



Leiters.

COMPOUNDING HEALTH™

ON-Q* Pain Relief System Pharmacy Fill Service



Leiters, founded in 1926, provides hospitals, surgery centers, clinics and physician offices access to high-quality 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

- 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)
- Continuous facility environmental monitoring to maintain product quality standards

PRODUCT

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

Quality. Compliance. Consistency.

Leiters.

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. They face additional in-house challenges as well such as:

- Continuing drug shortages and escalating drug costs
- Shorter in house shelf life can lead to medication waste
- Costly investments in equipment and staff training to ensure compliance

Leiters is pleased to offer our customers a pharmacy fill service for the AVANOS Medical ON-Q* Pain Relief System pumps.

CURRENT OFFERING:

ON-Q* Pain Relief System (Pump/Drug)	Leiters Item No.
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

““ The partnership between AVANOS Acute Pain and Leiters is our ongoing commitment to provide non-opioid solutions to patients for post-surgical pain management. Combining Leiters superior pharmacy services and AVANOS Acute Pain ON-Q* Pain Relief solutions is simple, convenient, and most importantly integral in achieving our vision of getting patients back to the things that matter. ””

Michael Acevedo, General Manager Acute Pain, AVANOS Medical

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. This includes, sterility, endotoxin, potency, identification, impurities, particulate (sub visible), visual appearance and pH testing

Orders & Inquiries



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