluation of an Ayurvedic tablet using Neem (*Azadirachta indica*) leaf extract, known for its hypoglycemic, antioxidant, and anti-inflammatory properties. A wet granulation method was employed to prepare three batches of 450 mg tablets using pharmaceutically acceptable excipients. The tablets were subjected to various physicochemical evaluations including hardness, friability, disintegration, weight variation, drug content, and in-vitro drug release. Preformulation parameters confirmed the suitability of the Neem extract for tablet formulation. The resulting formulation met official pharmacopeial standards, demonstrating its potential as a safe, effective, and natural alternative or adjunct to conventional diabetes therapy.

Keywords: Diabetes mellitus

I. INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by elevated blood glucose levels resulting from defects in insulin secretion, insulin action, or both. It is one of the most prevalent non-communicable diseases worldwide, with significant morbidity and mortality. The condition is commonly classified into Type 1 diabetes (insulin-dependent), Type 2 diabetes (non-insulin-dependent), and gestational diabetes. Type 2 diabetes mellitus (T2DM) accounts for the majority of cases and is often associated with obesity, sedentary lifestyle, and genetic predisposition. According to the International Diabetes Federation (IDF, 2021), approximately 537 million adults (20–79 years) were living with diabetes globally, and the number is projected to rise to 783 million by 2045 [1].

Conventional anti-diabetic drugs such as sulfonylureas, biguanides, and insulin are effective but may cause adverse effects like hypoglycemia, weight gain, and gastrointestinal disturbances. In recent years, there has been growing interest in the use of herbal medicines and Ayurvedic formulations for the management of diabetes, as they offer a safer and more holistic approach with minimal side effects [2].

Neem (*Azadirachta indica*), a well-known medicinal plant in Ayurveda, has been extensively used for its hypoglycemic, anti-inflammatory, antimicrobial, and antioxidant properties. The plant belongs to the family Meliaceae and is native to the Indian subcontinent. Various parts of the Neem tree—leaves, bark, seeds, and flowers—have demonstrated therapeutic potential. In the context of diabetes, Neem leaf extract has shown significant antihyperglycemic effects by enhancing insulin sensitivity, promoting glucose uptake, and protecting pancreatic β -cells from oxidative damage [3][4].

The formulation of an Ayurvedic tablet using Neem aims to provide a standardized, convenient, and effective dosage form for diabetic patients. This project focuses on the formulation, standardization, and evaluation of Neem-based tablets using pharmaceutically accepted excipients. The study includes preformulation studies, tablet formulation (using direct compression or wet granulation method), and both official (e.g., hardness, friability, disintegration) and non-official (e.g., weight variation, in-vitro drug release) evaluation tests.



This research integrates traditional Ayurvedic knowledge with modern pharmaceutical techniques to develop a viable natural remedy for diabetes mellitus.

PHARMACOGNOSY OF NEEM (*Azadirachta indica* A. Juss)

Botanical Name: *Azadirachta indica* A. Juss

Family: Meliaceae

Common Names: Neem (English), Nimba (Sanskrit), Veppam (Tamil), Nim (Hindi)

Parts Used: Primarily leaves; also bark, seeds, and flowers are used medicinally

Habitat: Native to the Indian subcontinent; widely cultivated in tropical and subtropical regions

HEALTH BENEFITS OF NEEM (*Azadirachta indica*) IN DIABETES MELLITUS

Neem (*Azadirachta indica*) is a versatile medicinal plant that has been widely used in Ayurvedic and Unani systems of medicine. Its therapeutic potential spans a broad range of ailments, including skin disorders, infections, inflammation, and notably, diabetes mellitus. Several studies have confirmed the beneficial role of Neem in controlling blood glucose levels and improving metabolic health.

1. Hypoglycemic and Antidiabetic Activity

Neem leaves possess significant antihyperglycemic effects. Extracts from the leaves have been shown to lower blood glucose levels in both normal and diabetic animal models. This effect is believed to be mediated through mechanisms such as increased insulin sensitivity, improved peripheral glucose uptake, and regeneration of pancreatic β -cells.[5]

2. Antioxidant Activity

Oxidative stress plays a key role in the development of insulin resistance and β -cell dysfunction in diabetes. Neem is rich in flavonoids, tannins, and polyphenolic compounds that exhibit strong antioxidant activity, which can help scavenge free radicals and reduce oxidative damage.[6]

