Drug delivery profile of malic acid-phthalic acid-propane 1,2-diol copolyester (Article)

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Abstract

Five mixtures of malic acid and phthalic acid in mole combinations (1.0+0), (0.9+0.1), (0.8+0.2), (0.7+0.3) and (0.6+0.4) respectively were separately reacted with 1 mole of propane 1,2-diol following the Dean-Stark method using xylene as the reaction medium, thereby five copolyesters (I-V) were obtained. The copolyesters were characterized by their IR spectra, molecular weight, elemental analysis and solubility behaviour in common organic solvents. The polymer III had the highest molecular weight and it was selected for subsequent experimens. Its hydrolytic degradation study in solutions of different pH values showed that it remained intact in solutions of pH values 1.2-6.0, but gradually degraded in solutions of pH values >6.0. In the first case, it was observed that the copolyester did not degrade in the simulated gastric fluid (pH 1.2) when coated on a core tablet of diclofenac sodium or naproxen for as long as two hours. But in the simulated intestinal fluid (pH 7.4) it gradually degraded and thereby helped drug release up to 4 hours from the coated tablets, and the drug release pattern did not comply with enteric coating characteristics. In the second case, pure drugs Diclofenac Socium and Naproxen, 20-21% w/w, were separately incorporated in the copolyester by the dispersed method and the drug loaded polymer matrices were investigated in phosphate buffer solution of pH 7.4 to observe the release pattern of the drugs. It was found that the drug delivery profile of the copolyester was zero order up to 11 hours releasing 89.1% of Diclofenac Sodium and up to 12 hours releasing 88.0% of Naproxen; afterwards release of drugs was negligible.