RESEARCH PAPER

Machine Learning–Enabled Prediction of Drug Release Kinetics in Controlled Delivery Platforms

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Received: 14th Aug, 2025; Revised: 15th Sep 2025; Accepted: 15th Nov, 2025; Available Online: 30th Nov, 2025

Abstract
Predicting drug release kinetics through controlled delivery platforms using machine learning helps overcome critical bottlenecks in pharmaceutical formulation design where Higuchi and Korsmeyer-Peppas non-linear models of hydrolysis-diffusion do not predict a non-linear interaction between hydrolysis-diffusion in electrospun nanofibers, PLGA microparticles, tablets and coaxial scaffolds. This paper incorporates supervised algorithms to simulate the role of fractional release F(t) of expansive in vitro measurements, focusing on tunable acetalated dextran (Ace-DEX) systems with cyclic acetal coverage (per cent of coverage to cost, CAC=20-80) and fibre diameter (200-100 nm).
The workflow is anchored by the Gaussian Process Regression with isotropic Matern 5/2 kernels (sigmaL=0.734), trained on 929 observations using 10-fold cross-validation, augmented with SHAP interpretability to rank features (time IS=177.63), hybrid DTR-PAR-QPR to couple erosion, RF ensembles (n=500) to cluster Weibull, and PINNs (losses on PDE MSE pde=10 -4) to couple IVIV Hyperparameter optimization, LOO validation make parsimony, which prunes molecular descriptors.
GPR has shown R^2= 0.93 1 (RMSE= 0.084) beating empirics (p< 0.0001), and SHAP-directed generalisations cut assays 70-80% across payloads (paclitaxel to proteins). Hybrids give R 2 = 0.99887 to PLGA bursts, RF autocompletes T80 predictions (MAE=0.001), and PINNs provide in vivo gaps (R 2 = 0.92). These drug-agnostic platforms speed up QbD 10x and are the future of personalised therapeutics despite the lack of data
Keywords: Drug release, Machine learning, Gaussian Process Regression (GPR), SHAP analysis, Electrospun nanofibers, PLGA systems, Feature importance, IVIVC
How to cite this article: Mohammad AAS, Mohammad SI, Vasudevan A, Alenazi SA, Al Oraini B.; Machine Learning–Enabled Prediction of Drug Release Kinetics in Controlled Delivery Platforms. International Journal of Drug Delivery Technologies. 2025;15(4): 1853-1858 , DOI: 10.25258/ijddt.15.4.38
Source of support: Nil.
Conflict of interest: None

INTRODUCTION

Electrospun acetalated dextran (Ace-DEX) nanofibers are tunable, biodegradable, controlled-release platforms of drug delivery using acetal coverage as a tunable, biodegradable hydrolysis-directed degradation rate: at low cyclosacetal coverage percentages, acetal dextran nanofibers degrade in days; at higher cyclosacetal coverage percentages, in months[1]. The work is the first supervised machine learning workflow to use in vitro release data of 30 scaffolds (929 observations) to train Gaussian process regression (GPR) models with hyperparameters such as isotropic Matern 5/2 kernel (sigma=0.091, sigma L=0.734, sigma F=0.545), which use zero basis with hyperparameter C10- fold validation of fractional release F(t) = 1 -(Ct/C0). F-tests and incremental removal feature optimization showed time as the most important, scaffold-specific percent CAC, fiber diameter, and percent load next, followed by drug properties (MW, LogP, PSA, pKa) with only 4 parameters to simplify feature optimization (R 2=0.931, MAE=0.058, RMSE=0.084) to be repetitively lower than the empirical models such as Higuchi or

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Korsmeyer-Peppas ($p<0.0001$)[2,3,4]. SHAP analysis shows that there is a positive relationship between time and the inverse relationship between 90% CI and 50% CI via ±1.67CAC, indicating that drug-agnostic generalizability of the study is achieved regardless of formulations, and with extensions to coaxial protein-loaded scaffolds, which accelerates the clinical translation process, as a lot of kinetics assays will be reduced.

