

ABSTRACT

LYOPHILIZED FACTOR IX FORMULATIONS

The present invention provides, among other things, pre-tyophilization formulations, reconstituted formulations, and lyophilate powder compositions comprising a Factor IX (FIX) polypeptide. The present invention also provides lyophilization methods for producing lyophilate powder comprising a FIX polypeptide. The present invention is directed to a pre-tyophilization formulation comprising: (a) a Factor IX (FIX) polypeptide having FIX coagulation activity; (b) a buffering agent; (c) a stabilizing agent; (d) a bulking agent; and (e) a surfactant, wherein the formulation has a fill volume of less than about 5 mL, and wherein each of (a) - (e) are at an amount per vial (mg/vial) sufficient to allow (1) improved stability of the FIX polypeptide when lyophilized.

Fig. 1