HIGH-CONCENTRATION MONOCLONAL ANTIBODY FORMULATIONS

Abstract

The present application discloses high-concentration monoclonal antibody formulations suitable for subcutaneous administration, e.g. via a pre-filled syringe. In particular, it discloses a formulation comprising a spray dried monoclonal antibody at a concentration of about 200 mg/mL or more suspended in a non-aqueous suspension vehicle where the viscocity of the suspension vehicle is less than about 20 centipoise. Also disclosed are: a subcutaneous administration device with the formulation therein, a method of making the formulation, a method of making an article of manufacture comprising the suspension formulation, use of the formulation in the preparation of a medicament, and a method of treating a patient with the formulation.

(FIG. 2)