
FORMULATION AND EVALUATION OF ANTI-DIABETIC DRUG

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ABSTRACT

Diabetes mellitus is a chronic metabolic disorder characterized by elevated blood glucose levels resulting from impaired insulin secretion, insulin resistance, or both. The increasing global prevalence of diabetes has created a significant demand for effective and patient-friendly antidiabetic therapies. Antidiabetic drug formulation plays an essential role in enhancing therapeutic efficacy, improving patient compliance, and minimizing adverse effects. Various conventional and novel drug delivery systems have been developed to optimize the release, absorption, and bioavailability of antidiabetic agents. These formulations include tablets, capsules, sustained-release systems, transdermal patches, nanoparticles, oral dispersible tablets, and herbal-based preparations. The selection of suitable excipients and formulation techniques is crucial to maintain stability, safety, and effectiveness of the drug product. Furthermore, advancements in pharmaceutical technology have contributed to the development of controlled and targeted drug delivery approaches for better glycemic control. This review highlights the importance of antidiabetic drug formulation, different formulation strategies, evaluation parameters, and recent developments aimed at improving diabetes management and patient outcomes.

KEYWORDS: Antidiabetic drugs, Diabetes mellitus, Drug formulation, Controlled drug delivery, Bioavailability, Sustained release, Oral dosage form, Glycemic control, Pharmaceutical formulation, Novel drug delivery system.

I. INTRODUCTION

Antidiabetic drug formulations are pharmaceutical preparations developed for the prevention, management, and treatment of diabetes mellitus, a chronic metabolic disorder characterized

by elevated blood glucose levels due to inadequate insulin secretion, impaired insulin action, or both. Diabetes mellitus has become a major global health concern because of its increasing prevalence and associated complications such as cardiovascular diseases, kidney damage, neuropathy, retinopathy, and delayed wound healing. The development of effective antidiabetic formulations aims to maintain normal blood glucose levels, improve patient compliance, and minimize complications associated with long-term hyperglycemia. Antidiabetic drugs are designed to regulate blood sugar through different mechanisms depending on the type and severity of diabetes. These formulations may include synthetic drugs, herbal preparations, or a combination of both. Conventional antidiabetic medications include insulin preparations and oral hypoglycemic agents that act by increasing insulin secretion, enhancing insulin sensitivity, reducing glucose absorption, or decreasing hepatic glucose production.

Preformulation studies play a significant role in the development of antidiabetic formulations by evaluating the physicochemical properties of the drug substance, including solubility, stability, compatibility with excipients, particle size, and dissolution characteristics. These studies help in selecting suitable formulation techniques and ensuring product safety, stability, and efficacy. Following formulation, the prepared dosage form is subjected to evaluation parameters such as hardness, friability, weight variation, disintegration time, dissolution profile, drug content uniformity, stability, and in vitro drug release studies.

II. DRUG PROFILE

1. Metformin

- **Category/Class:** Biguanide antidiabetic agent
- **Mechanism of Action:** Metformin lowers blood glucose by decreasing glucose production in the liver and improving insulin sensitivity in body tissues. It also reduces intestinal absorption of glucose.
- **Molecular Formula:** $C_4H_{11}N_5$
- **Molecular Weight:** 129.16 g/mol
- **Solubility:** Freely soluble in water and slightly soluble in alcohol.
- **Melting Point:** Approximately 223–226°C
- **Dose:** Usually 500–2000 mg/day in divided doses.
- **Uses/Indications:** Used for the management of type 2 diabetes mellitus to control blood sugar levels.
- **Common Side Effects:** Nausea, abdominal discomfort, diarrhea, and metallic taste.

- **Storage Conditions:** Store in a cool, dry place away from moisture and heat.

2. Glimepiride

- **Category/Class:** Sulfonylurea antidiabetic drug
- **Mechanism of Action:** Glimepiride stimulates insulin release from pancreatic beta cells, helping reduce blood glucose levels.
- **Molecular Formula:** $C_{24}H_{34}N_4O_5S$
- **Molecular Weight:** 490.62 g/mol
- **Solubility:** Slightly soluble in water and soluble in organic solvents.
- **Melting Point:** Approximately 207–209°C
- **Dose:** Usually 1–8 mg/day.
- **Uses/Indications:** Used in type 2 diabetes mellitus for glycemic control.
- **Common Side Effects:** Hypoglycemia, dizziness, headache, and nausea.
- **Storage Conditions:** Keep in a tightly closed container at room temperature.

