High Shear Granulation Process: Assessing Impact of Formulation Variables on Granules and Tablets Characteristics of High Drug Loading Formulation Using Design of Experiment Methodology


Abstract:

High shear wet granulation is a significant component procedure in the pharmaceutical industry. The objective of the study was to investigate the influence of two independent formulation variables; polyvinylpyrrolidone (PVP) as a binder (X1) and croscarmellose sodium (CCS) as a disintegrant (X2) on the critical quality attributes of acetaminophen granules and their corresponding tablets using design of experiment (DoE) approach. A two factor, three level (3²) full factorial design has been applied; each variable was investigated at three levels to characterize their strength and interaction. The dried granules have been analyzed for their density, granule size and flowability. Additionally, the produced tablets have been investigated for: breaking force, friability, disintegration time and t80 of drug dissolution. The analysis of variance (ANOVA) showed that the two variables had a significant impact (p)

Keywords:

High shear granulation, design of experiment, crosscarmellose sodium, polyvinylpyrrolidone, granules, tablets, acetaminophen.

Published In:

Acta Poloniae Pharmaceutica - Drug Research, Vol. 74, No. 2, pp. 551-564