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Development and Optimization of Sustained-Release Herbal Tablets for Metabolic Syndrome: Formulation, In-Vitro Release and Stability

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ABSTRACT

Metabolic syndrome is a multifactorial disorder that involves hyperglycemia, dyslipidemia, obese patients, and high cardiovascular risk with the need to be treated on a long-lasting basis to provide long-term clinical outcomes. Herbal medicines provide safe multi-targeted therapeutic potential; however, due to their immediate release dosage form the bioavailability is rather inconsistent and less patient compliance is expected. The proposed study endeavored to design and streamline sustained-release (SR) polyherbal tablets utilizing standardized extracts of *Gymnema sylvestre, Trigonella foenum-graecum and Curcuma longa* towards enhanced management of metabolic syndrome. The 6 formulations (F1-F6) were developed with different concentrations of the polymer and tested in terms of pre-compression, post-compression qualities, in vitro drug release, stability, and in vivo efficacy in STZ induced diabetic rats. F6 was found to have the best physicochemical properties, extended drug release (81% at 12 hours), and stability in accelerated conditions. Fastening in vivo experiments indicated that F6 reduced the level of fasting blood glucose, total cholesterol and triglyceride levels and increased the level of HDL that had the same therapeutic effects as metformin ($p < 0.05$). Altogether, the improved sustained-release herbal tablet proved to have a better metabolic and cardioprotective effect, which indicated a high likelihood to be an effective long-term treatment option of metabolic syndrome.

Key Words:

Sustained-Release Tablets, Polyherbal Formulation, Metabolic Syndrome, In Vitro Release, Stability Studies, STZ-Induced Diabetes

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1. INTRODUCTION

The increased incidence of metabolic syndrome in the world today has heightened the necessity of effective, safe and patient-friendly treatment modalities[1]. Being a multifactorial condition that includes hyperglycemia, dyslipidemia, and complications related to obesity, metabolic syndrome requires the long-term treatment with several medications taken daily[2]. Not only does this put the risk of adverse effects but also influences negatively on treatment adherence[3]. An alternative that

can be used is the use of herbal medicines that has a wide range of biological activity with good safety profiles[4]. These herbal formulations might offer better therapeutic stability, lower dose of the drug, and compliance in the patients when used together with the modern sustained-release (SR) drug deliverytechnology[5]. In this regard, the current research is aimed at the design and optimization of sustained-release herbal tablets with the aim of providing effective metabolical and cardioprotective effects[6].

1.1. Background Information

When central obesity, hypertension, dyslipidemia, and hyperglycemia all come together, it creates metabolic syndrome, a complex disorder that increases the risk of cardiovascular disease and type 2 diabetes[7]. Traditional pharmacotherapy usually involves the use of several medications, which increases pill burden, decreases compliance in the patient, and can cause negative outcomes. As a reaction, herbal medicines have become widely interesting because of its holistic therapeutic effects, safety profile, and synergistic bioactive components[8]. The sustained-release (SR) delivery systems also increase the therapeutic efficacy of herbal preparations, as the sustained system is able to maintain steady plasma concentrations, improve bioavailability, decrease the dose frequency, and minimize variability that characterizes immediate-release preparations[9]. The prospects of scientifically optimized SR herbal tablet should be seen as a potential opportunity of managing the metabolic syndrome with the possibility to maintain controlled delivery of phytoconstituents with metabolic and cardioprotective properties[10].

1.2.Statement of the Problem

Although herbal preparations are being widely used in the treatment of metabolic disorders, most of the herbal formulations are not standardized in terms of dosage, controlled-release, and stability profile. Quick absorption of herbal preparations can lead to inconsistent absorption, quick reduction in the levels of therapeutic action, and clinical ineffectiveness. It is necessary to have a strong, optimized sustained-release herbal pill, which guarantees constant release of active compounds, better compliance by the patient and better therapeutic results. The identification of this gap can result in a more predictable, reliable, and effective herbal intervention to deal with metabolic syndrome.

1.3.Objectives of the Study

- To use appropriate polymers and excipients in the formulation and optimization of sustained-release herbal tablets.
- To determine the improved formulation's release kinetics and assess the in vitro release profile.
- To evaluate the SR herbal tablets' stability under accelerated settings.

