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DEVELOPMENT OF A FREE SOLUTION CAPILLARY ELECTROPHORESIS METHOD TO ASSAY AMINOPHYLLINE IN PHARMACEUTICALS

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Introduction and Objectives: Aminophylline is a 2:1 complex of theophylline and ethylenediamine. It is used to treat wheezing caused by asthma. The objective of the present work was to develop and validate a fast and economical method by free solution capillary electrophoresis (FSCE) to determine aminophylline in tablets.
Material and Methods: The analyses were carried out in a Beckman and Coulter P/ACE MDQ capillary electrophoresis equipment equipped with a UV-VIS detector. A fused-silica capillary was used with an effective lenght of 20 cm x 75 µm i.d. The background electrolyte consisted of 20 mmol L^{-1} sodium tetraborate buffer solution, pH 9.2. The applied voltage was 17 kV, and the sample injection was performed hydrodynamically at 0.3 psi for 3s. The detection of the samples was set at 200 nm.
Results and Conclusions: Good linearity ($R^2 > 0.99$) over a concentration range from 56.00 µg mL^{-1} to 84.00 µg mL^{-1} was obtained; detection and quantitation limits were 5.71 µg mL^{-1} and 17.30 µg mL^{-1}, respectively. The migration times for diphenhydramine (used as internal standard) and aminophyline were 0.5 min and 1.3 min respectively. The intra-day precision expressed as % RSD was less than 2%. The proposed FSCE method was found appropriate for determination of aminophylline in pharmaceutical formulations and could be successfully applied in quality control laboratories.
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DEVELOPMENT AND CHARACTERIZATION OF EFAVIRENZ AMORPHOUS SOLID DISPERSIONS

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Introduction and Objectives: Efavirenz (EFV) is an antiretroviral non-nucleoside reverse transcriptase inhibitor (NNRTI) part of the first-line treatment of HIV-1 infection. This compound belongs to class II of the biopharmaceutical classification system, i.e, it exhibits high permeability and low solubility (less than 10 mg/L). Due to this characteristic, the dissolution and, consequently, its bioavailability may be impaired, compromising the therapeutic efficacy of the medicine. In this study, EFV solid dispersions (SD) were obtained by solvent evaporation method aiming to enhance its solubility through amorphization.
Material and Methods: During the SD development stage, a fast screening was performed to identify the best polymeric carriers to produce stable amorphous EFV dispersions. At this stage, SD were prepared on glass slides containing drug:carrier (PVP K-28/32, copovidone, poloxamer 188, poloxamer 407, HPMCP-55, HPMCP-55s and HPMCP-50) proportion of 1:3. The slides were submitted to stability study under accelerated conditions (40°C/75%) and the occurrence of crystallization was monitored by x-ray diffraction. The analyzes were conducted at the following time intervals: initial (T0), after 7 days (T1) and after 30 days (T2).
Results and Conclusions: Results have shown that carriers poloxamer 188 and 407 were unable to promote the amorphization of SD and there are significant evidences of changes in crystalline structure during process of recrystallization.
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