Leiters.

COMPOUNDING HEALTH™

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 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

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.

Orders & Inquiries ☎ 800.292.6772 🌐 www.leiters.com ✉ info@leiters.com

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ABOUT LEITERS

Leiters, founded in 1926, provides hospitals, surgery centers, clinics and physician offices access to critically needed compounded sterile preparations. 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 is elevating the standards in pharmaceutical outsourcing.

PEOPLE

Let our team become an extension of your pharmacy. Our multi-disciplinary team of professionals includes quality assurance experts, microbiologists, pharmacists, ophthalmology specialists and health system pharmacy experts.

- We have a legacy of deep experience in current Good Manufacturing Practices (cGMP), sterile pharmaceutical product development, manufacturing, compounding, and repackaging.
- Our leadership team has relevant industry experience with sterile pharmaceutical companies, hospital pharmacies, regulatory compliance, 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

This is the place where quality means something. With increasing regulatory pressure, there is a growing need for higher standards in pharmaceutical outsourcing. Our state-of-the-art facility was designed to exceed traditional outsourcing facilities and ensures quality, consistency, and compliance with all released products.

- 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

Leiters offers a wide range of 503B ready-to-administer compounded sterile preparations.

- 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>.
- Independent laboratory testing of chemical and microbiological characteristics including identification, bioburden and endotoxin of all incoming active and inactive ingredients.
- Stability testing is performed before producing batches.
- Microbiological and chemistry testing (including sterility, endotoxin, potency, identification, impurities, particulate-sub visible, visual appearance, and pH testing) is completed before any product release.
- Beyond Use Dates (BUDs) are established based on product-specific stability testing of both chemical and microbiological characteristics.
- A batch specific Certificate of Analysis (CoA), detailing all the testing performed, is provided with every shipment.

Quality. Compliance. Consistency.

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†Fill volume +/-3%; not to exceed 550mL or 750mL. [1] BUD is from date of compounding. Leiters is a non-affiliated business partner of Avanos Medical, Inc. Leiters is solely responsible for the pharmaceutical filling services and Avanos is only the medical device manufacturer for the ON-Q® pump manufacturer.