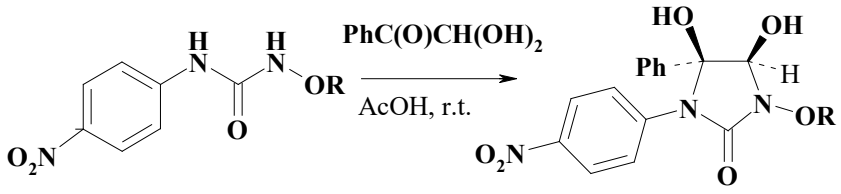
Phenylglyoxal interacts with *N*-alkoxy-*N*‘-(4-nitrophenyl)ureas in the same conditions yielding only 3-alkoxy-*cis*-4,5-dihydroxy-1-(4-nitrophenyl)-5-phenylimidazolidin-2-ones **4**.



R=Me,Et,Bn **4**

The structure of the all product has been proved by ^{1}H and ^{13}C NMR, and mass spectra. The structure of products **1**,**2**,**4** has been proved by XRD study.

VALIDATION OF NEW SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF LISINOPRIL WITH NINHYDRIN IN TABLETS

Shulyak N.S., Budzivula K.V., Kryskiw L.S., Kucher T.V., Logoyda L.S.
I. Horbachevsky Ternopil National Medical University, Ternopil, Ukraine
Kucher_tv@tdmu.edu.ua

Lisinopril (LP) is a competitive ACE inhibitor and prevents the conversion of angiotensin I to angiotensin II, which is a potent vasoconstrictor. Over the years, a vast array of analytic methods has been described for LP assay in its pure or in combination with other drugs in various biological liquids comprise UV-Vis spectroscopy, HPLC, gas chromatography etc. However, many of them are limited in their applications or rather much tedious and time consuming. Due to the presence of primary amino group in LP molecule we proposed to determine it spectrophotometrically using reaction of coloured complex formation of the latter with ninhydrin. In this message we reporting validation of the developed procedure for determination of LP with ninhydrin reaction in three commercially available tablet dosage forms. Standard calibration curve was generated by plotting absorbance of reaction product *vs* concentration of LP under known optimum conditions. The proposed method was validated as per the ICH guidelines. Beer's law limit, molar absorptivity, detection limit, regression equation and correlation coefficient were obtained by least square treatment of the results. The linear relationship between absorbance at λ_{max}=400 nm and concentration of API ranging 40-60 μg/mL was found. Regression analysis of Beer's law plot yielded the regression equation, y=7.4929x–0.0545. High values of correlations coefficient R^2=0.9917 and small values of intercept validated the linearity of calibration curve and obedience to Beer's law. To determine limits of detection and quantification we involved method based on the standard deviation of the response and the slope. The LOD and LOQ values were expressed as $3.3\sigma/b$ and $10\sigma/b$ and were calculated to be 6.91 μg/mL and 23.01 μg/mL. Proposed method was tested in order to assess its selectivity using the model mixtures for analysis. It has been confirmed that the measured absorbance was only produced by the analyte. Replicate analysis (n = 5) for a concentration level of 52 μg/mL LP has yielded the % of LP recovery at 100.42 ± 1.25 and thus revealed that the inactive ingredients did not interfere with LP determination. Intra-day and inter-day precision values have been calculated by replicate analysis (n = 5) of calibration standard, at three different concentration levels, during the same day, and then during 5 consecutive days. The RSD (%) values of intra-day and inter-day measurements have indicated a good precision (intra-day RSD_{max}=1.31 %, inter-day RSD_{max}=1.14 %). Accuracy, defined as the closeness between the reference and found values, has been evaluated, on the other hand, as percentage relative error between the measured and theoretical concentration of LP ($RE_{intra\text{-}day}$=1.09 %, $RE_{inter\text{-}day}$=0.85 %).

Proposed method was successfully applied for the quantification of LP in tablets pertaining to three commercial formulations (Lisinopril-Astrapharm (Ukraine), Lisinopril-KRKA (Slovenia), Lisinopril-Teva (Germany)) and reveal no significant differences compared to the reference method (101.08±0.65, 100.35±0.41, 100.96±0.57, respectively).