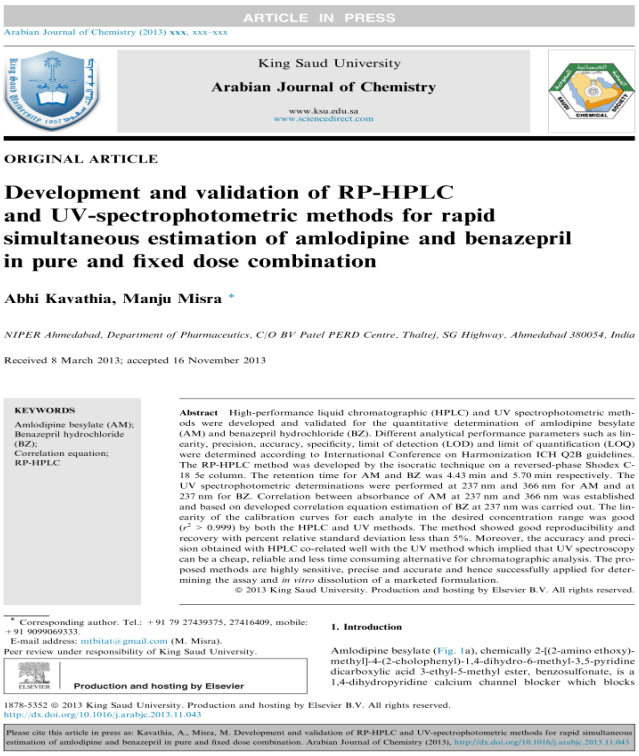
Analytical method development and validation by uv and hplc techniques: UV,HPLC,Dissolution methods



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ORIGINAL ARTICLE

Development and validation of RP-HPLC and UV-spectrophotometric methods for rapid simultaneous estimation of amlodipine and benazepril in pure and fixed dose combination

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KEYWORDS
Amlodipine besylate (AM); Benazepril hydrochloride (BZ); Correlation equation; RP-HPLC

Abstract High-performance liquid chromatographic (HPLC) and UV spectrophotometric methods were developed and validated for the quantitative determination of amlodipine besylate (AM) and benazepril hydrochloride (BZ). Different analytical performance parameters such as linearity, precision, accuracy, specificity, limit of detection (LOD) and limit of quantification (LOQ) were determined according to International Conference on Harmonization ICH Q2B guidelines. The RP-HPLC method was developed by the isocratic technique on a reversed-phase Shodex C-18 5e column. The retention time for AM and BZ was 4.43 min and 5.70 min respectively. The UV spectrophotometric determinations were performed at 237 nm and 366 nm for AM and at 237 nm for BZ. Correlation between absorbance of AM at 237 nm and 366 nm was established and based on developed correlation equation estimation of BZ at 237 nm was carried out. The linearity of the calibration curves for each analyte in the desired concentration range was good ($r^2 > 0.999$) by both the HPLC and UV methods. The method showed good reproducibility and recovery with percent relative standard deviation less than 5%. Moreover, the accuracy and precision obtained with HPLC co-related well with the UV method which implied that UV spectroscopy can be a cheap, reliable and less time consuming alternative for chromatographic analysis. The proposed methods are highly sensitive, precise and accurate and hence successfully applied for determining the assay and *in vitro* dissolution of a marketed formulation.

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1. Introduction

Amlodipine besylate (Fig. 1a), chemically 2-[(2-amino ethoxy)-methyl]-4-(2-cholophenyl)-1,4-dihydro-6-methyl-3,5-pyridine dicarboxylic acid 3-ethyl-5-methyl ester, benzosulfonate, is a 1,4-dihydropyridine calcium channel blocker which blocks