3. Anti-inflammatory and Immunomodulatory Effects

Chronic inflammation is a known contributor to insulin resistance. Neem exhibits anti-inflammatory properties by inhibiting pro-inflammatory cytokines such as $\text{TNF-}\alpha$ and IL-6. These effects can potentially enhance insulin sensitivity and glucose utilization in peripheral tissues.[7]

4. Hypolipidemic Activity

Neem has shown the ability to reduce serum cholesterol and triglyceride levels in diabetic subjects, thus lowering the risk of cardiovascular complications commonly associated with diabetes mellitus.[8]

5. Hepatoprotective Effects

Neem leaf extract helps protect the liver from damage caused by diabetes-induced oxidative stress, thus supporting metabolic regulation and detoxification processes in diabetic patients.[9]

6. Antibacterial and Wound Healing Properties

Diabetic patients are more prone to infections and delayed wound healing. Neem's antibacterial, antifungal, and wound-healing properties make it highly valuable in preventing and treating diabetic foot ulcers and skin infections.[10]





Figure 1

ADVANTAGES

- **Natural and Safe:** Neem is a traditionally used herbal medicine with a good safety profile and minimal side effects compared to synthetic drugs.
- **Multifunctional Action:** Exhibits hypoglycemic, antioxidant, anti-inflammatory, and hepatoprotective effects, all beneficial in diabetic care.
- **Cost-Effective:** Herbal formulations are generally more affordable and accessible than synthetic medications.
- **Better Compliance:** Tablets are easy to administer and carry, improving patient adherence to treatment regimens.
- **Standardization Potential:** Tablet formulation allows for dosage accuracy and reproducibility, which is often lacking in crude herbal preparations.
- **Improved Shelf Life:** Dry tablet form has a longer shelf life than decoctions or juices traditionally used in Ayurveda.

DISADVANTAGES

- **Slower Onset of Action:** Herbal remedies may take longer to show therapeutic effects compared to allopathic medications.
- **Variability in Plant Constituents:** The active compounds in Neem may vary due to differences in plant source, harvest time, and processing methods.
- **Lack of Extensive Clinical Data:** While traditional use and animal studies support Neem's antidiabetic effects, extensive human clinical trials are limited.
- **Potential for Herbal-Drug Interactions:** When used alongside conventional antidiabetic medications, Neem may interact and potentiate hypoglycemia.
- **Regulatory Challenges:** Herbal products often face less stringent regulatory controls, which can affect quality and standardization across formulations.

AIM – Formulation and evaluation of ayurvedic tablet for diabetic mellitus

OBJECTIVE

The primary objective of this study is to:

- Formulate and evaluate an Ayurvedic herbal tablet using Neem (*Azadirachta indica*) leaf extract for the management of Diabetes Mellitus.



- Standardize the tablet formulation through preformulation studies, physicochemical evaluation, and in-vitro drug release studies.
- Assess the therapeutic potential of Neem in tablet form as an alternative or complementary treatment to synthetic antidiabetic drugs.
- Secondary objectives include:
 - To enhance patient compliance by converting traditional herbal remedies into a stable, solid dosage form.
 - To investigate the antioxidant, hypoglycemic, and anti-inflammatory potential of Neem in a standardized dosage.
- Phytochemical Constituents
- Neem contains a wide range of bioactive compounds, many of which contribute to its antidiabetic and other therapeutic properties:

Table 1

Class of Compounds	Examples	Activity
Limonoids	Azadirachtin, Nimbin, Salannin	Hypoglycemic, antifungal, insecticidal
Flavonoids	Quercetin, Kaempferol	Antioxidant, anti-inflammatory
Tannins	Catechin, Gallic acid	Astringent, antimicrobial
Glycosides	Nimbidin	Anti-inflammatory, hypoglycemic
Saponins	Triterpenoid saponins	Immunomodulatory
Polysaccharides	Glucans	Antioxidant, immune support

Pharmacological Activities Relevant to Diabetes

Antihyperglycemic – Enhances insulin sensitivity and glucose uptake

Antioxidant – Reduces oxidative stress implicated in β -cell damage

Anti-inflammatory – Modulates inflammatory cytokines (e.g., TNF- α)

Hepatoprotective – Protects the liver from diabetic complications

Immunomodulatory – Improves overall immune function

Reference Standards (as per Pharmacopoeia)

Neem leaf powder should comply with standard tests for:

