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Formulation And In-Vitro Evaluation of Simvastatin Matrix Tablets Using Nelumbo Nucifera Leaf Mucilage as A Release Retardant

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ABSTRACT

The present study investigated the formulation and in-vitro evaluation of sustained-release matrix tablets of simvastatin using Nelumbo nucifera leaf mucilage as a natural release-retarding polymer. Six formulations (F1–F6) containing 20 mg simvastatin were prepared by wet granulation, with mucilage concentrations ranging from 5 to 30 mg per 100 mg tablet. Microcrystalline cellulose was used as diluent and magnesium stearate as lubricant. Granules were evaluated for bulk and tapped density, compressibility index, Hausner ratio and angle of repose. Tablets were assessed for weight variation, hardness, thickness and friability. The reported granule data showed bulk density values of 0.42–0.52 g/cm³, tapped density values of 0.52–0.62 g/cm³ and angles of repose of approximately 30.15–33.62°. Tablet friability was reported between 0.12 and 0.35%, while hardness ranged from 6.32 to 7.55 kg/cm². In-vitro dissolution data showed 52.19% release from pure simvastatin at 960 min. Formulation F6 released 91.36% at 960 min, whereas F5 released 98.45% at the same time point. The thesis reports F6 as the formulation with the most prolonged release and describes first-order and Korsmeyer–Peppas models as suitable release models; however, the supplied kinetic table does not fully establish a single best-fit model without additional model details. Overall, the findings suggest that Nelumbo nucifera leaf mucilage may be explored as a matrix-forming release retardant. Data inconsistencies and missing methodological details must be verified against original laboratory records before submission.

Keywords: Simvastatin; Nelumbo nucifera; leaf mucilage; matrix tablet; sustained release; dissolution.

INTRODUCTION

Oral tablets remain a widely used dosage form because they are convenient to administer, comparatively stable and suitable for large-scale manufacture. Sustained-release matrix tablets are designed to modulate drug liberation over an extended period, potentially reducing fluctuations in drug exposure and dosing frequency. In hydrophilic or natural-polymer matrices, hydration, swelling, diffusion and matrix erosion can collectively influence the release profile.^[3,5] Simvastatin is an HMG-CoA reductase inhibitor used in the management of dyslipidaemia. The dissertation motivating this work identifies its relatively short plasma half-life as a rationale for examining modified-release delivery. Plant-derived mucilages are of interest as pharmaceutical excipients because polysaccharide-rich materials can form hydrated matrices and may be economical alternatives to some synthetic polymers. Nelumbo nucifera leaf mucilage was therefore selected as the release-retarding material.^[14,15] The objective of this study was to prepare simvastatin matrix tablets containing increasing amounts of Nelumbo nucifera leaf mucilage and compare their granule properties, tablet quality attributes and in-vitro dissolution behaviour.

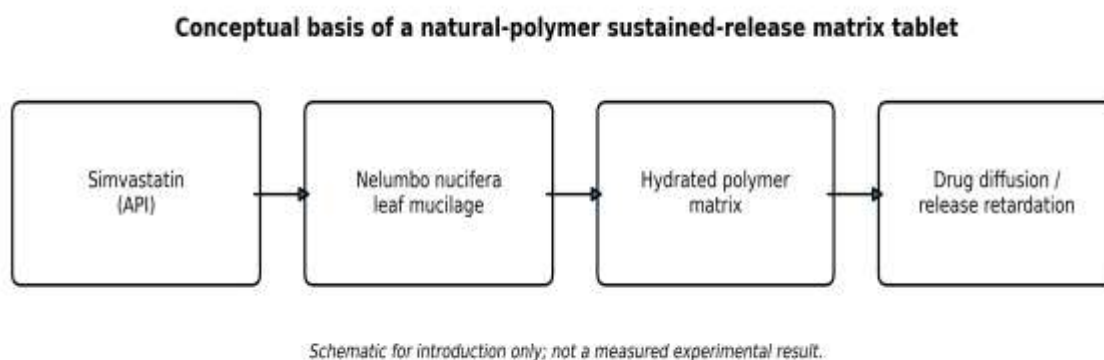


Figure 1. Conceptual schematic of simvastatin release from a natural-polymer matrix. Schematic only; not experimental evidence.^[14]

The proposed formulation concept is illustrated in Figure 1: the active ingredient is incorporated into a matrix-forming natural mucilage, which hydrates in dissolution medium and may retard drug transport through diffusion and matrix relaxation/erosion. This diagram is conceptual and does not represent a measured result.

