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Design and Characterization of Sitagliptin-Loaded Solid Lipid Nanoparticles Embedded in PVA–Gelatin Nanofibers for Co-Delivery with Metformin

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Abstract: *Electrospun fibers can act as drug matrices, while lipid nanoparticles may provide an additional release-controlling compartment. This study describes a hybrid PVA–gelatin fiber system intended to carry metformin in the polymer phase and sitagliptin in solid lipid nanoparticles.The supplied thesis describes hot-emulsification/ultrasonication preparation of sitagliptin-loaded solid lipid nanoparticles (SLNs), followed by incorporation into PVA–gelatin solutions and electrospinning. Particle and fiber attributes, drug loading, tensile properties, and release kinetics were summarized.The thesis table reports SLN size of 152.3 ± 5.8 nm, polydispersity index (PDI) 0.21 ± 0.02, zeta potential −28.4 ± 1.7 mV, and entrapment efficiency 81.5 ± 3.2%. Hybrid fibers were reported as 355 ± 62 nm in diameter, with 9.5 ± 0.4% drug loading. The table lists t50% and t90% release times of 13.9 h and approximately 72 h for the hybrid formulation, versus 8.3 h and 24 h for plain fibers.The supplied results suggest that embedding SLNs in PVA–gelatin fibers may alter release duration and provide a dual-compartment formulation. These measurements require reconciliation with conflicting values elsewhere in the thesis, including different fiber sizes and release durations, before conclusions can be treated as verified.*

Keywords: electrospinning; solid lipid nanoparticles; hybrid nanofibers; metformin; sitagliptin; sustained release; formulation development

I. INTRODUCTION

Diabetes mellitus is a major and growing health burden. The Global Burden of Disease Study estimated 529 million people living with diabetes in 2021 and projected more than 1.31 billion by 2050 [1]. Long-term treatment often involves repeated oral dosing, and formulation approaches that improve convenience or control drug release remain of pharmaceutical interest. Electrospinning can produce high-surface-area fibrous matrices with tunable composition and drug-release behavior [2].

Combining a fibrous matrix with a secondary nanocarrier may add a further level of control. Reviews of hybrid nanoparticle–nanofiber systems describe strategies in which nanoparticles are dispersed within or deposited onto electrospun fibers to combine the properties of both structures [3]. Solid lipid nanoparticles (SLNs) are one such carrier class, with preparation and characterization approaches established in pharmaceutical research [4]. Design of experiments can support systematic formulation optimization where multiple material and process factors influence critical quality attributes [5].

The thesis supplied for this manuscript proposes a dual-drug system in which metformin is carried in a PVA–gelatin fiber matrix and sitagliptin is associated with SLNs embedded in the fibers. The present manuscript organizes the

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supplied formulation and release results as a focused pharmaceutical technology study. It does not claim clinical efficacy or establish a transdermal dose for humans.

II. MATERIALS AND METHODS

2.1 Materials

The thesis identifies metformin hydrochloride and sitagliptin phosphate as active ingredients; PVA and gelatin as the fiber polymers; glyceryl monostearate and/or stearic acid as lipid materials; and Poloxamer 188 with Tween 80 as surfactant components. The exact reagent grades, supplier details, lot numbers, and final excipient composition should be confirmed from procurement and batch records before submission.

2.2 Preparation of sitagliptin-loaded SLNs

The described process used a hot-emulsification/ultrasonication approach. The lipid phase was melted above its melting point and combined with sitagliptin. A heated aqueous surfactant phase was prepared separately. The lipid phase was added to the aqueous phase under high-shear homogenization, followed by probe sonication and cooling to solidify the lipid droplets. The resulting dispersion was centrifuged, washed, and resuspended. Exact lipid identity and concentration, drug-to-lipid ratio, homogenization speed and duration, sonication amplitude and cycle, centrifugation conditions, and batch replication must be confirmed against the laboratory notebook. General SLN preparation and characterization approaches are described by Mehnert and Mäder [4].

2.3 Preparation of nanofibers

The thesis describes preparation of a PVA–gelatin aqueous polymer blend, addition of metformin, and incorporation of a concentrated sitagliptin-SLN dispersion into the polymer solution. The resulting dispersion was electrospun using a syringe and needle onto a collector. Reported process settings include a 16 kV voltage, 15 cm tip-to-collector distance, and 0.3 mL/h flow rate for the hybrid formulation. The thesis also describes a plain drug-loaded fiber control. Polymer concentrations, solvent composition, emulsion ratio, drug mass per batch, spinning duration, environmental humidity, and independent batch count require confirmation. Electrospinning conditions are known to affect fiber morphology and performance [2].

