


**Quality
is Our Promise.**



Our goal at KRS Global Biotechnology is to provide the highest quality pharmaceutical preparations. We accomplish this with an unrivaled quality assurance and quality control program focusing on strict compliance with current Good Manufacturing Practices (cGMP) and U.S. Pharmacopeia (USP) standards.

AN FDA HUMAN OUTSOURCING FACILITY



KRS is the industry leading FDA registered and inspected 503b Human Outsourcing Facility that provides sterile, non-sterile and sterile intravenous admixture compounding services to patients, surgery centers, ophthalmology clinics, universities and hospitals nationwide.

KRS is committed to being the top provider of these compounding services while developing quality processes that facilitates the highest level of safety for patients of parenteral, enteral, oral and topical preparations.



KRS GLOBAL
BIOTECHNOLOGY
AN FDA HUMAN OUTSOURCING FACILITY



WORLD CLASS PREPARATIONS

Our team of professionals is dedicated to delivering the most effective preparations possible, to meet patients' and health care professionals' needs.

In November of 2013, President Barack Obama signed into law the Compounding Quality Act which states that the compounding industry be made to follow certain guidelines to ensure safety and quality of the products they prepare. Far removed from the days of mortar and pestle compounding, we are now known as a 503B Human Outsourcing Facility.

OUR CORPORATE VISION:

- To provide the highest quality pharmaceutical medications in a timely manner without compromising patient safety
- To set the standard for all other human outsourcing facilities through utilization of manufacturer guidelines

WHO IS KRS GLOBAL BIOTECHNOLOGY?

- Outsourcing facility specializing in sterile injectables and other superior preparations
- Compliance with cGMP—Held to same standards as FDA registered manufacturers
- Specific reporting requirements, including source of ingredients
- Accountability, traceability, and trackability of all preparations
- Validations and closed-system automations that mirror those of pharmaceutical manufacturers
- Double sterilization process: filter and terminal sterilization utilizing autoclave
- Quality assurance with a full analytical laboratory



The FDA is encouraging all hospitals, surgical centers, universities and ophthalmologists to utilize the services of a registered and inspected 503B outsourcing facility to meet their admixing, repackaging and compounding needs. As the laws continue to evolve, only 503B facilities will be able to fill your hospital use needs.

503B CAPABILITIES AND SERVICES

At KRS we provide innovative, effective, and safe solutions to some of the greatest challenges in today's medical environment.

SPECIALIZING IN:

Sterile, non-sterile and sterile intravenous admixture compounding services performed in a quality controlled, closed-system, automated environment.

OUR CUSTOMERS

- Hospitals
- Medical Centers
- Surgical Centers
- Universities
- Ophthalmologists
- IV Centers

OUR CUSTOMERS RELY ON US FOR:

- Our ability to ship for hospital use in states where the law allows
- Specialized drugs for patients which typical pharmacies cannot satisfy
- Custom dosages and delivery methods available upon request
- Testing of preparations with in-house, state-of-the-art quality control equipment
- Shipping nationwide with next day delivery

AVAILABLE DOSAGE FORMS

- Injectables
- Capsules/Tablets
- Lozenges/Troches
- Rectal & Vaginal Suppositories
- Nasal Sprays
- Oral Rinses
- Sublingual Drops
- Sublingual Tablets
- Topical Ointments
- Topical Sprays
- Topical Creams
- Topical Gels
- Topical Solutions
- Oral Solutions
- Oral Suspensions
- Cartridges
- IV Bags
- Lyophilized Vials
- Ophthalmic Ointments
- Ophthalmic Solutions
- Ophthalmic Suspensions

**SAFE
EFFECTIVE
INNOVATIVE**



IN-PROCESS TESTING

We now have the unique ability to switch once and for all from retrospective to real time microbial control.

Industry trends show that our partners have moved from a mere reliance on finished product testing towards comprehensive “in-process” testing at every crucial stage of production. This shift is especially critical to the Pharmaceutical industry, where microbial contamination is a prime concern. Delays associated with the traditional 14 day growth stage have motivated this shift in emphasis. These delays in microbial testing can directly impact effective consumer protection. With our leading edge equipment, we eliminate these possibilities.



BIOBURDEN TESTING

- Testing for the amount of CFUs (bacteria) present in a preparation before sterilization via filtration

DOSAGE TESTING TO ENSURE ACCURACY

BUBBLE-POINT FILTER TESTING

- Testing to ensure filter functionality after sterilization

LEADING EDGE EQUIPMENT

We test 100% of the injectable products compounded for sterility, potency, pH, and endotoxins.

