

FORMULATION, FILL AND KIT ASSEMBLY FOR CHEMICAL COMPOUNDS

GOAL: Design a kit to allow an unstable formulation containing 3 components to be delivered to patients at bedside.

CHALLENGE: To create the entire process and delivery system from scratch.

OUTCOME: Successfully developed, produced and shipped multi-component patient infusion kits with detailed instructions.

PROCESS DEVELOPMENT STEPS:

- Sourced all raw materials
- Developed and optimized filtration process for liquid component
- Set up sterilization process for dry components
- Conducted solubility studies and developed mixing protocol, while keeping total solution volume minimized
- Sourced and designed a multi-component sterile delivery system
- Wrote instructions to ensure proper mixing of kit components and delivery to patients

cGMP ACTIVITIES:

- Prepared the kit components
 - Aseptically filled the liquid component into bottles and tested for sterility
 - Filled both of the chemical compounds into bottles and terminally sterilized
 - Aseptically assembled multi-component delivery system
- Packaged and labeled the kit
- Quality control release tested and Quality Assurance reviewed documentation
- Designed and executed stability program