- Foreign matter
- Total ash (max 12%)
- Acid-insoluble ash (max 1.5%)
- Alcohol and water-soluble extractives
- Loss on drying (not more than 8%)[11]

Material And Methods

Formulation Table in Grams (for 80 Tablets \times 3 Batches)

Table 2

Ingredient	Function	Per Tablet (mg)	Batch I (g)	Batch II (g)	Batch III (g)
Neem leaf extract	Active ingredient	250	20.0 g	20.0 g	20.0 g
Microcrystalline cellulose	Diluent/Filler	100	8.0 g	6.0 g	4.0 g
Starch (maize)	Disintegrant	50	4.0 g	5.6 g	6.4 g

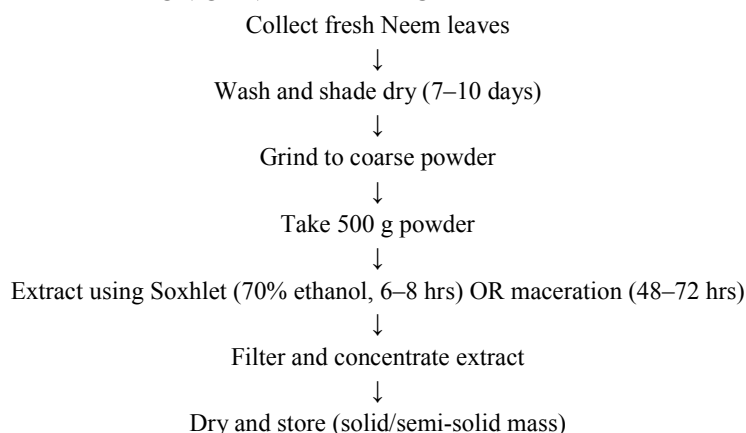


PVP K-30	Binder (in IPA)	30	2.4 g	2.4 g	2.4 g
Magnesium stearate	Lubricant	10	0.8 g	0.8 g	0.8 g
Talc	Glidant	10	0.8 g	0.8 g	0.8 g
Total weight (per 80 tablets)		450 mg	36.0 g	35.6 g	34.4 g

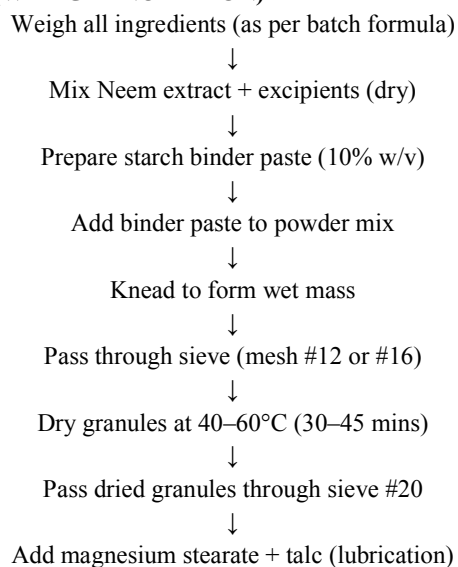
Procedure

Here is the formulation table in grams for 80 tablets per batch (3 batches), based on a tablet weight of 450 mg:

COLLECTION AND PREPARATION OF NEEM EXTRACT



FORMULATION OF TABLETS (WET GRANULATION)



↓
Comperation
↓
Final Product



Final product

Figure 2

Table: Preformulation Parameters of Neem (*Azadirachta indica*) Leaf Powder

Table 3

S/ N	Parameter	Result (Example)	Acceptance Criteria
1	Organoleptic Properties		
	Color	Greenish-brown	Characteristic
	Odor	Bitter, characteristic	Characteristic
	Taste	Bitter	Characteristic
	Texture	Fine powder	Smooth and uniform
2	Solubility		
	In Water	Slightly soluble	Slightly to moderately soluble
	In Ethanol	Soluble	Acceptable
	In Methanol	Soluble	Acceptable
3	pH (1% solution)	6.3	5.0–7.0
4	Loss on Drying (%)	6.5%	Not more than 8% (IP)
5	Bulk Density (g/mL)	0.50	0.3–0.8 g/mL
6	Tapped Density (g/mL)	0.65	Should be greater than bulk density
7	Carr's Index (%)	23.1%	5–25% (Fair to good flowability)
8	Hausner Ratio	1.23	≤1.25 (Good flow property)
9	Angle of Repose (°)	29°	25°–30° (Good flow)
10	Compatibility Study	No interaction (FTIR)	No major shifts or peak loss in spectra

