



Softgel
Sofgen
SITE



SOFGEN

PHARMACEUTICALS

We are an integrated CDMO that offers end-to-end solutions, from development throughout delivery, in innovative Softgel technologies for pharma and healthcare companies interested in launching novel products within North America and other Highly regulated markets.

OUR PURPOSE

To provide an **unparalleled experience** with reliable development manufacturing services and niche proprietary products, innovation in technologies, contributing to health and well-being of consumers and patients in key markets.





WHY SOFGEN Pharmaceuticals?

*Specialized in the Development and manufacturing of Softgel and advanced technologies for **Generics, Rx, Otc, and Specialized Nutraceuticals.***



Innovation led, focused on **advanced softgel technologies.**



Experience in **Tech-Transfers**, emphasized in **quality assurance and time-to-market.**



Client-centered experience model based on flexibility, connectivity, trust and empathy.



Experts in the development of **NCEs in Softgel technologies** for specialized and complex molecules. Regulatory knowledge and support for **New Drug Applications.**



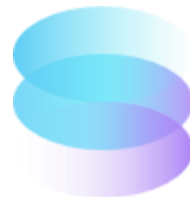
Strong and **proven capabilities** to develop landmark products under strict **cGMP environment.**



Extensive knowledge, robust system, and state-of-the-art facilities for handling **High Potent Compounds, including hormonal products and other complex oral modalities.**



Multi-Site Manufacturing and development capabilities **achieving supply chain efficiency.**



Softgel Site

CPhe

Center for Pharmaceutical Excellence

West Palm Beach, FL





Softgel Site

CENTER FOR PHARMACEUTICAL EXCELLENCE

With a comprehensive range of **CDMO services in diverse technologies**, designed to elevate any pharmaceutical projects, we are focused on supporting **customer needs and exceeding their expectations.**



Our softgel facility offers

Integrated Services in **Development, Scale up, Commercial Manufacturing and Packaging**



CAPABILITY

- **4 Softgel Encapsulation Lines.**
- **Preclinical, clinical trial, launch and commercial** manufacturing of softgels.
- **Softgel Encapsulation machines** that can produce **3,000 to 500,000 capsules per hour, offering volume flexibility** to our customers.
- **Analytical and formulation development** laboratories.



COMPLIANCE

- **Quality Control Systems** to support **cGMP manufacturing. (Rx and Nutra)** 
- **Impeccable history** with recent **FDA inspection.** 
- Certified by **Health Canada.**  
- **Dietary Supplements Good Manufacturing Practice (GMP) certification.** 
- Registered with the **DEA for scheduled compounds.** 



CONVENIENCE

- **Strategically located U.S.-based** with an excellent **South Florida location**
- With **International airports** within **85 miles** of the facility.



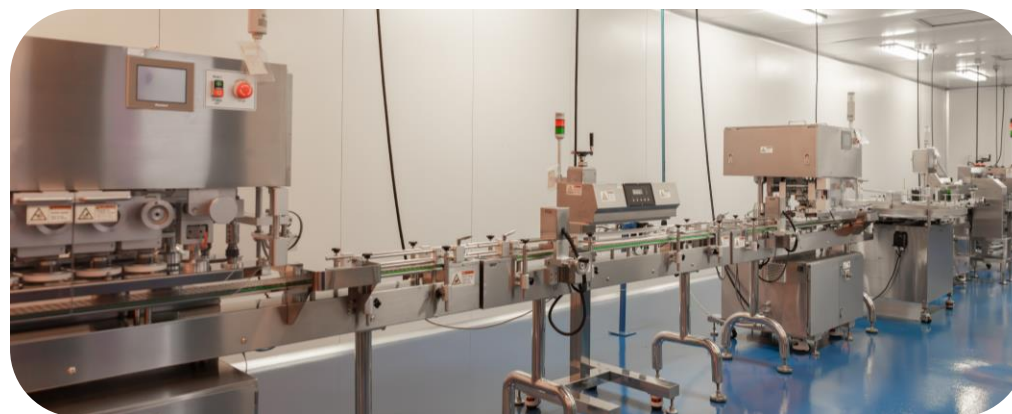


Bottle Packaging Line Capability



Bottle Packaging Line CAPABILITY

2.5M Bottles x 60 / Monthly





Analytical Capabilities



- **Analytical method development, validation, and testing**
- Validation of **Swab Methods** for Cleaning Verification
- **Batch/lot release testing** for **APIs, raw materials** and **formulated drug products**
- **Stability testing**
- **Compendial testing**
- **Micro testing of raw materials** and **finished products** and **critical utilities.**

