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## Biodegradable, biocompatible and functional pentablock copolymer based nanoformulations for sustained ocular delivery of macromolecules

Vibhuti Agrahari

University of Missouri-Kansas City, USA

Vision threatening disorders such as age-related macular degeneration (wet-AMD), diabetic retinopathy (DR) and diabetic macular edema (DME) require frequent intravitreal injections of anti-VEGF antibodies or fragments thereof. Frequent intravitreal injections are associated with many complications such as secondary infections (endophthalmitis), retinal hemorrhage, retinal detachment and more importantly patient non-compliance. Therefore, development of sustained release formulation which can reduce the frequency of intravitreal injection is a better therapeutic option. The objective of this study is to evaluate tolerability and biocompatibility of novel PB copolymers based formulations including thermosensitive gel, nanoparticles (NPs) and a composite formulation comprising NPs dispersed in gel following topical instillation as well as single intravitreal injection in rabbits. In this study, NP preparation method was successfully optimized to improve entrapment efficiency (EE) and drug loading (DL) of model macromolecules such as IgG Fab and Catalase. With this optimized method, a remarkably improved EE (~46% to 76%) and DL (~15% to 18%) have been observed. Results of *in vitro* studies depicted a nearly zero order release for significantly longer duration of time (~120 days) without showing any burst release effect. Moreover, *in vitro* biocompatibility assay exhibited negligible release of cytokines suggesting biocompatible nature of PB copolymers. Further, *in vivo* tolerability study was performed following topical instillation and intravitreal injection. Results of *in vivo* tolerability study exhibited excellent biocompatibility without any perceptible signs of inflammation or cataract. Results revealed that PB copolymer based formulation can be used as a platform for the treatment of posterior segment ocular diseases.

### Biography

Vibhuti Agrahari is pursuing her Graduate (Ph.D.) study at the University of Missouri Kansas City (UMKC), Kansas City, MO, USA, under the supervision of Dr. Ashim K. Mitra. She did her Master of Pharmacy studies with specialization in Medicinal & Pharmaceutical Chemistry from Shri G. S. Institute of Technology and Science, Indore, India. During her Master's studies she worked on the research projects involved with Development and validation of stability indicating and bio-analytical assays in human plasma using HPLC method. Currently, in her Ph.D. program in Dr. Mitra's lab, she is working on the project entitled as 'Development and evaluation of novel penta-block co-polymers as a nanotechnology platform for sustained ocular delivery of peptides and proteins therapeutics'. She has participated and presented her research works at various national & international conferences and authored several peer reviewed papers. Vibhuti is also actively involved with various professional organizations such as, AAPS, IPC and APTI. At present, Vibhuti is contributing her services as vice-chair of AAPS-UMKC Student Chapter and also a student representative of the Graduate Professional Council (GPC) Committee, School of Pharmacy, UMKC. She worked as a Lecturer for about two years at Acropolis Institute of Pharmaceutical Education & Research, Indore, India. She has also been appointed as a Teaching Assistant for various pharmacy courses at UMKC.

vk896@mail.umkc.edu