Table: Evaluation Parameters of Neem Tablets

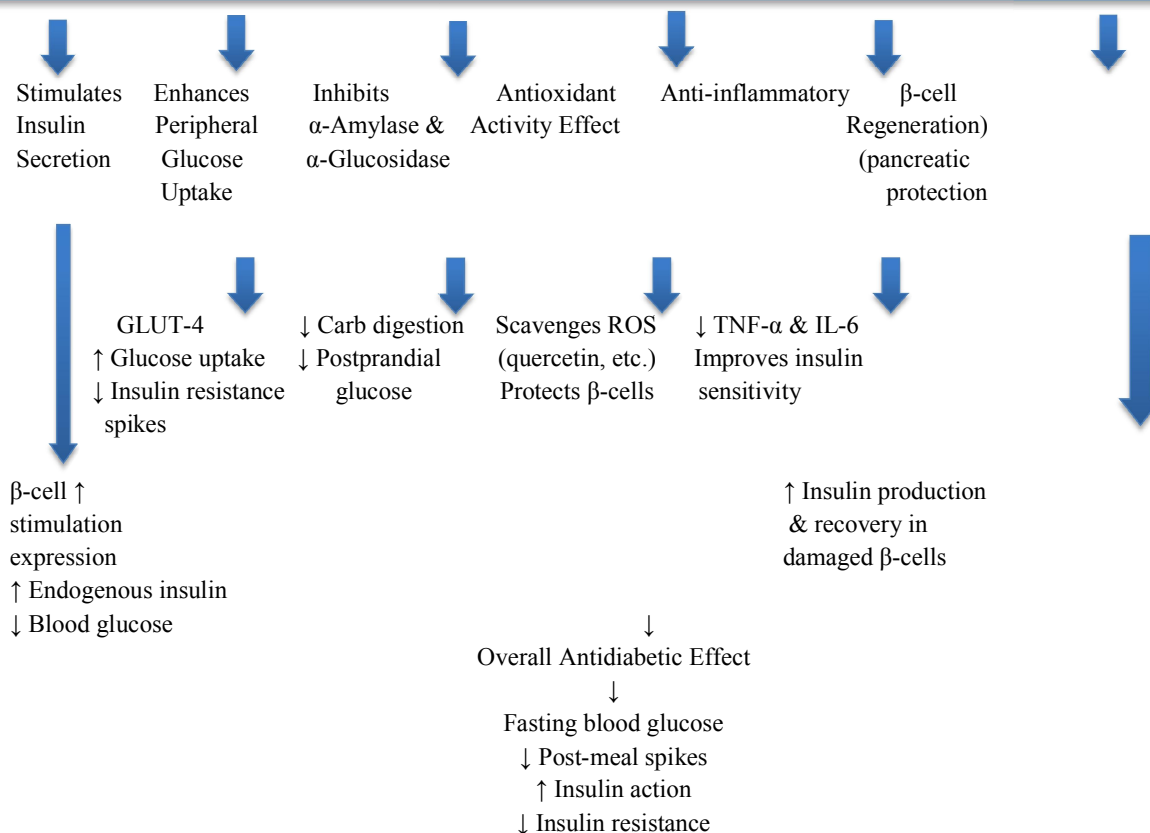
Table 4

S/ N	Test Parameter	Method Used	Result (Example)	Acceptance Criteria (IP/BP/USP)
1	Tablet Appearance	Visual inspection	Smooth, round	Uniform in color, shape, no cracks or defects
2	Weight Variation	Weigh 20 tablets individually & calculate % deviation	±3.2%	±5% (for tablets 250–500 mg)



S/ N	Test Parameter	Method Used	Result (Example)	Acceptance Criteria (IP/BP/USP)
3	Hardness (kg/cm ²)	Monsanto or Pfizer hardness tester	5.0 kg/cm ²	4–8 kg/cm ² (for uncoated tablets)
4	Thickness (mm)	Vernier caliper	4.2 mm	±5% variation from standard
5	Friability (%)	Roche Friabilator @ 25 rpm, 4 mins (100 revolutions)	0.61%	Not more than 1%
6	Disintegration Time (min)	USP disintegration apparatus in distilled water (37 ± 2°C)	12 minutes	Not more than 15 minutes (uncoated herbal tabs)
7	Drug Content (%)	UV/Vis spectrophotometry or HPLC	98.5%	85%–115% of label claim
8	Uniformity of Content	Analyze 10 tablets individually	Within range	85%–115% of average content
9	In-vitro Dissolution (%)	Paddle method (USP-II), 900 mL medium at 37°C	85% in 45 min	NLT 80% drug release within 60 minutes
10	Moisture Content (%)	Loss on drying method at 105°C	6.4%	Not more than 8%