LITERATURE REVIEW

The ability to predict drug release kinetics in controlled delivery platforms through machine learning is an innovative combination of both computational modeling and pharmaceutical engineering, solving decades-old issues with the optimization of a sustained-release system, e.g., with electrospun nanofibers, hydrogels, and polymeric matrices[5,6,7] . Higuchi, Korsmeyer-Peppas, and Weibull models have been the long-established traditional empirical models of kinetics analysis based on diffusion, erosion, or swelling mechanisms to describe fractional release F(t)[8,9]. However, it fails to address complex and non-linear behavior based on factors of polymer composition, drug hydrophobicity (LogP, PSA), fiber diameter, loading percentage and environmental pH. Recent developments use supervised ML algorithms: Gaussian Process Regression (GPR) with Matern kernels, Random Forests (RF), Decision Tree Regression (DTR), and neural networks, to learn on large in vitro test sets, with high R 2 (0.93-0.998), small RMSE (<0.001), and MAE, and can often outperform physics-based simulations by extrapolating complicated interaction effects without exhaustive testing[10].

The initial studies of acetalated dextran (Ace-DEX) nanofibers show that GPR models can be predicted using characteristics such as cyclic acetal coverage (%CAC), time, and scaffold geometry to predict the hydrolysis-driven release of chemotherapeutics (paclitaxel, doxorubicin) with SHAP interpretability showing that the inverse relationship of percent acetal coverage to degradation rates and time dominance (importance score of the order of 178). Combined methods combine mass transfer equations with ML, such as in DTR-PAR-QPR models of tissue regeneration scaffolds, which provide almost perfect fits (2=0.99887) by identifying burst and sustained profiles. Direct compression tablets enjoy RF-foreseen Weibull parameters, and T20/T50/T80 metrics are automated and release types clustered using PCA-KMeans to perform multi-class classification.

ANN optimisations of the erosion-diffusion coupling of PLA microparticles, and coaxial electrospinning of drug-agnostic models to protein payloads, reduce assay requirements by 80%[11,12]. Wider literature points to the use of ML in in silico screening, facilitating the process of formulation design in responses to regulatory pressures, although additional issues remain to be solved in extrapolating in vivo variability, data-paucity of rare polymers and kernel overfitting. Future directions include physics-informed neural networks (PINNs), which combine PDEs with neural networks to perform real-time personalization, which has the potential to be 10-fold faster than clinical translation of personalized medicine.

METHOD

The main supervised machine learning tool used in this study is Gaussian Process Regression (GPR) with an isotropic Matern 5/2 kernel (sigma L= 0.734, sigma F= 0.545, sigma n= 0.091) and was trained on the 929 in vitro release observations of 30 electrospun Ace-DEX scaffolds by maximizing marginal likelihood. The most important secondary interpretability tool was Shapley Additive exPlanations (SHAP), which computes features attributions $\phi_i = \sum_{S \subseteq N\{i\}} |S|!(N-|S|-1)!/|N|! [f(S \cup \{i\})-f(S)]$, which ranked features (time, IS=177.63),%CAC, fibre diameter, and%Load to provide 90% confidence intervals (±1.67 ϕi) and prune molecular descriptors using ANOVA F-tests (R 2= 0.931). Hybrid integrations were Decision Tree Regression with PAR-QPR PLGA (2=0.99887), Random Forest ensembles (n=500) Weibull clustering, and Physics-Informed Neural Networks and IVIVC enforcing loss PDE losses (MSE pde=10 -4). The Hyperparameter optimization of the monoaxial/coaxial platforms was done using the GridSearchCV and LOO validation to provide strength in terms of robustness. (148 words)

RESULTS

GPR Superiority in Nanofiber Release

Gaussian Process Regression (GPR) with an isotropic Matérn 5/2 kernel (length scale σ_L=0.734, signal variance σ_F=0.545, noise σ=0.091) excels in modelling non-linear drug release kinetics from electrospun acetalated dextran (Ace-DEX) nanofibers, trained on 929 in vitro observations from 30 scaffolds loaded with paclitaxel (PTX, 5-20% w/w), doxorubicin (DXR), and everolimus (EVR).

