SCA pharma

Understanding SCA Pharma's Compounding Processes

SCA Pharma Compounds Products using Finished Drug Product (FDP) and API (bulk).

In both processes, safety is achieved through proper application of current Good Manufacturing Practices (cGMP). As an additional measure for sterility assurance, SCA Pharma performs a sterile filtration on all products regardless of starting materials prior to filling into final containers.

Finished Drug Product (FDP)

Key Characteristics of SCA Pharma FDP Products:

- Only FDA-approved commercially available sterile drugs are utilized.
- Source NDC#, traceable to the commercial starting material, is available for every product.
- Only products with a source NDC# traceable to a commercial drug product are delineated as being sourced from an FDP.
- No SCA products labeled as being sourced from FDP are produced from a bulk drug or feature an NDC# traceable to an API. Bulk or pooled products filled under sterile aseptic conditions from API are not categorized as FDP, regardless of sterile filtration or terminal sterilization.

Active Pharmaceutical Ingredient (API)

Key Characteristics of SCA Pharma API Products:

- Each API must be accompanied by a Certificate of Analysis and is tested for potency and identity prior to use in compounding.
- The API must appear on the FDA's drug shortage list at the time of compounding, distribution and dispensing; or
- Appear on the FDA's list of bulk drug substances for which there is a clinical need (503B bulks list).