Renaissance

US-based CDMO for Nasal Sprays & Aseptic Filling

OUR CAPABILITIES

Unit-dose and bi-dose nasal spray development and manufacturing + Aseptic vial fill-finish development and manufacturing
Analytical development & testing services + Spray characterization development and testing services + Global regulatory experience
Preserved and Aseptic multi-dose nasal spray development and manufacturing + Formulation development & optimization
Dedicated GMP clinical manufacturing suite + Tech transfers + DEA Schedule I-V products

MANUFACTURING CAPABILITIES

Our state-of-the-art manufacturing facilities located in New Jersey are equipped to handle projects from small-scale clinical manufacturing to large-batch commercial manufacturing. Our site is also set up to manufacture cold-chain products as well as DEA Scheduled I-V products.

UNIT-DOSE AND BI-DOSE NASAL

+ **6 filling lines capable of supporting a wide range of batch sizes**
  - Vacuum stoppering and mechanical stoppering are available
+ **5 device assembly and labeling lines with line speeds of up to 200 units/min**
+ **Small-batch clinical filling and assembly line**
  - Batch sizes: 0.5-5L
+ **High-speed, fully automated assembly line with in-line cartoning and serialization**
+ **3 secondary packaging lines with in-line blistering, cartoning, and serialization**

MULTI-DOSE NASAL

+ **High-speed automated filling line for sterile preservative-free nasal formulations**
  - In-line vial washing and depyrogenation prior to filling
  - Product is filled and sealed in Grade A environment
+ **High-speed automated filling line for preserved nasal formulations**
  - Can support multiple nasal spray pump types in snap and crimp-on
  - Glass and plastic bottles
+ **Small-scale filler for development and clinical trial batches**
+ **Automated secondary packaging line**

ASEPTIC FILLING

+ **High-speed vial filling line to support late-stage clinical and commercial manufacturing**
  - Batch sizes: 20-1,200L
  - In-line vial washing and depyrogenation prior to filling
  - Vial sizes: 2-100mL
+ **Full automated and semi-automated visual inspection**
+ **Automated secondary packaging line**

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DEVELOPMENT CAPABILITIES

+ Dedicated R&D laboratory for the development of nasal sprays and small-volume parenteral products
+ Formulation development and optimization
+ Analytical method development
+ Spray characterization method development
+ Small-scale manufacturing to support pre-clinical studies
+ Stability storage for ICH conditions

SPEED TO CLINIC MANUFACTURING PROGRAM

We have recently installed a dedicated clinical trial manufacturing suite for manufacturing unit-dose and bi-dose nasal sprays. This dedicated space allows for faster and more economical clinical trial manufacturing. Contact us to learn more about this new service.

TESTING SERVICES

Nasal Spray Development & Testing

+ Device selection
+ Device reliability
+ Device functionality testing
+ Spray Method Development & Validation
  - Spray Pattern*
  - Plume Geometry*
  - Droplet Size Distribution*
  - Actuation Parameters*
  - Spray Content Uniformity*
+ Method transfer
+ Bioequivalence testing
+ Particle size distribution
+ Priming & repriming
+ Temperature cycling
+ Robustness
+ Effect of dosing orientation
+ Device QA release
+ Finished product batch release

**These services are also offered as a stand-alone contract offering.*

ADDITIONAL TEST METHODS

+ Assay *(HPLC, GC, UPLC, etc.)*
+ Impurities and Degradation
+ Related Substances
+ Preservative Assay
+ Particle Size Analysis
+ Particulate Matter
+ Viscosity
+ Microbial Limits
+ Sterility*

**These services are also offered as a stand-alone contract offering.*