MATERIALS AND METHODS

Materials

Simvastatin was an active pharmaceutical ingredient. Nelumbo nucifera leaf mucilage was used as the matrix-forming release retardant, microcrystalline cellulose as diluent and magnesium stearate as lubricant. The supplied dissertation should be consulted about the exact suppliers, grades and batch details; these were not reproduced in the accessible formulation table.^[3]

Formulation design

Six 100 mg tablet formulations were described. The amount of simvastatin and magnesium stearate was held constant, while the mucilage amount increased from 5 to 30 mg and microcrystalline cellulose was reduced correspondingly.^[5,14]

Table 1. Composition of simvastatin matrix tablet formulations (mg/tablet).

Ingredient (mg/tablet)	F1	F2	F3	F4	F5	F6
Simvastatin	20	20	20	20	20	20
Nelumbo nucifera leaf mucilage	5	10	15	20	25	30
Microcrystalline cellulose	72.5	67.5	62.5	57.5	52.5	47.5
Magnesium stearate	2.5	2.5	2.5	2.5	2.5	2.5
Total tablet weight	100	100	100	100	100	100

Preparation of matrix tablets

According to the dissertation, the ingredients were passed through a #100 sieve, weighed and blended. Granules were prepared using a wet-granulation technique and compressed using an 8/32 flat punch. The source does not provide sufficient detail in the extracted method to reproduce the binder solution, granulation end-point, drying temperature and duration, final granule size, compression force or batch yield. These parameters should be added from the original laboratory notebook before journal submission.

Pre-compression evaluation

Granule blends were evaluated for bulk density, tapped density, compressibility index, Hausner ratio and angle of repose. Bulk and tapped densities were obtained using a graduated cylinder. Compressibility index and Hausner ratio were calculated from the density measurements, while angle of repose was assessed using a funnel method, as described in the dissertation.^[1,2]

Post-compression evaluation

The tablets were assessed for weight variation, hardness, thickness and friability. The reported method descriptions refer to conventional tablet quality tests; however, instrument models, sample numbers and detailed test settings should be confirmed and reported.^[1,2]

In-vitro dissolution and release kinetics^[6,7,8]

The thesis reports comparative in-vitro dissolution data for pure simvastatin and formulations F1–F6 over 0–960 min. The dissolution medium, apparatus type, medium volume, temperature, agitation speed, sampling/replacement procedure and analytical wavelength were not consistently available in the extracted results text and must be verified before submission. The dissertation includes kinetic-model correlation coefficients for zero-order, first-order, Higuchi and Korsmeyer–Peppas models.

3. RESULTS AND DISCUSSION OF RESULTS

The following figures have been added from values reported in the thesis. Calibration-curve points are the source-table values. Kinetic plots are linearized plots recalculated from the reported dissolution table, not screenshots of the thesis's original regression outputs. The supplied four-panel FTIR spectra are included as provided and should be checked against original instrument records.

