

Quality Assurance



SOPs and Documentation

- SOPs in place for every process from receipt of incoming materials through production, packaging and shipping to ensure consistency and conformity
- Master batch records detail and document preparation of each product
- Licensed pharmacists verify critical operations
- Experienced Quality Assurance professionals complete, collect, review and store all documentation associated with every facet of operations

Environmental Control

- Validated, calibrated and certified equipment
- Monitoring of clean room environments, differential pressure differentials, surfaces and air quality
- Thorough cleaning program utilizing rotational disinfection
- Clean rooms are routinely certified to ensure ISO 14644 compliance

Personnel Control

- Multi-level training program consists of procedural review, task-based training and proficiency evaluation
- Media fills performed for each process to ensure proper aseptic controls

Validation Program

- Equipment qualified (IQ, OQ, PQ) to ensure proper performance
- Cleaning procedures verified
- Manufacturing processes qualified
- Qualification of critical utilities
- Periodic media fills performed to ensure proper aseptic processing

Finished Product

- Comprehensive stability program to ensure products meet specifications throughout the life cycle of the products
- Multi-layered quality control verification process to ensure each unit is made correctly and to the highest standards
- Final product testing to ensure all preparations meet specifications

Quality Systems

- Comprehensive investigation system
- Customer complaints investigated
- Extensive change control program
- Corrective and preventive actions based on in-depth root cause investigations to ensure remediation of issues
- Ongoing trending for key quality systems evaluate data from a broader perspective to implement change from a strategic perspective

SterRx is a registered trademark of SterRx, LLC.

Products compounded by SterRx in accordance with Section 503B are statutorily exempt from FDA's drug approval and adequate directions for use requirements in FDCA Sections 505 and 502(f)(1). SterRx compounded formulations are not FDA-approved or reviewed by FDA for safety or efficacy.