

The method for the modified chromatographic purification of the human insulin drug substance comprises the dissolution of the insulin drug substance in the buffer solution, the equilibration of the column, the loading of the solution onto the column, the gradient elution, and the analysis of the peaks by the analytical HPLC. Propanol or propanol-2 is used as the organic modifier of the buffer solution. pH is adjusted to 2.4-2.6. For dissolution of the insulin drug substance the organic modifier is used at a concentration of 13-14 volume %. The sustained-release dosage form of the human insulin based on the substance produced by the process disclosed contains also protamine sulfate and zinc chloride as the prolongators, glycerol and sodium chloride as the isotonic agents, m-cresol and phenol as the preserving agents, monobasic sodium phosphate dehydrate as the buffering agent, and the water.