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ABSTRACT BOOK

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Abstract No. PSP.12

Peculiarities of the pharmaceutical analysis of the Clarithromycin substance by the method of high-performance liquid chromatography

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Objectives: The actual task of this experimental study is to adapt the conditions of chromatography using the method of high-performance liquid chromatography (HPLC) for determining accompanying impurities of Clarithromycin substance taking into account the selection and properties of the stationary phase (chromatographic columns), the parameters of the mobile phase to obtain the separation of the peaks of accompanying impurities of Clarithromycin within the limits allowed by the State Pharmacopoeia of Ukraine (SPU), evaluation of the obtained results.

Methods: Samples of Clarithromycin substance, pharmacopoeial standard sample of SPU - Clarithromycin, HPLC with UV detection (Agilent 1260 Infinity II chromatograph with UV detector), method of computer analysis using software OpenLab CDS; reagents with purity for HPLC (acetonitrile *P*, phosphoric acid *P*, potassium dihydrogen phosphate *P*, water for chromatography; mobile phase *A* (a solution of 4.6 g/l of potassium dihydrogen phosphate *P*, the pH of which is adjusted to 4.4 with diluted phosphoric acid *P*), mobile phase B (acetonitrile *P*).

Results: We selected the optimal conditions for the separation of accompanying impurities, taking into account their separation. As a result of the conducted research, it was established that the Clarithromycin substance contains identified accompanying impurities in its composition. The total content of specified accompanying impurities does not exceed 3%, which is acceptable for the use of antibiotics in the production of medicinal products (fig.1).

When conducting research, we used a longer HPLC column with a modified C18 phase, which provided better separation of peaks. Changing the time of chromatography and time parameters of the gradient, as well as its percentage content (within the limits allowed by SPU) had a positive effect on the shape of the peaks and their separation.

Conclusions: According to the results of the HPLC study of Clarithromycin substances, it was established that a longer HPLC column with a modified C18 phase provided better peak separation; the mobile phase was adapted and the optimal conditions for the gradient were selected (within the limits allowed by the DFU), which had a positive effect on the shape of the peaks and their separation.

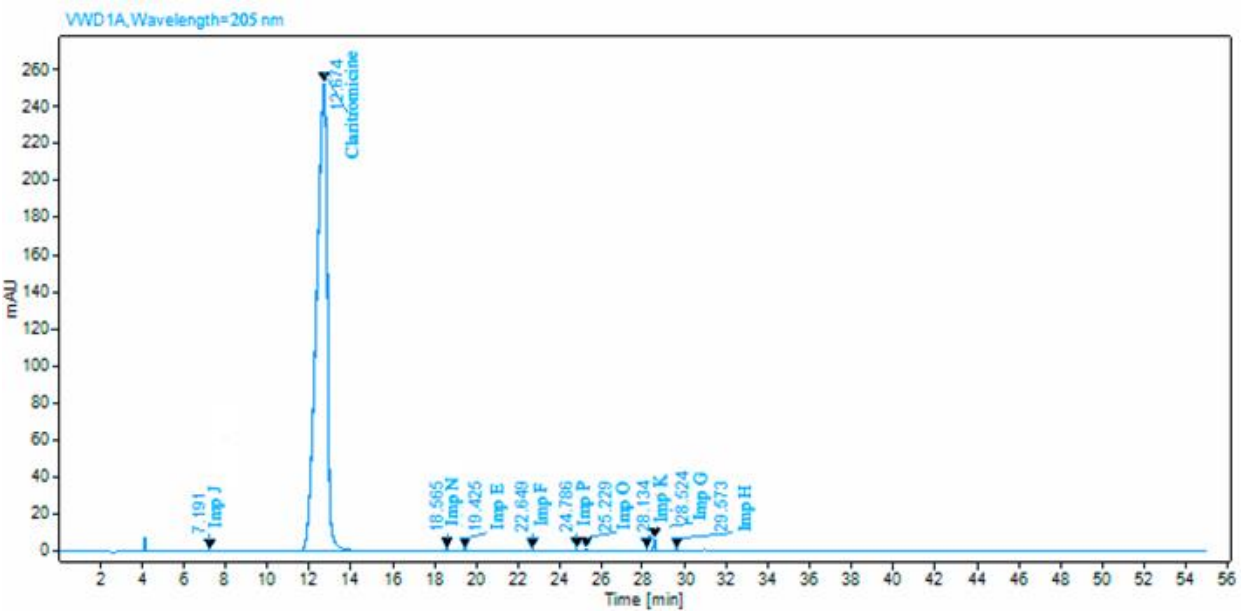

Figure 1. Chromatogram of Clarithromycin sample (Rt=12.674 min); identified impurities: J (Rt=7.191 min), N (Rt=18.565 min), E (Rt=19.425 min), F (Rt=122.649 min), P (Rt=24.786 min), O (Rt=25.229 min), K (Rt=28.134 min), G (Rt=28.524 min), H (Rt=28.524 min).