

8th International Conference and Exhibition on

Pharmaceutics & Novel Drug Delivery Systems

March 07-09, 2016 Madrid, Spain

Application of central composite design in the preparation and optimization of poly(lactic-co-glycolic acid) nanoparticles for systemic immune responses of Hepatitis B antigen

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Hepatitis B is the most prominent viral disease worldwide. According to WHO, it affected 350 million people per year and 1 million people a year, die from chronic active hepatitis, cirrhosis or primary liver cancer. The conventional dose requires booster dose as well as relapse case were also reported. The aim of present study was to prepare Hepatitis B antigen loaded nanovaccine, to enhance the antibody production efficiency and cure of relapse cases. Polymeric nanoparticle were prepared by double emulsion solvent evaporation technique, utilized a central composite design for optimization of the formulation parameters and process parameter. The effect of independent variables like amount of polymer, stabilizer concentration, aqueous organic phase ratio and homogenizer speed was studied on particle size and entrapment efficiency. The independent variables have significant effects ($p < 0.05$) on the responses and provide desirable approach and overlay contour plots, therefore it gives the perfect experimental results in accordance with the estimated data. Nanoparticles were characterized *in-vitro* for their size, shape, entrapment efficiency, zeta potential, SEM and AFM. The antigen integrity, *in-vitro* release and its stability at 37°C were also evaluated. The designed nanoparticles demonstrate -41.2 mV zeta potential and an average particle size 266 nm with antigen loading efficiency $92 \pm 5\%$. Surface morphology revealed irregular shape of nanoparticles. *In-vitro* release showed biphasic behavior i.e., initial burst release followed by sustained release up to 36 days. The drug release from the polymeric nanoparticle followed Higuchi model indicating diffusion controlled non-Fickian drug release. These data demonstrate high potential of modified PLGA nanoparticles for their use as a carrier adjuvant for subunit vaccines. The developed nanoparticles will be further used for induction of humoral and cellular immunization.

Biography

Hitesh Kumar Dewangan is currently pursuing PhD from Indian Institute of Technology, Banaras Hindu University (IIT-BHU) Varanasi, Uttar Pradesh, India. He qualified GPAT examination and was selected for MHRD Post-graduate scholarship. Currently, he is in third year of his PhD degree and received teaching assistantship fellowship, under supervision of Prof. Sanjay Singh, (MPharm, PhD, Department of Pharmaceutics, IIT-BHU).

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