Leiters.
COMPOUNDING HEALTH™

Pre-filled Intravenous (IV) Bags

Leiters is expanding its portfolio of compounded sterile preparations to include IV bags. Our new pre-filled, ready-to-administer IV bags offer efficiencies to pharmacies and clinical teams without sacrificing quality. These ready-to-administer bags eliminate the need to compound in-house, resulting in increased productivity, mitigated risk of error and contamination, enhanced workflow and increased time for what matters most — patient care.

Our IV bag 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]
F3341	71449-072-77	Fentanyl citrate 1,000 mcg added to 0.9% Sodium Chloride, PF (API)	10 mcg/mL	100 mL	100 mL bag	120
F3342	71449-072-82	Fentanyl citrate 2,500 mcg added to 0.9% Sodium Chloride, PF (API)	10 mcg/mL	250 mL	250 mL bag	120
F3344	71449-019-77	Fentanyl citrate 2,000 mcg added to 0.9% Sodium Chloride, PF (API)	20 mcg/mL	100 mL	100 mL bag	120
F3350	71449-148-82	Phenylephrine HCl 20 mg added to 0.9% Sodium Chloride (FDP)	80 mcg/mL	250 mL	250 mL bag	150
F3352	71449-150-82	Phenylephrine HCl 40 mg added to 0.9% Sodium Chloride (FDP)	160 mcg/mL	250 mL	250 mL bag	150
F3353	71449-151-82	Phenylephrine HCl 50 mg added to 0.9% Sodium Chloride (FDP)	200 mcg/mL	250 mL	250 mL bag	150
F3354	71449-152-82	Phenylephrine HCl 100 mg added to 0.9% Sodium Chloride (FDP)	400 mcg/mL	250 mL	250 mL bag	150
F3337	71449-124-83	Ropivacaine HCl 0.2%, 2 mg/mL in 0.9% Sodium Chloride, PF (API)	2 mg/mL	500 mL	500 mL bag	180
F3340	71449-124-91	Ropivacaine HCl 0.2%, 2 mg/mL in 0.9% Sodium Chloride, PF (API)	2 mg/mL	1000 mL	1000 mL bag	180
F3204	71449-027-68	Vancomycin HCl 1 g added to 0.9% Sodium Chloride, PF (FDP)	1 g	250 mL	250 mL bag	90
F3206	71449-028-68	Vancomycin HCl 1.25 g added to 0.9% Sodium Chloride, PF (FDP)	1.25 g	250 mL	250 mL bag	90
F3208	71449-029-68	Vancomycin HCl 1.5 g added to 0.9% Sodium Chloride, PF (FDP)	1.5 g	250 mL	250 mL bag	90
F3211	71449-030-70	Vancomycin HCl 1.75 g added to 0.9% Sodium Chloride, PF (FDP)	1.75 g	500 mL	500 mL bag	90
F3213	71449-031-70	Vancomycin HCl 2 g added to 0.9% Sodium Chloride, PF (FDP)	2 g	500 mL	500 mL bag	90

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

- Ready-to-administer compounded sterile preparations of the most used critical IV medications and strengths.
- Available pre-filled in the most utilized bag sizes.
- Room temperature storage for most presentations[2]
- Labeling including TALLman lettering, barcodes and color-coding for drug/strength differentiation to help reduce medication errors.
- 90-180 day Beyond Use Dates (BUD)[1]
- Latex-free

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.

 [1]Beyond Use Date is from date of compounding. [2]Vancomycin presentations must be refrigerated. 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.