SUMMARY OF UGC MINOR RESEARCH PROJECT FOR WEBSITE

Grant Details

F. No.: 47-989/14 (WRO) dated 20th Feb 2015

Title: Enhancement of Dissolution and *In vivo* Performance of BCS Class-II Drug by Freeze Drying Technique

Principal Investigator: Dr. Vinod L. Gaikwad

Duration: 2015-2017 (Two Years)

College: P E Society's Modern College of Pharmacy, Nigdi, Pune 411044.

Effective date of starting the period: 20th Feb 2015

Total Grant Approved: Rs. 4,40,000 /-

SUMMARY OF THE RESEARCH PROJECT:

In the present research, preparation of solid dispersion by freeze drying technology resulted in improvement of solubility of gliclazide. It resulted into formulation of free flowing solid dispersion with high rate of dissolution. Freeze drying is very efficient technique that requires low amount of polymeric carriers which results into formation of uniform size particles in amorphous state. A novel polymer soluplus, designed for dissolution enhancement using Hot Melt Extrusion & Spray Drying technology can also be successfully applied in freeze drying technology for same purpose. Present study concludes with enhanced flow properties, solubility and dissolution of gliclazide (a BCS class II drug) using poloxamer 407 and soluplus polymer composite.

Characterization of gliclazide by analytical methods FT-IR, DSC, PXRD and SEM confirmed the chemical moiety. FT-IR and DSC studies indicated the compatibility of Gliclazide with poloxamer 407 and soluplus which can be used for preparation of freeze dried solid dispersion. DSC, PXRD, PSD and SEM analysis confirmed the conversion of Gliclazide from crystalline to amorphous state. Saturation solubility and dissolution study proved that poloxamer 407 and soluplus have potential of enhancing the solubility and dissolution rate of Gliclazide. This was attributed to the conversion from crystalline to amorphous state of gliclazide and the stability to this metastable amorphous state was imparted with use of polymers simultaneously during freeze drying process. Factorial design was implemented to study the effect of variables on quality attributes of solid dispersions, where quantities of poloxamer 407 and soluplus were taken as independent variables and different evaluation parameters as dependent variables like drug content, saturation solubility, micromeritic properties and in vitro drug release kinetics. Process efficiency study shown that freeze drying technique was suitable for preparation of micron sized particles by using poloxamer 407 and soluplus. Freeze drying technique resulted into formulation of free

flowing solid dispersion. Saturation solubility and dissolution study showed concentration dependent effect of both polymers on drug dissolution. However, when used in combination, poloxamer 407 and soluplus showed predominant effect on saturation solubility which was supported by enhanced dissolution rate. Therefore, soluplus which was designed for dissolution enhancement by Hot Melt Extrusion & Spray Drying technology can also be used successfully for dissolution enhancement by freeze drying technology.