

DEVELOPMENT OF QUANTITATIVE DETERMINATION METHOD FOR SPIRONOLACTONE IN COMPOUNDED SYRUPS

Alfred-Ugbenbo D., Zdoryk O. A.

National University of Pharmacy, Kharkiv, Ukraine

audeghinmotei@gmail.com

Spirolactone is a potassium-sparing diuretic used in congestive heart failure, oedema, hepatic cirrhosis, nephrotic syndrome, hypokalaemia and management of hypertension. The range of its indications makes it a regularly prescribed drug in most health service facilities both for paediatric and geriatric patients. Compounded syrups of spironolactone from pure substances and manufactured (capsules, tablets etc.) are common to many countries. Although some pharmacopoeias recommend liquid chromatography and ultraviolet spectroscopy for substance and tablet forms of spironolactone, there isn't an assay method for the increasingly popular compounded forms such as syrups.

Therefore, the aim of our work was to develop method for quantitative determination of spironolactone in compounded syrups.

For the purpose of this study spironolactone substance (Tianjin Jinjin Pharmaceutical Co., Ltd batch SA0456) as reference and manufactured spironolactone tablets (Darnitsa, Ukraine batch 4-823006-400706) were obtained. 5 mg/ml syrups of pharmaceutical substance spironolactone and crushed spironolactone tablets were compounded using simple syrup USP. Appropriate quantity of the samples containing 25 mg spironolactone equivalent was shaken with 35 ml of 96 % ethanol in a 50 ml volumetric flask for 4 minutes, allowed to stand for 10 minutes and then filled to the mark. Apart from the solution of the reference substance, other samples were filtered. The first 10 ml of the filtrate was discarded and 2 ml aliquots each were dissolved separately in 100 ml of the same solvent to form 0.01 mg/ml solutions. The absorbance of 0.01 mg/ml analytical solutions of these samples in 96 % ethanol were measured at a wavelength of 238 nm, using an ultraviolet spectrometer («Evolution 60s»). 96 % ethanol was used as blank. Each sample was measured in replicates of five. Laboratory temperature 18–20 °C.

Results of the assay show that the content of the spironolactone was within the recommended limits (substance: 97.5–102 %; tablets: 95–105 %). After five measurements the spironolactone percentage content ($p = 0.05$) of 101.62 ± 0.29 %, 101.10 ± 0.29 %, 100.84 ± 0.63 % and 100.60 ± 0.25 % corresponding to samples of the pharmaceutical substance, spironolactone tablets, compounded syrups from substance and the commercial tablets was obtained.

This method could be used for quantitative determination of spironolactone in syrups since the excipients in tablets and simple syrup seem not to significantly affect the results obtained using UV-spectrometry. To further prove the possibility of using this method in pharmaceutical analysis its subsequent validation is required.