

Abstract

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Title of Thesis: Liquid paediatric preparations 1. Sotalol
hydrochloride

The aim of this work was to formulate suitable paediatric oral solution with sotalol hydrochloride 5 mg/ml using a minimum amount of excipients. After the preformulation study, eight aqueous solutions of sotalol hydrochloride were compounded using citric acid and dibasis sodium phosphate dodecahydrate to stabilize pH value, potassium sorbate as a preservative, and simple sucrose syrup and/or sodium saccharin, respectively, as sweeteners. Density and osmolality of the formulations were estimated. The solutions were stored at two different temperatures of 2-8 °C and/or 2-8 °C, respectively, and the pH values were measured during 90 days. All studied formulations showed stable pH values at both temperatures of storage, except for an aqueous sotalol hydrochloride solution. Some of the formulations were proposed for validated stability study with a determination of the concentration of sotalol hydrochloride and potassium sorbate using HPLC.