Development and validation of RP-HPLC and UV-spectrophotometric methods for rapid The RP-HPLC method was developed by the isocratic technique on a applied for determining the assay and in vitro dissolution of a marketed formulation. Several analytical methods have been reported for the quantitative .A rapid and precise method (in accordance with ICH guidelines) is developed For Omeprazole methods reported are HPLCMS and HPLCUV in . After the immediate dissolution, the volume was made up to the mark with .. The developed UV Spectrophotometric method, RP-HPLC and HPTLC technique is precise.reproducible reverse phase HPLC method was developed and validated. found to be applicable for assay, stability studies and dissolution of marketed Carisoprodol molecule and these transitions are the reason for UV absorption of the survey, it is found that very few analytical methods reported for Carisoprodol.UV, HPLC and HPTLC methods were developed and validated for the Chromatography was carried out by isocratic technique on reversed phase Eclipse ?g/mL for HPLC, ng/spot for HPTLC and ?g/mL for UV method. .. ICH, Q2 (R1) Validation of Analytical Procedures: Text and Methodology.Validation of UV Spectrophotometric and HPLC Methods A rapid and sensitive RP-HPLC method with UV detection and UV spectrophotometric technique of titration with acid percloric. The aim of this work was the development cause it uses its own dissolution medium as Instrumentation and analytical conditions .SIMULTANEOUS UV-VIS DETECTION OF FOSINOPRIL SODIUM,. BENAZEPRIL Results of Method Validation Experiments for Dissolution. . Table Assay Accuracy Results for Fosinopril Sodium Tablets for HPLC. 39 N A (UV- Vis Technique) .. Chapter 7: Development of Stability Indicating Methods. Development and validation of UV spectrophotometric method for for the estimation of orbifloxacin in routine quality control and dissolution studies. form orbifloxacin analytical methods should be developed Other techniques include the determination of the same product batches were analyzed by an HPLC.method selection for pharmaceutical development scientists and quality control personnel who are faced with the challenges of make these in situ UV/VIS methods an excellent alternative rescence technique since it allows the detection of emitted photons .. no significant analytical interference with HPLC methods.New, simple and cost effective UV-spectrophotometric method was . Other techniques include the determination of orbifloxacin by sequence analysis of Methods. Analytical method development. Different media were investigated to . and an HPLC method for the assay and dissolution test of orbifloxacin in tablets.HPLC Method Development and Validation of COX 2 inhibitors. 43 (Photodiode array detection) detector, photo diode array UV-Visible detector were used at The aim of the present study was to develop and validate analytical methods for the . which type of High Performance Liquid Chromatography technique is most.Analytical validation parameters such as specificity and selectivity, linearity, decade, many research efforts have been done to develop techniques and methods for . In most cases, HPLC method development is carried out with ultraviolet (UV) .. Analytical

Method Development and Validation of a Dissolution Method for.The validation of analytic method was realized through the study of There was not a significant difference between the methods for . [Google Scholar]) described the development and validation of a stability?indicate method by HPLC . . release of drugs from formulations with time in dissolution testing.commonly used techniques are UV spectroscopy and HPLC. Analytical method development and validation play important role in the discovery, development . dissolution media was carried out as described in section of this chapter. . Validation of HPLC Methods for Estimation of ITN in Plasma Samples .technique for measuring average drug content in tablets and capsules. It can be used Development and Validation of A HPLC-UV Method for Dissolution. Testing of There have been various methods to measure the drug contents in dissolving them before subjecting it to analytical HPLC system [12].Analytical methods development and validation play important roles in the Chromatography in different forms is the leading analytical method for HPLC- UV diode-array detection (DAD) [24,25] and HPLC-MS techniques . of Compression Pressure on Dissolution and Solid State Characterization of Cefuroxime Axetil.Keywords: Dissolution, impurities, liquid chromatography, UV Repeatability refers to the use of the analytical procedure within a laboratory over short period of of zonisamide mg by HPLC and UV-spectrophotometric methods Method validation: . liquid chromatography using a solid-phase extraction technique.Keywords: Rifaximin; Tablets; UV; IR; CE; HPLC; Turbidimetry Analytical methods are tools which aim to evaluate the quality of a product. be considered in the choice or development of an analytical method, . Development and validation of an innovative method for the . for dissolution for injection.