ABSTRACT

The aim of this study was to develop the nanosuspension of clarithromycin for enhancing the solubility and in vitro drug release property of drug. In the present study the area of interest are drugs belonging to class II of BCS classification. Nanosuspension is a submicron colloidal dispersion of drug particles which are stabilized by surfactants ranging between 200-600nm, and is considered as a viable drug delivery strategy to develop the poorly soluble drugs. The drug nanosuspension was prepared by precipitation-sonication method using 23 factorial design to conduct the experiments. PEG-200 as polymer, Poloxamer-188 as co-polymer and stabilizer, two different solvents - acetone and water were used in the process. FTIR analysis and thermal analysis proved compatibility between drug and polymers. Characterization parameters such as the FTIR analysis, TG-DT analysis, particle size analysis, AFM analysis, poly dispersity indexanalysis, solubility studies, entrapment efficiency, drug content estimation, in vitro drug release studies, zeta potential analysis were carried out. All formulations were in the size range of 200-900nm where as the best formulation (F4) was around 218nm. Marked improvement in solubility and drug release studies were observed when compared to that of pure drug (of size ranging up to 5μm). Zeta potential and poly dispersity index determined the stability of the best formulation (F4). Short term stability studies carried out for the best formulation (F4) showed that nanosuspension formulation of clarithromycin will remain stable at 4°C compared to room temperature. Based on the R2 and N values, it was concluded that the best formulation (F4) follows zero order drug release and mechanism of drug release was anomalous (diffusion coupled with erosion). Finally it can be stated that formulating poorly water soluble drugs of BCS class II in the form of nanosuspension would be a promising approach in delivery by oral route.

**Keywords:** Nanosuspension, Clarithromycin, Precipitation-Sonication method, Solubility.