3. Glibenclamide

- **Category/Class:** Sulfonylurea antidiabetic drug
- **Mechanism of Action:** Glibenclamide increases insulin secretion from the pancreas, lowering blood sugar concentration.
- **Molecular Formula:** $C_{23}H_{28}ClN_3O_5S$
- **Molecular Weight:** 494.00 g/mol
- **Solubility:** Slightly soluble in water.
- **Melting Point:** Approximately 170–175°C
- **Dose:** Usually 2.5–20 mg/day.
- **Uses/Indications:** Prescribed for type 2 diabetes mellitus.
- **Common Side Effects:** Low blood sugar, weight gain, stomach upset, and skin reactions.
- **Storage Conditions:** Store below room temperature in a dry environment.

4. Pioglitazone

- **Category/Class:** Thiazolidinedione antidiabetic agent
- **Mechanism of Action:** Pioglitazone improves insulin sensitivity in muscles and fat tissue, enhancing glucose utilization.
- **Molecular Formula:** $C_{19}H_{20}N_2O_3S$
- **Molecular Weight:** 356.44 g/mol

- **Solubility:** Slightly soluble in water.
- **Melting Point:** Approximately 184–188°C
- **Dose:** Usually 15–45 mg/day.
- **Uses/Indications:** Used to treat type 2 diabetes mellitus.
- **Common Side Effects:** Weight gain, swelling, fatigue, and headache.
- **Storage Conditions:** Store in a cool and dry place protected from light.

EXPERIMENTAL

○ **Preformulation Study**

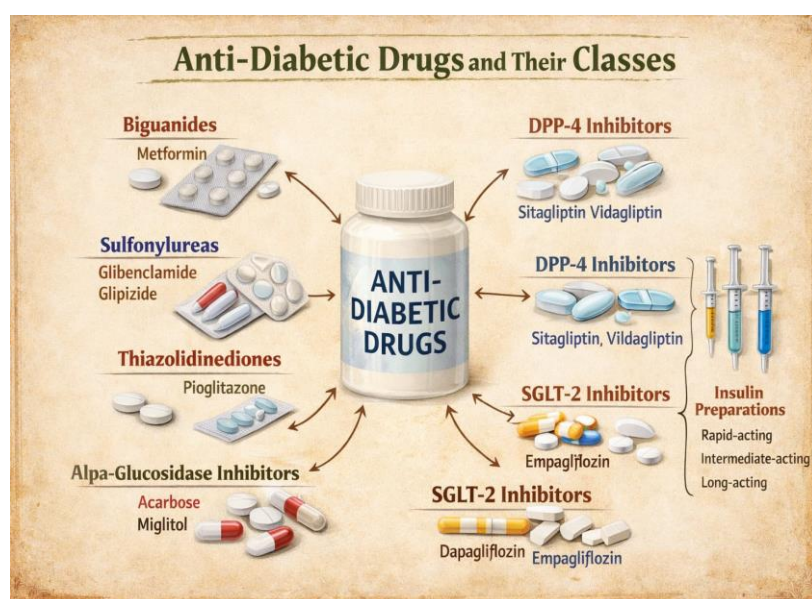
Preformulation studies play a significant role in the successful development of a formulation that is safe, stable, and effective. These investigations are performed to examine the physical and chemical properties of the materials used in the formulation and to understand how they behave under different processing and storage conditions. In the preparation of herbal shampoo, preformulation studies are useful for evaluating the interaction of herbal ingredients with excipients, which helps maintain product stability, safety, and overall performance. Such studies also contribute to the selection of appropriate formulation components and optimization of product quality and efficacy.

○ **Objectives of Preformulation Study**

- To assess the essential physicochemical characteristics of herbal extracts and active ingredients involved in the formulation process.
- To examine the compatibility between herbal constituents and excipients in order to minimize the possibility of instability or unwanted interactions.
- To facilitate the development of a formulation that exhibits desirable quality, stability, and effectiveness.
- To help in the selection of suitable excipients and manufacturing techniques for preparing an optimized final product.

