

Vat-Photopolymerised Drug-Delivery and Pharmaceutical Devices

Resin Identity, Dose Incorporation, Release, Residuals and Qualification

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Statement of Significance

Vat photopolymerisation can shape drug-loaded devices and use geometry to modify release, but printability is not pharmaceutical qualification. ER-193 separates resin identity, dose incorporation, delivered cure, residual chemistry, geometry, degradation, release and biological evidence. It uses two directly read primary abstracts as bounded anchors and does not convert research feasibility into a safety, efficacy, dosing or regulatory claim.

Abstract

Drug-loaded devices produced by vat photopolymerisation couple formulation and geometry with dose, degradation and release. One primary study used biodegradable vat-photopolymerisation resins containing a fluorescent surrogate and varied device geometry, reporting that surface-area-to-volume ratio, strut dimensions and pore size affected degradation and release [1]. A second study reported risperidone-loaded subcutaneous research implants based on PEGDA 700 systems, including a PLA-PUA-containing composition, and evaluated morphology, swelling, release, physicochemical state and cytotoxicity [2]. These studies demonstrate distinct research routes for engineering prolonged release; they do not establish an approved medicine, clinically valid dose, universal material suitability or transferable release duration. ER-193 proposes a qualification framework in which formulation identity, drug content and uniformity, optical process, geometry, residuals, stability, release method and biological evidence are independently controlled. No universal resin, dose, exposure, release model, residual limit or clinical performance is proposed.

Keywords: vat photopolymerisation; drug delivery; pharmaceutical devices; implants; controlled release; residuals; qualification

1. Scope and boundary

ER-193 addresses drug-loaded and pharmaceutical-device research manufactured by vat photopolymerisation. It owns the engineering relationship among resin chemistry, active incorporation, delivered cure, geometry, degradation and release.

It does not establish good manufacturing practice compliance, pharmacopeial compliance, toxicological acceptability, sterility, regulatory approval, clinical safety, efficacy or an administered dose. No 3Dresyns product is claimed to be qualified for pharmaceutical or implant use.

The evidence is bounded to directly read primary abstracts for [1] and [2]. Numerical durations or compositions remain study-specific and are not acceptance criteria.

2. Evidence anchors

The first study loaded relatively fast-degrading polyester vat-photopolymerisation resins with Rhodamine B as a surrogate and varied device geometry [1]. Its abstract reports that surface-area-to-volume ratio, beam or strut dimensions and pore size affected degradation and release and implies that the onset of degradation-controlled release could be a factor in achieving constant release in the studied system [1]. Because the payload was a surrogate, the work does not establish performance for a therapeutic active.

The second study reported vat-photopolymerised risperidone-loaded subcutaneous research implants with varied polymers and loading [2]. The authors evaluated morphology, swelling, in-vitro release, physicochemical state and cytotoxicity in 3T3 murine fibroblasts [2]. The abstract reports extended in-vitro release for particular PEGDA 700-based systems, including one containing PLA-PUA [2]. These are laboratory feasibility results, not clinical duration or therapeutic equivalence.

3. Resin and active identity

A qualification record should identify every monomer, oligomer, crosslinker, initiator, absorber, solvent, excipient and active, including grade, supplier, lot and concentration basis where relevant. The as-mixed formulation, printed object, washed object, post-cured object and aged device are different material states.

An active can absorb or scatter curing light, react during processing, partition within the network or change conversion and swelling. A placebo process cannot automatically qualify a loaded formulation. Likewise, a fluorescent surrogate can reveal mechanisms without reproducing the solubility, stability, potency or transport of a medicine.

4. Dose incorporation and uniformity

Nominal addition is not delivered dose. The process may introduce mixing error, settling, adsorption, incomplete transfer, degradation or spatial gradients. Verification should distinguish batch concentration, individual-device content and content uniformity. Analytical specificity, recovery and sampling location should be declared.

Where geometry changes, dose can change even if concentration is constant. Device volume, porosity and mass therefore belong in the dose record. ER-193 provides no universal content-uniformity limit.

5. Optical process and residual chemistry

Exposure must be established for the loaded formulation and representative geometry. Machine settings alone do not define delivered dose. Wavelength, irradiance or calibrated output, exposure sequence, layer thickness, orientation, resin state and post-cure should be recorded.

Geometric completion does not prove acceptable conversion or residual state. Residual monomers, initiator fragments, solvent, wash residues, degradation products and active-related impurities may require measurement. The relevant methods and limits depend on intended use and competent toxicological and regulatory assessment.