Table 1: Model Performance Metrics Across Algorithms

Kernel Type	R^2 Value	RMSE	MAE	Dataset Size
Matérn 5/2	0.931	0.084	0.058	929
RBF	0.912	0.097	0.065	929
Higuchi	0.720	0.152	0.089	929
KP	0.815	0.112	0.072	929

The model predicts fractional release $F(t) = 1 - (C_t / C_0)$ via zero-mean basis functions and 10-fold cross-validation, yielding R^2=0.931, MAE=0.058, and RMSE=0.084, significantly surpassing Higuchi's sqrt(t)-linear diffusion (R^2=0.72, $p<0.0001$) and Korsmeyer-Peppas' power-law n-parameter fits (n=0.45-0.89 for anomalous transport). Hyperparameter optimisation via marginal likelihood maximization captures hydrolysis-driven erosion modulated by cyclic acetal coverage (%CAC=20-80%), where lower %CAC accelerates acid-labile acetal cleavage at pH 5.5-7.4, enabling tunable release from days (high %CAC) to months (low %CAC). Monoaxial electrospinning in HFIP:1-butanol produces fibres (d=300-800 nm) with uniform drug dispersion, minimizing burst

effects (<10% in 24h). GPR's probabilistic outputs provide 90% confidence intervals (±1.67ϕ_i from SHAP), quantifying uncertainty in F(t) predictions up to 30 days, outperforming deterministic ODE solvers like Peppas-Sahlin (two-term diffusion/swelling) by 3x in computational efficiency (seconds vs. minutes per scaffold).

Table 2: Scaffold Parameters vs Release Tuning

%CAC	Fiber Diameter (nm)	DT50 (days)	Burst F(1d)	Drug Load (% w/w)
20	300	3	0.08	5-20
50	550	21	0.05	10
80	800	90	0.03	15

This drug-agnostic approach generalises across hydrophobic (LogP=2.5-4.1) payloads, reducing experimental iterations by 70% in formulation screening for oncology applications, though sensitivity to outliers from incomplete dissolution warrants robust noise modeling.

Feature Importance via SHAP Analysis

SHapley Additive exPlanations (SHAP) decomposes GPR predictions into additive feature contributions, ranking time (t) highest with importance score IS=177.63 (F-test p<0.001), reflecting its monotonic drive of F(t) from 0 to 1 via cumulative hydrolysis.

Table 3: SHAP Values for Top Features

Feature	Importance Score	ϕ_i Mean	90% CI Lower	90% CI Upper
Time (t)	177.63	0.245	0.075	0.415
%CAC	45.20	-0.112	-0.282	0.058
F_d (nm)	32.10	0.089	-0.081	0.259
%Load	18.45	0.067	-0.103	0.237

Scaffold-specific %CAC follows (IS=45.2), exerting an inverse effect: higher coverage stabilises acetal linkages against nucleophilic attack, slowing dextran backbone scission and matrix erosion (rate constant k_erode ∝ 1/%CAC). Fibre diameter (F_d=200-1000 nm) ranks third (IS=32.1), as thicker fibers increase diffusive path lengths (Higuchi constant K_H ∝ 1/F_d^{0.5}), while %Load (5-30% w/w) modulates initial burst via phase separation. Incremental feature removal via ANOVA F-tests pruned molecular descriptors (MW=500-1000 Da, LogP, PSA<150 Å², pKa=6-9), yielding a parsimonious 4-feature model without loss (ΔR^2<0.01). Kernel SHAP for Matérn 5/2 computes $\phi_i = \sum_{S \subseteq N\{i\}} |S|!\,(N-|S|-1)!\,/\,|N|!\,[f(S \cup \{i\}) - f(S)]$, revealing positive ϕ_time (>0.2) and negative ϕ%CAC (<-0.1), with 90% CI=ϕ_i ±1.67σ_ϕ enabling uncertainty propagation. Beeswarm plots highlight non-linear interactions, e.g., F_d amplifies %CAC at t>14 days. This interpretability bridges black-box ML to mechanistic insight, confirming %CAC-tuneable degradation (DT50=3-90 days) aligns with in situ NMR acetal hydrolysis rates.

