Leiters.

COMPOUNDING HEALTH™

Introducing IV Solutions

An innovative new offering
available exclusively from Leiters.

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As the healthcare landscape changes, so do the pressures on hospitals, surgery centers and healthcare providers. With challenges including drug and labor shortages, mounting regulatory pressure, expanding workload, and increasing financial constraints, our IV Solutions product line offers numerous benefits.

IV Solutions is a new portfolio of pre-filled IV bags and concentrated vials that simplify the delivery of critical medications and allow pharmacy and clinical staff to spend more time on what matters most - providing superior patient care.

Available exclusively from Leiters, these products enable timely, precise drug delivery without sacrificing quality and safety. And our IV Solutions offer you options that meet the unique needs of your facility.

When you need options, Leiters provides the solutions.

Benefits of Leiters' IV Solutions

Enables rapid precise dose with increased quality and dosing accuracy to enhance patient safety.

Facilitates efficiency without sacrificing compliance and safety.

Allows providers to focus on enhancing the patient experience.

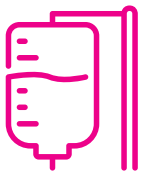
Supports doing more with less while maintaining the highest level of quality.

IV Solutions from Leiters is a comprehensive product line that helps standardize your formulary while offering flexibility. We offer presentations in either IV bags or concentrated vials. You choose what best meets the needs of your facility.

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.

Delivered with documented accuracy and enhanced patient safety, IV bags offer the convenience of a finished dose product. When time means everything, our IV bags provide an accurate dose with greater speed and efficiency in the emergency department or anywhere within your facility.



Leiters comprehensive IV bag offering will include multiple presentations of:

Fentanyl Citrate
Hydromorphone HCl
Midazolam
Norepinephrine Bitartrate
Oxytocin
Phenylephrine HCl
Ropivacaine HCl
Vancomycin HCl
Vasopressin

Product Benefits and Details

Ready-to-administer compounded sterile preparations of the most used critical IV medication and strengths.

Available pre-filled in the most utilized bag sizes.

90-180 day Beyond Use Dates (BUD)[1].

Individually wrapped IV bags are shipped in packs of 6 and 12 in minimalistic shipping containers to maximize shelf space at your facility.

Tamper-evident sealed medication port to ensure product integrity.

Labeling features TALLman lettering, barcodes and color-coding for drug/strength differentiation to help reduce medication errors.

Latex-free

Room temperature storage for most presentations[2].

Concentrated Vials

Hospitals, surgery centers and physician offices 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.

Leiters concentrated vial offering will include multiple presentations of:

Epinephrine

Hydromorphone HCl

Norepinephrine Bitartrate

Oxytocin

Phenylephrine HCl

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 featuring 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.

IV Solutions Product Portfolio

Our IV Solutions portfolio will be expanded in 2022. Additional medications and presentations coming soon. Please reach out to Leiters for additional information.

