Leiters.
COMPOUNDING HEALTH™

Concentrated Vials

Hospitals, surgery centers and clinics each have unique needs, and these needs may vary widely within an individual facility. When caring for patients, there is zero room for error. Concentrated vials from Leiters, help to enhance patient safety, provide efficiency, and help to eliminate waste.

Our concentrated vials are innovative compounded sterile solutions that deliver a rapid, precise dose or concentration when introduced into the patient specific diluent bag. They bring stability and consistency to the supply chain, especially for the critically needed medicines in less than 24-hour pharmacies.

Our concentrated vial offering will be expanded in 2022 with additional products expected to be added to the portfolio. As many of these products are in high-demand, please contact us today to reserve your inventory.

Item No.	NDC	Item Description	Strength	Fill	Container	BUD[1]
F4005	71449-142-19	Hydromorphone HCl 30 mg (API)	25 mg/mL	1.2 mL	5 mL vial	90
F4006	71449-142-95	Hydromorphone HCl 50 mg (API)	25 mg/mL	2 mL	5 mL vial	90
F4007	71449-142-97	Hydromorphone HCl 100 mg (API)	25 mg/mL	4 mL	5 mL vial	90
F4008	71449-142-39	Hydromorphone HCl 200 mg (API)	25 mg/mL	8 mL	10 mL vial	90
F4009	71449-142-23	Hydromorphone HCl 250 mg (API)	25 mg/mL	10 mL	10 mL vial	90
F4002	71449-133-95	Norepinephrine Bitartrate 4 mg (API)	2 mg/mL	2 mL	5 mL vial	90
F4003	71449-133-97	Norepinephrine Bitartrate 8 mg (API)	2 mg/mL	4 mL	5 mL vial	90
F4004	71449-133-39	Norepinephrine Bitartrate 16 mg (API)	2 mg/mL	8 mL	10 mL vial	90
F4010	71449-146-26	Phenylephrine HCl 20 mg (API)	20 mg/mL	1 mL	5 mL vial	180
F4011	71449-146-95	Phenylephrine HCl 40 mg (API)	20 mg/mL	2 mL	5 mL vial	180
F4012	71449-146-27	Phenylephrine HCl 50 mg (API)	20 mg/mL	2.5 mL	5 mL vial	180
F4013	71449-146-97	Phenylephrine HCl 80 mg (API)	20 mg/mL	4 mL	5 mL vial	180
F4014	71449-146-21	Phenylephrine HCl 100 mg (API)	20 mg/mL	5 mL	5 mL vial	180

Additional products coming soon. Please reach out to your local representative or contact us at 800.292.6772 for current availability.
PF: Preservative-free | API: Active Pharmaceutical Ingredient | FDP: Finished Dose Product

Product Benefits and Details

- Compliant with all IV workflow and IV compounding software and all vial docking technologies.
- The concentrated vial sterile preparations are in solution, making them easier to dilute, with no waiting for reconstitution of a lyophilized powder.
- Reduce inventory space, minimize waste, and increase your inventory turns.
- In the forward positions, the vials can be stored in automated dispensing machines (ADMs) for rapid retrieval, dose tracking and subsequent administration to a patient by a nurse utilizing your institution's vial-to-bag adapter and activation process.
- Pre-labeled vials and boxes include TALLman lettering, barcodes and color-coding for drug/strength differentiation to help reduce medication errors.
- Leiters provides an additional vial top seal as a safety feature to help prevent the potential of misuse from a healthcare professional.

Orders and inquiries: 800.292.6772 www.leiters.com info@leiters.com

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.
- 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.
- 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.

Customer represents that the 503B outsourced drug will be administered or dispensed only to a patient for whom there is a clinical difference from an approved drug, as determined by the prescribing practitioner for that patient.