OMICS International
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Pharm Anal Acta 2016, 7:1 (Suppl)
http://dx.doi.org/10.4172/2153-2435.C1.028

8th International Conference and Exhibition on

Pharmaceutics & Novel Drug Delivery Systems

March 07-09, 2016 Madrid, Spain

Novel polymer for gene and stem cell delivery

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The disulfide-linked bioreducible polymer poly (cystaminebisacrylamide-diaminohexane) [CBA-DAH] was synthesized. Primary rat skeletal myoblasts were transfected with poly (CBA-DAH)/pCMV-VEGF165. MRI analysis of the treatment groups reveled a significant recovery of ejection fraction in the VEGF myoblast treatment over myoblasts only and ligation control. Apoptotic cell population reveled a significant attenuation of apoptosis in the myoblast only group but a higher attenuation in the VEGF myoblast group compared to ligation controls. This indicated that while myoblast implantation alone limits apoptosis in the myocardium, the VEGF myoblast group is producing a significantly higher protective effect. The work demonstrates that bioreducible polymers can successfully be used to transfect skeletal myoblasts with angiogenic factors. We proposed that the hMSCs delivered by our PLGA/PEI 1.8k (PPP) microparticles produce *in-vivo* cardioprotective effects on post-infarct cardiac remodeling. We demonstrated that intramyocardial delivery of hMSCs by porous PPP particles in infarcted rats preserved engraftment of hMSCs in infarcted myocardium, cardiac geometry, and left ventricular systolic function. In addition, hMSCs-loaded PPP delivery augmented blood flow to coronary artery. The reduced infarct size of hMSC-loaded PPP delivery was followed by a decrease in fibrosis, protection from cardiomyocyte loss, and down-regulation of apoptotic activity. Furthermore, the increased angiogenesis and decreased myofibroblast density in the border zone of the infarct support the beneficial effects of hMSC-loaded PPP administration. These results of hMSC therapy delivered by PPP particles provide insight into the hMSC therapy translation in the treatment of acute myocardial infarct to human trials.

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Modelling chemical and physical stability of cocrystals. Case study: Sulfadimidine: 4-Amino salycilic acid cocrystal

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Salt formation is a common approach to enhance drug solubility but it is not successful when the API does not contain ionisable functional groups in its chemical structure. Engineering of pharmaceutical cocrystals can be an advantageous strategy to overcome poor drug solubility, without the need to break or create covalent bonds. Predicting the shelf life of solid-dose pharmaceutical products using both stressed and accelerated stability data is often desired in order to avoid long development times and costs, associated with real-time stability testing. However, using an accelerated stability programme, stability data gathered over two to four weeks at elevated temperature and humidity conditions can be used to predict stability at lower temperatures. Modelling of physico-chemical stability of cocrystal systems using an accelerated stability program has not been documented. Statistical estimation of both physical and chemical stability parameters is not straightforward due to the non-linearity of modified versions of the Arrhenius equation. Sulfadimidine (SDM) is a poorly-soluble anti-infective agent. In order to improve its aqueous solubility, several cocrystal habits were formed using a GRAS coformer, 4-aminosalycilic acid (4-ASA). Two different polymorphic forms of the cocrystal were prepared containing equimolar ratios of 4-ASA and SDM. The hypothesis underpinning this work is that cocrystal engineering can be used not only to improve the aqueous solubility of the SDM but also its physicochemical stability by changing the cocrystal habit. A four week accelerated stability approach was used to predict the long term physical and chemical stability of different SDM:4-ASA cocrystals with different polymorphic forms and crystal habits.

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