As these therapeutic proteins are available in market, in the formulation of these drugs should ensure safety, consistency, potency and effectiveness of delivery systems. Despite the attractive features that protein offers, a large number of them have serious limitations (Nayak, 2014).

The chemical and structural complexities involved demand an effective delivery system in which the physicochemical and biological properties including molecular size, solubility, stability, light sensitivity, moisture, temperature, and biological half-life are duly main considerations (Bandyopadhyay, 2013).

Physical instabilities like denaturation, aggregation, precipitation and adsorption onto surfaces and chemical instabilities as oxidation, hydrolysis, deamidation and disulfide exchange, may occur for a given protein, due to the presence of multiple susceptible sites (Hasija et al., 2013).

The most important challenge to formulations of therapeutic proteins into effective dosage forms is to ensure their stability over their shelf lives. In the GIT, digestive enzymes normally break down proteins (Morishita & Peppas, 2006).

Therefore, formulation of therapeutic proteins is very critical, regardless of the route of administration, protein drug development should start with preformulation studies including physicochemical characterization, solubility and stability determination under various conditions, pH determination, also, the choice of buffer system and pH of vehicle, solvent selection as well as preservation of the formulation (Carpenter & Manning, 2002).

Among the factors that should be considered in the formulation of therapeutic proteins, in order to prevent the degradation pathways. Pharmaceutical formulations