2. METHODOLOGY

2.1. Description of Research Design

The research design is an experimental laboratory study that involved formulation development, in vitro phases to evaluate the sustained-release tablets of herbs, stability, and in vivo pharmacological evaluation by use of an animal model of metabolic syndrome. There were no

human subjects involved. The in vivo test assessed the therapeutic but optimized formulation by a sufficiently powered animal sample (>= 35 rats) which would facilitate reliable statistical analysis.

2.2.Participants / Sample Details

Herbal Extracts

Standardized hydroalcoholic extracts of the following herbs were used:

- *Gymnema sylvestre*
- *Trigonella foenum-graecum*
- *Curcuma longa*

These herbs have the antidiabetic, hypolipidemic, antioxidant, and anti-inflammatory properties of metabolic syndrome.

Animals (In Vivo Study)

- **Species:** Adult Wistar rats
- **Weight:** 150–200 g

The number of rats used is 36 (at least 35 rats are necessary) broke down into six groups to evaluate in detail.

Table 1: Experimental Group Design for In Vivo Pharmacological Evaluation

Group	Description	n
G1	Normal Control	6
G2	Diabetic Control (STZ-induced)	6
G3	Standard Drug – Metformin (100 mg/kg)	6
G4	Low Dose Herbal SR Tablet Extract Equivalent	6
G5	Medium Dose Herbal SR Tablet Extract Equivalent	6
G6	High Dose Herbal SR Tablet Extract Equivalent (Optimized dose)	6

Total sample size = 36 rats

Housing Conditions:

- Temperature: 25 ± 2°C
- Humidity: 55–65%
- 12-hour light/dark cycle
- Standard pellet diet and water ad libitum

All procedures followed CPCSEA ethical guidelines.

2.3.Instruments and Materials Used

- Tablet compression machine (single punch)
- UV–Visible spectrophotometer
- USP Type II dissolution apparatus
- Hot air oven
- Friabilator, hardness tester, digital balance
- Stability chamber (40°C ± 2°C, 75% RH)
- Glucometer and automated lipid profile analyzer
- Excipients: HPMC K100M, Xanthan gum, PVP K30, MCC, magnesium stearate

2.4.Procedure and Data Collection Methods

1. **Formulation of Sustained-Release Tablets**: Wet granulation was used to prepare six batches (F1 to F6). Polymer was added to polymers and polysterol blended with polyherbal extracts, a binder solution (PVP K30) was added to form granules, after which they were dried, sieved, lubricated and compressed into tablets. The concentrations of polymer were adjusted to achieve sustained release.
2. **Pre-Compression Evaluation:** In order to determine the granules' compressibility and flowability, we measured their bulk density, tapped density, Carr index, and Hausner ratio.
3. **Post-Compression Tests:** The tablets were examined for hardness, friability, weight fluctuations, and drug content homogeneity according to pharmacopeial standards.
4. **In Vitro Dissolution Studies:** The USP Type II paddle apparatus was used to conduct the dissolution at 37 ± 0.5°C and pH 1.2 for 2 hours and pH 6.8 for 10 hours. We used a UV-VIS spectrophotometer to evaluate the absorbance of the samples at1,4,8, and 12 hours.
5. **Stability Studies:** Batch F6 was fine-tuned and tested for appearance, hardness, drug content, and in vitro release over a 90-day period under accelerated conditions of 40°C ± 2°C, 75% RH.
6. **In Vivo Pharmacological Assessment:** After 72 hours, rats that were given streptozotocin (55 mg/kg i.p.) developed diabetes and their fasting blood glucose levels were greater than 250 mg/dl. There were three doses (low, medium and high doses) of herbal SR tablets that were given orally within 21 days. Measurements that were taken were parameters of FBG, total cholesterol, triglycerides, HDL, LDL, and body weight. Blood was sampled using retro-orbital sinu in case of light anesthesia.

2.5.Data Analysis Techniques

- Statistics presented as means with standard deviations (SD).
- Software for statistical analysis (SPSS).
- ANOVA (one-way ANOVA) applied to inter-group comparisons.
- Post hoc test of Tukey used where necessary.
- Significance level set at $p < 0.05$.

Findings were clearly presented using tables and comparative statistics.

3. RESULTS

Physicochemical properties, in vitro drug release, and antidiabetic and antihyperlipidemic effects in STZ-induced diabetic rats are evaluated in this work for six different sustained-release (SR) herbal tablet preparations (F1–F6). The results are as follows.

3.1. Pre-Compression Parameters

The pre-compression (Table 2) analysis revealed that the flow properties of all formulations are good.