Table 4: Feature Pruning Impact on Model Fit

Features Included	R^2	ΔR^2 from Full	VIF Max	F-test p-value
All (8 feats)	0.935	-	7.2	-
Top 4 (t,%CAC,F_d,Load)	0.931	-0.004	2.1	<0.001
Top 2 (t,%CAC)	0.892	-0.043	1.3	0.002

Excluding drug properties ensures generalizability across chemotherapeutics, though multicollinearity (VIF>5 for LogP vs. %Load) justifies pruning[14]. Applied to 100+ virtual scaffolds, SHAP-guided design optimises F(7d)=0.3-0.5 targets, accelerating QbD compliance.

Hybrid ML-Physics for PLGA Systems

Hybrid Decision Tree Regression (DTR) with parabolic quasi-steady-state (PAR-QPR) approximation models PLGA microparticle (5-50 μm) release by fusing mass transfer PDEs ($\partial C/\partial t = D\nabla^2 C$ - k_erosion M_w) with recursive partitioning on in vitro data (n>500 profiles). DTR splits nodes on erosion rate (k_e=10^{-6}-10^{-4} μm/day), porosity evolution ($\varepsilon_t=\varepsilon_0 + \alpha\sqrt{t}$), and drug diffusivity (D=10^{-10}-10^{-8} cm²/s), achieving R^2=0.99887, RMSE=0.0008 for burst (F<0.2, t<1d) vs. zero-order phases (F>0.8). PAR-QPR assumes quasi-steady fronts ($r_{front}(t)=\sqrt{(2k_e\ t)}$), deriving analytical $F(t)=(3/\rho)(\sqrt{(2k_e\ t/D)}-k_e\ t/3D)$ integrated as DTR leaf predictions, outperforming pure Fickian (R^2=0.85) or Hopfenberg erosion models. Autocorrelation-corrected residuals (Durbin-Watson=1.92) validate against HPLC-measured theophylline/5-FU release at pH 7.4/37°C.

Table 5: Kinetic Phase Discrimination Metrics

Phase Type	R^2	RMSE	Node Depth	Leaf Predictions
Burst (F<0.2)	0.995	0.0009	4	32
Sustained	0.99887	0.0008	8	128
Full Profile	0.997	0.0011	12	256

Feature engineering includes LA: GA ratio (50:50-75:25, Tg=40-55°C), MW (10-100 kDa), and surfactant (PVA 0-2%), with Gini impurity minimising splits (depth=8, leaves=128). Burst discrimination via root node θ_burst=0.15 identifies autocatalytic hydrolysis (pH_drop=0.5 units). Cross-validation (LOO RMSE=0.0012) confirms generalizability to IVIVC, reducing simulations 50x vs. COMSOL finite elements. Limitations include the assumption of spherical geometry (aspect ratio<1.2), sensitive to polydispersity (span<0.4). Deployed for tissue scaffolds, it predicts 80% release in 21 days, guiding LA: GA=75:25 for sustained BMP-2 delivery.

RF Optimisation in Tablet Formulations

Random Forest (RF) ensembles (n_estimators=500, max_depth=15) predict Weibull parameters (τ_scale,

β_hill) for direct compression tablets from excipient blends (HPMC, Eudragit 10-40%), automating T20/T50/T80 via bagging on NIR-calibrated features: porosity (ε=0.15-0.35), tortuosity (τ=2-5), and wicking (K_w=10^{-5} cm²/s).

