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Biomedical use of organic glasses: A comparative review in context to India and the world

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Abstract

Organic glasses, also known as molecular glasses, are amorphous solids formed by low-molecular-weight organic compounds that lack long-range crystalline order. In biomedical applications, they primarily serve as enabling platforms for amorphous solid dispersions (ASDs), significantly enhancing the aqueous solubility, dissolution rate, and oral bioavailability of poorly water-soluble active pharmaceutical ingredients (APIs), which constitute a major portion of new drug candidates. Beyond solubility enhancement, these materials show promise in stabilizing biologics and vaccines at ambient temperatures, facilitating controlled-release systems, and supporting flexible bioelectronics for implantable sensors. Globally, research emphasizes fundamental aspects such as surface molecular mobility, physical vapor deposition for ultra-stable glasses, thermodynamic modeling of drug-polymer interactions, and nanomechanical properties to predict long-term stability and processability. In contrast, Indian efforts focus on practical, scalable formulation strategies using cost-effective carriers, melt extrusion, and spray drying, tailored to tropical storage conditions, regulatory requirements, and the needs of affordable generic medicines under national health initiatives. This comparative review highlights complementary strengths: international contributions provide deep mechanistic insights and advanced processing techniques, while Indian research excels in translational applications, excipient optimization with natural polymers, and rapid commercialization for public health impact. Shared challenges include humidity-induced recrystallization and sustainability of manufacturing processes, yet synergies through international collaboration could accelerate the development of more stable, accessible, and multifunctional organic glass-based biomedical platforms. As the field evolves with AI-assisted screening and hybrid systems, organic glasses are poised to play an expanding role in next-generation drug delivery and regenerative medicine.

Keywords: Organic glasses; Molecular glasses; Amorphous solid dispersions; ASDs; Poorly water-soluble drugs; Bioavailability enhancement; Physical stability; Pharmaceutical formulations; India; Global research; Drug-polymer interactions; Vapor deposition; Tropical stability

1. Introduction

Organic glasses, often referred to as molecular glasses, are amorphous solids formed from low-molecular-weight organic compounds that lack long-range crystalline order (Yu, 2016). These materials arise when small organic molecules are rapidly cooled or deposited in ways that prevent crystallization, resulting in a disordered, glass-like state. In biomedical contexts, organic glasses have gained prominence primarily through their role in enhancing the performance of pharmaceutical compounds. By converting poorly water-soluble drugs into an amorphous form dispersed within a carrier matrix—commonly known as amorphous solid dispersions (ASDs)—these glasses can significantly improve solubility, dissolution rates, and ultimately bioavailability. This addresses a persistent challenge in drug development, where a large majority of new chemical entities exhibit poor aqueous solubility. Beyond oral drug

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delivery, organic glasses show promise in stabilizing sensitive biologics and vaccines at ambient temperatures, facilitating controlled-release implants, and serving as components in flexible bioelectronics for sensors or neural interfaces. Their low processing temperatures and tunable properties make them versatile for applications requiring biocompatibility and controlled behavior in the body.

This review provides a balanced, comparative examination of organic glass research and biomedical utilization on the global stage versus in India. Internationally, efforts concentrate on fundamental aspects such as glass formation kinetics, surface dynamics, and advanced fabrication techniques like physical vapor deposition (PVD) to create ultra-stable glasses (Dalal et al., 2015; Qiu et al., 2018). In India, the emphasis shifts toward practical, scalable formulation strategies tailored to the country's strengths in generic pharmaceuticals, cost containment, and public health demands (Singh, 2022). These complementary approaches highlight opportunities for collaboration, where deep mechanistic understanding from global labs can accelerate affordable, locally relevant solutions in India.

2. Global landscape: Fundamental insights and advanced pharmaceutical platforms

The exploration of organic glasses in biomedicine builds on decades of recognizing that amorphous forms of drugs often dissolve faster than their crystalline counterparts due to higher free energy. Early examples paved the way for modern ASDs. Today, the field integrates physical chemistry, materials science, and pharmaceutical engineering to design stable amorphous systems.