2.4 Characterization and release testing

The thesis reports dynamic light scattering measurements for particle size and PDI, electrophoretic measurement of zeta potential, and entrapment efficiency determined by separating free drug and assaying it. Fiber diameter was assessed by microscopy, and tensile properties were measured. In vitro release was reportedly tested in phosphate buffer at pH 7.4 and 37 °C, with samples collected over time and quantified by HPLC or UV-based analysis. The assay validation, chromatographic conditions, sink-condition assessment, sampling schedule, release medium replacement, replicate count, and the drug-specific release curves must be supplied. A dual-phase model was reported for the hybrid fiber; the model selection and fitted statistics need raw-data verification.

2.5 Data analysis

The thesis refers to reporting means and standard deviations and use of design-of-experiments methods. The complete design matrix, factor levels, response definitions, software version, model equations, ANOVA outputs, post-hoc comparisons, and number of independent batches were not available in a form sufficient for reproducibility. These details should be inserted from primary records. Stability claims should be assessed using a defined protocol and interpreted in line with applicable stability guidance [7].

III. RESULTS

The following values are transcribed from the summary tables in the supplied Results chapter. The same chapters contain other nonmatching values; these table values are therefore provisional rather than independently verified.

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Table 1. Reported physicochemical properties of the two nanoparticle systems.

Carrier	Particle size (nm)	PDI	Zeta potential (mV)	Entrapment efficiency (%)
Sitagliptin SLNs	152.3 ± 5.8	0.21 ± 0.02	−28.4 ± 1.7	81.5 ± 3.2
Sitagliptin niosomes	205.7 ± 9.4	0.26 ± 0.03	−15.2 ± 2.5	64.7 ± 4.8

Table 2. Reported physical and mechanical properties of plain and hybrid nanofiber mats.

Formulation	Mean fiber diameter (nm)	Drug loading (% w/w)	Tensile strength (MPa)	Elongation at break (%)
Plain drug nanofiber	302 ± 47	9.0 ± 0.3	2.52 ± 0.15	50.1 ± 4.2
Hybrid nano-in-nanofiber	355 ± 62	9.5 ± 0.4	2.18 ± 0.10	45.3 ± 3.8

Table 3. Reported release-kinetic summary.

Formulation	t10% (h)	t50% (h)	t90% (h)	Reported model
Plain nanofiber patch	1.2	8.3	24	Higuchi / diffusion
Hybrid nano-in-nanofiber	2.5	13.9	~72	Biphasic: initial diffusion followed by prolonged phase

IV. DISCUSSION

The reported SLN table values show smaller mean particle size and higher entrapment efficiency for the SLN formulation than for the niosome comparator. Such differences are formulation-specific and should be interpreted only after checking the replicate count and assay procedure. The hybrid fiber table reports a modest increase in mean diameter and drug loading, alongside lower tensile strength and elongation than the plain fiber control. These observations are consistent with the possibility that nanoparticle incorporation changes fiber formation and mechanical response, but the supplied data do not establish the underlying mechanism.

The release table reports longer t50% and t90% values for the hybrid formulation. A multi-compartment release design can plausibly create sequential transport barriers, but the table's approximate 72-hour t90% conflicts with other thesis passages that describe release over approximately 24–48 hours. Similarly, the thesis reports fiber diameters near 500 nm in narrative sections, compared with 355 ± 62 nm and 302 ± 47 nm in its summary table. The abstract and conclusion also report different encapsulation and stability outcomes. Consequently, the present draft reports the table values while treating release superiority as a hypothesis requiring confirmation from the original curves and batch records.

Prior publications establish feasibility of electrospun fibers for antidiabetic delivery, including an insulin-loaded PVA–alginate transmucosal patch [6], and of nanoparticle–fiber hybrid architectures in drug delivery [3]. These precedents support the general formulation rationale, but they do not validate the specific performance of the metformin–sitagliptin formulation described here. Further development should include validated, drug-specific assays; mass balance; release testing with justified sink conditions; ex vivo permeation; skin irritation testing; and reproducibility across independently prepared batches. The current data alone do not establish human transdermal bioavailability or a clinically useful dose.

V. CONCLUSION

The supplied thesis describes a PVA–gelatin nanofiber system incorporating sitagliptin-loaded SLNs and metformin in the fiber phase. Its summary tables report submicron fibers, measurable drug loading, and a longer release interval for the hybrid formulation than for the plain-fiber control. These results provide a basis for a formulation-focused

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manuscript, but key values, methods, and stability findings must be reconciled with the underlying laboratory records before the work can support journal submission or claims of sustained transdermal therapy.

Declarations

Ethics approval: Not applicable to the in vitro formulation study described here; verify if any animal data are retained in the submitted manuscript.

Funding: [Insert funding source or "No external funding" after author confirmation.]

Conflicts of interest: [Authors to declare.]

Data availability: [Provide raw particle-size, microscopy, release, and batch data or repository link.]

Author contributions: [Confirm each author's contributions; do not infer from academic roles.]

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