○ Parameters Evaluated in Preformulation Studies

1. Organoleptic Properties
2. Solubility Analysis
3. Melting Point Determination
4. pH Determination
5. Drug–Excipient Compatibility Study
6. Particle Size Analysis
7. Bulk Density and Tapped Density
8. Angle of Repose
9. Compressibility Index (Carr's Index)
10. Hausner Ratio
11. Moisture Content
12. Stability Studies



REVIEW OF LITERATURE

2015

- **Cause/Topic:** Formulation strategies for oral antidiabetic drug
- **By Whom:** P. K. Lakshmi, S. K. Shrivastava, and collaborators
- **Pharmaceutical Importance:** Evaluated oral dosage modifications to improve patient adherence.
- **Conclusion:** Modified-release systems enhanced therapeutic effectiveness and compliance.

➤ **Number of Contributors:Multiple authors**

- **Summary:** Researchers reviewed formulation strategies such as controlled-release tablets, matrix systems, and coated formulations for oral antidiabetic drugs. Findings suggested that modified dosage forms can improve patient convenience and reduce fluctuations in blood glucose levels.

2016

- **Cause/Topic:** Nanoparticle-based antidiabetic drug delivery systems
- **By Whom:** M. K. Gupta, S. Agrawal, and co-researchers
- **Pharmaceutical Importance:** Studied nanoparticles for improving drug absorption and efficacy.
- **Conclusion:** Nanoparticle systems improved bioavailability and therapeutic action.
- **Number of Contributors:Multiple authors**
- **Summary:** This study investigated nanoformulations for antidiabetic drugs to overcome poor absorption and low bioavailability. Researchers found that nanoparticles improved targeted delivery and sustained drug release, making them promising alternatives for diabetes management.

2017

- **Cause/Topic:** Oral controlled-release formulations for diabetes therapy
- **By Whom:** N. A. Peppas and Joseph R. Robinson
- **Pharmaceutical Importance:** Improved drug release and minimized dosing frequency.
- **Conclusion:** Controlled-release formulations enhanced long-term diabetic management.
- **Number of Contributors:2 authors**
- **Summary:** This review discussed the pharmaceutical importance of oral controlled-release systems for chronic diseases like diabetes. Controlled drug delivery helped maintain stable plasma concentrations, reducing fluctuations in blood glucose levels and improving patient compliance.

2018

- **Cause/Topic:** Herbal and synthetic antidiabetic drug formulations
- **By Whom:** S. K. Gupta, P. Sharma, and co-researchers
- **Pharmaceutical Importance:** Compared formulation approaches in diabetes management.

- **Conclusion:** Both herbal and synthetic systems demonstrated promising antidiabetic activity.
- **Number of Contributors:** Multiple authors
- **Summary:** The study emphasized combining pharmaceutical excipients with antidiabetic agents to improve stability, efficacy, and patient compliance. Researchers highlighted the growing interest in safer and more efficient dosage forms for diabetes treatment.

2019

- **Cause/Topic:** Sustained-release matrix tablets of metformin hydrochloride
- **By Whom:** Harshita Sharma, Amit Chaudhary, and colleagues
- **Pharmaceutical Importance:** Developed prolonged-release dosage forms for diabetes therapy.
- **Conclusion:** Matrix tablets improved sustained drug release and therapeutic effectiveness.
- **Number of Contributors:** Multiple authors
- **Summary:** Researchers developed metformin sustained-release matrix tablets to achieve prolonged glucose control and reduce dosing frequency. The formulation demonstrated acceptable stability, dissolution profile, and patient convenience, making it suitable for chronic diabetic treatment.

2020

- **Cause/Topic:** Nanotechnology in antidiabetic drug formulation
- **By Whom:** Muhammad Sohail Arshad, Muhammad Mudassir, and co-researchers
- **Pharmaceutical Importance:** Investigated nanocarriers for targeted antidiabetic drug delivery.
- **Conclusion:** Nanotechnology improved therapeutic efficacy and drug targeting.
- **Number of Contributors:** Multiple authors
- **Summary:** The study reviewed nanocarriers such as liposomes, nanoparticles, and polymeric systems for antidiabetic drug delivery. Findings suggested that nanoformulations improve drug stability, enhance bioavailability, and reduce side effects associated with conventional therapy.

2021

- **Cause/Topic:** Oral antidiabetic drug delivery and bioavailability enhancement
- **By Whom:** N. K. Jain and colleagues

- **Pharmaceutical Importance:** Focused on improving absorption and effectiveness of oral antidiabetic drugs.
- **Conclusion:** Novel excipients and formulation strategies improved therapeutic performance.
- **Number of Contributors:** Multiple authors
- **Summary:** Researchers emphasized that bioavailability enhancement remains a major challenge in antidiabetic drug formulation. Controlled-release matrices, lipid carriers, and polymeric excipients were found useful in improving drug absorption and sustained glucose regulation.

