SCA Pharma End Product Testing

Delivering the Highest Quality Medications to Our Partners and Their Patients

To guarantee product quality and safety, each batch is tested against rigorous specification criteria prior to release. SCA Pharma's End Product Testing protocol covers five major components and includes the generation and approval of a Certificate of Conformance (C of C) by Quality Assurance.

C of C acceptance criteria and test results become part of the completed batch record and can be viewed via our eCommerce Portal.

End Product Testing Components:

Defect-Free

All sterile products must be free of critical/major defects prior to release. Skilled operators inspect 100% of units and an AQL level is independently verified.

Environmental Monitoring

Comprehensive environmental monitoring is performed during compounding per USP <1116> and cGMP.

Endotoxin Limits

All sterile products must pass applicable standards for endotoxin (pyrogen) limits. Test methods have been validated per USP <85> and cGMP guidelines.

Sterility Testing

Scan RDI (Rapid Microbiological Technology) enables quick turnaround time for sterility testing of sterile products which maximizes usable shelf life. Scan RDI usage has been qualified to be equivalent to or better than USP <71> traditional sterility methods.

Potency/Identity Specifications

Scientifically sound and appropriate specifications have been established for all products. Every log is tested for both strength (potency) and identity by methods which are highly specific.

SCA Pharma's Commitment to Quality

Delivering the highest quality medications to our partners and their patients is SCA Pharma's top priority. Our comprehensive training and personnel qualification criteria ensure full compliance with regulatory requirements on every batch we produce.