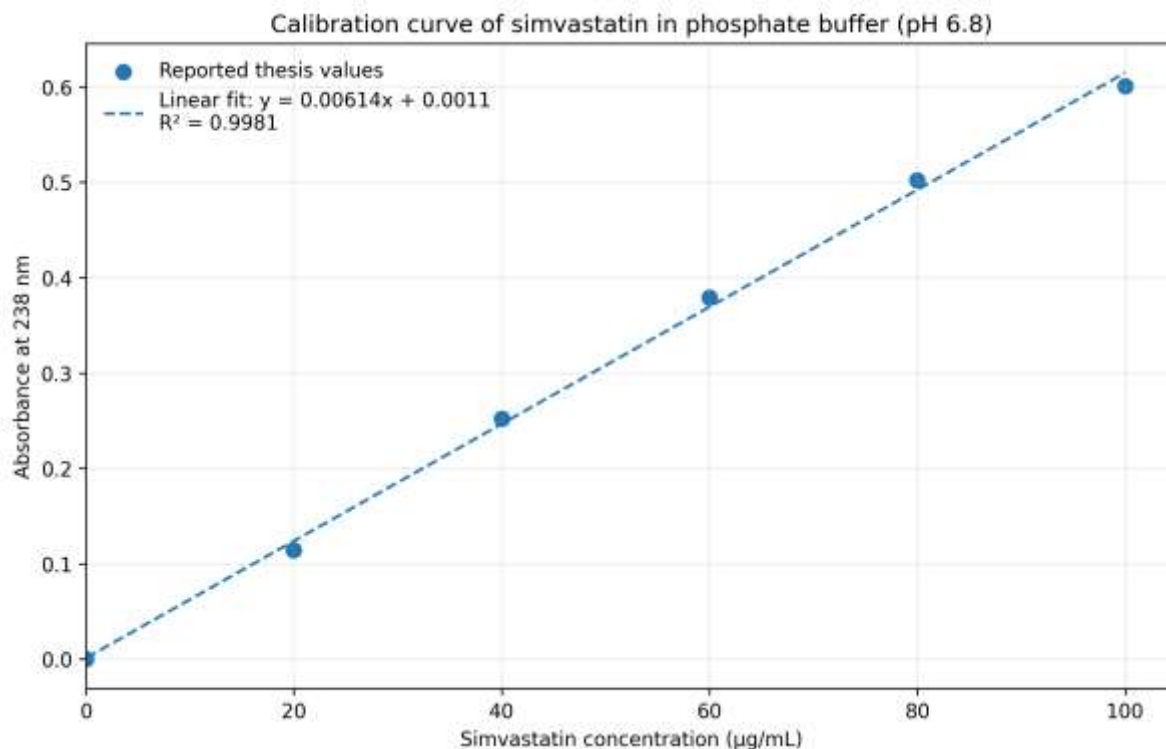


Figure 2. Simvastatin calibration curve at 238 nm

Linear regression recalculated from the six reported points: $A = 0.00614C + 0.0011$; $R^2 = 0.9981$. The thesis reports slope 0.0061 and $R^2 = 0.9981$, consistent after rounding.

FTIR spectra of simvastatin, polymer and physical mixture

The supplied FTIR figure compares pure simvastatin, polymer, the simvastatin–polymer physical mixture, and an overlay of the three spectra. The interpretation values transcribed from the supplied source table are shown in Table 7.