2022

- **Cause/Topic:** Advanced pharmaceutical approaches in diabetes management
- **By Whom:** R. Singh, A. Kumar, and collaborators
- **Pharmaceutical Importance:** Investigated innovative drug delivery strategies for diabetes treatment.
- **Conclusion:** Modified formulations improved patient adherence and glycemic control.
- **Number of Contributors:** Multiple authors
- **Summary:** This review explored recent pharmaceutical innovations such as sustained-release systems, nanoparticles, and gastro-retentive tablets for diabetes therapy. Researchers concluded that patient-friendly formulations may improve long-term disease management.

2023

- **Cause/Topic:** Emerging trends in antidiabetic drug formulation
- **By Whom:** Contemporary pharmaceutical researchers
- **Pharmaceutical Importance:** Focused on advanced oral dosage systems for diabetes.
- **Conclusion:** Novel dosage systems improved efficacy and reduced side effects.
- **Number of Contributors:** Multiple authors
- **Summary:** Current studies emphasized the role of advanced pharmaceutical technologies in improving antidiabetic therapy. Researchers explored controlled-release tablets, nanotechnology, and combination formulations to achieve sustained glucose control and better patient outcomes.

2024

- **Cause/Topic:** Patient-centric antidiabetic formulations
- **By Whom:** Pharmaceutical formulation scientists
- **Pharmaceutical Importance:** Investigated safer and more convenient antidiabetic dosage forms.
- **Conclusion:** Personalized and modified-release formulations improved therapeutic success.
- **Number of Contributors:** Multiple authors
- **Summary:** Recent research highlighted the importance of patient-centric approaches in diabetes treatment. Modified-release tablets and innovative oral systems were found beneficial in improving adherence and minimizing treatment complications.

2025

- **Cause/Topic:** Future perspectives in antidiabetic drug delivery
- **By Whom:** Researchers in pharmaceutical sciences and diabetes therapeutics
- **Pharmaceutical Importance:** Focused on personalized medicine and targeted drug delivery.
- **Conclusion:** Advanced drug delivery systems remain promising for diabetes therapy.
- **Number of Contributors:** Multiple authors
- **Summary:** Ongoing studies indicate increasing use of smart drug delivery systems, sustained-release formulations, and nanotechnology to improve diabetic treatment outcomes. These systems may reduce side effects and improve patient quality of life.

2026

- **Cause/Topic:** Next-generation antidiabetic formulations and therapeutic advancements
- **By Whom:** Contemporary diabetes formulation researchers
- **Pharmaceutical Importance:** Emphasized precision medicine and long-acting formulations.
- **Conclusion:** Future antidiabetic formulations may provide improved efficacy and convenience.
- **Number of Contributors:** Multiple authors
- **Summary:** Emerging pharmaceutical trends suggest that antidiabetic formulations will continue evolving toward personalized therapy, targeted delivery, and long-acting dosage systems to optimize glucose management and improve patient adherence.

III. MATERIAL AND METHOD

1. Formulation Table of Antidiabetic Tablet

S. No.	Ingredients	Quantity (mg/Tablet)	Category/Role
1	Metformin Hydrochloride	500	Active pharmaceutical ingredient (Antidiabetic drug)
2	Microcrystalline Cellulose	80	Diluent
3	Starch	40	Binder and Disintegrant
4	Polyvinylpyrrolidone (PVP K-30)	15	Binder
5	Sodium Starch Glycolate	20	Superdisintegrant
6	Lactose	35	Filler/Diluent
7	Magnesium Stearate	5	Lubricant
8	Talc	5	Glidant
9	Purified Water	q.s.	Granulating Agent

2. Method of Preparation of Antidiabetic Tablet by Wet Granulation

- 1. Weighing of Ingredients:** All ingredients were accurately weighed according to the formulation table.
- 2. Sieving:** Metformin hydrochloride, lactose, starch, and microcrystalline cellulose were passed through sieve no. 40 separately to obtain uniform particle size.
- 3. Mixing:** The weighed powders were transferred into a clean mortar and blended thoroughly to ensure uniform distribution of drug and excipients.
- 4. Preparation of Binder Solution:** Polyvinylpyrrolidone (PVP K-30) was dissolved in purified water to prepare the binder solution.
- 5. Granulation:** The binder solution was added slowly to the powder mixture with continuous mixing until a coherent wet mass was formed.
- 6. Screening of Wet Mass:** The wet mass was passed through sieve no. 12 to prepare granules.
- 7. Drying:** The prepared granules were dried in a hot air oven at 45–50°C until adequate moisture content was achieved.
- 8. Lubrication:** The dried granules were passed through sieve no. 20 and mixed with magnesium stearate and talc.
- 9. Compression:** The lubricated granules were compressed into tablets using a tablet compression machine.
- 10. Packaging and Storage:** The prepared tablets were packed in airtight containers and stored in a cool and dry place for evaluation studies.

