

503B outsourcing





At CAPS®, we remain committed to quality in everything we do. As the nation's largest network of outsourcing admixture pharmacy services, we're ready to supply you with a wide array of 503B compounded sterile preparations (CSPs). We adhere to cGMP quality standards using the same process and systems as our B. Braun Pharmaceutical Division so you can meet the needs of even your most critical patients—all while minimizing the risk, cost of labor, waste and resources associated with in-house compounding.

CAPS. Quality, for life.

CAPS[®] 503B Solutions

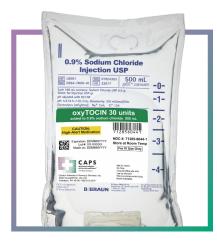
CAPS is registered to dispense batched, non-patient-specific CSPs, such as cardioplegia, critical care and specialty drugs, neonatal parenteral nutrition (PN) starter bags and pre-filled anesthesia syringes. We help hospital pharmacies mitigate risk associated with preparation of high-volume compounded sterile products.



Cardioplegia

CAPS offers cardioplegia with the highest quality standards, including blood cardioplegia, crystalloid cardioplegia, del Nido and microplegia. CAPS cardioplegia features:

- Stended beyond use date (BUD)
- Formulas used by the largest heart programs in the country



Critical Care and Specialty Products

CAPS offers a broad range of premixed drug solutions, such as oxytocin for labor and delivery and vancomycin for treating infections. We also provide products that address needs for critical care, medical surgical nursing and more.



Neonatal PN Starter Bags

PN is essential in the medical management of preterm neonates who experience an abrupt disruption of nutrient delivery. Low birth weight (LBW) and very low birth weight (VLBW) neonates rely on the administration of a "starter" PN solution within the first few hours of life as an important standard of care.

Our neonatal PN starter bags feature:

- Sextended 90-day beyond use date (BUD)
- Multiple standard formulations



Pre-filled Anesthesia Syringes

Built to reduce medication errors in the operating room, improve efficiency and decrease waste, our pre-filled, labeled anesthesia syringes are easy to order and come in the most frequently used drug concentrations and fill volumes. CAPS ready-to-use syringes feature:

- Secure, tamper-evident caps

Committed to Improvements

At CAPS®, we're committed to improving our 503B products and processes to meet critical patient needs through transparent communication of supply, secure ordering through programs like CAPSLink™ and consulting services to navigate the regulation of CSPs.

Programs and Services



CAPSLink™

CAPSLink is a HITRUST-certified portal, featuring a secure back-end architecture specifically designed to reduce the risk of unauthorized access to customer data. For a more efficient process, you can order through CAPSLink and receive most deliveries in two to four business days.



Test, Hold and Release® (THR)

THR integrates cGMP-level end product testing with the release process for our 503B compounded drugs. This program assures that every compounded drug batch from our 503B outsourcing facilities meets strict specifications for sterility, endotoxin and potency release testing before it reaches you and your patients. These test specifications include:

Endotoxin

Documentation

Potency

- pH levels
- Environmental monitoring
- Sterility

Visual inspection





Consulting Expertise

CAPS ConsultingSM Services can help you navigate the complex nature of USP <797>, state regulations and FDA guidelines that require a comprehensive strategy for managing CSPs.

Proven Quality

As a network of FDA-registered 503B outsourcing facilities, our goal is to provide the most comprehensive and continuous quality assurance program in the industry. So you can help more patients get access to the safest, most reliable treatment possible and reassured quality for life.



Product Integrity

Because our 503B Outsourcing Facilities are accredited drug distributors by the National Association of Boards of Pharmacy (NABP), we prioritize the integrity of our products and processes every step of the way. Our automated electronic batch record ensures that all SOPs and applicable quality indicators are fully compliant prior to each batch release, while also improving efficiency.

Expiration Dating

We understand the importance of expiration dating for pharmacy directors in keeping products efficiently stocked. That's why we base our expiration dates on real-time data. By using stability-indicating test methods and container closure integrity tests, we can ensure that each drug is appropriate for patient administration and prolong the life of your inventory.



Environmental Monitoring

The CAPS® compounding clean rooms and ISO Class 5 laminar airflow hoods are monitored daily under dynamic conditions for particulate matter air counts, bioburden air counts and surface bioburden counts.



Personnel Monitoring

All operators must successfully complete a series of media fill, glove tip monitoring and sterile sleeve tests under dynamic, worst-case conditions to participate in sterile compounding. Each operator is retested on a routine basis.



Clear Labeling

Our enhanced labeling system is designed to address:

- Institute for Safe Medication Practices (ISMP) recommendations for compounded sterile preparations, including Tall Man lettering
- 2 USP medication labeling standards
- The Joint Commission's National Patient
 Safety Goals for Medication Management
- ASTM color differentiation by drug class for medications used in the operating room







GPO Trusted

We believe that good partnerships go a long way for the quality and accessibility of our products, which is why CAPS® has a long-term relationship with the largest group purchasing organizations (GPOs) to ensure contract access regardless of affiliation. This helps with:

- **⊘** Potential cost savings
- **⊗** Streamlined supply chain
- **⊗** Regulatory compliance

Backed by B. Braun

CAPS® is proud to be backed by B. Braun,

a leader in effective pharmaceutical and medical device manufacturing, patient and provider safety and sustainable health solutions. Our 503B facilities use IV bags not made with DEHP from B. Braun, and we adhere to cGMP quality standards using the same process and systems as our B. Braun Pharmaceutical Division.

Together, our mission is to enable quality care to an ever-increasing number of patients. Because when lives are on the line, providers like you should be able to get the best care for as many patients as possible.

To learn more, visit capspharmacy.com/qualityforlife.