IR-SPECTROMETER | PERKIN ELMER SPECTRUM 100 FT-IR

- Allows for a quick identification of every active pharmaceutical ingredient (API) received at our facility

HIGH PERFORMANCE LIQUID CHROMATOGRAPHY:

- **LaCHROM ULTRA L-2160U HPLC/MASS SPECTROMETRY**
- **LaCHROM ELITE L-2200 HPLC**

- Determines the potency of the medications we prepare

GAS CHROMATOGRAPHY/MASS SPECTROMETRY | PERKINS ELMER CLARUS 600 GAS CHROMATOGRAPH

- Provides identification of molecular content based on characteristic fragmentation patterns at specific retention times
- Detects benzyl alcohol preservative content

STABILITY CHAMBERS | LABONCE

- Temperature-controlled, humidity-controlled environmental unit that provides stable conditions for storage and testing of our pharmaceutical preparations
- Confirms expiration dates on products for beyond use date

STATE-OF-THE-ART CLEANROOMS AND LAMINAR AIR FLOW HOODS

- Independent, semi-annual certifications of our clean rooms and laminar air flow hoods
- Monthly independent lab tests of air and surface samples
- Daily monitoring and documentation of clean-room temperature and humidity
- Our entire general compounding lab is engineered with a HEPA filtration system to further reduce particulates

METTLER TOLEDO - QUANTOS

- Provides for accurate dosing down to the microgram
- Doses automatically with interchangeable dosing heads
- High-precision engineering and intelligent electronics ensure that the heads are tailored to the dosing device

- UV/VIS
- HPLC
- TITRATION METHOD
- OSMOMETER



COMPETITIVE EDGE

We perform different tests for potency depending on the specification of the compound according to USP guidelines, with same day results available on most preparations.

CHEMSCAN RDI CHEMUNEX RAPID SCAN

- Can detect and identify microorganisms in three hours (this scan is run in parallel to the traditional injection method with a 14 day incubation period)
- Real-time detection of microorganisms in filterable samples with a sensitivity down to one cell
- Provides total traceability for each analyzed sample

UV/VIS SPECTROPHOTOMETER

- We use this quantitative instrument to measure the absorption of a solution to determine concentration

TITRIMETRY

- Is also used to determine concentration of in-process and final products following USP guidelines

OSMETTE XL

- The Osmette is a precise instrument for measuring freezing point depression
- The freezing point of a solution is a measurement of the solution's concentration, and the Osmette allows for a very accurate method for determining concentration

ENDOTOXIN TESTING

- 100% testing is performed on all sterile injectable compounds
- A quantitative in-vitro end-point test and a qualitative test (depending on the compound) is used to detect endotoxins present in all injectables

