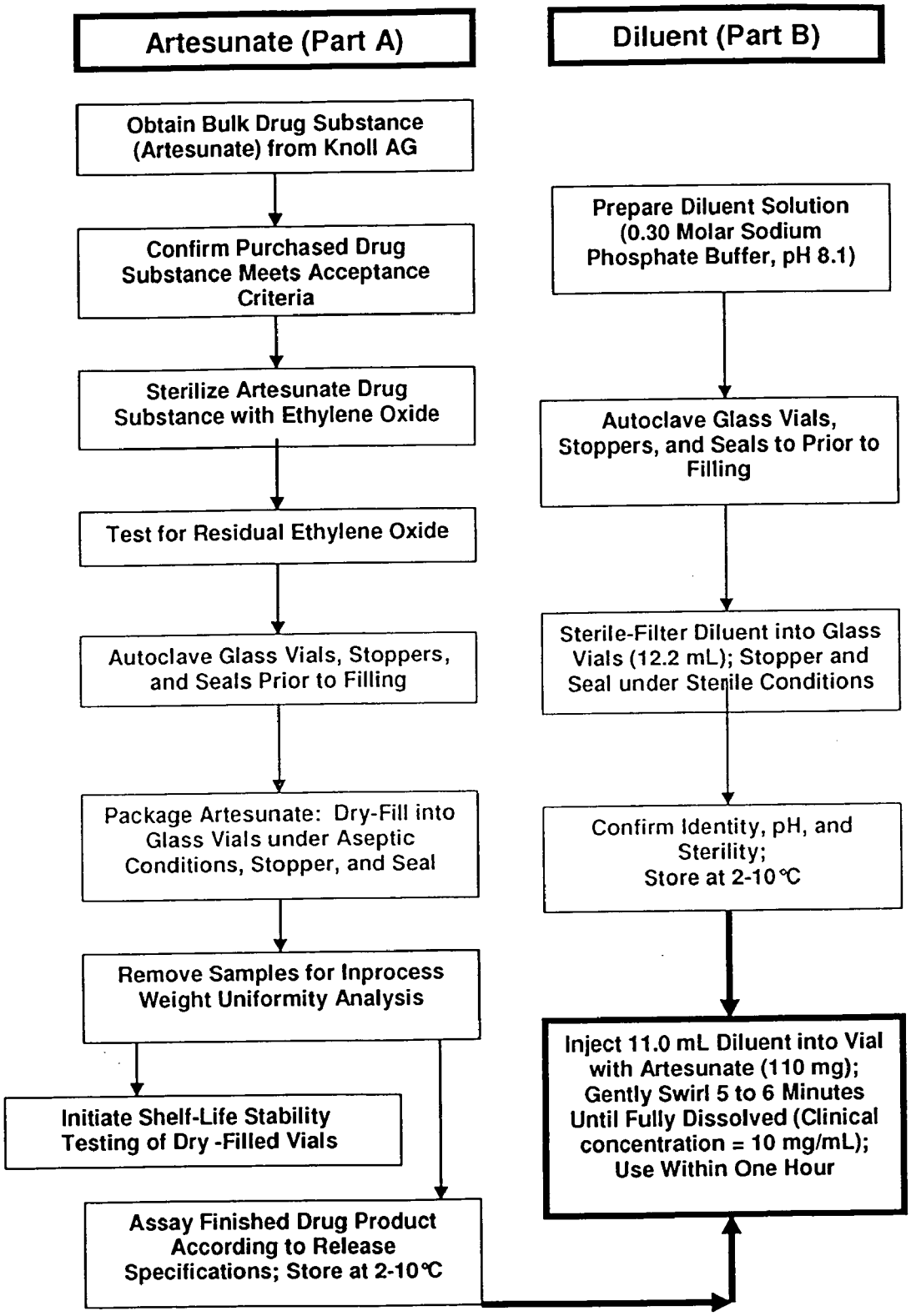
Artesunate (Part A)
Diluent (Part B)
Obtain Bulk Drug Substance (Artesunate) from Knoll AG
Confirm Purchased Drug Substance Meets Acceptance Criteria
Sterilize Artesunate Drug Substance with Ethylene Oxide
Test for Residual Ethylene Oxide
Autoclave Glass Vials, Stoppers, and Seals Prior to Filling
Package Artesunate: Dry-Fill into Glass Vials under Aseptic Conditions, Stopper, and Seal
Remove Samples for Inprocess Weight Uniformity Analysis
Initiate Shelf-Life Stability Testing of Dry -Filled Vials
Assay Finished Drug Product According to Release Specifications; Store at 2-10°C
Prepare Diluent Solution (0.30 Molar Sodium Phosphate Buffer, pH 8.1)
Autoclave Glass Vials, Stoppers, and Seals to Prior to Filling
Sterile-Filter Diluent into Glass Vials (12.2 mL); Stopper and Seal under Sterile Conditions
Confirm Identity, pH, and Sterility; Store at 2-10°C
Inject 11.0 mL Diluent into Vial with Artesunate (110 mg); Gently Swirl 5 to 6 Minutes Until Fully Dissolved (Clinical concentration = 10 mg/mL); Use Within One Hour

Fig. 1