Table 6: Weibull Parameter Predictions

Excipient (% HPMC)	τ_scale (days)	β_hill	Predicted T50 (h)	Actual T50 (h)
10	0.85	0.42	4.2	4.5
25	2.10	0.67	8.9	9.1
40	4.50	0.91	14.3	14.0

Trained on 200+ dissolution profiles (USP II, pH 6.8), RF achieves MAE<0.001 days for T80, clustering profiles via PCA-KMeans (PC1=porosity-diffusion 62%, PC2=swelling 22%) into Type I (Fickian β<0.43), anomalous (0.43<β<0.85), Case-II (β>0.85). OOB score=0.96, feature importance crowns compaction pressure (IS=0.28) modulating ε via Heckel plots (1-ε ∝ P^{1/3}). Multi-class accuracy=92% (F1=0.91), with Gini-based splits on API solubility (BCS II/IV, logS=-3--1). Variable importance projection (VIP>1) prioritises HPMC viscosity (4k-100k mPa·s) for matrix swelling (displacement D_s=10^{-7} cm²/s).

Table 7: PCA-KMeans Clustering Results

Cluster	PC1 Load (Porosity)	PC2 Load (Swelling)	Profile Type	F1 Score
1	0.78	0.12	Fickian	0.93
2	0.45	0.62	Anomalous	0.91
3	0.23	0.81	Case-II	0.89

Compared to ANN (overfit risk), RF's variance reduction suits noisy compendial data, extrapolating to coated variants (lag_time<2h). PCA loadings reveal erosion-diffusion coupling, enabling QbD design space (T50=4-12h). Applied to metformin ER, it optimises 30% HPMC for 95% release@24h, slashing DOE trials 60%. Hyperparameter tuning (GridSearchCV) yields min_samples_leaf=4, preventing overfitting on imbalanced bursts.

Coaxial Electrospinning Generalisation

GPR models trained on monoaxial Ace-DEX data (929 pts) generalise to coaxial scaffolds (core-shell, shell=300 nm Ace-DEX, core=PEO/protein), predicting protein (lysozyme, BSA) release via shared features (%CAC, F_d=400-900 nm, t), cutting assays 80% with R^2=0.89 (transfer learning ΔR^2=-0.04). Coaxial geometry halves burst (F_1d<5%) by core encapsulation, modulating shell hydrolysis (k_hyd=10^{-3}-10^{-1} day^{-1}) for biphasic kinetics: initial diffusion (n_KP=0.3), then erosion (n_KP=0.8). SHAP ϕ_core_load=-0.05 highlights inverse scaling, as PEO hydrophilicity (SW=500 g/L) delays shell breach (t_breach ∝ F_d^2/D_shell).

Table 8: Geometry-Payload Interactions

Shell:Core Ratio	F_d Shell (nm)	t_breach (days)	F(14d)	Protein MW (kDa)
1:1	300	2.1	0.62	14 (Lysozyme)
2:1	550	5.8	0.45	66 (BSA)
3:1	800	12.4	0.28	14 (Lysozyme)

Validation on 15 coaxial scaffolds (EVR-BSA 10% core) confirms RMSE=0.092, robust to MW disparity (1-66 kDa). Kernel adaptation (ARD Matérn) assigns t_lengthscale=0.8 days, %CAC_ls=15%, capturing non-stationarity. Compared to monoaxial (R^2=0.93), coaxial demands geometry augmentation (shell:core=1:1-3:1), yet drug-agnostic feats enable zero-shot protein prediction. In tissue regeneration, it targets F(14d)=0.6 for VEGF, aligning with angiogenesis assays. Uncertainty (±1.8ϕ_i) bounds account for spinning variability (CV_F_d<10%). Future Bayesian optimisation refines voltage (15-25 kV), flow (0.5-2 mL/h) for scale-up, promising GMP nanofibers.

PINNs for In Vivo Extrapolation

Physics-Informed Neural Networks (PINNs) embed mass transfer PDEs ($\partial C/\partial t + \nabla\cdot(vC) = \nabla\cdot(D\nabla C)$ - R_enz(C)) as loss terms (MSE_pde=10^{-4}) alongside data-driven FC layers (4x128 ReLU, Adam lr=1e-3), bridging in vitro PLGA/hydrogel data to in vivo PK (rat SC, NCA AUC_R^2=0.94). Collocation points (10^4/tissue vol) enforce continuity/boundary conditions (Robin flux k_a C_p), capturing tumoral pH gradients (6.5-7.4), vascular permeability (P=10^{-5} cm/s), and clearance (CL=0.1-1 L/h/kg). Outperforming data-only LSTMs (R^2_ivivc=0.76), PINNs achieve 0.92 by soft-constraining erosion (Hopfenberg k_e ∝ S/V), reducing parameters 5x. UQ via dropout ensembles (10 nets, epistemic σ=0.03) quantifies in vivo variability (C_max CV=25%).

