LipoEdge™

LIPOSOMAL TECHNOLOGY

US-FDA REGD. · FSSAI · WHO-GMP · cGMP · ISO · HACCP

Inside This Brochure

- Why *in vitro* biochemical testing matters
- Stability testing: oxidative & osmotic
- Release studies in simulated digestive fluids
- Product-specific bioassays
- Product testing & validation workflow
- Common problems & our solution
- Practical support

Why *In Vitro* Biochemical Testing Matters

While physical characterisation confirms a liposome has been correctly synthesised, *in vitro* biochemical testing proves how it will actually behave in the human body — mimicking real physiological environments to evaluate true efficacy, protective strength, and digestive survival before further cellular and in vivo studies.

Stability Testing	Release Studies	Product Research
Oxidative & osmotic resilience under real-world stress	INFOGEST-aligned release across salivary, gastric & intestinal fluids	Assay-backed proof of antioxidant, whitening, permeation & anticancer activity

Contact: info@thelipoedge.com · www.thelipoedge.com · +91 33 4025 1539

Stability testing: oxidative & osmotic

Stability testing evaluates how a liposomal formulation holds up under oxidative and osmotic stress before it ever reaches biological systems.

01· Is your formulation chemically & physically stable? — STABILITY TESTING

Oxidative Stability	**Lower Lipid Peroxidation**	**What this means:** Liposomal formulations exposed to oxidative stress exhibit lower lipid peroxidation than free active pharmaceutical ingredient (API), indicating greater protection of the active ingredient against oxidative degradation.
Osmotic Stability	**Hypo- / Iso- / Hypertonic**	**What this means:** Stability is assessed across solutions of different salt concentrations. Consistent release patterns with only slight deviation confirm superior liposomal integrity.

Why This Matters for Your Product

Protects the active from degradation

Encapsulation shields sensitive actives from oxidative breakdown, preserving potency from manufacture through to point of use.

Confirms integrity across formulation conditions

Testing across hypotonic, isotonic and hypertonic environments verifies the bilayer holds together under the range of conditions a product may encounter.

Release Studies in Simulated Digestive Fluids

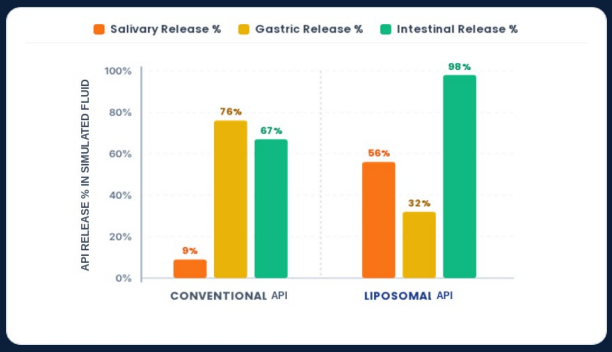
Liposomal formulations are assessed using the INFOGEST-aligned protocol for *in vitro* digestion, tracking API release across each phase of the digestive tract using simulated fluids.

02 · How does your API release through digestion? — *IN VITRO* RELEASE STUDY

SSF	Mouth Phase	**What this means:** Simulated Salivary Fluid (SSF) studies the release pattern in the mouth — important for understanding release behaviour of sublingual formulations.
SGF	Gastric Phase	**What this means:** Simulated Gastric Fluid (SGF) studies release in the gastric environment. A lower release here indicates greater stability of the liposomal formulation.
SIF	Intestinal Phase	**What this means:** Simulated Intestinal Fluid (SIF) studies release in the intestine. Higher, sustained release of API indicates greater bioavailability over a prolonged period.

Instrument Evidence — API Release in Simulated Fluids

Conventional API releases early and unpredictably — 76% in the gastric phase alone. Liposomal API holds back release in the gastric phase (32%) and delivers 98% in the intestinal phase, the sharpest sign of protected, targeted release.



Salivary / Gastric / Intestinal release — Conventional vs Liposomal API

What This Proves

Digestive survival, phase by phase

Mapping release across the mouth, stomach and intestine shows exactly where and how much of the active is delivered — not just whether it survives.

Bioavailability evidence for your claims

Sustained intestinal-phase release is direct *in vitro* evidence supporting bioavailability and prolonged-delivery claims on your product.

Product-specific bioassays

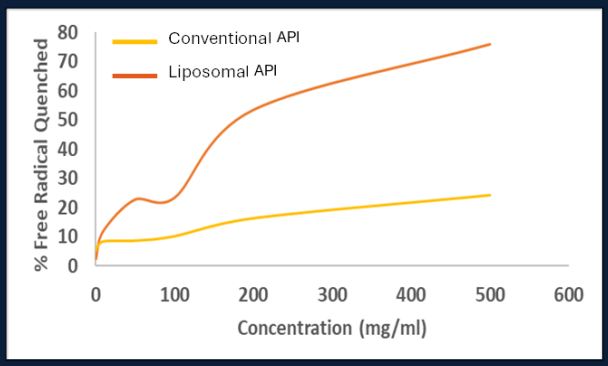
Beyond general stability and release, product-specific assays quantify the functional, therapeutic performance of your exact formulation.