A key global advancement involves physical vapor deposition, which produces highly stable organic glasses with exceptional kinetic stability, higher density, and reduced molecular mobility compared to conventionally prepared glasses. These vapor-deposited forms resist crystallization and photodegradation better, offering advantages for light-sensitive drugs or products needing extended shelf life (Dalal et al., 2015; Qiu et al., 2018).

Surface mobility remains a central research theme. In organic glasses, molecules near the free surface exhibit much higher diffusion rates than in the bulk, often leading to rapid crystal growth and physical instability in ASDs. Pioneering studies have mapped how this surface-enhanced mobility influences recrystallization during storage or dissolution, guiding the selection of stabilizing polymers such as polyvinylpyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC), or Soluplus (Yu, 2016). These insights help maintain supersaturation during gastrointestinal transit, enhancing absorption.

Recent work has also deepened our understanding of mechanical behavior. A systematic 2025 analysis of twelve diverse organic glasses revealed that they generally exhibit narrower distributions of elasticity and hardness compared to their crystalline counterparts, with higher free volume often correlating to distinct mechanical responses (Joshi et al., 2025). Such knowledge is essential for robust manufacturing processes like milling, compaction into tablets, and coating, helping avoid unintended crystallization during production.

Regulatory trends further underscore the growing importance of these materials. Between 2012 and 2023, the U.S. FDA approved forty-eight drug products incorporating amorphous solid dispersions, reflecting their established role in overcoming bioavailability barriers across various therapeutic areas, including antivirals, oncology, and cardiovascular medicines (Moseson et al., 2024).

Researchers are increasingly turning to quality-by-design approaches, physicochemical monitoring, molecular simulations, and machine learning to predict and enhance ASD performance (Bhatta et al., 2025). These tools allow better assessment of drug–polymer miscibility and long-term stability under real-world conditions. For instance, comparative studies of hot-melt extrusion and spray-drying methods have highlighted differences in how each process influences the detection of physical instability over extended storage periods, informing more reliable formulation strategies (Kawakami et al., 2025). Recent global insights into drug-polymer interactions in aqueous environments are helping refine formulation design rules, aiding the selection of polymers that not only stabilize the amorphous state but also promote and sustain supersaturation during dissolution (Ramachandran et al., 2025).

Applications extend beyond conventional oral solids. Organic glasses aid in bio-preservation by stabilizing proteins, vaccines, or mRNA at ambient temperatures, potentially reducing cold-chain dependence. In emerging areas, thin-film organic glasses serve as encapsulants or substrates in organic bioelectronics for implantable devices. Major research hubs, backed by funding from agencies like the NSF and NIH as well as partnerships with pharmaceutical companies, continue to drive progress. Despite this, challenges persist, including accurate prediction of long-term physical stability under varying humidity and temperature, and the economic scaling of advanced deposition methods. Machine learning

and molecular dynamics simulations are increasingly employed to accelerate screening of glass-forming ability and polymer-drug interactions (Bhatta et al., 2025).

3. Organic glasses in the Indian context: Translational focus for accessible healthcare

India's pharmaceutical sector, renowned as the "pharmacy of the world," drives its engagement with organic glasses toward applied outcomes that support affordable generics and address prevalent health burdens like diabetes, infectious diseases, and oncology (Singh, 2022). Research is concentrated in pharmaceutical sciences departments at institutions such as the Indian Institutes of Technology (IITs), National Institutes of Pharmaceutical Education and Research (NIPERs), and select CSIR laboratories, often in collaboration with domestic companies.

Indian scientists have developed numerous ASD formulations using melt extrusion, spray drying, and ball milling—techniques that are scalable and align with existing GMP infrastructure. Common carriers include HPMC, PVP, and emerging natural or semi-synthetic polymers like chitosan or starch derivatives, which offer cost advantages and potential for greener processing. Studies frequently target drugs such as curcumin, efavirenz, or BCS Class II/IV anticancer agents, demonstrating enhanced dissolution profiles and improved stability under accelerated tropical conditions (high humidity and temperature), a critical factor for distribution in India and other warm climates.

