DEVELOPMENT OF QUALITY ASSURANCE METHODS OF HYDROCHLOROTHIAZIDE IN COMPOUNDED POWDER AND SYRUP PREPARATIONS

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Introduction. Hydrochlorothiazide is a thiazide diuretic prescribed for both adults and children in the treatment of hypertension, congestive heart failure, symptomatic oedema and in the prevention of kidney stones. Compounded preparations are drug preparations in concentrations and dosage forms made to meet unique prescriber and patient needs. According to the requirements of Ukrainian legislation, batches of compounded preparations should pass quality control. Although the powders have a relatively long shelf life, the same cannot be said for liquids. It is necessary therefore to develop quality control methods and study the stability of compounded powders and syrups containing hydrochlorothiazide.

The **aim** of this study is to develop identification and assay methods for compounded formulations of hydrochlorothiazide (HCT) in powders and simple syrup using thin layer chromatography (TLC) and ultraviolet (UV) spectrometry.

Materials and methods. Powder composition: HCT - 5 mg, glucose up to 0.2 g; syrup composition: HCT – 200 mg, simple syrup qs 20 ml. Active pharmaceutical ingredients (API) used for compounding of powder and syrup were commercial tablets (Sanofi-Aventis, Ukraine LLC). 2 μL each of 5 mg/ml preparations of reference substance, powder and syrup of HCT in acetone were applied to TLC aluminium plates (silica gel $60F_{254}$, Merck KGaA). The chromatographic plates were developed over a distance of 10 cm in ethyl acetate mobile phase and observed under UV light. A UV spectrophotometer («Evolution 60s») was used to assay 0.01 mg/ml preparations of HCT from stock solutions of the reference substance, powder and syrup in 0.01 M sodium hydroxide solution. The absorbance at a wavelength of 273 nm was measured and results were compared with that of reference standards.

Results and discussion. The chromatograms showed good separation, sugar components remained on the start line while three aligned brown spots (under UV-light) were observed with R_f- 0.38, 0.38 and 0.39, corresponding to HCT of reference substance, powder and syrup. When sprayed with sublimed iodine, yellow aligned spots were seen corresponding to the above-mentioned substances. The calculated percentage content of HCT in samples of reference substance, powder and syrup were 101%, 106% and 99.94% respectively. The excipients in both powder and syrup did not significantly affect the results obtained using TLC and UV-spectrometry methods.

Conclusions. These methods could be used for quality control of HCT in compounded preparations of powders and syrups after validation.