

## NOVASTERILIS SERVICES

### Supercritical CO<sub>2</sub> (scCO<sub>2</sub>) Testing Services

NovaSterilis provides proof-of-concept testing through development processes across a variety of scCO<sub>2</sub> 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 scCO<sub>2</sub> 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)
  - 5.5" 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 CO<sub>2</sub> regulatory services can be contracted through iFyber LLC. iFyber is the global leader in scCO<sub>2</sub> 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