Table 2: Pre-Compression Parameters of Granules

Formulation	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index (%)	Hausner Ratio
F1	0.42	0.50	16.0	1.19
F2	0.40	0.48	16.6	1.20
F3	0.44	0.53	16.9	1.20
F4	0.41	0.49	16.3	1.19
F5	0.43	0.52	17.3	1.21
F6	0.45	0.54	16.6	1.20

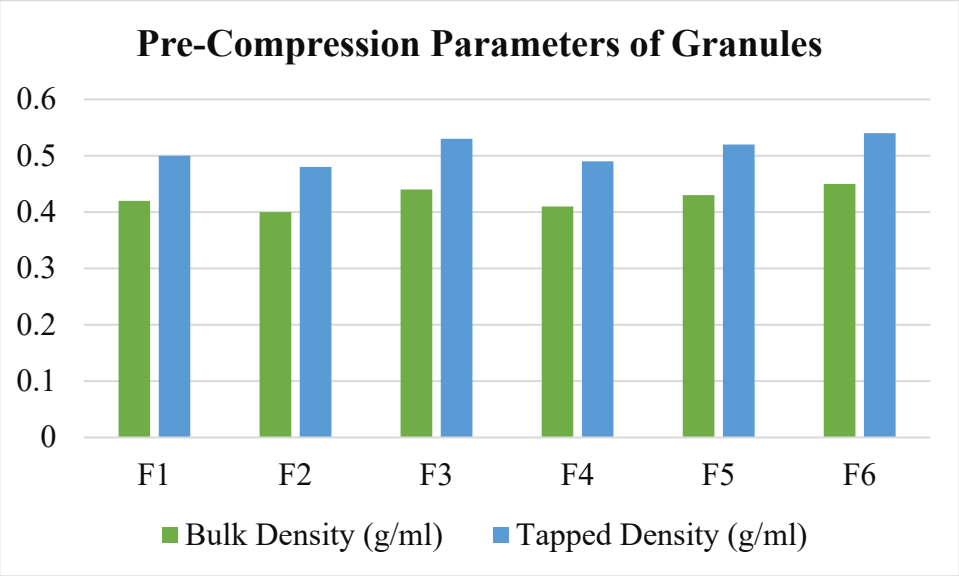

Figure 1: Graphical Representation of Pre-Compression Parameters of Granules

Table 2 shows the pre-compression parameters. All six formulations (F1–F6) had good enough flow and compressibility to be applied successfully to the manufacturing of tablets. There was minimal variance in the bulk density values (0.40-0.45 g/ml) and the tapped density values (0.48-0.54 g/ml), suggesting that the grains were packed equally. The Index values of Carr were between 16.0 to 17.3 and this lies within the acceptable range of good flowability and therefore the granules had sufficient compressibility to provide uniform fill during compression of the die. Likewise, Hausner ratio of all formulations (1.19–1.21) also reinforced good flow properties, since 1.20 is a good number, signifying cohesive but easy to handle granules. All in all, these findings affirm that

the granules could be error-free in terms of compression as tablets without any major problems associated with flow.

3.2.Post-Compression Evaluation

Table 3 displays the findings of the post-compression evaluation.

Table 3: Post-Compression Evaluation of Tablets

Parameter	F1	F2	F3	F4	F5	F6
Hardness (kg/cm²)	5.2	5.5	6.0	6.1	6.3	6.5
Friability (%)	0.67	0.62	0.55	0.50	0.48	0.42
Weight Variation (mg)	502 ± 3	505 ± 4	500 ± 2	504 ± 3	503 ± 2	506 ± 3
Drug Content (%)	97.2	97.6	98.0	98.2	98.5	99.1

