

Custom Lipid Synthesis for Pharmaceutical Applications

GMP-compliant lipid manufacturing tailored to your needs

NOF CORPORATION has manufactured and supplied high purity GMP-grade phospholipids and other lipid derivatives to pharmaceutical companies worldwide since the early 1990s.

Our high-quality lipid portfolio includes:

- **PEG Lipids & PEG Phospholipids**
- **Cationic Lipids & Proprietary Ionizable Lipids**
- **Synthetic Phospholipids**

These are suitable for lipid emulsion, liposome, and **lipid nanoparticle (LNP / targeted LNP)** formulations.

With **over 45 DMFs** submitted to the US FDA and **GMP-compliant manufacturing facilities in Japan**, we provide consistently high-quality and flexible custom synthesis to support your development and regulatory requirements. Even if you require tailor-made structures, we offer reliable, **end-to-end support** across all stages of development with proven regulatory experience and flexible timelines to meet your program needs.

Why Choose NOF

- ✓ **GMP lipid manufacturing at qualified facilities in Japan**
- ✓ **High-quality production from lab to commercial scale**
- ✓ **Design and optimization of scalable, robust synthetic routes**
- ✓ **Proven regulatory support and responsive technical support**
- ✓ **Extensive experience with customer audits**
- ✓ **Used in numerous marketed drugs and clinical trials**
- ✓ **In-house sourcing of high-quality PEGs enabling integrated PEG lipid production**
- ✓ **Fully synthetic and free from BSE and TSE risk**



Seamless Support from Early Research to Commercial Supply

We support your pharmaceutical lipid needs from feasibility assessment to GMP commercial manufacturing.

Preclinical

incl. Early Research



- Feasibility assessment of customer-defined lipid structures
- Synthetic route optimization and early process development
- Analytical method development support
- Non-GMP small-scale manufacturing for early evaluation

Clinical



- Scale-up from preclinical to large-scale manufacturing under GMP
- Robust GMP quality management and compliance systems
- Regulatory documentation support (e.g., DMF submission, LoA)
- Specification setting aligned with development requirements

Commercial



- Process validation and supply of GMP-compliant commercial batches
- Secure, traceable supply chain ensuring dependable supply
- Continuous support for repeat manufacturing and inventory coordination

NOF supports a wide range of custom lipid designs.

PEG Lipids (variable PEG molecular weights and acyl chain lengths)

Activated PEG Lipids

Ionizable Lipids

Other Functional Lipids

Discover more

about how NOF's proven portfolio, trusted by our partners, can support your next pharmaceutical project.

Activated PEGs for PEGylated pharmaceuticals.

Ultrapure Polysorbate 80.

Lipid derivatives and integrated services for lipids and LNPs.

- Custom lipid synthesis and GMP lipid production
- Screening and optimization for LNP formulations
- Scale-up production for LNPs



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