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Preparation and Characterization ofsustained Release Ranolazine Microcapsules by W/O Emulsification-Solvent Evaporation Method

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Abstract: Objective: The aim and objective of the present study is to prepare ranolazine sustained release microcapsules were successfully prepared using different ratios of polymers ethyl cellulose (EC) and hydroxy propyl methyl cellulose K4M (HPMC K4M) and tween-80 as emulsifying agent by w/o single emulsification-solvent evaporation method. **Materials and Methods:** Ranolazine is an anti-anginaldrug, it is given in the management of angina pectoris. On oral administration, this undergoes extensive first pass metabolism. Delivery of ranolazine microcapsules would minimize some of the deficiencies associated with the oral delivery, different batches of ranolazine loaded ethyl cellulose and HPMC K4M microcapsules were prepared to overcome the problem of low encapsulation efficiency of water soluble drug ranolazine, in different drug and polymers ratios using tween-80 as emulsifing agent and stabilizer with constant stirring by magnetic stirrer (Model-1 MLA, Remi motors, vasai, Mumbai, India) at 1500 rpm for 3 to 4 hours and centrifuged by cooling centrifuge (Hittich, Zentrifugen, model-1195 a, Mikro 220R, Germany) by w/o single emulsification-solvent evaporation method. The prepared microcapsules were evaluated and characterized for particle size, percentage yield, drug entrapment efficiency, surface morphology by scanning electron microscopy (SEM),drug-excipient compatibility studies byfourier transform infrared (FTIR), solid state properties (crystalline or amorphous) by differential scanning colorimetry (DSC), *in-vitro* drug release studies and release kinetics were determined. **Results:** It was observed that particle size decreased and was found to be in the range 220 to 350 µm, and highest percentage yield of 89.82% was shown, increased drug entrapment efficiency of 87% and increase in dissolution rate with sustained release property of drug with increase in concentration ratio of hydrophilic polymer HPMC and hydrophobic polymer ethyl cellulose were achieved. Based on the particle size, drug entrapment efficiency and in-vitro drug release data an optimized formulation having maximum drug release was selected. The optimized formulation F5 was characterized for particle size and surface morphology using optical microscopy method and scanning electron microscopy. The surfaceof the microcapsules were found to be wavy, smooth and spherical in micron size particles. FTIR studies indicated that polymers selected in the study are compatible with the drug, where there is no shift of drug peaks in the formulation. DSC studies indicated that the drug changed its physical structure in the presence of combination of polymers in the formulation F5.Ranolazinedrug release rate was observed highest with the increase in concentration of HPMC K4M and decreased particle size of microcapsules and showed sustained release property of drug by ethyl cellulose in pH 6.8 phosphate buffersup to 7 hrs.

From the formulation F1 to F8, F5 showed high dissolution rate.The percentage drug release of optimized formulation F5 was compared with the percentage drug release of pure drug. The data obtained from the dissolution profiles were compared for the different release kinetics models and the regression coefficients. The drug release profile follows zero order release and higuchi model kinetics; it was found that optimized formulation of ranolazine microcapsules showed sustained release property. All the results are reported.
Keywords: Ranolazine, hydroxyl propyl methyl cellulose, ethyl cellulose, tween-80, sustained release, microcapsule, single emulsification-solvent evaporation method, zero order release and higuchi model kinetics.

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