Qalitex Laboratories Raises Concern Over Stability Data Gaps in Novel Dosage Formats

Qalitex urges brands to rethink how gummies and stick packs are validated, highlighting stability issues missed by standard testing protocols.

IRVINE, CA, UNITED STATES, June 30, 2025 /EINPresswire.com/ -- As innovation in consumer product delivery formats accelerates, Qalitex Laboratories is calling attention to a growing gap in shelf-life validation for non-traditional dosage forms.

The California-based laboratory has reviewed stability profiles of a wide range of emerging products—including gummies, soft chews, stick packs, and dissolvable films—and found that many lack the format-specific data needed to meet regulatory expectations or support reliable shelf-life claims.

While alternative formats continue to gain popularity for their convenience and appeal, their structural and chemical characteristics often fall outside the scope of conventional stability protocols. Unlike standard tablets or capsules, these formats may contain elevated moisture levels, pH-sensitive actives, or multi-phase components, all of which can interact in unpredictable ways under various environmental conditions.

> “What works for capsules doesn’t always work for gummies. Each novel format behaves differently—and if stability isn’t tested for that, your shelf life may not hold.”
>
> *Nour Abochama, Vice President for Operations at Qalitex*

“Many existing protocols were designed for solid oral forms with low water activity and inert excipients,” said Nour Abochama, Vice President of Operations at Qalitex.

“When those same protocols are applied to more complex delivery systems, critical degradation pathways are often missed. This presents both a regulatory and quality assurance concern.”

Physical Changes May Indicate Underlying Instability

Instability in novel formats can appear as texture softening, discoloration, moisture uptake, or phase separation. These changes may affect not only appearance but also potency, microbial integrity, or dosing consistency. Qalitex reports that such issues are often revealed during stress testing or distribution simulation, where elevated temperature and humidity conditions trigger visible and measurable changes in the finished product.

For example, certain high-moisture formats have demonstrated early microbial growth during routine testing when preservatives or water activity levels were insufficient. Other products containing reactive components, such as minerals or acids, have shown oxidation or internal pH shifts that result in physical degradation or off-odors.

“These are not isolated cases,” Abochama said. “They’re representative of the types of challenges we routinely identify when evaluating new delivery systems under validated test conditions.”

Standard Protocols May Miss Format-Specific Risks

Stability testing in most product categories adheres to the ICH Q1A(R2) guidelines, which outline best practices for assessing physical and chemical stability over time. However, these protocols were primarily intended for conventional formats and may not address moisture sensitivity, delamination, or ingredient migration commonly seen in more complex structures.

Qalitex has found that relying exclusively on generalized protocols can result in delayed failure identification. In some cases, changes emerged within the first eight weeks of testing—well before long-term storage milestones.

“Data from accelerated testing is only valuable if it reflects the real risks posed by the product’s structure and ingredient profile,” Abochama noted. “We recommend incorporating matrix-specific stress conditions that mimic transit, storage, and usage environments.”

Shelf-Life Claims Subject to Greater Regulatory and Retail Scrutiny

Regulatory agencies require that label claims, including expiration dates and dosing consistency, be supported by validated data that reflects how the product will perform in its final packaged form. This includes confirming that the product remains stable throughout its distribution chain and shelf life.

Qalitex notes an increase in inquiries from brands responding to retailer requests for updated shelf-life documentation. On e-commerce platforms, customer feedback highlighting changes in texture, separation, or packaging degradation can trigger compliance reviews. In some cases, products have been delisted or flagged for investigation due to unresolved quality concerns.

“Retailers are increasingly data-driven in how they monitor product consistency,” Abochama said. “Even if actives remain within range, physical instability can affect how a product is received—and reported—by customers.”

Packaging Alone Is Not a Complete Solution

While protective packaging can help mitigate some environmental exposure, Qalitex cautions that packaging solutions must be developed in tandem with the formulation itself. High-barrier films or oxygen absorbers may slow degradation, but they cannot fully compensate for an inherently unstable matrix or insufficient preservation system.

Qalitex frequently conducts packaging feasibility studies in parallel with stability testing. These assessments evaluate how moisture migration, temperature cycling, and handling conditions affect product performance inside its final packaging.

“In several documented cases, we observed microbial growth or potency drift despite robust packaging,” said Abochama. “The root cause was linked to formulation design, not external exposure alone.”

Need for Broader Training in R&D and QA Teams

Through its technical collaborations, Qalitex has observed that many early-stage product development teams are still gaining familiarity with the testing demands of alternative formats. While marketing teams often drive innovation in texture or user experience, quality assurance and regulatory teams must ensure that the product remains compliant and stable throughout its life cycle.

To support this, Qalitex offers technical education services for R&D and QA teams, focusing on excipient interaction, moisture management, and matrix-specific degradation mechanisms. These sessions are designed to help teams identify risks early and build stability into the development process.

Format-Specific Testing Is Becoming a Standard Practice

Some product developers are now conducting parallel studies to compare different delivery methods for the same formulation. These tests help determine which format offers better performance under accelerated and long-term storage conditions.

Qalitex has also supported projects that apply predictive modeling tools—such as water activity mapping and ingredient compatibility studies—prior to pilot production. This data informs formulation decisions and reduces the likelihood of costly reformulation or revalidation later in the process.

“We’re seeing more clients apply stability-by-design principles from the outset,” said Abochama. “When shelf life is treated as a design parameter rather than a post-launch concern, the results are more robust and audit-ready.”

Expanded Services for Format-Specific Stability Validation
To meet evolving industry needs, Qalitex offers customized services that address the challenges of novel delivery formats. These include:

Excipient interaction assessments tailored to moisture- and pH-sensitive formulations
Real-world distribution simulation based on likely transport routes and environmental conditions
Accelerated stress testing for high-risk formulations and packaging types
Customized microbial limit testing for multi-phase or semi-solid formats
Regulatory documentation aligned with FDA and retailer requirements

For more information on Qalitex's format-specific testing capabilities and regulatory advisory services, visit www.qalitex.com.

Nour Abochama
Qalitex Laboratories
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