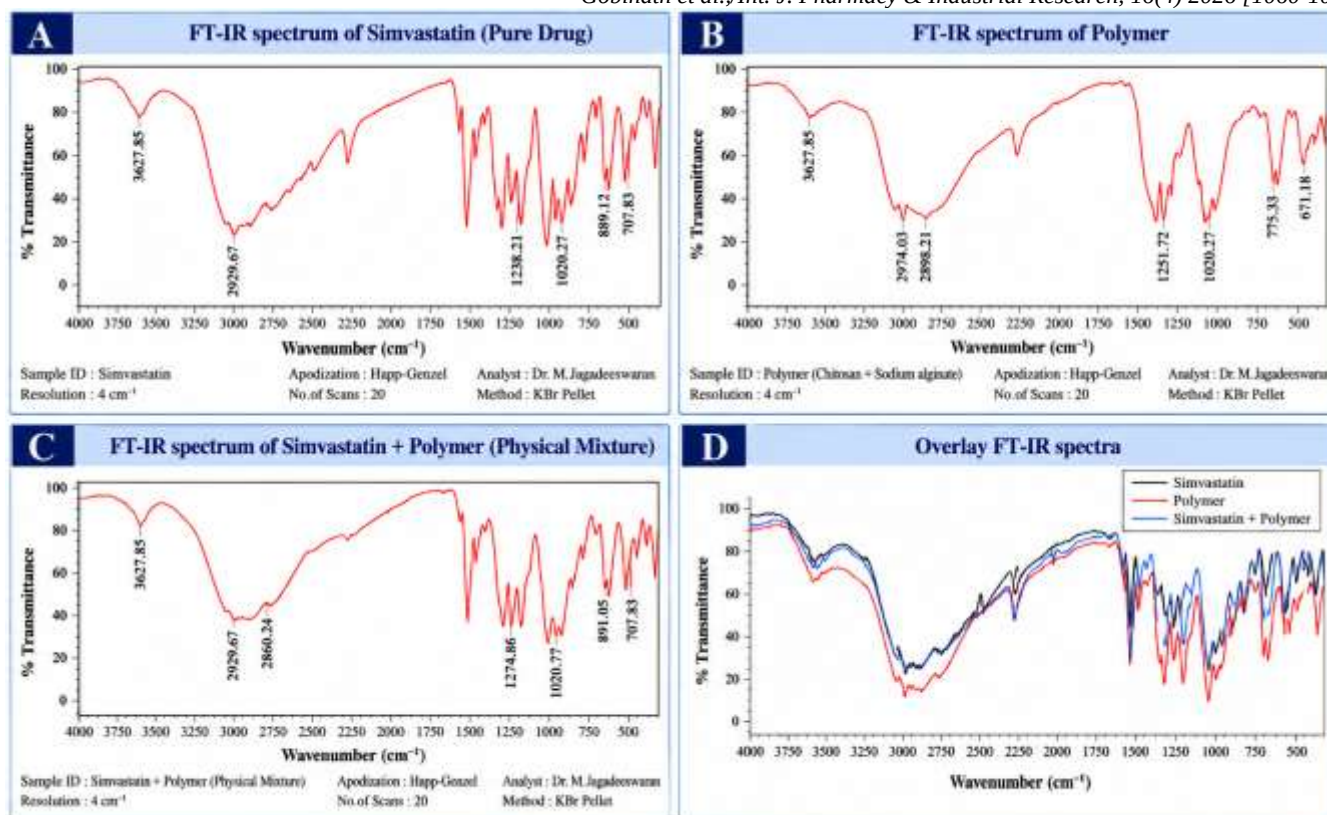


Figure 3. FT-IR spectra of (A) simvastatin (pure drug), (B) polymer, (C) simvastatin + polymer (physical mixture), and (D) overlay spectra.

Table 2. FTIR peak positions reported for simvastatin, polymer and physical mixture (cm^{-1}).

Reported transition	Simvastatin (cm^{-1})	Polymer (cm^{-1})	Physical mixture (cm^{-1})
O–H stretch (reported range 3640–3610 cm^{-1})	3627.85	3627.85	3627.85
C–H stretch (reported range 3000–2850 cm^{-1})	2929.67	2898.21–2974.03	2860.24; 2929.67
Lower-wavenumber bands (source table labels N–H stretch)	889.12–707.83	775.33; 671.18	891.05–707.83
C–O stretch (reported range 1320–1000 cm^{-1})	1238.21–1020.27	1251.72–1020.27	1274.86–1020.77

The supplied table reports an O–H band at 3627.85 cm^{-1} in all three samples. The C–H and C–O regions overlap broadly, although the reported positions/regions differ in some entries. The thesis narrative describes no obvious peak shift or disappearance in the physical mixture. This is consistent with no major readily detectable change in the reported bands, but it does not establish complete drug–excipient compatibility. The lower-wavenumber region is labelled as N–H stretching in the supplied source table; this assignment must be verified against the original spectrum before submission.

Pre-compression parameters

The reported bulk density ranged from 0.42 to 0.52 g/cm^3 and tapped density from 0.52 to 0.62 g/cm^3 . The compressibility index values were approximately 11.97–13.46%, while Hausner ratios were reported as 1.04–1.18. Angles of repose ranged from 30.15° to 33.62° . Some density and derived-index combinations in the source table do not appear arithmetically consistent; values are transcribed as reported and require checking against raw data.

Table 3. Pre-compression properties of granule blends.

Formulation	Bulk density (g/cm ³)	Tapped density (g/cm ³)	Compressibility index (%)	Hausner ratio	Angle of repose (°)
F1	0.47±0.04	0.57±0.03	11.97±0.06	1.04±0.07	33.62±0.24
F2	0.45±0.09	0.52±0.08	12.50±0.12	1.13±0.04	32.83±0.51
F3	0.42±0.03	0.56±0.02	12.73±0.05	1.14±0.08	31.44±0.23
F4	0.50±0.07	0.58±0.09	13.36±0.09	1.10±0.05	30.15±0.42
F5	0.52±0.09	0.62±0.07	13.13±0.03	1.18±0.01	31.89±0.37
F6	0.51±0.05	0.57±0.06	13.46±0.07	1.16±0.07	31.47±0.71

Post-compression parameters

Tablet hardness was reported between 6.32 and 7.55 kg/cm², thickness between 4.48 and 4.59 mm, and friability between 0.12 and 0.35%. The source table contains a wide range of reported weight-variation values and some unusually large standard deviations; these entries should be verified before the manuscript is submitted.