ANALYTICAL TESTING



Analytical Capabilities



ANALYTICAL INSTRUMENTATION

- HPLC (High Performance Liquid Chromatography)
- LCMS
- Gas Chromatography
- Dissolution (Apparatus I, II, III, IV)
- UV-Vis Spectroscopy
- FTIR (Fourier-Transform Infrared Spectroscopy)
- TLC (Thin-Layer Chromatography)
- Karl Fischer
- Viscometer
- Texture Analyzer



Equipment &
CAPABILITIES



Encapsulation Equipment & Manufacturing Output Capacity



ENCAPSULATION EQUIPMENT

- Sky 6" Encapsulation Line (R&D Suite)
- Sky 6" Encapsulation Line (Drug Manufacturing Suite)
- Sky 10" Encapsulation Line (Suite 250)
- Pharmagel 12" Encapsulation Line (Suite 225)



MANUFACTURING OUTPUT CAPACITY

- 3,000 to 500,000 capsules per hour
- Capacity of ~500mm-1.5 b capsules per annum





Complete
FORMULATION & R&D
Capabilities



Formulation & **R&D CAPABILITIES***

Our **R&D team** is always in the search of new formulations and innovative solutions that satisfy patient's needs.



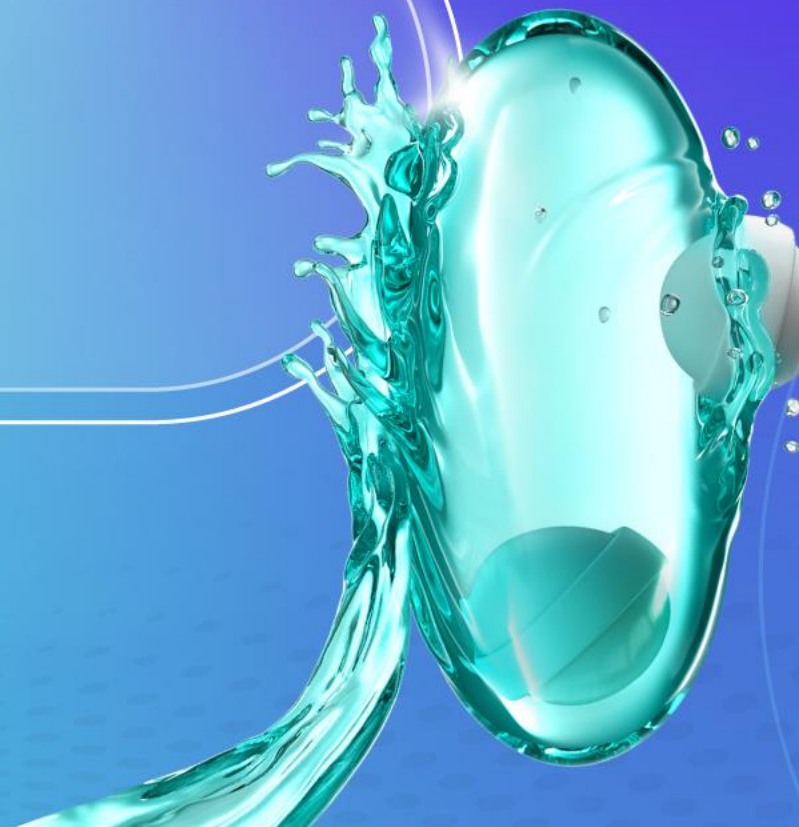
- Development of **novel patentable formulations**
- **Solubility Screening**
- **Fill formulation development** (Solution, suspension, self emulsifying drug delivery systems, lipid-based drug delivery systems and controlled release)
- **Gel formulation development**
- Gel/ Fill **compatibility studies**
- **Small-scale encapsulation** for early development and **final formulation selection following Quality by Design (QBD)**
- **cGMP clinical supplies manufacturing and Packaging**

*Provided From Colombia.





Innovative Softgel Technologies





Innovative Softgel Technologies

AVAILABLE ON SITE





TECHNOLOGIES

Consumers prefer and deserve





For more information about Sofgen Pharmaceuticals visit:

www.sofgenpharma.com

