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COMPATIBILITY DETERMINATION OF POTASSIUM OROTATE WITH SPIRONOLACTONE BY HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY

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Introduction

Nowadays, the number of new fixed-dose combinations (FDCs) is rising significantly. FDC is a medicine that includes two or more active pharmaceutical ingredients (APIs) combined in a single dasage form. Therefore, compatibility determination between APIs in fixed-dose combinations is an indispensable step in the elaboration. To investigate the compatibility of the components of a formulation, techniques, such as X-ray diffraction, FT-IR spectroscopy, high-performance liquid chromatography (HPLC) and thermal analysis (especially differential scanning calorimetry - DSC) are used. The present study is based HPLC High-performance liquid chromatography provides information on possible interactions between APIs and their related interaction products.

Keywords

HPLC, combination, potassium orotate, spironolactone.

Purpose

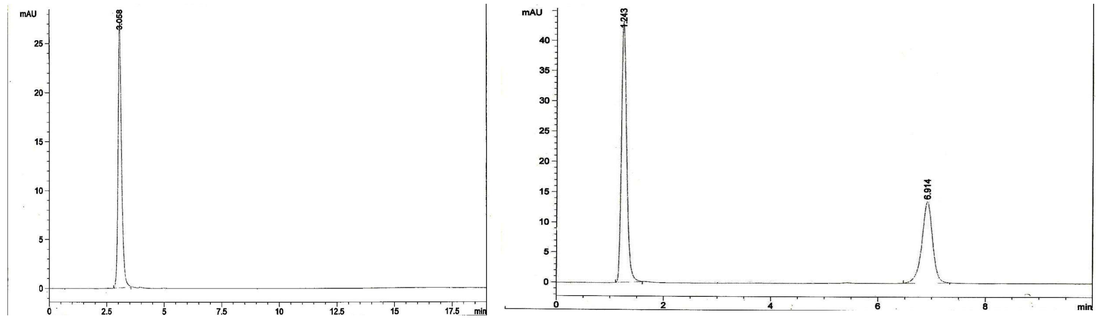
The purpose of the present study was to investigate the compatibility of potassium orotate in combination with spironolactone by the HPLC method.

Material and methods

The detection was carried out using Liquid Chromatograph Agilent 1100 equipped with autosampler, UV-VIS detector, applying mobile phase, which consists of acetonitrile and phosphate buffer solution (pH=4.0) ratio in 1:49 and 1:1, at flow rates 1 and 1.5 mL/min, injection volume 20 μL. The study was made on a RP-18 reversed column (250mm long by 4 mm internal diameter, particle size 5μm) and at an isocratic elution method. The APIs (potassium orotate and spironolactone) were provided by Sigma Aldrich, USA.

Results

Due to developed method both separation and simultaneous qualitative and quantitative determination of APIs in the mechanical mixture were carried out, using HPLC. Spironolactone: retention time 6.9 min, concentration 98.1% (±0.21); potassium orotate: retention time 3.06 min, concentration 91.67% (±0.15). There were just well-separated symmetrical peaks of APIs and no additional peak in the chromatograms.



Chromatograms of mixture (potassium orotate with spironolactone) at 278 nm and 240nm simultaneously mobile phase N1 and mobile phase N2.

Conclusions

There is compatibility between APIs. Further studies will be performed by other methods (DSC, FT-IF Spectrometry) to confirm the obtained result.

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