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Effect of Die Taper and Precompression on Air Entrapment during Tablet Compression

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PURPOSE

- Air entrapment during tablet compression can severely deteriorate tablet appearance and mechanical properties.
- Low-clearance tooling, high powder plasticity, and lack of a deaeration step can exacerbate air entrapment issues.
- Use of a tapered die and a precompression step are commonly employed to reduce lamination defects due to air entrapment.
- A comparison of die tapering and precompression is needed.

OBJECTIVES

Assess the effectiveness of precompression and die tapering in eliminating air entrapment issues in a highly plastic formulation prone to air entrapment.

METHODS

Materials

A formulation containing common tableting excipients (microcrystalline cellulose, mannitol, crospovidone, colloidal silica, and magnesium stearate) and a model plastic active pharmaceutical ingredient (API) was used.

Methods

Tablets were prepared on a compaction simulator (Styl'One Evolution, MedelPharm) simulating a Korsch XL100 rotary press operating at 103 rpm. 600 mg, oval-shaped, embossed tablets were made between compaction forces of 5 and 20 kN using either 0% or 10% precompression and with either a straight bore die or a tapered die.

Friability was tested by coding and weighing each tablet, then dropping them 100 times in a friabilator and reweighing. Plasticity was assessed using an in-die Heckel analysis to quantify mean yield pressure (P_y).

RESULTS

Material Characterization

- The API plasticity (P_y=70.5 MPa) is on par with highly plastic microcrystalline cellulose (P_y=72.6) and is much more plastic compared to brittle excipients like lactose (P_y=145.6).[1]

Qualitative assessment of air entrapment

- Tablets made with a tapered die were fully intact and pristine, whereas those made with a straight bore die had surface defects (Figure 1).
- Defects occurred on the surface contacting the punch, not in the tablet band.
- Whether or not precompression was used did not influence whether defects were visually observed.

Tablet friability

- Tablet friability falls below 1%, which is the cut-off for adequate friability, above 5 kN for tablets made with a tapered die (Figure 2).
- Tablet friability falls below 1%, between 7 kN and 10 kN for tablets made with a straight bore die (Figure 2).
- The friability of tablets made with a tapered die was lower at nearly all pressures than those made with the straight bore die.
- Precompression did not seem to have a large effect on friability.

Tapered-die versus precompression

Rationalizing the effectiveness of using a tapered die:

- The increased tolerance between the punch and the tapered die may facilitate air escape during the initial stage of compression compared to the straight-bore die.
- The lack of difference when combining precompression and a tapered die compared to just a tapered die may be attributed to sufficient air escape facilitated by the tapered die alone.

Rationalizing the ineffectiveness of precompression:

- For the low-tolerance straight-bore die, air may be entrapped within the compact regardless of whether precompression was used.
- Precompression itself may entrap air within the compact by sealing pores if the material is highly plastic.

Figure 1: *Tablet visual appearance directly after compression under different tooling and precompression conditions.*

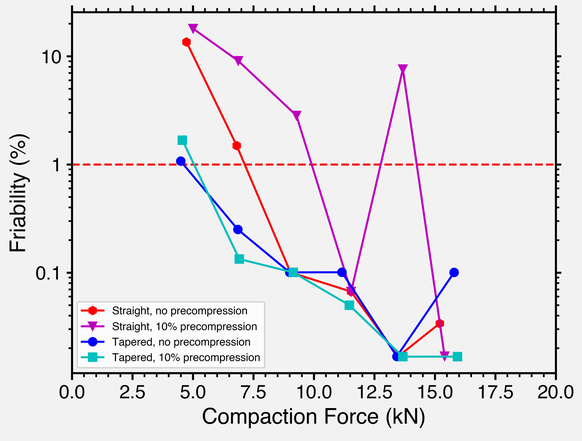

Figure 2: *Friability of tablets produced under conditions of different combinations of tooling design and precompression. The dashed horizontal line indicates maximal acceptable tablet friability (1%).*

CONCLUSIONS

- The deleterious effects of air entrapment during compaction may be improved using a tapered die.
- For a highly plastic model formulation, a tapered die was effective at alleviating air entrapment-related defects, while precompression was not.
- The effectiveness of the die taper, both with and without precompression, may be attributed to the increase in clearance between the punch and die, allowing air to escape during the initial stage of compression.
- While precompression has previously been successfully used for deaeration, its lack of effectiveness with a straight bore die in this study may be attributed to low punch-die clearance or precompression magnitude in combination with the high plasticity of the powder.
- These results indicate that a tapered die may solve air entrapment issues in cases where precompression fails. For extreme safety when choosing processing techniques, both may be employed.

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