Table 4. Post-compression evaluation of simvastatin matrix tablets.

Formulation	Weight variation (%)	Hardness (kg/cm ²)	Thickness (mm)	Friability (%)
F1	0.45±0.06	6.44±0.12	4.56±0.06	0.35±0.22
F2	0.52±0.03	6.32±0.22	4.54±0.03	0.25±0.17
F3	0.41±0.87	7.39±0.36	4.48±0.06	0.12±0.14
F4	0.84±0.04	7.10±0.58	4.49±0.04	0.28±0.11
F5	0.36±0.43	7.39±0.34	4.53±0.02	0.14±0.15
F6	0.25±0.14	7.55±0.63	4.59±0.07	0.29±0.12

In-vitro dissolution profile

The reported dissolution profile showed 52.19% release from pure simvastatin at 960 min. At the same time point, F5 released 98.45% and F6 released 91.36%. F6 displayed the lowest reported release at several early and intermediate time points among the tablet formulations, consistent with a comparatively prolonged release profile. However, F1 reached 96.00% at 480 min, indicating that the comparative profile is not uniformly slower for F6 at all times. The thesis narrative also contains a wording inconsistency by describing F6 as showing “increased dissolution” while simultaneously identifying it as the most sustained formulation.

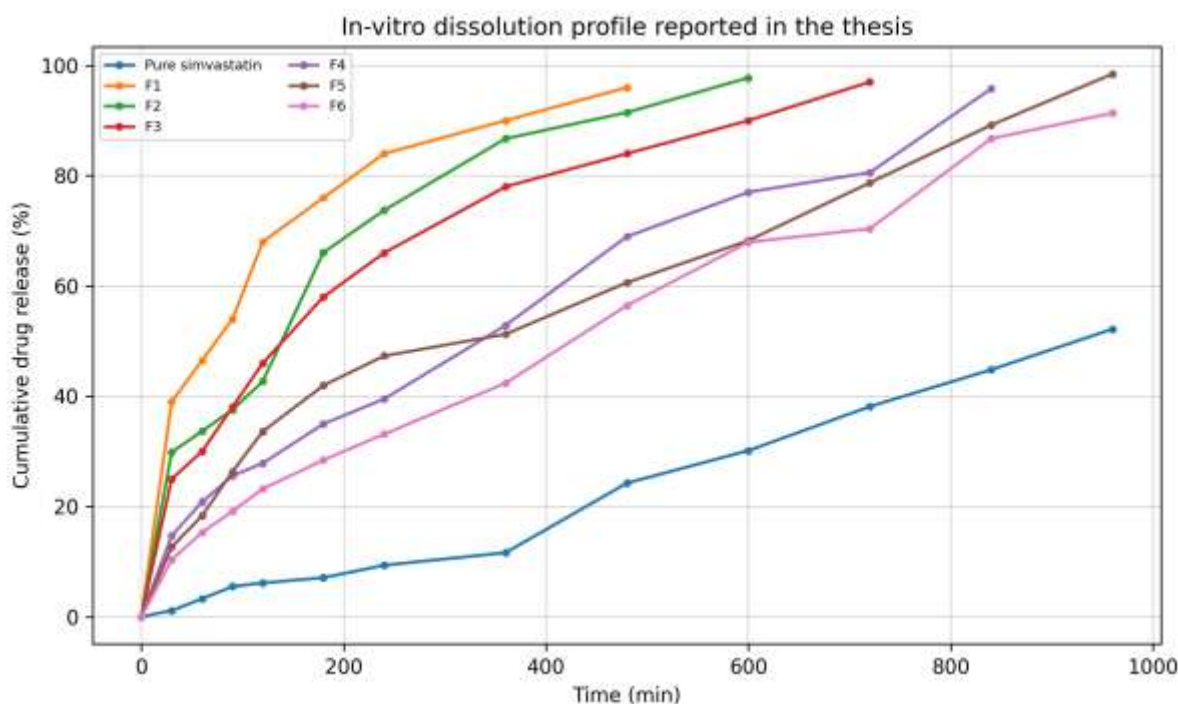


Figure 4. Comparative in-vitro dissolution profile reconstructed from the numerical values in reported dissolution table in the supplied dissertation. Missing entries are left unplotted; no values were imputed.

