DEVELOPMENT OF HPTLC METHODS FOR QUALITY CONTROL OF COMPOUNDING ORAL SOLUTION WITH HERBALS

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Introduction. There are list of often prescribed compounding preparations in pharmacies of Ukraine, which have license for preparation of compounding formulations. The necessary requirements for all drugs are its safety, efficacy and quality. To ensure the quality of preparations during their storage period they should be controlled with the usage of appropriate quality control methods developed and validated with modern techniques and stability study should be carried out.

The aim of this paper was development of quality control methods for compounding oral drops with herbals.

Material and Methods. The object of our work was compounding oral solution with herbals for internal usage. As active ingredients oral drops contained mixture of Leonurus and Valeriana tinctures and 2 % solution of Sodium Bromide. This preparation is often used as sedative drug in pediatrics. As quality control technique high performance thin layer chromatography (HPTLC) was used. Instrumentation used was: CAMAG ATS 4; ADC 2; Plate Heater; Immersion Device III; TLC Visualizer; vision CATS software; Analytical Balance MS 205 DU, Mettler-Toledo.

Results and Conclusions. For identification of oral solution the marker substances such as valerenic and acetoxivalerenic acids specific for Valeriana and flavonoids specific for Leonurus were used. In addition the HPTLC fingerprints of oral drops were compared with fingerprints of Valeriana and Leonurus tinctures and its mixtures. To determine the presence of Valeriana root in composition of oral drops such chromatographic conditions were selected: solvent for sample preparation – butanol; the mobile phase – cyclohexane, ethylacetate, glacial acetic acid (60:38:2); derivatization – anisaldehyde reagent, use (dipping time – 0, speed – 5), heat at 100°C for 3 min; examination under white light and under UV 366 nm. To determine the presence of Leonurus herba in composition of oral drops such chromatographic conditions were selected: solvent for sample preparation – butanol, the mobile phase – ethyl acetate, methylethylketone, formic acid, water (5:3:1:1); derivatization – NP/PEG, use (dipping time – 0, speed – 5), heat at 100°C for 3 min; examination under UV 366 nm. Thus, the optimal chromatographic conditions that ensure specific, robust and precision results of identifications were determined. Developed methods will be used for stability study of compounding preparation.