Corden Pharma

CordenPharma Nanomedicine & Lipid CDMO Services

for Efficient Nanoparticles

Factsheet

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... for Efficient Nanoparticles

CordenPharma Caponago is a state-of-the-art facility, globally GMP-approved (FDA, EMA, PMDA, NMPA, ANVISA, etc) specializing in injectable formulations, offering world-class expertise in non-viral delivery, including Lipid Nanoparticle (LNP) development, cGMP manufacture, and Fill & Finish.

We accompany your project from concept to vial with offered project management services to reduce timelines, risks, and complexity while safeguarding quality.

Watch our LNP GMP manufacturing services

Bioburden reduction filtration at the LNP GMP manufacturing facility at CordenPharma Capanogo (IT).

Nanoparticle Assembly Technologies

CordenPharma offers a range of mixing technologies, adopting a technology-agnostic approach:

Research & Development (R&D):

Unchained Labs ANPS	Inside Tx Tamara	Knauer NanoScaler-IJM	Cytiva NA Blaze Plus

Good Manufacturing Practice (GMP):

Knauer Duo Core NanoProducer-IJM	Cytiva NA GMP	Custom-Made Mixing Setup

Development Purification Technologies – Ultrafiltration/Diafiltration

R&D		GMP
Cytiva ÄKTA flux s	Cytiva ÄKTA flux 6	Repligen KTM1600®

Note: An Amicon centrifugal filter or dialysis bag is used for very early stages. TFF systems from Merck (Cogent µScale and M) are also available.

Four stainless steel vessels located in an ATEX Class C LNP assembly room, compatible with organic solvents for the organic phase preparation at CordenPharma Caponago (IT).

Primarily Offered Nanomedicine Services:

- LNP Screening
- Formulation Development
- Process Development or Feasibility Studies
- Scale Up Studies
- Engineering Batch Manufacturing
- GMP Batch Manufacturing
- Analytical Method Development or Feasibility Studies
- Cleaning Method Development
- Method Validation Studies
- Microbiological Studies
- Stability Studies
- Fill and Finish for PFS (1-10 mL), Vials from (2R to 20R)
- Lyophilization
- Packaging and Distribution
- Tox/Animal Use Batches

Analytical Methods:

A list of primary methods is given below. Additional methods are organized with qualified third parties, depending on the formulation requirements.

- High Performance Liquid Chromatography (HPLC) and Ultra-HPLC (UHPLC) with various detectors, e.g., CAD, DAD, UV, RI, ELSD, etc.
- Gas Chromatography with downstream flame ionization detector (GC-FID)
- Dynamic Light Scattering (DLS)
- Capillary Electrophoresis (CE)
- Fluorescence Spectroscopy
- UV Spectrophotometer
- Endotoxin and Sterility
- Regulatory Support

For comprehensive analytical development methods, reach out to us to organize a meeting with your Drug Product Development Team.

Get in touch with our experts

Primarily Offered Lipid Development Services:

CordenPharma's unique position as a leader in catalog and custom lipid manufacturing plays a crucial role in advancing your RNA therapy projects. As a key lipid supplier during the COVID-19 pandemic, and having an established lipid development site since 1987, we bring proven know-how to not only provide the purest lipids available in the market, but also draw upon decades of experience in custom lipid manufacturing to deliver commercial scale ionizable lipids to global markets:

- Standard lipid supply such as ionizable lipids, phospholipids, and sterols at R&D and GMP grades.
- Custom lipid process development and manufacturing
- Regulatory support, including DMF Filing
- Active targeting solutions with DSPE-PEG-xk-derivatives such as azide, maleimide, DBCO, TCO, etc.
- Back integration of key lipid excipients

LNP Assembly Technologies at our GMP LNP facility, CordenPharma Caponago (IT).

CordenPharma
International

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Peptides

Oligonucleotides

Lipids & LNPs

Injectables

Highly Potent
& Oncology

Small Molecules

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