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(54) Title: INSOLUBLE COMPOSITIONS FOR CONTROLLING BLOOD GLUCOSE

(57) Abstract

The present invention relates to insoluble compositions comprising a protein selected from the group consisting of insulin, insulin analogs, and proinsulins; a derivatized protein selected from the group consisting of derivatized insulin, derivatized insulin analog, and derivatized proinsulin; a complexing compound; a hexamer-stabilizing compound; and a divalent metal cation. Formulations of the insoluble composition are suitable for both parenteral and non-parenteral delivery for treating hyperglycemia and diabetes. Microcrystal forms of the insoluble precipitate are pharmaceutically analogous to the neutral protamine Hagedorn (NPH) insulin crystal form. Surprisingly, it has been discovered that suspension formulations of such insoluble compositions possess unique and controllable dissolution properties that provide therapeutically advantageous glucodynamics compared with insulin NPH formulations.