Table 5. In-vitro dissolution data reported for simvastatin and formulations F1–F6 (% cumulative release).

Time (min)	Pure drug (%)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)
30	1.14	39.00	29.86	25.00	14.71	12.67	10.35
60	3.28	46.50	33.65	30.00	20.85	18.33	15.31
120	6.14	68.00	42.71	46.00	27.87	33.62	23.21
240	9.35	84.00	73.74	66.00	39.52	47.32	33.14
480	24.26	96.00	91.47	84.00	68.97	60.63	56.46
600	30.15	—	97.75	90.00	77.01	68.24	67.95
720	38.14	—	—	97.00	80.57	78.72	70.38
840	44.82	—	—	—	95.78	89.19	86.72
960	52.19	—	—	—	—	98.45	91.36

Release-kinetic analysis

The dissertation provides correlation coefficients for the tested kinetic models. For F6, the reported values were 0.937 for zero-order, 0.990 for first-order, 0.941 for Higuchi diffusion and 0.993 for Korsmeyer–Peppas. On the basis of these reported coefficients, Korsmeyer–Peppas had the highest R^2 for F6, followed by first-order kinetics. The exponent n and the model-fitting procedure are not clearly provided in the extracted summary; therefore, the release mechanism should not be assigned definitively without checking the original calculations.

Table 6. Reported coefficients of determination (R^2) for release-kinetic models.

Formulation	Zero-order R^2	First-order R^2	Higuchi R^2	Korsmeyer–Peppas R^2
F1	0.984	0.994	0.931	0.975
F2	0.980	0.990	0.934	0.989
F3	0.985	0.995	0.931	0.994
F4	0.883	0.986	0.941	0.989
F5	0.804	0.968	0.965	0.984
F6	0.937	0.990	0.941	0.993

