EXECUTIVE SUMMARY OF UGC MINOR RESEARCH PROJECT

F. No.: Approval letter No F-47- 864/13 (WRO) dated 17 OCT 2014

Title: Development and evaluation of Microcrystal's formed by controlled crystallization techniques: Optimization of process parameters

Name of Principal Investigator: Uttekar Pravin Shantaram

Duration: 2015-2017

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Effective date of starting the project: 28/01/2015

Grant Sanctioned: Rs. 3, 85,000/-

Summary:

Aceclofenac is a non steroidal anti- inflammatory drug characterized by low solubility and high permeability which corresponds to BCS class II drug. The strategy of increasing the in vitro dissolution has the potential to enhance the oral bioavailability when using nanosized crystalline drugs. The purpose of this study was to evaluate a novel in situ micronization method avoiding any milling techniques to produce nano- or microsized drug particles by controlled crystallization to enhance the dissolution rate of poorly water-soluble drugs. Aceclofenac microcrystals were prepared by the association of the previously molecularly dispersed drug using a rapid solvent change process. The drug was precipitated in the presence of stabilizing agents, such as hydrocolloids. The obtained dispersion was spray-dried. Particle size, morphology, flow property, zeta potential and dissolution rate were analyzed. Physicochemical properties were characterized using differential scanning calorimetry and X-ray diffractometry. The obtained dispersions showed a homogeneous particle size distribution. Drugs are obtained in a mean particle size of approximately 3μm and below. A high specific surface area was created and in situ stabilized. The surface was hydrophilized because of the adsorbed stabilizer. The solubility of the drug was increased by 2 folds. Thus, a drug powder with markedly enhanced dissolution rate was obtained. In situ micronization is a suitable method for the production of micro-sized drugs. This technique can be performed continuously or discontinuously and uses only common technical equipment. Compared to milled products drug properties are optimized as all particle surfaces are naturally grown, the particle size is more uniformly distributed and the powder is less cohesive.