

## Formulation of Highly Dosed Drugs Using Different Granulation Techniques: A Comparative Study

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**Abstract :** Paracetamol tablets and cimetidine tablets were prepared by single-step granulation/tabletting and by compression after high shear granulation. The addition of PVP (polyvinylpyrrolidone) was essential for single-step granulation/tabletting of formulation containing high concentrations of paracetamol or cimetidine. Paracetamol tablets without and with PVP obtained by single-step granulation/tabletting exhibited a significantly higher tensile strength, a significantly lower disintegration time, a lower friability and a faster dissolution compared to those prepared by compression after high shear granulation. Cimetidine tablets with PVP obtained by single-step granulation/tabletting exhibited a significantly lower tensile strength, a significantly lower disintegration time and a faster dissolution compared to those prepared by compression after high shear granulation. Single-step granulation/tabletting allowed to produce tablets containing up to 80% paracetamol or cimetidine with a dissolution profile complying with the USP requirements. For pure paracetamol or pure cimetidine the addition of crospovidone as a disintegrant was required to obtain a dissolution profile that complied with the pharmacopoeial requirements. Long term and accelerated stability studies of paracetamol tablets produced by single-step granulation/tabletting over a period of one year showed no significant influence on the tablet tensile strength, friability and dissolution. Although a significant increase of the disintegration time was observed, it remained below 10 min. These results indicated that single-step granulation/tabletting could be an efficient technique for the production of highly dosed drugs such as paracetamol and cimetidine.

**Keywords :** single-step granulation/tabletting, twin screw extrusion, high shear granulation, high dosage drugs, paracetamol, cimetidine

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