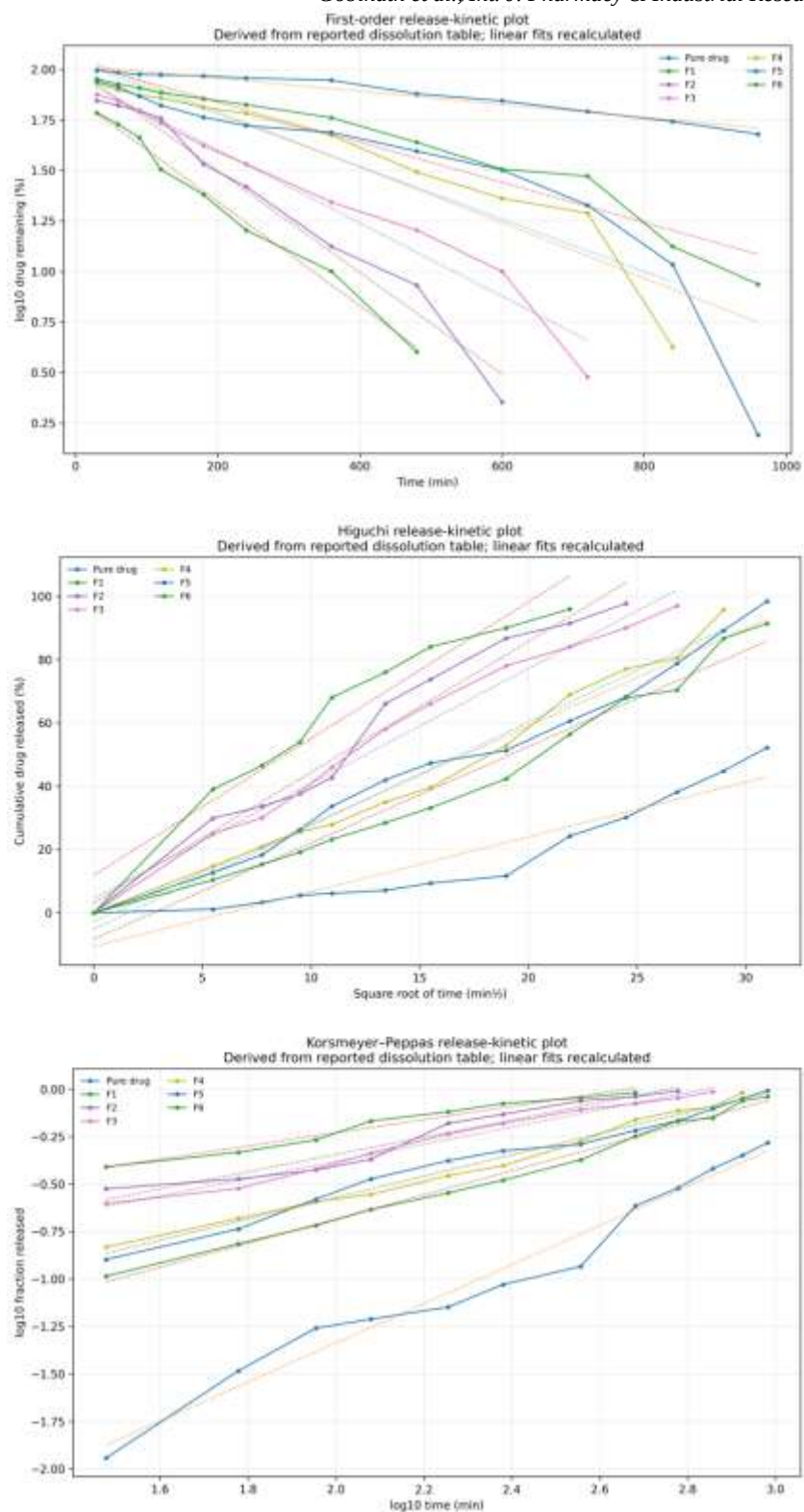


Figure 5. Linearized release-kinetic plots: first-order, Higuchi and Korsmeyer–Peppas models. Lines were recalculated from the reported dissolution table.

DISCUSSION

Increasing the amount of *Nelumbo nucifera* leaf mucilage was accompanied by a general reduction in the early dissolution values across the formulation series, particularly for F6. This observation is consistent with the potential role of a hydrated polymeric matrix in restricting medium penetration and drug diffusion. The higher late-time release of F5 relative to F6 suggests that polymer amount may influence the balance between matrix hydration, diffusion and erosion, although the present dataset alone cannot establish the mechanism.^[3,4,5,6,7] The physical evaluation results indicate that the prepared tablets had measurable hardness and low reported friability. Interpretation is limited by internal inconsistencies in several standard-deviation entries and some derived granule parameters. Further, the thesis refers to FTIR compatibility, but a quantitative peak table and spectra should be included in the submission only after verifying the original figure and assignments. The current manuscript therefore avoids claiming a definitive compatibility outcome beyond the dissertation's qualitative statement.^[1,2] The dissolution table contains blank entries after certain time points, likely reflecting sampling schedules or reported table omissions. These have been retained as missing rather than interpolated. Before publication, the authors should reconcile the time-point schedule, confirm the dissolution conditions and repeat the kinetic analysis from the complete original dataset. Statistical significance cannot be assessed because the number of replicates and raw replicate values are not clearly stated in the extracted results.^[11,12,13]

CONCLUSION

The supplied dissertation reports the preparation of six simvastatin matrix tablet formulations using *Nelumbo nucifera* leaf mucilage at 5–30 mg per 100 mg tablet. The in-vitro dissolution data suggest that F6, containing 30 mg mucilage, provided a more prolonged release profile than several lower-mucilage formulations, with 91.36% release at 960 min. However, F5 reached 98.45% at the same time point, and the reported data require verification before identifying a definitive optimum. *Nelumbo nucifera* leaf mucilage merits further evaluation as a natural release-retarding excipient, subject to confirmation of raw data, method details and kinetic calculations.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

All authors contributed to the conceptualization, methodology, formulation development, investigation, data analysis, interpretation of results, and preparation of the manuscript. All authors reviewed and approved the final version of the manuscript.

DATA AVAILABILITY

The experimental data generated and/or analyzed during the current study, including formulation, evaluation, drug-release and stability data, are available from the corresponding author on reasonable request.

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