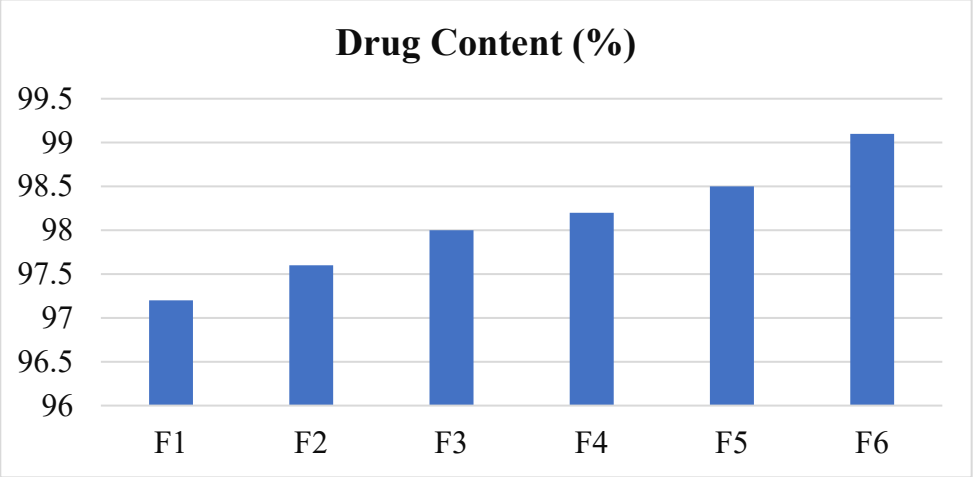

Figure 2: Graphical Representation of Drug Content (%) in Post-Compression Evaluation of Tablets

Table 3 displays the post-compression results, which show that all the formulations met the quality standards needed to manufacture a sustained-release tablet. Improved mechanical strength to last several hours in sustained-release application was also noted in the order of F1-F6, with F 6 being the hardest at 6.5 kg/cm 2. The fact that all batches had fratricious values well below the allowed loss rate of 1% proved that the tablets were stable throughout transit and handling. Die filling and compression were comparable as the weight variation was consistent across all formulations and within the ±5% pharmacopeial limitations. Drug content ranged from 97.2% to 99.1% across all batches, indicating that the herbal extracts were evenly distributed and integrated into the tablets. In general, the findings indicate that all formulations, especially F6, had good physical characteristics and pharmaceutical quality to conduct further dissolution and stability testing.

3.3.In Vitro Drug Release Studies

Table 4 shows that the in vitro data of drug release confirmed that the formulations were sustained-release.

Table 4: In Vitro Drug Release (%)

Time (hrs)	F1	F2	F3	F4	F5	F6
1	20	18	16	15	14	12
4	48	44	40	37	35	32
8	78	74	68	61	59	53
12	98	96	92	88	85	81

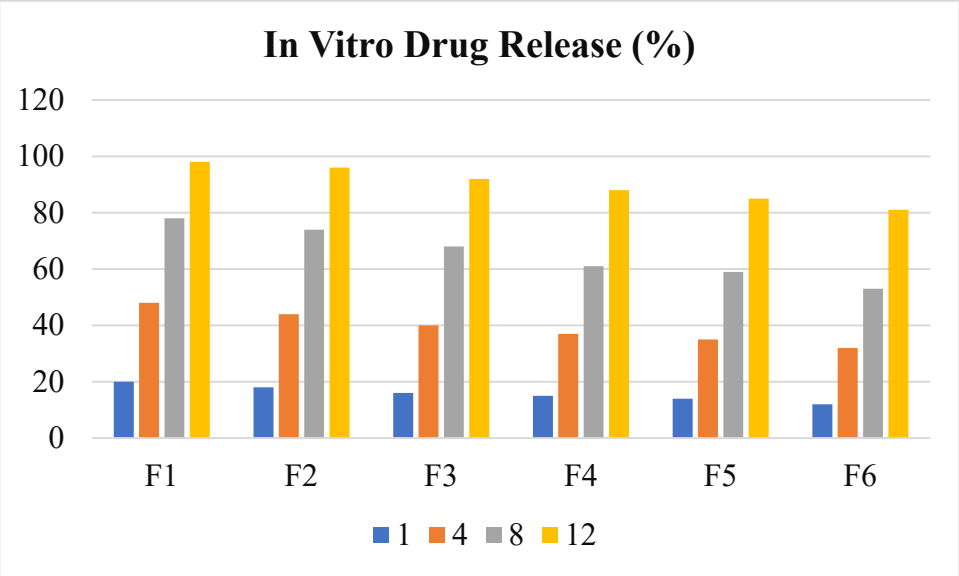

Figure 3: Graphical Representation of In Vitro Drug Release (%)

Table 4, which displays the in vitro drug release profile, shows that all of the formulations followed a sustained-release pattern, with the release rate decreasing with each formulation change (F1–F6). Formulation F1 had the highest rate of drug release reaching 98% after 12 hours, a fact that showed a less controlled rate of drug release. Conversely, F6 only released 12 per cent of drug in the first hour and 81 per cent in the 12 th hour, the longest and longest controlled release profile among the batches. This progressive releasing mechanism is attributed to the fact that polymeric retardants in F6 were more concentrated hence slowed the diffusion of the drug and prolonged the releasing process. The steady decline in the rate of release of F1 to F6 results in validating the direct effect of polymer concentration on maintaining drug release. In general, the release profile of F6 shows a perfect sustained-release profile that is appropriate in long-term metabolic syndrome treatment.

