Research Article

Preparation, process optimization and cytotoxicity evaluation of lyophilized Mitomycin C loaded nanoparticles

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Abstract

Objective: The purpose of this study was to develop freeze dried Polylactide (PLA) nanoparticles loaded with Mitomycin C intended to be administered intravenously with improved therapeutic efficiency of the drug and thereby reduced dose related toxicity associated with oncology drugs. **Materials and methods**: The Mitomycin C loaded nanoparticles were prepared using modified spontaneous emulsification solvent diffusion method (SESD) and nanoprecipitation method. The in Vitro Release study of Mitomycin C loaded Polylactide (PLA) –NP was carried by dialysis bag diffusion technique. **Results and discussion**: The incorporation efficiency was found to be higher in Modified SESD technique than emulsification solvent evaporation method. The release behavior of Mitomycin C exhibited a biphasic pattern characterized by an initial burst release followed by a slower and continuous release. The nanoparticles were characterized by particle size, zeta potential, polydispersity index, DSC and FTIR. The long term stability was achieved by lyophilisation technique. The cell line study using XTT assay on LNCaP prostate tumor cell lines revealed that Mitomycin C loaded nanoparticles showed greater cancer cell inhibition compared to plain nanoparticles and marketed conventional formulation.

***Keyword*:** PLA, Mitomycin C, Lyophilization, Cryoprotectant, cell line studies, cytotoxicity studies

Introduction

Submicronic colloidal vectors have gained a considerable interest in the last few years because of their ability to ensure a specific drug targeting by both the oral route and the parenteral route. Such particulate systems have been widely investigated for gene delivery to cells and tissues as in the delivery of anti-sense oligonucleotides and also in cancer therapy and diagnosis. Among these vectors, liposomes and nanoparticles have special advantages with regards to the modulation of an active ingredient distribution within the human body.

In the development process of a nanoparticulate drug delivery system for *in vivo* application, biodegradability without toxic by-products is one of the major claims, a potential matrix molecule has to fulfill. Within the past decades, a multitude of protocols described in literature used synthetic or natural base products for the preparation of biodegradable nanoparticles. Instead of a complete listing of all approaches, only a selection of the most significant biodegradable nanoparticle types will be reviewed here. With regards to nanoparticles based on synthetic polymers, polylactide (PLA), polyglycolide (PLG), and poly(D,L-lactide-co-glycolide) (PLGA) nanoparticles represent the most extensively investigated ones (Panyam and Labhasetwar, 2003).

Poorly water soluble drugs pose a significant challenge in their delivery. A large number of drugs are discarded from consideration in their early stages of development owing to poor bioavailability. Such drugs are an excellent candidate for nanoparticulate drug delivery, which can avoid the allergic side effects due to the use of cremophors (e.g. polyethyoxylated caster oil) in conventional formulations used for effective solubilization of drugs. However, for drugs with crystal forming habits, there is always a hazard of the formation of large micro particles from aggregation/bonding of nanoparticles; this can lead to infarction or blockage of the capillaries, resulting in ischemia or oxygen deprivation and

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