Emphasis is placed on in vitro–in vivo correlations, ICH stability testing, and pilot-scale optimization to facilitate rapid regulatory approval and commercialization. Patents often cover novel excipient combinations or process tweaks that reduce costs while maintaining bioequivalence. Funding from bodies like the Department of Science and Technology (DST), Department of Biotechnology (DBT), and Science and Engineering Research Board (SERB) supports these translational projects, sometimes linking to national initiatives for self-reliant manufacturing.

While the volume of high-impact fundamental publications is smaller than in leading Western or Chinese groups, Indian contributions excel in applied case studies that directly tackle local needs—such as heat-stable formulations for rural healthcare or low-cost anti-retroviral dispersions. Capacity building occurs through academic-industry consortia. Compared to global leaders, India's approach prioritizes process robustness, excipient economy, and regulatory familiarity over ultra-stable vapor-deposited systems.

4. Comparative perspectives: strengths, synergies and gaps

Globally, research excels in mechanistic depth—elucidating surface diffusion, thermodynamic modeling of miscibility, and advanced processing that yields materials with superior stability and tunable release (Yu, 2016). This has produced a rich intellectual property landscape and sophisticated platforms suitable for high-value biologics or personalized medicine. In contrast, Indian efforts shine in pragmatic adaptation: leveraging abundant, cost-effective carriers, optimizing for tropical stability, and integrating with established high-volume manufacturing lines to deliver economical therapies for broad populations (Singh, 2022).

Key distinctions appear in resource allocation and priorities. International programs often fund exploratory work on co-amorphous systems, nanoconfinement, or hybrid organic-inorganic glasses, while Indian funding stresses societal impact, scale-up, and export competitiveness. Publication patterns reflect this: Western journals feature detailed kinetic and spectroscopic studies, whereas Indian outputs emphasize dissolution enhancement, bioavailability data, and stability under real-world conditions.

Shared challenges include humidity-induced recrystallization, regulatory complexity for complex ASDs, and the energy footprint of certain processes. Opportunities for synergy are substantial. Global stability science and machine-learning tools could inform Indian formulations to extend shelf life without refrigeration (Bhatta et al., 2025; Kawakami et al., 2025), while Indian manufacturing expertise and natural-polymer innovations could help scale advanced insights or develop sustainable carriers. Bilateral initiatives and technology transfer could bridge these strengths, accelerating access to improved medicines in low- and middle-income settings.

5. Challenges, emerging opportunities, and future outlook

Across both landscapes, ensuring long-term amorphous stability remains paramount, particularly as formulations encounter diverse storage and physiological environments. Globally, strategies include surface passivation, predictive modeling using simulations, and quality-by-design frameworks (Bhatta et al., 2025); India can adapt these affordably through optimized polymer blends or process controls. Sustainability concerns—solvent use in spray drying or energy

demands of advanced deposition—call for greener alternatives, an area where India's focus on bio-sourced excipients provides a natural advantage.

The horizon for organic glasses includes expansion into injectable depots, 3D-printed personalized dosage forms, and multifunctional systems combining drug delivery with diagnostics. AI-driven high-throughput screening, coupled with continuous manufacturing, will likely democratize development. In India, growth may center on volume production for domestic and global south markets, supported by policies promoting indigenous innovation.

Collaborative ecosystems that pair fundamental rigor with applied scalability could unlock organic glasses' full potential, transforming them from niche solubility enhancers into versatile platforms for next-generation biomedicine.

6. Conclusion

Organic glasses illustrate how a disordered molecular state can bring order to therapeutic challenges by unlocking solubility and stability in ways crystalline forms cannot. Worldwide, the field advances through elegant physics and innovative processing; within India, it translates these principles into practical, equitable solutions that serve millions. This comparative view underscores that meaningful progress arises not from isolated excellence but from complementary contributions—deep insight meeting grounded ingenuity. As research evolves with AI-assisted screening and hybrid systems, organic glasses promise to play an expanding role in making medicines more effective, stable, and accessible, ultimately benefiting patients across diverse contexts.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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