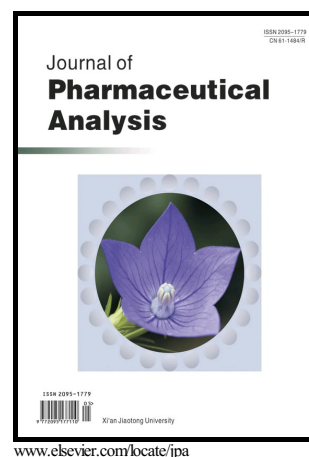


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Effect of nonionic surfactants in release media on accelerated in-vitro release profile of sirolimus eluting stents with biodegradable polymeric coating

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Abstract

It is a well-known fact that sirolimus (SRL) undergoes degradation process via hydrolysis in aqueous media leading to incorrect assessment of drug amount and thus release characteristics of formulations. The main objective of the present study was to evaluate the effect of nonionic surfactants in media on *in-vitro* release profiles for sirolimus eluting stents (SES) coated with biodegradable polymeric matrix. Phosphate buffer and acetate buffer incorporating nonionic surfactants with varying concentrations were examined for adequate solubility and stability (by RP-HPLC). Good sink condition was achieved in phosphate buffer (at pH 4.0) with 1.0% Tween 20, 1.0% Brij 35 and 0.5% Brij 58. Hydrodynamic size (by DLS) and the micelle-water partition coefficient (P) with standard free energy of solubilization (ΔG_s°) of drug were evaluated to get some understanding about the solubilization phenomena. About 80% of drug release during the period of 48 h was achieved in optimized drug release media which is 1.0% Tween 20 in phosphate buffer pH 4.0. The obtained accelerated SRL release profile in optimized medium correlated well with the real time *in-vitro* release in phosphate buffer (pH 7.4). Surface morphology changes (by SEM), changes in gravimetric weights and molecular weight change (by GPC) were examined pre and post drug release to

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