

● ● ● **Fagron**
● ● ● **Sterile**
● ● ● **Services US**

503B OUTSOURCING



Find your solution at
fagronsterile.com

Fagron Sterile Services US

Nearly 30 Years of Compounding to serve you better

Founded in 1990, Fagron is the world's leading pharmaceutical company dedicated to safe, quality pharmaceutical compounding and personalized medicine. An unwavering dedication to quality and providing superior products has fueled growth for almost three decades. Today, Fagron provides compounding solutions in over 60 countries to more than 200,000 customers.

In 2010, Fagron entered the North American market. As part of the only vertically integrated pharmaceutical company dedicated to sterile compounding, our 503B facilities drive outsourcing solutions on a comprehensive level across the continuum of care.

As a forward-thinking pharmaceutical supplier, Fagron recognized the opportunity to serve you and your patients better by acquiring JCB Laboratories. JCB was at the forefront of shaping industry standards in sterile preparations for nearly two decades and was one of the first 503Bs in the country to register with the FDA.

In 2019, JCB Laboratories and Fagron Sterile Services synchronized branding to serve customers better and became Fagron Sterile Services US (FSS).

FSS offers specialized solutions to acute care hospitals, ambulatory surgery centers and physician offices to provide the highest quality service across the continuum of care – putting you and your patients first.

- Significant capabilities in research, development, manufacturing and distribution
- Heavy investment in state-of-the-art facilities and cutting edge automation
- Shared belief in the need to improve safety and efficiency for 503B FDA registered Outsourcing Facilities compounding sterile preparations (CSPs)

Product Overview

- **Operating Room (OR) Syringes**

Reduce waste and cut down on number of touch-points/steps in surgery prep. FSS OR solutions are prepared with the most stringent testing processes available. We understand the importance of quality, accuracy and efficiency.

- **Ophthalmics**

Support safety and improved efficiency with high-quality ophthalmic products. Learn more about our Avastin® purchase programs and other solutions. FSS sets the standard for safety, value pricing and clinical expertise.

- **Topical Anesthesia**

Use an economical, easy-to-administer sterile solution to provide patients rapid topical anesthesia. Lidocaine-Epinephrine-Tetracaine (LET) solution provides and maintains anesthesia without the use of controlled substances.

- **Corticosteroids**

Give your patients peace of mind with preservative-free corticosteroids. We offer unit-of-use alternatives made under stringent cGMP guidelines.

- **Urology (Mito Bladder)**

Ensure your patients receive safe and effective mitoMYcin bladder therapy for intravesical use. We offer leading urology solutions produced in state-of-the-art hazardous drug clean room environments.

- **Dialysis**

Provide safe treatment solutions for patients on dialysis by using quality products developed by clinical experts and produced following cGMP standards.

Ready-to-Use OR Syringes

Time and accuracy matter in the operating room, which is why every OR Syringe from Fagron Sterile Services is thoroughly tested. No syringe is released from quarantine until all testing is complete and approved by our Quality team.

All OR Syringes are clearly labeled, adhering to ASTM, DQSA and ISMP medication and anesthesia labeling standards. This includes TALLman lettering, presentation specifications, bar codes, expiration dating and room temperature storage requirements.

FSS offers multiple presentations of the most commonly used anesthesia syringes.

Compounded OR Anesthesia:

- atropine
- lidocaine
- ePHEDrine
- neostigmine
- glycopyrrolate
- PHENYLephine
- HYDROmorphone
- rocuronium
- ketamine
- succinylcholine



Quality by Design

FDA Inspected, In-House Quality Testing Labs

We comply with all FDA regulations, cGMP, GDP and strive to achieve the highest quality standards within the industry.

- 100% of batches tested for sterility, P.M. and potency
- State-of-the-Art environmental monitoring
- Multiple VHP isolators for sterility testing
- 16 ISO 5 classified aseptic processing environments
- Industry-leading automation
- In house lab capabilities for all cGMP finished drug testing requirements, including potency*, sterility, endotoxin and particulate matter

* All methods utilized are validated according to cGMP requirements.



Ophthalmics

Ophthalmic preparations support patient health, safety and effective treatment outcomes, but present unique production challenges. FSS is recognized as the industry standard for ophthalmic compounding.

Ophthalmic compounding is one of the cornerstones of DQSA because of the need for high concentration, small volume compounded sterile preparations. FSS delivers ophthalmic solutions you can rely on.

Ophthalmic Solutions:

- moxifloxacin HCl (Generic for Avelox®)
- moxifloxacin HCl (Vigamox®)
- vancomycin
- combination eye drops
- bevacizumab (Avastin®)
- EPINEPHrine
- mitoMYcin
- PHENYLephine
- lidocaine 1% / PHENYLephine 1.5% in BSS



State-of-the-Art Facilities

Two FDA registered 503B compounding pharmacies located in Wichita, KS. With over 15,000 sq. ft. of space dedicated to cGMP clean room suites, our facilities are designed to ensure unilateral movement of product and people.

Introducing the next generation in sterile compounding:

- 16 ISO 5 classified aseptic processing environments
- Industry-leading, state-of-the-art environmental monitoring system
- Stringent testing on each and every batch
- In-house lab capabilities for all cGMP finished drug testing requirements
- Industry-leading automation

Your patient's safety is important to us, so quality is our priority. We are dedicated to the safety of the customers and patients we serve.

Each cGMP cleanroom is equipped with independent HVAC systems and is fitted with industry-leading automation and depyrogenation technology. All lots are stringently tested and no product is released before all testing is documented and complete.

Transactional Ease

Fagron Sterile Services commits to patient safety and excellence in customer service. You will always talk directly to a member of our knowledgeable staff who will handle your requests quickly and accurately.

Setup an account to access our mobile friendly web shop and conveniently place an order 24/7 to enjoy quick access to: full order history, COAs and invoices, batch details, shipment tracking, environmental monitoring reports, centralized purchasing, and more.

Committed Supply

We are committed to delivering a 503B solution you can rely on. That is why we drew a line in the sand and developed our Committed Supply Program. Tired of dealing with multiple 503Bs or shortages?

Contact us at CSPprogram@fagronsterile.com to learn more!

Our Values



Customer is Number 1



Speed of Execution



Entrepreneurship



Creativity



Quality



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