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Preparation and evaluation of agglomerated crystals by crystallo-co-agglomeration: An integrated approach of principal component analysis and Box-Behnken experimental design

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Poor mechanical properties of crystalline drug particles require wet granulation technique for tablet production which is uneconomical, laborious, and tedious. The present investigation was aimed to improve flow and mechanical properties of Racecadotril (RCD), a poor water soluble antidiarrheal agent by a crystallo-co-agglomeration (CCA) technique. The influence of various excipients and processing conditions on formation of directly compressible agglomerates of RCD was evaluated. Principal component analysis and Box-Behnken experimental design was implemented to optimize the agglomerates with good micromeritics and mechanical properties. The overall yield of the process was 88 - 98% with size of agglomerates ranging between 351 and 1214 µm. Further, higher rotational speed reduced the size of agglomerates and disturbed sphericity. The optimized batch of agglomerates exhibited excellent flow ability and crushing strength. The optimized batch of RCD agglomerates was characterized by Fourier Transform Infrared Spectroscopy, Differential Scanning Calorimeter, Powder X-ray Diffractometer and Gas Chromatography which illustrated absence of drug - excipient interaction with minimal entrapment of residual solvent. Hence, it was concluded that both excipients and processing conditions played a vital role in preparing spherical crystal agglomerates of RCD by CCA and this can be adopted as an excellent alternative to wet granulation.

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