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International Journal of Medical Science and Dental Health (ISSN: 2454-4191)
Volume 11, Issue 12, December 2025
Doi: https://doi.org/10.55640/ijmsdh-11-12-06

Diffusion, Kinetics, And Thermal Transport in Sol–Gel–Derived Pharmaceutical Manufacturing Technique: An Applied Physics Review

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Received: 29 November 2025, **accepted:** 12 December 2025, **Published Date:** 20 December 2025

Abstract

Sol-gel (S-G) provides an attractive, low-temperature approach for encapsulating sensitive drugs and has thus become a key method in the modern pharmaceutical manufacturing. Yet successful industrialization depends on being able to control the basic laws of physics underpinning formation and properties of materials. This review in applied physics compiles and distills recent literature around these three interacting pillars—diffusion, reaction kinetics, and thermal transport. Drug release kinetics are controlled by the diffusion mechanisms, following non-Fickian behavior modulated by matrix porosity and drug–matrix interaction. The kinetics of the reaction (pH-dependent hydrolysis and condensation) itself program the final material structure, density, and longer-term hydrolytic and chemical stability of the encapsulated payload. Thermal transport and heat/mass coupling during drying constitute the principal engineering problem: uncontrolled gradients lead to internal stresses, cracking and unacceptable heterogeneities of batches. We believe the rational design, scale-up and robust, compliant drug product manufacturing of S-G derived pharmaceutical products necessitates the integration of predictive tools (e.g., computational fluid dynamics and advanced in situ characterization).

Keywords: Sol-gel, Fickian Diffusion, predictive models, CFD

Introduction

The pharmaceutical manufacturing and advanced drug delivery field currently depends more heavily on materials science than ever in order to solve some of the most challenging issues related to bioavailability, chemical stability and controlled release kinetics (Ezike et al., 2023). Traditional methods of formulation frequently do so under rugged conditions (including high temperatures, detrimental organic solvents or high levels of shear) and as a result therapeutically delicate molecules like complex biologics or nucleic acids are likely to be compromised. In this specific framework, the sol-gel (S-G) process has appeared as a highly versatile and potential production platform. This process consists of transforming a colloidal suspension (sol) into a continuous solid network (gel), and is usually carried out under gentle aqueous media. The S-G process can encapsulate various payloads into well-controlled structures of glass or ceramics through room temperature processing, with superior protection and regulation than those systems prepared by polymer encapsulation. The obtained materials, which include xerogels, aerogels or nanoscale carriers, are porous with high specific surface area and pure chemical composition

that is inherently significant for drug dissolution increase as well as the modulation of drug release kinetics (Merghes et al., 2024).

The successful development and industrialization of S-G manufacturing does not only rely on the control over the precursor chemistry, but primarily on understanding and controlling the applied physics that decides about how to effectively go from solution to final solid. Although much literature has focused on the conditions factors for chemical synthesis (e.g., pH, precursor concentration and choice of solvents), within material science community, extensive research themes mostly emphasize multicentral attributes in the chemical level, ignoring some essential physics related phenomena. Rational design requires an in-depth but cohesive understanding with respect to the fundamental physical principles, including diffusion phenomena, reaction kinetics and thermal transport (Szczyglewska et al., 2023).

Diffusion is the main principle for all drug delivery systems based on S-G. After the loading of therapeutic agent into the porous gel network, its release to the biological surroundings mainly depends on molecular diffusion in confined space of matrix (Adepu et al., 2021). For the period post-2015, research has shifted to establish predictive kinetics model of drug release beyond pure Fickian diffusion. The intricate nature of S-G matrics (ie., pore size distribution, tortuosity, and surface chemistry) leads to non Fickian or anomalous transport phenomena with drug release frequently following zero-order or first-order kinetics that is essential for sustained release formulations. Advanced investigations employ, for example, techniques such as PFG-NMR (Pulsed-Field Gradient Nuclear Magnetic Resonance) to determine local diffusion coefficients in situ and to correlate them with the gel aging and drying behavior affording a mechanistic connection from S-G processing physics to the intended therapeutic outcome (Fu & Kao, 2009).

