PROCESS FOR LYOPHILIZED PHARMACEUTICAL FORMULATION OF A THERAPEUTIC PROTEIN

ABSTRACT

This invention concerns a process for making a lyophilized pharmaceutical formulation of a therapeutic protein, which comprises (a) providing a formulation of a bulk amount of the therapeutic protein, (b) measuring the concentration of the therapeutic protein in said bulk formulation, (c) adjusting the fill weight of the protein in said bulk formulation to achieve a fixed dose of the protein, and (d) lyophilizing the protein fill weight-adjusted formulation to achieve a final formulation in a container, wherein the product concentration post reconstitution with a fixed volume is within a predetermined acceptance range. The process is particularly suitable for formulations with low protein concentrations (e.g., 0.05 mg/mL to 20 mg/mL).

Fig. 5