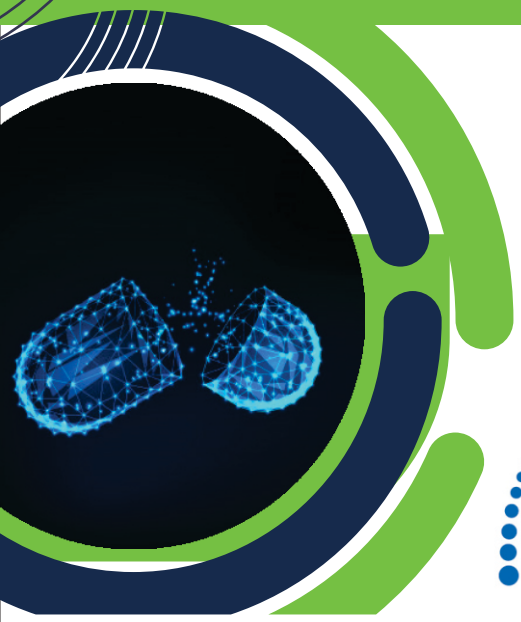

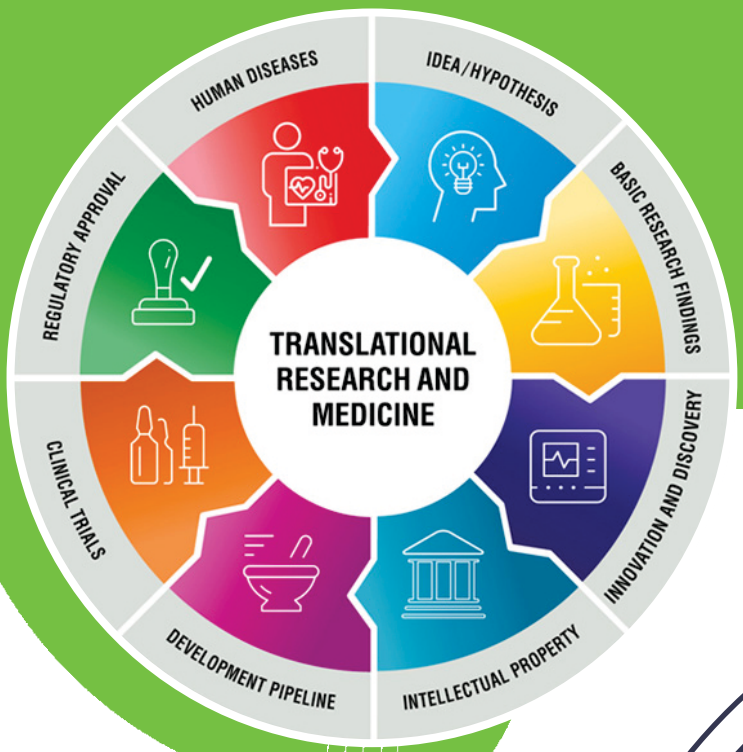

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ENHANCEMENT OF EZETIMIBE PHYSICOHEMICAL PROPERTIES BY A CRYSTAL ENGINEERING METHOD

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Abstract:

Aim: Enhancement of Ezetimibephysicohemical properties by crystal engineering method. Objective: The present research purpose was to get agglomerates of Ezetimibe containing diluents by unique crystallo-co-agglomeration(CCA) technique.Methodology: The characterizations of agglomerates and pure drug are done by using Phase, Saturation solubility, Flowability, Drug content, Scanning Electron Microscopy(SEM), FTIR, X-ray diffraction for powder(XRPD), Differential Scanning Calorimetry(DSC), dissolution studies.Results and discussion: The evaluation of Ezetimibe (Drug);Crystallo-co-agglomerates of Talc;Crystallo-co-agglomerates of Pregelatinized starch has Phase solubility(mg/ml) 0.13,1.39,1.10;Saturation solubility(mg/ml)0.082,1.04,0.85;Hauser's ratio 1.35-1.41,1.13-1.15,1.12-1.14;Carr's Index 26-27,13-15,12-14;Angle of repose(°)40.6,24.62,23.26;Drug content(% w/w)---, 96.24%,98.50%. The flowability of agglomerates was much improved compared to those of the original drug. SEMs revealed that Crystallo-co-agglomerates were spherical aggregates of plate-shaped crystals with clear evidence of porosity.InFTIR,There was no considerable-changes in the positions of characteristic absorption bands, bonds of various functional groups present in the drug. IR spectra indicated the absence of any well-defined interaction between drug;diluents;polymers.InXRPD,range10-80°,2showedCrystallo-co-agglomerates of Ezetimibe indicated decrease in crystallinity or partial amorphization of drug in agglomerated form.InDSC, Ezetimibeshown melting sharp endotherm at 173.770 C,physical-mixture-A at 173.170C,physical-mixture-B at 171.240 C and Crystallo-co-agglomerates of Talc,Pregelatinized starch were 169.130C, 170.700C. Dissolution studies shown enhancement in dissolution-rate of ezetimibe was observed 63.95% in-pure, upto 94% in Crystallo-co-agglomerates of Talc and upto 85% in Crystallo-co-agglomerates of Pregelatinized starch.ConclusionCrystallo-co-agglomeration of Ezetimibe with talc and Pregelatinized starch could be possible and served as an alternative and effective approach for improvement in physicochemical and micromeretic properties of Ezetimibe.

Keywords

Diluents ;Crystallo-co-agglomeration;Solubilit;Dissolution;Ezetimibe