INTRAVENOUS (IV) BAGS

Item Number	NDC	Item Description	Fill	Container	BUD (days)[1]	Pack Size
F3341*	71449-072-77	Fentanyl Citrate 1000 mcg (10 mcg/mL) added to 0.9% Sodium Chloride, PF (API)	100 mL	100 mL bag	120	12
F3342*	71449-072-82	Fentanyl Citrate 2500 mcg (10 mcg/mL) added to 0.9% Sodium Chloride, PF (API)	250 mL	250 mL bag	120	12
F3344*	71449-019-77	Fentanyl Citrate 2000 mcg (20 mcg/mL) added to 0.9% Sodium Chloride, PF (API)	100 mL	100 mL bag	120	12
F3350*	71449-148-82	Phenylephrine HCl 20 mg (80 mcg/mL) added to 0.9% Sodium Chloride (FDP)	250 mL	250 mL bag	120	12
F3352*	71449-150-82	Phenylephrine HCl 40 mg (160 mcg/mL) added to 0.9% Sodium Chloride (FDP)	250 mL	250 mL bag	150	12
F3353*	71449-151-82	Phenylephrine HCl 50 mg (200 mcg/mL) added to 0.9% Sodium Chloride (FDP)	250 mL	250 mL bag	150	12
F3354*	71449-152-82	Phenylephrine HCl 100 mg (400 mcg/mL) added to 0.9% Sodium Chloride (FDP)	250 mL	250 mL bag	150	12
F3337	71449-124-83	Ropivacaine HCl 0.2% (2 mg/mL) in 0.9% Sodium Chloride, PF (API)	500 mL	500 mL bag	180	6
F3340	71449-124-91	Ropivacaine HCl 0.2% (2 mg/mL) in 0.9% Sodium Chloride, PF (API)	1000 mL	1000 mL bag	180	6
F3204*	71449-027-68	Vancomycin HCl 1 gm added to 0.9% Sodium Chloride, PF (FDP)	250 mL	250 mL bag	90	12
F3206*	71449-028-68	Vancomycin HCl 1.25 gm added to 0.9% Sodium Chloride, PF (FDP)	250 mL	250 mL bag	90	12
F3208*	71449-029-68	Vancomycin HCl 1.5 gm added to 0.9% Sodium Chloride, PF (FDP)	250 mL	250 mL bag	90	12
F3211*	71449-030-70	Vancomycin HCl 1.75 gm added to 0.9% Sodium Chloride, PF (FDP)	500 mL	500 mL bag	90	6
F3213*	71449-031-70	Vancomycin HCl 2 gm added to 0.9% Sodium Chloride, PF (FDP)	500 mL	500 mL bag	90	6

CONCENTRATED VIALS

Item Number	NDC	Item Description	Fill	Container	BUD (days)[1]	Pack Size
F4005*	71449-142-19	Hydromorphone HCl 30 mg (25 mg/mL) (API)	1.2 mL	5 mL vial	90	10
F4006*	71449-142-95	Hydromorphone HCl 50 mg (25 mg/mL) (API)	2 mL	5 mL vial	90	10
F4007*	71449-142-97	Hydromorphone HCl 100 mg (25 mg/mL) (API)	4 mL	5 mL vial	90	10
F4008*	71449-142-39	Hydromorphone HCl 200 mg (25 mg/mL) (API)	10 mL	10 mL vial	90	10
F4009*	71449-142-23	Hydromorphone HCl 250 mg (25 mg/mL) (API)	10 mL	10 mL vial	90	10
F4004*	71449-133-39	Norepinephrine Bitartrate 16 mg (2 mg/mL) (API)	8 mL	10 mL vial	90	10
F4002*	71449-133-95	Norepinephrine Bitartrate 4 mg (2 mg/mL) (API)	2 mL	5 mL vial	90	10
F4003*	71449-133-97	Norepinephrine Bitartrate 8 mg (2 mg/mL) (API)	4 mL	5mL vial	90	10
F4010*	71449-146-26	Phenylephrine HCl 20 mg (20 mg/mL) (API)	1 mL	5mL vial	180	10
F4011*	71449-146-95	Phenylephrine HCl 40 mg (20 mg/mL) (API)	2 mL	5mL vial	180	10
F4012*	71449-146-27	Phenylephrine HCl 50 mg (20 mg/mL) (API)	2.5 mL	5mL vial	180	10
F4013*	71449-146-97	Phenylephrine HCl 80 mg (20 mg/mL) (API)	4 mL	5mL vial	180	10
F4014*	71449-146-21	Phenylephrine HCl 100 mg (20 mg/mL) (API)	5mL	5mL vial	180	10

*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

Why Leiters

Leiters provides one of the most comprehensive, trusted offerings of high-quality sterile preparations.

In today's complex healthcare environment there is no room for error and time is critical. With immense cost pressures, intensive and evolving regulatory oversight, safely and effectively in-house compounding of sterile preparations is becoming increasingly difficult and expensive. Our products and services offer peace of mind when faced with these challenges.