6. Geometry, degradation and release

Study [1] directly supports geometry as a release and degradation variable in its specific polyester/surrogate system. Surface-area-to-volume ratio, strut scale and pore structure can alter exposed area and transport paths. That mechanism must still be verified for each formulation and active.

Release results require a declared medium, volume, temperature, agitation, sink condition, sampling plan, analytical method, mass balance and endpoint. An in-vitro duration is a property of that method and device state. It is not automatically an in-vivo duration, dose interval or therapeutic claim.

Degradation, swelling, diffusion and network relaxation may overlap. A fitted release model does not by itself prove mechanism. Discriminating experiments should be selected before assigning control to one process.

7. Stability and active state

The active should be assessed before and after mixing, printing, washing, post-cure and aging using methods capable of detecting loss or transformation. Thermal or spectroscopic compatibility can support interpretation but does not replace a stability-indicating assay when a pharmaceutical claim is made.

Storage and packaging can change water content, residuals, network state and release. Shelf-life therefore requires the final package and defined storage conditions. Neither anchor establishes general shelf-life.

8. Biological evidence

The cytotoxicity work reported in [2] belongs to the stated murine fibroblast method. It does not establish implantation safety, systemic toxicology, local tolerance or clinical efficacy. Biological evaluation should follow the intended contact route, duration, dose and degradation state.

Drug release alone does not demonstrate bioavailability or therapeutic effect. Conversely, a favourable cell assay cannot qualify impurities, dose accuracy or long-term degradation products.

9. Qualification sequence

ER-193 proposes the following linked sequence: define the intended device and claim; lock formulation and active identity; demonstrate mixing and content uniformity; establish a formulation-specific optical and post-cure window; verify geometry and dose; characterise residual and stability state; measure swelling, degradation and release under declared methods; assess biological endpoints appropriate to intended use; and define change-control triggers.

This is an engineering framework, not a protocol validated by [1] or [2]. Acceptance limits must be established for the specific product and jurisdiction.

10. Change control

Potential triggers include supplier or lot, resin composition, active identity or form, loading, mixing history, pigment or absorber, printer or light engine, exposure, layer strategy, wash, post-cure, geometry, packaging and storage. Each change should be screened against dose, conversion, residuals, mechanics, degradation, release and biological evidence.

Geometry is not a cosmetic change when it controls mass, surface area or transport. A bridge is acceptable only if the retained tests detect the relevant failure modes.

11. Evidence limitations

This version uses two directly read primary abstracts and is not a systematic review. It does not reproduce detailed methods absent from those records, rank material classes or establish universal numerical specifications. Full-text review would be required before making more granular comparative claims.

12. Conclusions

The evidence anchors show that vat photopolymerisation can be used to study geometry-controlled degradation and release with a surrogate [1] and to manufacture risperidone-loaded research implants with extended in-vitro release in selected formulations [2]. They do not prove clinical performance or general pharmaceutical suitability.

A defensible qualification programme must keep separate the nominal formulation, delivered dose, cured network, residual state, geometry, degradation, in-vitro release and biological evidence. ER-193 rejects automatic transfer from surrogate to drug, from in-vitro duration to dosing interval, from cytotoxicity to implant safety and from printability to regulatory qualification.

Related Engineering Review boundaries

ER-192 owns hearing-device shell and earmould mechanics, contact state, biofilm, acoustics and fit. ER-193 owns formulation identity, dose incorporation, residuals, degradation and release qualification for drug-delivery and pharmaceutical devices.

References

- [1] Busari, H.; Mefford, O. T.; Vaughn, M. A. Engineering long-term controlled drug release from biodegradable devices 3D printed with vat polymerization. *Journal of Materials Chemistry B* 13(22) (2025) 6456–6468. <https://doi.org/10.1039/D5TB00456J>. PMID: 40365912.
- [2] Picco, C. J.; Utomo, E.; Magill, E. R.; Anjani, Q. K.; Adhami, M.; Lu, Y.; Byrne, N. M.; Abu Ammar, A.; Coulter, J. A.; Donnelly, R. F.; Domínguez-Robles, J.; Larrañeta, E. 3D-printed long-acting implants for risperidone delivery using VAT photopolymerisation: a potential alternative for schizophrenia treatment. *International Journal of Pharmaceutics* 701 (2026) 127092. <https://doi.org/10.1016/j.ijpharm.2026.127092>. PMID: 42289210.

Competing interests

The author is Founder, CEO and CTO of 3Dresyns by Resyner Technologies S.L. This review does not claim that any 3Dresyns product is qualified for pharmaceutical, drug-delivery or implant use.

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Data availability

No new experimental dataset was generated for this review.