METHOD AND FORMULATION FOR REDUCING AGGREGATION OF A MACROMOLECULE UNDER PHYSIOLOGICAL CONDITIONS

Abstract

A method for reducing aggregation and inhibiting flocculation of a macromolecule, such as a protein, under physiological conditions by the addition of certain cyclodextrins (CDs) is disclosed. Also provided is a method to minimize inflammation at the injection site during subcutaneous administration of a macromolecule and pharmaceutical formulations for such administration. Further provided are methods of treating a CD20 positive cancer or an autoimmune disease, comprising administering a humanized anti-CD20 antibody in a pharmaceutical formulation of the invention. Further provided is an in vitro dialysis method to evaluate the ability of an excipient to reduce aggregation of an antibody or other macromolecule under physiological conditions.

Fig. 2