Leiters Health
QUALITY COMPOUNDING FOR LIFE™

ON-Q* Pain Relief System Pharmacy Fill Service

Healthcare providers today are challenged to do more with less while trying to improve patient care. Healthcare organizations that perform sterile drug compounding in-house continue to face new, heightened quality and patient safety requirements and intensive regulatory oversight to assure compliance with regulatory guidelines. As regulations continue to evolve, it is becoming more difficult for hospitals, surgery centers and clinics to safely and effectively compound drugs in house.

In addition, with ongoing national drug shortages, getting local anesthetic has been harder than ever. Pharmacists are struggling to get access to drugs which means health care providers are finding it difficult to offer continuous infusion therapy to their patients.

To help you address these challenges, Leiters Health is pleased to offer our customers a pharmacy fill service for the AVANOS Medical ON-Q* Pain Relief System pumps. Outsourcing the filling of pumps allows your pharmacy and clinical staff to spend more time on what matters most – providing superior patient care.

CURRENT OFFERING

ON-Q* Pain Relief System (Pump/Drug)	Item
ON-Q* CB004; 400ml Select-A-Flow*, 2-14ml/hr, Bupivacaine HCl 0.125% (1.25 mg/mL), 550mL†	K-F9102
ON-Q* CB004; 400ml Select-A-Flow*, 2-14ml/hr, Ropivacaine HCl 0.2% (2 mg/mL), 550mL†	K-F9202
ON-Q* CB006; 400ml Select-A-Flow*, ONDEMAND*, Ropivacaine HCl 0.2% (2 mg/mL), 550mL†	K-F9206
ON-Q* CB6004; 600ml Select-A-Flow*, 2-14ml/hr, Ropivacaine HCl 0.2% (2 mg/mL), 750mL†	K-F9208
ON-Q* CB6007; 600ml Select-A-Flow*, dual, 1-7ml/hr/site, Ropivacaine HCl 0.2% (2 mg/mL), 750mL†	K-F9210
ON-Q* P400X8; 400ml Fixed Flow, Ropivacaine HCl 0.2% (2 mg/mL), 550mL†	K-F9214

ambIT® Pain Control System (Pre-filled bags)	Item
Ropivacaine HCl 0.2% (2 mg/mL), 500 mL in a 500 mL bag	F3337
Ropivacaine HCl 0.2% (2 mg/mL), 1000 mL in a 1000 mL bag	F3340

ADDITIONAL INFORMATION

- 90 day Beyond Use Date (BUD)[1]
- Stability testing is completed prior to producing batches.
- Full microbiological and chemistry testing is performed prior to each batch being released.
- A batch specific Certificate of Analysis (CoA), detailing all the testing performed, is provided with every shipment.

Leiters Health

Elevating the standards in 503B pharmaceutical outsourcing.

The world of healthcare is constantly changing. With increasing regulatory pressure, treatment shortages and the need to do more with less, high quality pharmaceutical outsourcing is more important than ever.

Leiters Health, founded in 1926, is an FDA-registered 503B outsourcing provider of hospital and ophthalmic compounded sterile preparations and pharmacy services..

Our team of experts in sterile pharmaceutical manufacturing, repackaging, and compounding provide a sophisticated understanding of what it takes to elevate quality and consistency of supply. We combine our team, our robust processes and our state-of-the-art outsourcing facility to ensure the highest quality products and services.

THROUGH 3 KEY PILLARS, PEOPLE, PLACE AND PRODUCT, LEITERS HEALTH IS ELEVATING THE STANDARDS IN PHARMACEUTICAL OUTSOURCING.

PEOPLE

- Highly trained multifunctional teams of pharmaceutical experts ensure quality and regulatory compliance for all released product.
- Relevant industry experience with sterile injectable pharmaceutical companies, hospital pharmacies, and academia.
- Our customer experience team of regional based account representatives, account managers and customer service specialists work together to provide you with consistent and reliable service.

PLACE

- FDA-registered and inspected, cGMP compliant 503B outsourcing provider.
- Licensed to ship to all 50 states (+ the District of Columbia).
- State-of-the-art equipment and automation is used throughout our sterile manufacturing process.

PRODUCT

- All sterile preparations are produced under 503B of the FD&C act (503B Guidance), following current Good Manufacturing Practices (cGMP) and meet or exceed USP <797>.
- Full microbiological and chemistry testing is completed prior to each batch being released. This includes sterility, endotoxin, potency, identification, impurities, particulate (subvisible), visual appearance and pH testing.
- A batch specific Certificate of Analysis (CoA), detailing all the testing performed, is provided with every shipment.

Quality. Compliance. Consistency.

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