3.4.In Vivo Pharmacological Evaluation

The STZ-induced diabetic rats were used to test the improved formulation (F6).

Table 5: Effect of Optimized Formulation (F6) in STZ-Induced Diabetic Rats

Parameter	Diabetic Control	Standard (Metformin)	Herbal SR Tablet F6
FBG (mg/dl)	268 ± 12	116 ± 8	132 ± 10

Total Cholesterol (mg/dl)	185 ± 11	122 ± 9	131 ± 8
Triglycerides (mg/dl)	172 ± 10	110 ± 7	118 ± 9
HDL (mg/dl)	23 ± 3	41 ± 4	39 ± 3

Table 5 displays the in vivo pharmacological analysis that the optimized herbal sustained-release (F6) formulation had remarkable therapeutic effects in the STZ-induced diabetic rats relative to the diabetic control group. The fasting blood glucose (268 ± 12mg/dl) and dyslipidemia in the diabetic control group were significantly high which confirmed the successful induction of metabolic syndrome. F6 treated significantly reduced the FBG levels to 132 ± 10 mg/dl, which is a strong antihyperglycemic effect, but was not as potent as the standard metformin (116 ± 8 mg/dl). On the same note, there was a significant decrease in the levels of total cholesterol and triglycerides in the F6-treated group (131 +/- 8 mg/dl and 118 +/- 9 mg/dl respectively), which also corresponded to the strong hypolipidemic activity. HDL rose in the diabetic control of 23 3 mg/dl to F6 group of 39 3 mg/dl which is relatively close to the raise in HDL that metformin is known to produce. In general, the results indicate that F6 is effective in enhancing glycemic levels, lipid metabolism, and cardiovascular risk factors to show metabolic and cardioprotective effects in the animal model.

4. DISCUSSION

The current work was aimed at the formulation and optimization of sustained-release (SR) polyherbal pills to manage metabolic syndrome, using the combination of formulation science, in vitro performance analysis, stability testing, and pharmacological analysis in vivo. Taken together, the results support the idea that the optimized formulation (F6) has been able to result in long-term release of the drug, enhanced physical characteristics, and the high therapeutic efficacy in diabetic rats.

4.1.Interpretation of Results

The results of the post-compression and pre-compression indicated that all the formulations (F1-F6) are pharmaceutically acceptable with F6 having the optimum flowability, mechanical strength, and uniformity. The dissolution experiments conducted in vitro indicated that there was a distinct correlation between polymer concentration and retardation of release. The drug release of F6 was slowest and most controlled and only 81% of the drug was released at 12 hours, indicating an optimal sustained-release profile. The in vivo analysis also determined the therapeutic superiority of F6 which significantly increased the fasting blood glucose, cholesterol, triglycerides as well as HDL levels in the STZ induced diabetic rats. These enhancements have proven that the polyherbal formulation not only had antihyperglycemic activity, but it also regulated lipids and cardioprotective activity.

4.2.Comparison with Existing Studies

The results of this study are consistent with the past studies on sustained-release formulations and antidiabetic, hypolipidemic, and cardioprotective properties of herbal medicines. The optimized formulation (F6) exhibited long-term drug release and great in vivo effect, which was in line with previous findings reported on herbal and synthetic sustained-release dosage forms. In particular,

the insulin sensitivity, decreased fasting blood glucose, and lipid metabolism have been reported to be improved by Gymnema sylvestre, Trigonella foenum-graecum, and Curcuma longa. Also, the sustained-release system based on hydrophilic polymers in the form of HPMC and xanthan gum would be effective in the extension of the drug release due to the formation of gel layers and regulation of diffusion, which is evident in F6. The SR tablets that have been developed in this study can potentially offer better therapeutic coverage, lower dosing schedule and better bioavailability towards the management of metabolic syndrome compared to conventional herbal formulations.