The reaction kinetics of the hydrolysis and condensation during sol–to–gel-phase transition are equally important. The molecular level kinetics of the chemical transformations are very sensitive to temperature, pressure and the local concentration of catalysts (such as H+OH ions), all of which are governed by mass and heat transfer in the bulk phase. The mate-rial properties, such as bond density, network connectivity and pore wall thickness are direct consequences of these reaction rates (Espinosa et al., 2021). Weak interactions, such as slow kinetics, often form highly crosslinked, denser gels providing better mechanical stability and safeguarding of sensitive drugs. On the other hand, fast kinetics may result in kinetically driven, heterogeneous structures with potential adverse effects on the long-term chemical stability of the encapsulated content. Recent progress, typically utilizing in-situ spectroscopic techniques (such as Fourier Transform Infrared Spectroscopy, (FT-IR), Raman spectra) and computational fluid dynamics modeling representing the chromatographic approach, has made it possible to accurately describe these reaction kinetics for the ideal maximization of the encapsulation efficiency and a minimization of drug degradation during processing (exemplified by, e.g., kinetic control of recent S-G preparation methodology) (Workman, 2024).

Last, but not least, thermal transport and thermal management are important aspects especially for the post-gelation drying/aging process as well as in scaling up for manufacturing purposes. The transfer of heat during solvent removal (drying) needs to be strictly controlled, as local temperature gradients can generate capillary pressure which produces macro-scale defects in the form of cracking and 20 non-uniform density materials (Li et al., 2023). This type of heterogeneity leads to batch-to-batch variation in drug loading and release kinetics, which represents a substantial bottleneck for pharmaceutical regulatory approval. In the case of large reactors or continuous process lines, uniform thermal transport is required for reproducible material structures. Modern engineering workdays include sophisticated computational modeling of heat and mass transfer to estimate three-dimensional thermal profiles to enable the manufacturer to define a range of safe processing windows that avoid thermal damage to the drug, but promote formation of a structurally intact matrix (Lach & Svyetlichnyy, 2024).

Despite a proliferation of individual post-2015 studies on these phenomena, processing often disconnects these concepts in the current literature and there remains a recognized lack in systematically reviewing the applied physics principles that universally connect the processing conditions to the function of the end read pharmaceutical dosage form. It is essential integrate this various knowledge bases—diffusion, reaction kinetics,

and thermal transport—with one cultural canopied applied physics to generate new ideas for the design space and to be able troubleshoot product failures within the pharmaceutical industry (Musil et al., 2021).

We have reviewed recent literature (years 2015 to present) to summarize the quantitative, physics-based models that control the formation of S-G materials and their performance. Through this focus on these basic transport and kinetic processes, we arm researchers and engineers with the conceptual tools to move from an emprical trial-and-error approach in thier development of next generation S-G derived pharmaceutical products to one guided by rational, predictive design.

Diffusion Mechanisms and Kinetics in Sol-Gel Matrices

Sol-gel (S-G) processed pharmaceutical carriers, particularly in controlled release scenarios are largely driven by the physical mechanisms controlling transport of an encapsulated therapeutic agent from a solid matrix into surrounding biological fluid (Ezike et al., 2023). While the erosion or dissolution of some drug carriers is thought to facilitate drug release from them, S-G matrices are chemically stable in physiological conditions, particularly silica or organically modified silica (ORMOSIL)-derived ones, and molecular diffusion has been found to be the dominant contribution towards drug freedom/disassociation from them (Merghes et al., 2024). As a result, due to this fundamental importance of diffusion-related mechanisms and the corresponding release kinetics, it is required an in-depth understanding about it itself in order for successful design of S-G pharmaceutical formulations (permeation rate prediction and manipulation).

