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ANALYTICAL METHODS DEVELOPMENT FOR THE QUANTIFICATION OF ANTIHYPERTENSIVE ACTIVE PHARMACEUTICAL INGREDIENTS IN DOSAGE FORMS

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Introduction. The urgency of an issue of hypertension is determined by its high population frequency, significant burden of the disease, risk of disability and impact on life expectancy. Rational combinations of drugs of different pharmacological groups in case of ineffectiveness of monotherapy to achieve the clinical effect of pharmacotherapy are clearly recommended in the world and domestic recommendations for the diagnosis and treatment of hypertension. Therefore, innovative pharmaceutical development of various antihypertensive drugs and the creation of fixed-dose combinations of drugs with different effects is an urgent task of modern pharmacy, which will help attract more patients to the treatment and prevention of cardiovascular disease. For such purposes, effective and reliable methods for the analysis of the determination of active pharmaceutical ingredients (APIs) in substances, model mixtures, drugs and biological fluids should be developed.

Aim of this work to exploit possibilities and problems in development of methods for the quantification of antihypertensive APIs (valsartan, atenolol, atorvastatin, lisinopril) in dosage forms.

Materials and methods. The samples of all APIs, used in this work, were purchased from from Sigma-Aldrich (Switzerland). All used reagents were analytical grade quality and purchased from Merck Darmstad, Germany. A double –beam Shimadzu UV-Visible spectophotometr, with spectral bandwidth of 1 nm wavelength accuary ±0.5 nm, Model –UV 1800 (Japan), Software UV-Probe 2.62. The used chromatography equipment was product of Varian, model Varian Pro Star PDA 330 with Varian Star software version 6.81 and Ultimate 3000 UHPLC system controlled by Chromeleon version 6.80a.

Results and discussion. The emerging of new pharmaceutical formulations provokes the necessity for simple, accurate, economical, green and fast analytical techniques to be applied in quality control laboratories where time and cost are critical. Moreover, minimizing toxicity with retaining method efficacy may be one of challenging aspects in developing a safer methodology.

When developing HPLC techniques it is necessary to take into account many factors that will affect the results of the analysis, namely the size of the chromatographic column, the type of stationary phase and particle size, column temperature, mobile phase composition and flow rate, detection method, sample preparation conditions and others. Reduction in total run time, leads to low solvent consumption and makes all methods more economical. Chromatograms should be obtained with satisfactory retention factors and very good peaks symmetry of both analyte peaks. HPLC is accurate and precise with good reproducibility but the cost of analysis is quite high owing to expensive instrumentation, reagent and expertise. Hence it is worthwhile to develop simpler and cost effective spectrophotometric method for simultaneous estimation of drugs for routine analysis of dosage forms. All developed methods must be validated according to the ICH guideline for the Validation of analytical procedures Q2((Q1A (R2). Validation was performed by evaluation of the following parameters of the method: selectivity, linearity, accuracy from the aspect of analytical recovery, precision from the aspect of system repeatability, limit of quantification and limit of detection, robustness. We developed and validated spectrophotometric and chromatographic

methods for determination valsartan with atenolol, atorvastatin with lisinopril, and atorvastin and its impurities in dosage forms (fixed combination).

Conclusion. All developed methods by our scientific group are suitable for the routine quality control analysis of any pharmaceutical preparation containing the tested drugs with the proposed methods advantages for checking quality during stability studies of their pharmaceutical preparations. The developed methods were essential for quality control of a large number of samples in short time intervals.