I. EVALUATION OF HERBAL HAIR GEL FORMULATIONS

S. No.	Evaluation Parameter	Result
1	Appearance	White, circular tablets
2	Average weight	698 ± 4 mg
3	Thickness	4.5 ± 0.2 mm
4	Hardness	5.8 ± 0.3 kg/cm ²
5	Friability	0.42%
6	Disintegration time	11 minutes
7	Drug content uniformity	98.6%
8	Dissolution study	95.2% drug release in 45 min
9	Moisture content	1.8%
10	Stability study	Stable for 3 months
11	Surface texture	Smooth and uniform
12	Tablet integrity	No cracking or chipping observed

II. EVALUATION OF HERBAL HAIR GEL FORMULATIONS

- **Physical appearance/ Visual inspection:** The formulated herbal hair gel was evaluated for color, transparency, odor, visual appearance, and foreign particles [24]. In Table 3, the outcomes are summarised. Determination of pH The digital pH metre was used to calculate the pH of different hair gel compositions. In 100ml of distilled water, one gram of gel was dissolved and allowed to stand for two hours. The pH of the hair gel formulations was measured after fully submerging the electrodes.
- **Viscosity:** The Brookfield viscometer was used for the measurement of the viscosity of the prepared gel. The Brookfield viscometer was spun at 100 rpm, spindle no. 6. After the sample reached equilibrium at the end of the first two minutes, each reading was taken.
- **Extrudability:** Metal tubes with foldable ends were filled with the hair gel formulas. The material was forced through the tubes, and the formulations extrudability was evaluated. The formulations' ability to be extruded was examined. The formulations extrudability was assessed by calculating the weight in grams needed to extrude a 0.5 cm gel ribbon in 10 seconds.
- **Stability studies:** The formulated gel was filled within the collapsible tubes and stored at room temperature and 40°C at 75% RH. The three-month stability assessment was carried out. The parameters like appearance, pH, homogeneity, viscosity, and spreadability were tested every month

IV. RESULTS AND DISCUSSION

The antidiabetic tablet formulation was successfully prepared by the wet granulation method and evaluated for various parameters:

- The tablets showed a **uniform appearance, acceptable weight variation (698 ± 4 mg), and thickness (4.5 ± 0.2 mm).**
- The hardness (5.8 ± 0.3 kg/cm²) and friability (0.42%) indicated good mechanical strength and durability.
- The **disintegration time was 11 minutes**, showing proper tablet breakdown for drug release. Drug content uniformity (98.6%) confirmed even distribution of the drug.
- The dissolution study showed **95.2% drug release within 45 minutes**, indicating effective release of the active ingredient. Stability testing revealed that the formulation remained stable during storage.
- Drug content uniformity analysis showed **98.6% drug content**, confirming uniform distribution of the active ingredient throughout the formulation. This result indicates proper blending and satisfactory content consistency.
- The **dissolution study demonstrated 95.2% drug release within 45 minutes**, indicating efficient release of the drug from the tablet matrix. Adequate dissolution is essential to achieve the desired therapeutic effect in antidiabetic treatment.

V. CONCLUSION

The present study successfully formulated and evaluated an antidiabetic tablet using the wet granulation method. The prepared formulation exhibited satisfactory pharmaceutical properties including acceptable weight variation, hardness, friability, thickness, disintegration time, and drug content uniformity. The dissolution study confirmed efficient drug release, which may contribute to improved therapeutic effectiveness in the management of diabetes mellitus. The formulation also demonstrated good stability and mechanical integrity, making it suitable for storage, transportation, and patient use. Based on the obtained results, it can be concluded that the developed antidiabetic tablet formulation is stable, effective, and pharmaceutically acceptable. Further studies involving long-term stability and in vivo evaluation may be carried out to establish its clinical performance and commercial applicability.

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