The microstructure of the S-G matrix is a main factor that controls diffusion behavior. The S-G process—allowing different hydrolysis, condensation and subsequent aging and drying processes—is delicately tailored to create networks with well-defined porosity, pore size distribution, and surface area (Adepu et al., 2021). They possess highly connected pore networks and large surface area to volume ratios, which induce strong confinement effects. The tortuosity of the pore pathway (the ratio of actual path length) is especially important for diffusion rate slowing. In addition, the average radius of a pore should be some orders of magnitude larger than the size of the drug molecule in order to allow the transport. It has been shown that small changes in the gelation environment, which affect the extent of polymerization and aggregation, can significantly alter the final porous structure such that one directly programmes the time-dependent drug release kinetics (Li et al., 2023).

For an idealized high porous non-swelling inert matrix, the release may simulate initially Fickian diffusion in which the rate is proportional to concentration gradient (J=- D∇C) (Workman, 2024). However, the majority of model reporter S-G systems under biological conditions show a kinetic behaviour that is more complex than Fickian (non-Fickian or anomalous). 64 This non-linearity results from the fact that drug release is in many cases interrelated with time dependent effects within the matrix, such as swelling of the polymer (Higuchi type relaxation) or dissolution. These two processes together are often described by the empirical power law model, known as Korsmeyer-Peppas-model:

$$\frac{M_t}{M_\infty} = kt^n$$

where \(Mt/M∞) is the fraction of drug released over time \(t\), k indicates a kinetic constant and n corresponds to a diffusion exponent, representing the release mechanism. Values of n around 0.5 generally indicate classical Fickian diffusion, whereas values near 1 result from zero-order kinetics or highly complex diffusional mechanism controlled by swelling or relaxation of matrix (Case II transport) that are commonly found in a polymer-modified S-G system. S-G processing can be mastered to tailor the rheological properties of the material with intentional modification of the value of release exponent n hence able to develop formulations that achieve desired sustained, linear release profiles (zero-order kinetics) (Fu & Kao, 2009).

Apart from the physical framework, drug-matrix interactions have an important role in controlling diffusion kinetics. Lumina of silica-based materials usually carry some residual silanol (SiOH) groups that may participate in hydrogen bonding or electrostatic interactions with polar or charged drugs. Such interactions bring in a kinetic term -so called adsorption/desorption kinetics, in which the drug molecules are transiently adsorbed on the walls of pores reducing their net diffusive flux (Espinosa et al., 2021).

This effect is employed by researchers through chemically modifying the pore surface (e.g., silylation or grafting) to lower polarity or incorporate particular functional groups so that no adverse retention and a faster release rate is stimulated, or conversely, increasing binding for ultra-slow release. It is important to control these surface interactions in order to avoid the early "burst release," a characteristic of an unmet chemistry, which commonly occurs when drug molecules are only very weakly confined (Mohanan et al., 2024).

With the recent development in applied physics, advanced in situ characterizations can now be used to probe and quantify molecular transport into this confined S-G environment. Techniques such as Pulsed-Field Gradient Nuclear Magnetic Resonance (PFG-NMR) have been employed to measure the self-diffusion coefficient (*D*) of the drug and solvent molecules inside pore matrix directly, which is a non-invasive parameter for direct insight into the local mobility and interaction strength (Schiller et al., 2004). Also, techniques such as Fluorescence Recovery After Photobleaching (FRAP) are also used to probe diffusion in porous thin films and coatings where they connect macroscopic release rates with the microscopic molecular dynamics. These new analytical techniques are critical towards validating complex mathematical models (e.g., those which include distributed parameters or dynamic pore evolution) and transitioning the field from empirical observation to predictive engineering, thus providing a clear feedback loop between material microstructure and diffusion physics (Musil et al., 202)

Governing Material Structure and Chemical Stability

The transformation from the solution of the precursor (sol) to a porous solid structure (gel) is governed by a complex series of chemical events commonly referred to as sol-gel kinetics. A good mastering of these kinetics is necessary since it establish the instantaneous rates of these reactions, which control not only the texture (structure, density and porosity) at microscopic level but also in definitive terms, long-term chemical stability of final pharmaceutical carrier. In contrast to conventional approach for which the structural constitution of materials is established through physical mixing or annealing, the S-G strategy provides a solution method to chemically program the structure of the material (Espinosa et al., 2021).

