DEVELOPMENT OF METHODOLOGY FOR THE CHROMATOGRAPHIC DETERMINATION OF CAPTOPRIL IN MEDICINES

Logoyda Liliya*, Korobko Dmytro*, Kovalenko Sergiy**
I. Horbachevsky Ternopil State Medical University, Ternopil, Ukraine
** Zaporozhye State Medical University, Zaporizhzhya, Ukraine*

UHPLC and UPLC are both liquid chromatography techniques used to separate the different components found in mixtures. UPLC and UHPLC have been used for many purposes, including legal, pharmaceutical and medical. The systems are also important tools in the fields of research and manufacture. In 2004, separation science was revolutionized with the introduction of Ultra-Performance Liquid Chromatography [UPLC® Technology]. Significant advancement in instrumentation and column technology were made to achieve dramatic increases in resolution, speed and sensitivity of liquid chromatography. For the first time, a holistic approach involving simultaneous innovations in particle technology and instrument design was endeavored to meet and overcome the challenges of the analytical laboratory. This was done in order to make analytical scientists more successful and businesses more profitable and productive.

Captopril is a sulfhydryl-containing analog of proline with antihypertensive activity and potential antineoplastic activity. Captopril competitively inhibits angiotensin converting enzyme (ACE), thereby decreasing levels of angiotensin II, increasing plasma renin activity, and decreasing aldosterone secretion. This agent may also inhibit tumor angiogenesis by inhibiting endothelial cell matrix metalloproteinases (MMPs) and endothelial cell migration. Captopril may also exhibit antineoplastic activity independent of effects on tumor angiogenesis. Analysis of captopril are described in Pharmacopeia but the aim of our researches was to improve to more rapid, simple, selective, more accurate, precise, reliable, cheaper methods of analysis of captopril in medicines and for using this methods for analysis of captopril's metabolites in next step of researches.

According to American Pharmacopoeia, there is the following chromatographic conditions: column chromatographic categories L1 (with a fixed phase C18) size of 4.6 mm x 250 mm; mobile phase – methanol R:water R:phosphoric acid R (550:450:0.5); wavelength – 220 nm, flow rate – 1.0 ml / min.

In developing the methodology we have used chromatographic column Ascentis Express C18, which has several advantages for a number of columns L1. By using Fused-Core® technology Ascentis Express C18 column provides high speed and high efficiency at a lower pressure system. This reduces the number of used mobile phase and reduce the cost analysis. We have chosen conditions isocratic elution with binary mobile phase consisting of methanol and 0.1% trifluoroacetic acid solution in the ratio of 60:40 for optimum peak of symmetry of the active pharmaceutical ingredient.

This method has the advantage over pharmacopeia due to speed and ease of preparation of the mobile phase and reduced chromatography time. Accuracy was assessed using the three models of API solutions with concentrations of 70% – 100% – 130% on the nominal captopril concentration in the test solution. Model solutions were prepared according to the procedure completely repeating the procedure for preparing the test solution. By comparing the two solutions for each analyte built calibration graph (level 1-2, including all parallel injection and specifying the appropriate concentration reference solution), passing through zero.

Conclusion. Using this technique, we have analyzed medicines «Captopres 12.5 – Darnitsa» (tablets containing 50 mg of captopril and 12.5 mg hydrochlorothiazide) and Captopril (25 mg tablets produced by «Astrafarm»). The contents were 48.6 mg and 24.3 mg, respectively.