SOLID STATE INVESTIGATION OF FIMASARTAN FOR PHYSICOCHEMICAL PROPERTIES THROUGH NANOCRYSTALLIZATION

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ABSTRACT

Nanocrystals (NR) provide a promising strategy to enhance the solubility and dissolution rate of drugs with poor solubility. This study explores the use of anti-solvent sonoprecipitation to produce NR, resulting in stable NR with a consistent particle size (PS). Three different stabilizers, namely Luvitec® K 30 (polyvinyl pyrrolidone K30), Polymeg 6000 Ph (polyethylene glycol 6000) and GOHSENOL™ (polyvinyl alcohol) were used and impact of process variables such as stabilizer concentration, sonication time, and sonication amplitude on the PS was analyzed. The prepared NR were evaluated for PS, Zeta potential, differential scanning calorimetry (DSC), powder x-ray diffraction (PXRD), SEM, solubility and dissolution. The NR exhibit a PS below 360 nm and a zeta potential of -24.3 mV, which suggests good stability and resistance to aggregation. DSC and PXRD analysis confirmed their crystalline structure. SEM images showed that the NR have an irregular shape. The solubility of FS was improved 6.45-fold in water and 17.57-fold in 0.1N HCl through nanocrystallization and extent of dissolution was twice that of pure drug within 120 minutes.