Mechanism of Action of Neem (*Azadirachta indica*) in Diabetes Mellitus –
Neem (*Azadirachta indica*)



II. CONCLUSION

The formulation of Neem-based Ayurvedic tablets presents a promising natural approach for the management of diabetes mellitus. The prepared tablets showed acceptable pharmacotechnical properties and conformed to pharmacopeial quality standards. Neem's multifaceted pharmacological actions—including antihyperglycemic, antioxidant, anti-inflammatory, and hepatoprotective effects—offer a holistic strategy for glycemic control and overall metabolic support. Despite the slower onset of action and variability in phytochemical content, standardization through modern pharmaceutical techniques enhances dosage accuracy, stability, and patient compliance. Further clinical investigations are warranted to validate the efficacy and safety of this herbal formulation in human populations. Integrating traditional Ayurvedic wisdom with contemporary pharmaceutical practices, this research contributes to the development of a viable, safe, and cost-effective herbal remedy for diabetes care.

REFERENCES

- [1]. International Diabetes Federation. IDF Diabetes Atlas, 10th Edition. 2021. <https://diabetesatlas.org/>
- [2]. Modak, M., et al. (2007). Herbs for diabetes control: From traditional to modern medicine. Evidence-Based Complementary and Alternative Medicine, 4(1), 5–17. <https://doi.org/10.1093/ecam/nel002>
- [3]. Chattopadhyay, R. R. (1996). Possible mechanism of antihyperglycemic effect of Azadirachta indica leaf extract: Part I. Journal of Ethnopharmacology, 67(3), 373–376. [https://doi.org/10.1016/S0378-8741\(99\)00035-5](https://doi.org/10.1016/S0378-8741(99)00035-5)
- [4]. Biswas, K., et al. (2002). Biological activities and medicinal properties of Neem (Azadirachta indica). Current Science, 82(11), 1336–1345.
- [5]. Chattopadhyay, R. R. (1996). "Possible mechanism of antihyperglycemic effect of Azadirachta indica leaf extract." Journal of Ethnopharmacology, 67(3), 373–376. [https://doi.org/10.1016/S0378-8741\(99\)00035-5](https://doi.org/10.1016/S0378-8741(99)00035-5)
- [6]. Subapriya, R., & Nagini, S. (2005). "Medicinal properties of neem leaves: A review." Current Medicinal Chemistry – Anti-Cancer Agents, 5(2), 149–156. <https://doi.org/10.2174/1568011053174828>
- [7]. Biswas, K., et al. (2002). "Biological activities and medicinal properties of Neem (Azadirachta indica)." Current Science, 82(11), 1336–1345.
- [8]. Udeinya, I. J., et al. (2006). "Neem (Azadirachta indica) as a potential antimalarial agent: A review." African Journal of Biotechnology, 5(17), 1201–1205.
- [9]. Alzohairy, M. A. (2016). "Therapeutics role of Azadirachta indica (Neem) and their active constituents in disease prevention and treatment." Evidence-Based Complementary and Alternative Medicine, 2016, Article ID 7382506. <https://doi.org/10.1155/2016/7382506>
- [10]. Kokate, C.K., Purohit, A.P., & Gokhale, S.B. (2019). Pharmacognosy, 52nd ed. Pune: Nirali Prakashan.
- [11]. Trease, G.E., & Evans, W.C. (2009). Pharmacognosy, 16th ed. Saunders Elsevier.
- [12]. Biswas, K., et al. (2002). Biological activities and medicinal properties of Neem (Azadirachta indica). Current Science, 82(11), 1336–1345.
- [13]. Indian Pharmacopoeia, Vol. II. (2020). Neem Monograph. Government of India, Ministry of Health and Family Welfare.
- [14]. Alzohairy, M. A. (2016). Therapeutics role of Azadirachta indica (Neem) and their active constituents in disease prevention and treatment. Evidence-Based Complementary and Alternative Medicine, Article ID 7382506

