FACULTY OF PHARMACEUTICAL SCIENCES

LABORATORY OF PHARMACEUTICAL TECHNOLOGY

EVALUATION OF THE PERFORMANCE OF AN EXTERNAL LUBRICATION SYSTEM IMPLEMENTED IN A COMPACTION SIMULATOR

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1. Introduction

- **Internal lubrication** is often associated with decreasing tensile strengths and increasing disintegration times.
- Using **external lubrication**, the lubricant is sprayed on tablet tooling, thereby minimizing the negative effects involved with internal blending of the lubricant.

2. Objective

- Evaluation of the impact of an external lubrication system, implemented in a compaction simulator, on the tableting process and tablet quality.

3. Material & Methods

Styl'One Evolution compaction simulator

(Medelpharm, Beynost, France)

- **Tableting**

Constant settings		
Tooling	Euro B, Ø 10mm, flat faced	
Tablet weight	250 mg	325 mg
Simulated Modul P speed	40 rpm	
Pre compression force	2 kN	
Variable settings		
Main compression force (MCF)	5 kN	20 kN

- **External lubrication system**

Factors
- Spray time (0 – 1000 ms)
- Pressure of the compressed air (1 – 3 – 5 bar)

Responses
- Ejection force
- Tensile strength
- Disintegration time

- **Formulations**

➢ 90 % Filler + 10 % active pharmaceutical ingredient (API)

Filler	API
Microcrystalline cellulose (MCC)	Caffeine anhydrous powder
Lactose	Micronized metoprolol tartrate (MTP)
Mannitol	
Dicalcium phosphate (DCP)	

- **Non-lubricated blends:** used for external lubrication with MgSt as lubricant
- **Internally lubricated blends:**
  - ➢ Concentration of MgSt: 0.75 % and/or 1.25 %
  - ➢ 2 paddle speeds (PS) of the forced feeder were used: 60 rpm (20% PS) and 300 rpm (100% PS)
- **Inductively coupled plasma optical emission spectrometry** (ICP-OES) was used to determine the concentration of MgSt in externally lubricated tablets. (Varian Vista-MPX, Varian, Palo Alto, CA)

5. Conclusion

- **External lubrication** proved highly valuable for tableting of lubricant-sensitive formulations as **low ejection forces** were obtained **without lowering the tensile strength and/or prolonging the disintegration time**.

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4. Results

Ejection force Lactose – caffeine (90/10) (MCF: 5 kN)

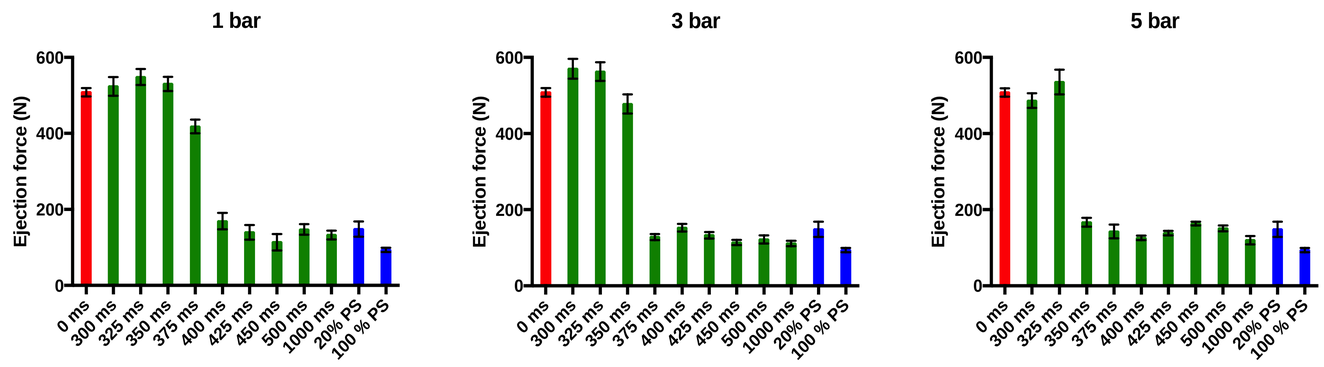

Fig. 1. Comparison of ejection forces between non-lubricated (red bars), extenally lubricated (green bars) and internally lubricated (blue bars) tablets.

Ejection force:
- ➢ Decrease in ejection force dependent on spray time and pressure of compressed air until plateau has been reached
- ➢ Equal ejection forces for external and internal lubrication can be reached:
  - MCC-, DCP- or lactose-based formulations: spray time needed of ≥ 350 ms
  - Mannitol- or MTP-based formulations: spray time needed of ≥ 400 ms, pressure of compressed air ≥ 3 bar
- ➢ Higher spray time (≥ 500 ms): no further decrease of ejection force

Tensile strength MCC – MTP (90/10) (MCF: 5 kN)