A Strong History of Quality and Compliance

Leiters has a long history of innovation to meet the latest regulatory requirements and market needs of its customers. Our sterile preparations are produced under Section 503B of the FD&C Act (503B Guidance), cGMP, and USP <797>, with every batch undergoing rigorous quality assurance processes and all testing is completed by independent laboratories before release.

Our facility consistently upholds all standards based on the audits conducted by the FDA, States of California and Florida Boards of Pharmacy, multiple health systems, group purchasing organizations, and other independent accreditation organizations. We maintain an outstanding industry-leading regulatory compliance record that includes:

No outstanding FDA Warning or Untitled Letters.

No repeat 483 observations.

No observations from DEA inspection.

Participation in FDA Compounding Centers of Excellence training sessions.

Trusted by more than 1,200 U.S. healthcare facilities, Leiters is DEA licensed and FDA registered, State Board of Pharmacy licensed, and follows cGMP and GDP guidelines.

About Leiters

Founded in 1926, Leiters 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 three 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 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 includes regional account representatives, account managers and customer service specialists who work together to provide consistent and reliable service.

Place

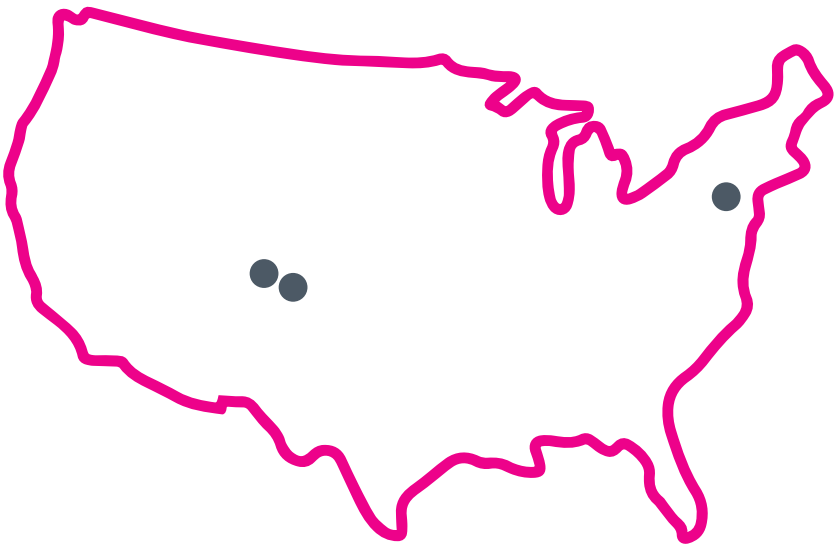
This is the place where quality means something. With increasing regulatory pressure, there is a growing need for higher standards in pharmaceutical outsourcing. Our state-of-the-art facility was designed to exceed traditional outsourcing facilities and ensure quality, consistency, and compliance with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

FDA-registered and inspected, cGMP compliant 503B outsourcing provider.

Licensed to ship to all 50 states and the District of Columbia.

State-of-the-art equipment and automation are used throughout our sterile manufacturing process.

We continue to expand and add automation to our facilities to ensure we are well-positioned to respond to the changing landscape of the 503B industry and the increasing demand for our high-quality products and services.



Englewood Colorado (Compark)
60,000 SF facility

Englewood Colorado (Highfield)
cGMP warehousing and Corporate employee offices

Buena, New Jersey
Newly acquired 110,000 SF facility that will be built out in 2022

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 prior to producing batches.

Full microbiological and chemistry testing is completed prior to each batch being released. This includes, sterility, endotoxin, potency, identification, impurities, particulate (sub visible), 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.

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Learn More

Our mission is to deliver better medicine to more people. We do this through a relentless focus on quality, consistency, and reliability. We are committed to developing innovative pharmacy products and services to ensure a reliable supply of high-quality medicines to you and your patients.

For more information or to learn how your facility can benefit from our products and services, contact us at:

800.292.6772

Leiters.com

info@leiters.com

[1]Beyond Use Date is from date of compounding or date of repackaging.

[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 the patient.

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