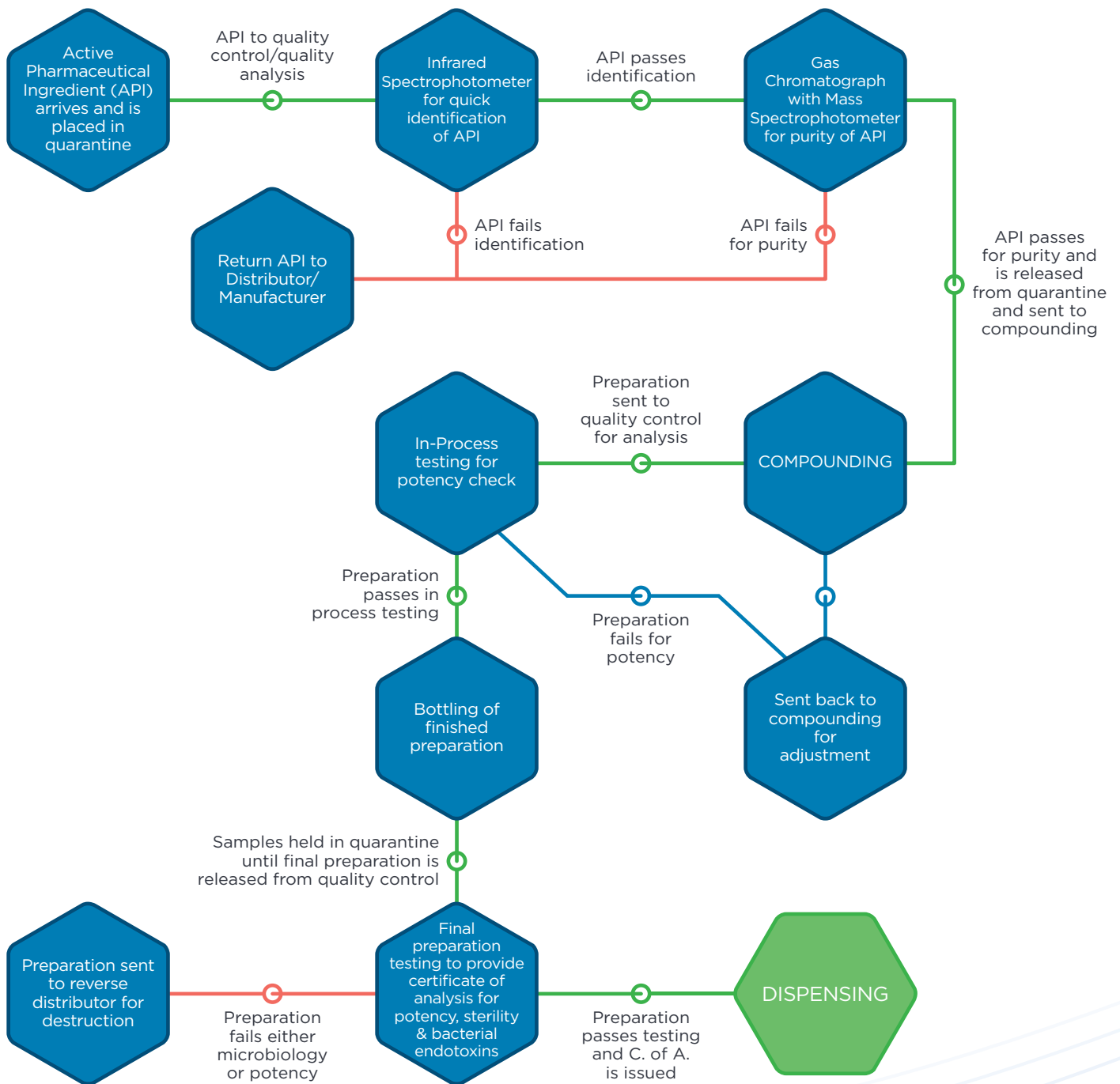
All instruments are IQ, OQ and PM'ed annually.

**THE KRS
QUALITY PROMISE**

Non-Sterile-to-Sterile Quality Control Protocol

At KRS, we value the welfare of your patients' health needs. We follow strict quality control procedures as per the standards of our analytical lab testing.

You can be confident that all of the medications we compound have been reviewed, analyzed and verified according to recognized standards for purity, concentration, endotoxins, sterility and other related attributes. Certificates of Analysis are available for all sterile injectable preparations.





ENHANCED ASSURANCES

The advantages of an FDA Human Outsourcing Facility with unmatched quality assurances and the advanced technology of a pharmaceutical.

At KRS, the quality of the compounds we provide directly affects the care your patients receive. We make no compromises; our compounding processes implement the highest standards of quality control and testing equipment. These processes greatly exceed that of most compounding pharmacies in the United States.

*Our staff
includes expert
microbiologists,
biochemists, chemists
and PhDs*

**THE KRS
QUALITY PROMISE**

On-site biochemists and microbiologists adhere to the strictest quality control measures, ensuring that your patients receive the highest quality compounds. Moreover, having an in-house, state-of-the-art analytical laboratory allows us to fully certify and conduct “in-process testing” with same-day results on final products. This is a clear advantage when it comes to assuring the identity, concentration, quality, and purity of compounds. This protocol allows us to complete a certificate of analysis before a compound is made available to our partners, eliminating the possibility of errors and identifying any potential risks.

KRS Global is a diversified company and a leader in providing innovative products and services to sustainable growth markets. Our capabilities include manufacturing, contract manufacturing, clinical research, FDA 503b Outsourcing and Life Sciences.

We provide leadership, resources, information, and a learning environment to enable all associates to be creative and innovative in their pursuit of continuous improvement. Our associates understand that taking care of our customers is number one. We believe our final responsibility is to ensure that all our partners find their success in ours.

503b
Compounding
Services

Manufacturing
Services

CMO
Services

Life
Sciences



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