

NOVASTERILIS SERVICES

Supercritical CO₂ (scCO₂) Testing Services

NovaSterilis provides proof-of-concept testing through development processes across a variety of scCO₂ use-cases including:

- Sterilization
- Decellularization
- Cleaning (contaminant removal)
- Impregnating (chemical or bioactives)
- Functionalizing

Materials can be processed in a variety of states including lyophilized, dry, hydrated, submerged, or liquid.

NovaSterilis Equipment Platforms

- Nova8800 – fully automated
 - 80 L vessel/Max. press. 2,000 psi
- Nova2200 – fully automated
 - 20 L vessel/Max. press. 2,000 psi
- NovaGenesis – manual controls
 - 600 mL to 20 L systems
 - Max. press. 2,900 psi

Laboratory Services

- Fully equipped BSL-2 lab
 - Enumeration/Fraction Negative
 - Endotoxin/Pyrogen testing
 - Crosslinking analysis
- Residual testing
 - Peroxide assays
- Liquid chromatography, mass spectrometry, NMR

Packaging

NovaSterilis has developed a broad offering of scCO₂ compatible packaging including both rigid and flexible packaging.

- NovaPouches (Tyvek-Poly pouches)
 - Variety of sizes
 - 3.5" x 5" through 10" x 18"
- Header Pouches (Poly-Poly pouches with Tyvek header)
 - 5.75" x 12.5"
- Vented-Lid Conical Tubes
 - 15 mL & 50 mL
- Vented-Lid Glass Bottles
 - 30 mL & 60 mL

NovaSterilis has a network of packaging providers that can develop custom solutions to meet specific product needs.

Regulatory Services

Supercritical CO₂ regulatory services can be contracted through iFyber LLC. iFyber is the global leader in scCO₂ regulatory services and collaborates extensively with NovaSterilis. iFyber has provided NovaSterilis customers and licensees the following services in addition to a full offering of pre-clinical CRO services:

- Regulatory strategy
- Process Development
- Verification Studies
- Validation Services
- Regulatory Submission Support