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Apr 23, 2010 · an important process development aspect of a final ufdf formulation step includes the final sterile filtration or bulk filtration of the product. In general, sterile filtration is an important concern for all intermediate purification pools, but considerably more so at the end of the process where the highest protein concentrations are present. E.g., personnel, materials, container closures, equipment, and the manufacturing facility environment. A list of all components (i.e., ingredients) used in the manufacture of the drug product formulation, regardless of whether they undergo chemical change.

Manufacturing Challenges and Rational Formulation

Jul 01, 2021 · This is because clinical development of AAV gene therapy has outpaced CMC, manufacturing, and

review discusses the various manufacturing steps and challenges encountered during AAV production and storage and provides a roadmap to improve the efficiency in manufacturing workflow and improve product shelf-life.

Aenova Invests In Sterile Fill/Finish Area For Vials And

Oct 25, 2021 · Aenova has unveiled a significant expansion of its sterile fill and finish capacity at its Italian site in Latina. The new state-of-the-art aseptic production area features a completely new high-speed flexible line for vials and prefilled syringes (PFS) as well as a brand new compounding area.