The S–G process involves two primary, interrelated reactions (usually for alkoxysilane precursors $(SiOR)_4$: hydrolysis and condensation. The first step of the hydrolysis is the reaction between the precursor and water, in which organic alkoxy groups (OR) are replaced with hard silanol cyclic structures (Si-OH). The mechanism of this step is highly responsive to the pH value of the solution and to the amount of water to precursor ratio (R). In acidic catalysis, the rate of the hydrolysis reaction is usually higher leading to more linear polymer structure prior to gelation. On the other hand, in an alkaline environment, condensation usually occurs more rapidly than hydrolysis, leading to the formation of small and spherical primary particles that connect each other to build up dense nanonetworks with many branches. This strong pH dependence of relative reactivities constitutes the central chemical handle by which manufacturers adjust pore size (Sinkó, 2010).

After hydrolysis, the condensation takes place when two silanol groups (or a silanol group and an alkoxy group) react during the formation of a stable siloxane bridge (Si-O-Si), with water/alcohol elimination. 7 This polymerization serves to create the three-dimensional, well-defined and strong network characteristic of the gel. The kinetics of the condensation is crucial, when the ctm value decreases with aging, a low into open network, presenting more activation sites as reactive functions convert into –COOH groups and forming a higher degree of connectivity materials (with few residual reactivity in comparison to initial structure), less pore size and denser than without. On the other hand, fast condensation traps the system in an unstable, open and less densely packed structure with a higher concentration of terminal Si-O groups. Therefore, regulating the kinetic competition between hydrolysis and condensation rates allows for a fine control of final matrix density and pore geometry – parameters that directly influence the diffusion rate described in the previous section (Zhang et al, 2023).

This correspondence is directly measurable by analyzing the fractal dimension of the gel network and the G' during reaction. Researches involving in-situ measurements, e.g. rheometry and small-angle X-ray scattering (SAXS), have followed the kinetics of the formation of gel point and consolidation that follows network. These findings further confirm that materials produced by slow, controlled kinetics are structurally homogeneous with excellent mechanical integrity and

well-defined pore size distribution, while materials where fast, uncontrolled kinetics predominate are characterized by structural defects and a large batch-to-batch variability (Lach & Svyetlichnyy, 2024).

Of particular importance is that the kinetics of reaction govern the thermochemical stability of the loaded drug. S-G processing, although performed at low temperature is felt to necessitate maintaining the drug active in the reactive sol environment for the time of gelling. If solid-state kinetics are retarded to produce a particular structural feature (e.g., tighter packing), the longer contact time with acidic or basic catalysts and residual solvents can lead to enhanced chemical breakdown or denaturation in sensitive drugs like proteins or vaccines. Thus, successful pharmaceutical S-G production requires the identification of an appropriate kinetic window: slow enough to achieve a uniform porous structure but fast enough not to expose the drug to the reactive medium (Robnik et al., 2019).

In addition, the extent of condensation (α) obtained during aging stages determines long-term hydrolytic stability of the material itself. Gels which are not fully condensed still have more unreacted silanol groups. These materials are vulnerable to hydrolytic degradation and material collapse when introduced into an aqueous physiological environment, resulting in unpredictable "dump" payload release. Regulating S-G kinetics for nearly full condensation produces a chemically resistant Si-O-Si network that can withstand months or years (and perhaps indefinitely) while retaining the zero-order or sustained release profiles. Accordingly, by managing reaction kinetics, the S-G material functions properly upon administration and remains structurally sound over both product shelf-life and therapeutic time (Merghes et al., 2024).

Heat Transfer Modeling for Manufacturing Scalability

The greatest challenge in scale-up of laboratory-scale S-G synthesis into a pharmaceutical production process is obtaining batch uniformity and reproducibility at the critical, post-gelation steps, i.e., aging and drying. As much as the kinetics of the sol-to-gel phase programming is responsible for designing the microscopic structure, it is thermal flow and heat/mass transfer coupled problems which are responsible for repeating over a macroscopic soundness and performance operation accommodation. Drying, which involves the extraction of residual solvent from a highly porous gel network, is essentially a heat and mass transfer process: heat is required to remove or evaporate the solvent (mass transfer), and the transport of vapour and liquid phase influences the temperature distribution inside the gel (Smith & Chen, 2017). The lack of control during this step leads to material bad[punctuation markerting, non-homogeneous structure as well as inability to achieve GMP grade (Boel et al., 2020).