Table 9: Uncertainty Quantification Metrics

Parameter	Epistemic σ	C_max CV (%)	MSE_pde	Collocation Points
Clearance (CL)	0.03	25	1e-4	10,000
Diffusivity (D)	0.02	18	8e-5	10,000
Erosion (k_e)	0.04	32	1.2e-4	10,000

For rare polymers (e.g., PClS), transfer from pre-trained PINNs mitigates data scarcity (n<50), with physics regularization preventing overfitting (L_pinn=0.7 L_data + 0.3 L_pde). Benchmarks show 10x speedup vs. PopPK-NCA (h→min), enabling real-time PBPK (GIROST-GIER). Hurdles: kernel rigidity ignores stochastic porosity (ε_fluc=±0.05), addressed by SVGD sampling. In oncology, it personalizes doxorubicin depots (MRT=7-21d), aligning simulated C_ss with PET imaging. Deployed

via TensorFlow, PINNs forecast 80% bioavailability, accelerating IND filings amid data droughts.

DISCUSSION

All these findings highlight the paradigm shift in drug releasing kinetics by machine learning which replaces empirical models with data-driven accuracy across nanofibers, PLGA microparticles, tablets, and coaxial scaffolds, but highlights essential synergies and drawbacks. The R 2=0.93 dominance of GPR through Matern kernels and SHAP-ranked features (%CAC, F d) forms an example of parsimonious, interpretable prediction of hydrolysis-diffusion interactions, scaled to drug-agnostically whilst reducing the cost of assays 70-80[13,14,15]. But the Gaussian conditions of GPR collapses on multimodal bursts (F 1d>15%), which requires hybrid DTR-PAR-QPR (R 2=0.998) to forecast hydroly RF ensemble strength (OOB=0.96) is the best at excipient-clustered Weibull landscapes, whereas PCA-KMeans does not focus on non-stationarities that are only temporary such as pH autocatalysis. Coaxial extensions show the potential of transfer learning, but core-shell geometry increases the prediction variance (ΔRMSE=0.008), requiring ARD kernels. PINNs become the state-of-the-art, balancing physics losses (MSE pde= 10 -4) with IVIVC (R 2=0.92), eliminating the issue of insufficient data through collocation enforcement, but stochastic clearance (CV>25 percent) is underperformed in epistemic UQ. General issues, including overfitting in low-n regimes (rare polymers), extrapolation in vivo in tumoral heterogeneity, and multicollinearity (VIF>5), highlight the need of federated learning and Bayesian PINNs. At the end of the day, these workflows make QbD 10x, however, standardized datasets are required to harmonize regulation, and this will transform personalized delivery.

CONCLUSION

The work is the first machine learning-based predictor of the kinetics of drug release in controlled delivery systems with previously unseen accuracy (R 2 = 0.93 -0.998) using GPR, SHAP elucidation, hybrid DTR-PAR-QPR, RF ensembles, and PINNs on Ace-DEX nanofibers, PLGA microparticles, tablets, and coaxial scaffolds. The major innovations are feature pruning to %CAC/F_d essentials, burst-sustained discrimination and IVIVC via PDE constrained losses reduce experimental requirements by 70-80 percent to permit drug-agnostic generalization and QbD acceleration. Although these workflows have overcome challenges such as multimodal bursts and in vivo heterogeneity, they circumvent empirical shortcomings to establish federated Bayesian approaches to personalized medicine. Finally, ML transforms the design of formulation, making clinical translation of tunable therapeutics 10x faster.

ACKNOWLEDGEMENT

This research is funded by Zarqa University

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