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High shear granulation as a promising technique in the direct pelletization process

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Pellets dosage form has a great beneficial impact on drug therapeutic effect especially in improvement of drug dissolution behaviour, and reducing drug toxicity beside masking of unpleasant taste, as well as improving of flow properties of drug powder which has a higher effect on formulation as tablet dosage form. Although it can prepare by different techniques, using of high shear granulator is considered a good tool to overcome the high cost, long time, and multiple steps that accompanied with other techniques.

This study aimed at preparation of hydrochlorothiazide and amlodipine besylate pellets using high shear mixer. The most critical process parameters that include: binder concentration, water volume, chopper speed and impeller speed were determined due to it has the highest risk outcome on pellets quality that obviously manifested in Quality by Design and screening design results. After that they optimized by using 26 experiments (central composite design) and then the optimized preparation was loaded with two drugs (hydrochlorothiazide and amlodipine besylate) and it obtained a successful pellets formulation with good physical characteristics (sphericity, hardness and size distribution) in addition of proper content uniformity and enhancement of drug dissolution that will be a suitable technique to prepare wide number of drugs.

References:

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