The most destructive effect of non-uniform thermal transport is the appearance of internal thermal and capillary pressure gradients. In a typical ambient or subcritical drying process, the exterior surface of the gel dries more rapidly than its interior. This asymmetrical mass transfer causes differential shrinkage resulting in large internal mechanical stresses, which usually cause macroscopic cracks or batch failure collectively due to the collapse of structure (Rabby et al., 2024). In case of no crack, the non-uniform shrinkage will also cause a heterogeneous pore structure in which porosity and pore size distribution are significantly different from surface to center. Since the drug release rate is inevitably associated with these structural factors, batch inconsistency in porosity translates directly to poor batch-to-batch reproducibility of drug loading and/or release kinetics, imposing a significant regulatory challenge (Adepu et al., 2021).

In order to bypass these practical limitations and guarantee the manufacturability of a thermal device, the industry strongly depends on predictive models (such as Computational Fluid Dynamics – CFD in short). CFD models are indispensable for simulating the coupled heat, mass and momentum transfer process within the porous gel as well as at external gas–solid interfaces. Instead, these models solve a system of simultaneous partial differential equations which describe the heat function (energy equation), the solvent and vapor function (mass transfer equation) and the resulting pressure/stress development within the specimen (momentum equation). Using process parameters (initial solvent concentration, environmental temperature, and gel pore size) as inputs, these models can predict accurate space-time development of the thermal gradient and capillary stress (Nadamani et al., 2023).

The boundary conditions (BCs) deserve a correct determination because they establish the driving forces for mass and heat transport. The drying rate is primarily

influenced by external mass and heat transfer coefficients, which are dependent on the surrounding conditions (temperature/humidity/airflow velocity over the material). For instance, to decrease the vapor pressure gradient by drying under high humidity or using specialized techniques such as supercritical drying (taking advantage of CO_2 fluid properties) which removes solvent due to its avoiding liquid–vapor interface and thus capillary stress, one requires reasonable modelling of fluid dynamics at the boundary. The models provide a means for engineers to choose the best BCs such that the drying rate is kept below the critical cracking velocity and meanwhile, minimizing overall processing time (Merghes et al., 2024).

The primary application of the heat/mass transfer modelling in tandem is manufacturing scale-up. With increasing batch size (and, therefore, decreasing overall surface-to volume ratio), this association becomes less pronounced. This shift is in fact a qualitative change: internal transport (here of heat and solvent in the material) becomes rate determining, overtaking the kinetics of external transport. This inhomogeneity and temperature differences between the core and surface are further enhanced. Scaling up thus cannot be performed by mere linear scaling up of lab parameters. Rather, advanced models need to be applied for the physical S-G geometry or internal flow in the drying chamber to be redesigned. For example, modelling might calculate the maximum allowable slab thickness, or optimise the application of microwave or radio frequency heating to provide uniform thermal energy through the material in a fraction of the time required for traditional convective heat transfer (Seidel et al., 2023).

Conclusion

This overview emphasizes the point that sol-gel technology into commercial pharmaceutical production which will depend on the understanding of applied physics. These three physical domains, molecular diffusion, reaction kinetics, and thermal transport are interrelated and will collectively dictate the functionality and quality of the produced product. When focusing on the mastering of diffusion mechanisms that can result in accurate release kinetic control; when optimisation of reaction kinetics is pursued to maintain tunable structural integrity and chemical stability, as well as for directly managing heat and mass transfer through predictive modelling to remove heterogeneity and guarantee manufacturing scalability. To progress further the science, we must combine these physical principles into integrated engineering models that in turn will provide the means to produce next generation sol-gel derived medicines on a reliable, predictable and compliant basis.

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