THE STUDY OF THE VALIDATION CHARACTERISTICS OF THE QUANTITATIVE DETERMINATION METHODS OF PYRIDOXINE HYDROCHLORIDE AND ASCORBIC ACID IN COMPOUNDING PREPARATIONS

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Introduction. Today there is a real need of compounded preparations which contain water-soluble vitamins, especially for pediatrics, geriatrics or treatment of patients with complex comorbidities. Development and validation of quality control methods for compounded preparations have great practical value in terms of quality improving of medicines. It is important that quality control methods for compounded preparations meet modern requirements of State Pharmacopoeia of Ukraine, Orders Ministry of Health and are reproducible in conditions of pharmacies and quality control laboratories.

The **aim** of this work was the development, improvement and validation of quantitative determination methods of the ascorbic acid and pyridoxine hydrochloride in two-component powders. Powders composition: Pyridoxine hydrochloride 0.005, Sugar 0.2.; Ascorbic acid 0.1 g; Glucose 0.3 g. According to the published data for quantitative determination of pyridoxine hydrochloride in powder two titrimetric methods (alkalimetric and argentometric) were chosen. For analysis of ascorbic acid alkalimetric and iodometric methods were selected.

Results and discussion. Before methods validation model samples of compounded powders were prepared. The exact sample weight of pyridoxine hydrochloride (0.035 g, 0.043 g, 0.05 g, 0,058 g, 0.065 g) was put in mortar and thoroughly mixed with 2.50 g of sugar. Model samples of ascorbic acid powders were prepared by the same scheme (0.80 g, 0.90 g, 1.00 g, 1.10 g, 1.20 g of ascorbic acid and 3.00 g of glucose). During the method validation basic parameters were studied: accuracy, precision (repeatability), linearity and range. During the validation of alkalimetric method determination of pyridoxine hydrochloride it was found that the method is linear in the range 70-130%, the linear equation $Y=0.98 \cdot X+2.68$, Z_{intra} – 100.47%, SD_z – 0.83%, Δ_{intra} – 0.52%. Metrological results of argentometric method determination of pyridoxine hydrochloride is: $Y=0.99 \cdot X+1.13$, Z_{intra} – 100.53%, SD_z – 0.49%, Δ_{intra} – 0.83%. Metrological characteristics of iodometric and alkalimetric methods determination of ascorbic acid are: $Y=1.03 \cdot X+0.75$ and $Y=1.0 \cdot X-1.82$, Z_{intra} – 101.15 and 100.89%, SD_z – 0.44 and 0.46%, Δ_{intra} – 0.77 and 0.81% respectively.

Conclusion. Experimental results of method validation prove the possibility of using given methods in pharmaceutical analysis in accordance with modern requirements to the quality control.