

Compounding and Stability Evaluation of Sitagliptin Solution

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Abstract

Background: Dipeptidyl peptidase Inhibitors 4 (DPP-4 inhibitors or gliptins)are oral hypoglycemic agents which use for Diabetes Mellitus type 2 . Sitagliptin is the first class of DPP-4 and the most used agent in the market.

Dipeptidyl peptidase-IV (DPP-4) inhibitors work by increasing and prolonging incretin hormone activity, which is inactivated by DPP-4 enzyme. Incretins increase insulin release and synthesis from pancreatic beta cells and reduce glucagon secretion from pancreatic alpha cells.

Objective: To facilitate the swallowing process for specific social groups. Sitagliptin powder was used as the source of the active pharmaceutical ingredient.

Method: Sundry sitagliptin solution formulations were prepared using pure powder of sitagliptin phosphate as the source of the active ingredient. The most compliance one in terms of clarity and the acceptable taste was selected for stability studies. For this aim, the final samples of sitagliptin solution were stored at room temperature and in the incubator. Assay, pH, viscosity, and microbial contamination were assessed according to the EP specifications. Sitagliptin solution in the studied samples was analyzed and quantified by High performance liquid chromatography device.

Results: The produced solution had the most appropriate taste. And the obtained formula has had unchanged pH, which remained around 9.9. Solutions were been free from microbial contamination. products showed good stability within the four weeks period under two conditions (24 c/ 40% humidity and 40c / 70% humidity).

Conclusions: sitagliptin extemporaneous solution was successfully prepared pure sitagliptin phosphate powder This study provides a solution for patients with swallowing difficulties or feeding tubes who are unable to take medicines in solid oral dosage forms. Community pharmacists can prepare the solution using sitagliptin powder as the source of the active ingredient.