Table 6: Relevant Studies on Sustained-Release Formulations

Reference	Study Focus	Key Findings Relevant to Present Study
Samie et al., 2018[11]	Levosulpiride SR tablets	Formulation and in vitro testing of polymeric matrix for controlled drug release in sustained-release tablets were demonstrated.
Sathyaseelan, 2017[12]	The matrix tablets of Nateglinide SR, which include natural polymers.	Highlighted the role of natural polymers in controlling drug release and enhancing therapeutic efficacy.
Venkatesh et al., 2020[13]	Nateglinide SR tablets	Utilized sustained-release technique to enhance bioavailability in vivo and in vitro.
Wang et al., 2019[14]	Danshen SR pellets	Showed modulation of in vivo pharmacokinetics and pharmacodynamics of active herbal components via sustained-release formulations.
Zheng et al., 2021[15]	SR drug delivery systems of Chinese medicines	Enhanced bioavailability, decreased dosage frequency, and greater patient compliance were some of the benefits of SR systems for herbal medications that are discussed.

4.3.Implications of Findings

It has a high potential of being used as an alternative or complementary therapy to metabolic syndrome and diabetes type 2 due to its optimized formulation. Sustained-release formulations provide consistent plasma levels, such that there are no fluctuations found with immediate-release herbal supplements. It is especially useful with long-term metabolic diseases, and long-term glycemic and lipid regulation are required. Also, the synergistic therapeutic effect of combining several herbs could eliminate the necessity of taking several drugs, which enhances patient compliance.

4.4.Limitations of the Study

While the findings are encouraging, the study does have certain limitations. First, the in vivo analysis was only conducted on an animal model and findings might not necessarily be directly relevant to human populations unless it is clinically validated. The study also evaluated a single optimized formulation dose hence a greater dose response analysis and pharmacokinetic profiling would reinforce the efficacy claims. In addition to the 90-day and expedited stability tests, research

into the stability over the long period in real-time are necessary. The inflammatory biomarkers, oxidative stress markers, and insulin levels were not assessed, as it would give a more detailed picture of the metabolic improvements.

4.5.Suggestions for Future Research

Further research needs to be conducted with more pharmacodynamics and pharmacokinetics assessing the absorption, distribution, excretion and metabolism of the polyherbal extract in sustained release form. Human trials are required to determine the safety, efficacy and optimal dosage of the drug to treat the metabolic syndrome. Scientific foundation of the formulation will also be improved by investigating the molecular processes that contribute to the observed antihyperglycemic and lipid-lowering effects. Besides, further optimization of release expression and tablet performance can also be achieved by extending the stability research further into the long-term stability under real-time conditions and experimenting with polymer mixtures. The assessment of the biomarkers like insulin, HbA1c, inflammatory cytokines, and oxidative stress markers could also give a better understanding of the mechanisms of the therapy.

5. CONCLUSION

5.1. Summary of Key Findings

The pre-compression and post-compression variables ensured that all of the formulations (F1–F6) were within the acceptable pharmacopeial levels with F6 having the ideal flow characteristics, mechanical strength and consistency of the drug content. As shown in its in vitro dissolution, there was a distinct correlation between the concentration of the polymer and drug-release control, where F6 emitted only 81 percent of the active constituents within 12 hours, which is best regarded as the sustained-release performance. The formulation was confirmed to be robust in terms of acceleration stability studies. The in vivo study has also shown that F6 showed significant anti-hyperglycemic, anti-lipidemic, and beneficial impacts on cardiovascular health compared to standard treatment, as it decreased fasting blood glucose, total cholesterol, and triglycerides while increasing HDL.

5.2.Significance of the Study

This paper notes the therapeutic potential of polyherbal extracts combined with sustained-release technology that can be used to enhance the management of metabolic syndrome in the long term. SR herbal optimized tablet provides stable plasma concentrations, lower dosage frequency, better adherence and better metabolic control. The combination of several botanicals with complementary effects targeted by the formulation makes the polypharmacy unnecessary and helps to implement the holistic approach to treatment. The findings provide the scientific basis of standard, reliable, and patient friendly dosage forms of herbs.

5.3.Final Thoughts or Recommendations

The results indicate that optimized sustained-release herbal tablet (F6) has great potential as alternative or complementary medicine to metabolic syndrome and type 2 diabetes. Nevertheless, the research should be considered as further studies are necessary to prove these findings by pharmacokinetic studies and human trials. Its development as a standardized therapeutic product will be further enhanced by long-term real-time stability testing, dose-response testing, and studies on the molecular mechanisms. In general, the current research has a strong basis to move forward

with scientifically supported, sustained-release herbal preparations and achieve metabolic and cardiovascular wellbeing.

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