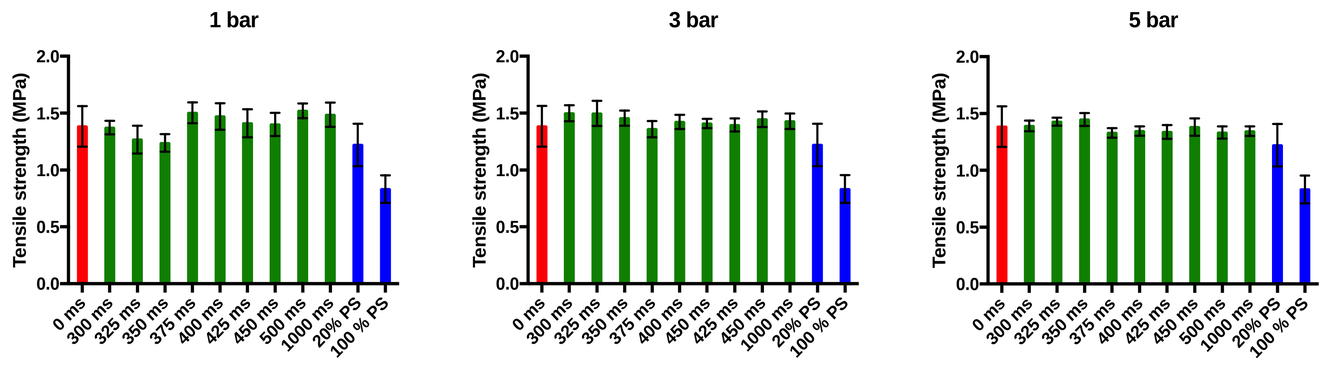

Fig. 2. Comparison of tensile strengths between non-lubricated (red bars), extenally lubricated (green bars) and internally lubricated (blue bars) tablets.

Tensile strength:
- ➢ Lower tensile strength of internally lubricated tablets compared to non-lubricated or externally lubricated tablets
- ➢ No influence of spray time, pressure of the compressed air

Disintegration time Lactose – caffeine (90/10) (MCF: 5 kN)

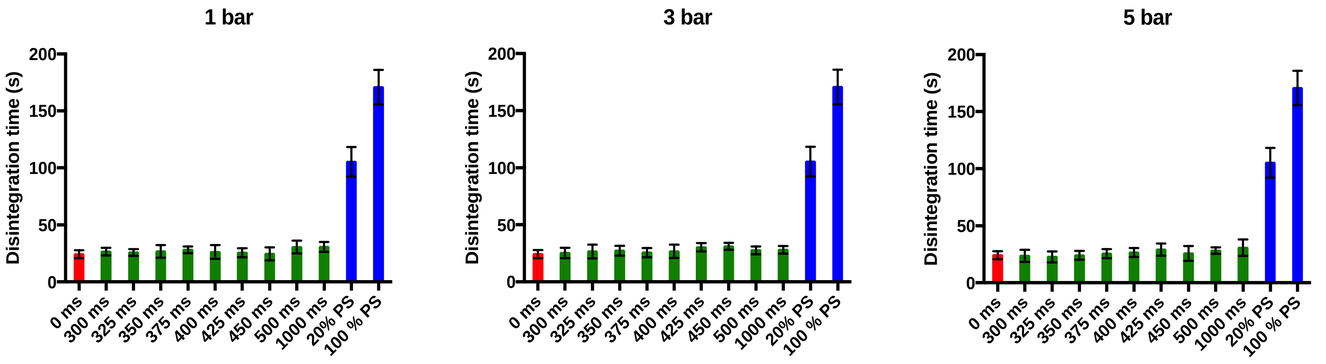

Fig. 3. Comparison of disintegration times between non-lubricated (red bars), extenally lubricated (green bars) and internally lubricated (blue bars) tablets.

Disintegration time:
- ➢ Higher disintegration time of internally lubricated tablets compared to non-lubricated or externally lubricated tablets
- ➢ No influence of spray time, pressure of the compressed air

Concentration of MgSt (mg/tab) MCC – MTP (90/10) (MCF: 5 kN)

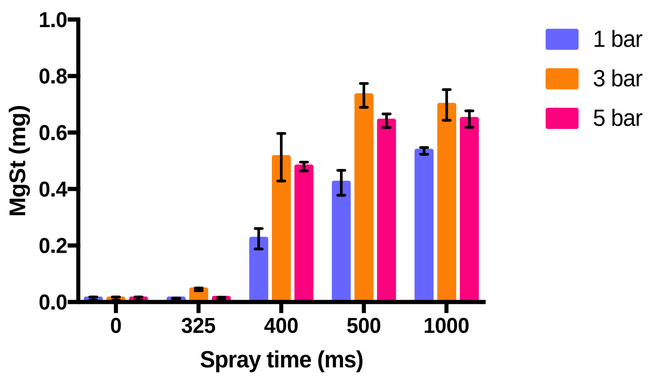

Fig. 4. Concentration of MgSt (mg/tab) as a function of spray time and pressure of the compressed air.

Concentration of Mgst:
- ➢ Increasing amount of MgSt when using higher spray time and atomizing pressure
- ➢ Higher spray times and higher atomizing pressure: no further increase in concentration

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