ABSTRACT

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Title of Doctoral Thesis: Formulation of extemporaneous paediatric liquid

preparations in the hospital pharmacy

In the paediatric population, oral solutions and/or suspensions represent a suitable alternative to preparation of hard capsules in the pharmacy. This thesis aims at formulation of stable liquid oral preparations with cardiologic drugs, propranol-hydrochloride, sotalol-hydrochloride and furosemide, for the children aged from newborn to approximately 6 year. At the formulation of the preparation compositions, the simple routine preparation in a pharmacy was the main target as well as the use of excipients safe for paediatric population in the minimal necessary amount.

Using a high performance liquid chromatography, chemical stability of the active ingredient and, simultaneously, the preservative was determined in all formulated preparations stored at two different temperatures at time points over minimum 180 days. In order to achieve this, the specific analytical methods were developed and validated at the department of Analytical chemistry, Faculty of Pharmacy in Hradec Králové. However, the samples were examinated visually and the pH value was measured. At least 95 % of the initial drug as well as 90% of the preservative concentrations (100 %) remaining at the end of the stability study period were required. Based on the experimental results, the optimal composition of eleven multidose paediatric oral solutions containing and propranol-hydrochloride, sotalolhydrochloride, and furosemide, respectively, and a preservative for the extemporaneous preparation were proposed, including the storage conditions, a suitable container and the shelf-life. The efficacy of the antimicrobial preservative (Ph.Eur., 5.1.3) for the chosen preparations was demonstrated by an accredited laboratory.