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Impact of drug loading and mixing time on the homogeneity and content uniformity of a low-dose tablet formulation using a new gentle-wing high shear mixer

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The objective of this study was to examine the influence of drug amount and mixing time on the homogeneity and content uniformity of a low-dose drug formulation during the dry mixing step using a new gentle-wing high shear mixer. Albuterol sulphate was used as a model drug and was mixed with the other ingredients at two different levels, 1% w/w and 5% w/w at high impeller speed (300) and high chopper speed (3000) up to 30 minutes. Triplicate samples were taken from nine different locations in the mixer bowl at specific time points using a 1 ml unit side-sampling thief probe. The final blends at mixing time of 30 min were compressed into tablets using an automated tablet press. Two methods were used for manufacturing albuterol sulphate tablets; direct compression and wet granulation. For the wet granulation method, mixing of drug and excipients as well as dissolving the drug in the granulating solution prior to massing of the formulation were used as two different methods for drug incorporation. The produced tablets were sampled at the beginning, middle, and end of the compression cycle. An ANOVA analysis indicated that the drug amount had a significant effect ($P < 0.05$) on the content uniformity of the powder blend and the corresponding tablets. For 1% w/w and 5% w/w formulations, incorporation of the drug in the granulating fluid provided tablets with excellent content uniformity and very low RSD during the whole tableting cycle compared to direct compression and granulation method with dry incorporation mode of the drug. Overall, gentle-wing mixer is a good candidate for mixing of low dose cohesive drug and provides tablets with acceptable content uniformity with no need of a pre-blending step.

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