03 · Does your formulation actually perform? — PRODUCT RESEARCH

Antioxidant Assay	**Free Radical Scavenging**	**What this means:** For liposomal APIs, this confirms free radical scavenging activity compared to non-liposomal APIs — indicating improved antioxidant capacity.
Melanogenesis Inhibition	**Anti-Tyrosinase Activity**	**What this means:** An *in vitro* enzymatic assay that determines the anti-tyrosinase activity of liposomal APIs, supporting skin-brightening and pigmentation claims.
GSH/GSSH Determination	**Oxidative Stability**	**What this means:** An *in vitro* enzymatic assay using DTNB to determine the stability of liposomal APIs when exposed to oxidative stress.
Franz Diffusion Assay	**Membrane Permeation**	**What this means:** An *in vitro* membrane permeation study evaluating transdermal or transmucosal penetration efficiency of liposomal APIs compared to non-liposomal forms.

Instrument Evidence — Antioxidant Assay

Across the full concentration range, liposomal API quenches substantially more free radicals than conventional API — reaching ~76% quenching at 500 mg/ml versus ~24% for the conventional form, confirming meaningfully improved antioxidant capacity.



% Free Radical Quenched vs Concentration — Conventional vs Liposomal API

Product Testing & Validation Workflow — 4 Steps

Every LipoEdge™ product moves through this validated pipeline, from raw sample to a regulatory-ready technical file.

01	**Biochemical Stability Testing** ✔ Oxidative stability (lipid peroxidation) ✔ Osmotic stability across hypo/iso/hypertonic → *Your formulation is baseline stress-tested before further studies begin.*
02	**Simulated Fluid Release Study** ✔ SSF — salivary phase release ✔ SGF — gastric phase release ✔ SIF — intestinal phase release (INFOGEST-aligned) → *Phase-by-phase release maps how and where your active is delivered through the digestive tract.*
03	**Product-Specific Bioassays** ✔ Antioxidant / free radical scavenging ✔ Melanogenesis inhibition / anti-tyrosinase ✔ GSH/GSSG oxidative stability ✔ Franz diffusion membrane permeation ✔ Antimicrobial effect ✔ Anticancer activity → *Targeted assays generate quantified, comparative evidence for your specific product claims.*
04	**Regulatory Dossier Compilation** ✔ Validation certificates issued ✓ Stability reports compiled ✓ Troubleshooting data included ✓ Regulatory-ready package delivered → *You receive a complete documentation package ready for regulatory submission and market approval.*

Common Problems & Our Solution

Four formulation failures we diagnose and fix.

PROBLEM: Active degrades before reaching the target site

OUR FIX: We reformulate the liposomal lipid bilayer composition to maximise protection against oxidative, enzymatic and acidic degradation.

PROBLEM: Can't prove the formulation survives stomach acid

OUR FIX: SGF release profiling shows exactly how much API is released in the gastric phase. We optimise formulation parameters until gastric phase release is minimised.

PROBLEM: Release data is inconsistent between runs

OUR FIX: Methodology troubleshooting identifies the source of variability — buffer preparation, enzyme activity, or membrane integrity. We validate the protocol before re-running.

PROBLEM: Need efficacy evidence to support product claims

OUR FIX: Product-specific assays (antioxidant, tyrosinase inhibition, antimicrobial, anticancer, permeation) generate quantified comparative data for liposomal vs conventional API to substantiate claims.

Practical Support

YOUR QUESTIONS	OUR SUPPORT
Does my formulation protect the active from oxidation?	Oxidative stability assay · Lipid peroxidation measurement
Does it survive the stomach and release in the intestine?	INFOGEST-aligned SSF / SGF / SIF release study · Phase-by-phase API quantification
Can I prove antioxidant activity vs the non-liposomal form?	Free radical scavenging assay
Can I substantiate skin-brightening or whitening claims?	Anti-tyrosinase activity assay
Can I prove better skin / mucosal penetration?	Franz diffusion assay
Do I need regulatory-aligned methodology?	Studies designed using established models · Full dossier compilation
My results look inconsistent — can you troubleshoot?	Methodology troubleshooting · Protocol optimisation

Request Product Testing
Send us your formulation for the full *in vitro* biochemical evaluation suite.

Design a Custom Study
We build product-specific assay protocols matched to your delivery route and claims.

Talk to Our Team
Discuss your validation and regulatory documentation needs with our scientists.

Let's Prove Your Formulation Performs

Talk to our team about your liposomal product. We'll handle the science. You'll get the proof.

www.thelipoedge.com
info@thelipoedge.com · +91 33 4025 1539
Bangur Avenue, Kolkata 700089 · Salt Lake City, Kolkata 700091, India