МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
ТЕРНОПІЛЬСЬКИЙ НАЦІОНАЛЬННИЙ МЕДИЧНИЙ
УНІВЕРСИТЕТ ІМЕНІ І. Я. ГОРБАЧЕВСЬКОГО

НАУКОВО-ТЕХНІЧНИЙ ПРОГРЕС І ОПТИМІЗАЦІЯ ТЕХНОЛОГІЧНИХ ПРОЦЕСІВ СТВОРЕННЯ ЛІКАРСЬКИХ ПРЕПАРАТІВ

МАТЕРІАЛИ VIII НАУКОВО-ПРАКТИЧНОЇ КОНФЕРЕНЦІЇ
З МІЖНАРОДНОЮ УЧАСТЮ
23–24 вересня 2020 р.

Тернопіль
ТНМУ
«Укрмедкнига»
2020

УДК 615.1

Науково-технічний прогрес і оптимізація технологічних процесів створення лікарських препаратів : матеріали VII наук.-практ. конф. з міжнар. участю (Тернопіль, 23-24 вересня 2020 р.). – Тернопіль : ТНМУ, 2020. – 320 с.

Усі матеріали збірника подаються в авторській редакції. Відповідальність за представлені результати досліджень несуть автори тез.

РОЗДІЛ 4
ОПТИМІЗАЦІЯ ФАРМАЦЕВТИЧНОГО АНАЛІЗУ ЛІКАРСЬКИХ ПРЕПАРАТІВ

DEVELOPMENT AND VALIDATION OF SPECTROPHOTOMETRIC METHOD FOR SIMULTANEOUS ESTIMATION OF VALSARTAN AND ATENOLOL IN DOSAGE FORMS

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Introduction. Analysis of modern publications in Pubmed and ScienceDirect shows there are no spectrophotometric method for simultaneous determination of valsartan and atenolol in dosage forms. In the contemporary literature, only one chromstographic method was reported and made by our group for quantification of valsartan and atenolol in dosage forms. However, to the best of our knowledge, the only published method for simultaneous analysis of valsartan and atenolol was developed this year by our group in order to introduce the *in vitro* dissolution profiles of their commercial tablets. This method 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 formulation.

The aim of the study was to develop simpler and cost effective spectrophotometric method for simultaneous estimation of valsartan and atenolol for routine analysis of formulation.

Research methods. A spectrophotometric method for the determination of valsartan and atenolol was developed with the study of green profile assessment and validated as per ICH guidelines.

Results and discussion. The drugs were found to obey beers law at the selected wavelength. The overlain spectra of the valsartan and atenolol in methanol were recorded and λmax values of both drugs and isobestic wavelength were noted. The linear regression data for the calibration curves showed good linear relationship over the concentration range 0.015 - 0.045 mg/mL for valsartan. Linear regression equation was found to be y = 30.627x-0.1347 (R^2=0.9997). The linear regression data for the calibration curves showed good linear relationship over the concentration range 0.12 – 0.25 mg/mL for atenolol. Linear regression equation was found to be y = 5.3018x-0.053

(R^2=0.999). The % RSD values found to be less than 2, indicating that the proposed method is precise for the determination of valsartan and atenolol in formulations The developed, validated method was successfully applied for the determination of valsartan and atenolol in their tablet dosage form. The results of proposed method found to be an excellent green analysis with a score of 90.

Conclusions. A rapid, simple, green, accurate and precise spectrophotometric method was developed and validated for the simultaneous estimation of valsartan and atenolol in its tables dosage form. From the results of validation obtained it is concluded that the proposed UV spectrophotomertic method developed is relatively simple, rapid, and cost effective and therefore, could be applied as alternative method for routine quality control assay of valsartan and atenolol in pharmaceutical raw material, binary mixture and dosage forms.

DEVELOPMENT HPLC METHOD FOR THE QUANTIFICATION OF ATORVASTATIN AND IST IMPURITIES IN TABLETS

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The search for adequate HPLC method for determination of atorvastatin and its impurities, related compounds is complicated by the scope of the analytical method application; is it going to be used for routine analysis by the quality control laboratories within the pharmaceutical industry, or the method will have additional research aim for atorvastatin impurities. In the first case of routine analysis using MS detectors is unnecessary and optional, whilst in second case it is an advantage. New rapid, simple, green high throughput chromatographic method for determination of atorvastatin and its 8 main specified impurities was developed. The main accent in our method development strategy were focused on powerful solid-phase particle C18 column and new concept of mobile phase, composed of simple binary system containing 0.05% *v/v* formic acid adjusted to pH 4.0 and acetonitrile, without use of tetrahydrofuran, an ion-pair reagents, trifluoroacetic acid and other modifiers with high ultraviolet (UV) cut-off like acetate, citrate buffers or amines. With this new concept of mobile phase and powerful core-shell based column, targeted parameters concerning essential critical peak resolution, run time length including column preparation and equilibration and column backpressure, were achieved. The column Shim-pack XR ODS II 75 mm x 3