

MEETING MEDELPHARM

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OVERVIEW

1. External lubrication system on the Styl'One Evolution

- Results
- Remarks / issues / questions
- Future plans

2. Styl'One Evolution

- Issues
- Feedback
- Questions

1.

THE EXTERNAL LUBRICATION SYSTEM ON THE STYL'ONE EVOLUTION

OBJECTIVES OF THIS PHD

- Investigate the **overall performance** of the external lubrication system implemented in the Styl'One Evolution
- Definition of the **critical process parameters (CPPs)** towards the **critical quality attributes (CQAs)** of tablets and evaluation of the repeatability and reproducibility
- **Scale-up** of the external lubrication system from the Styl'One Evolution to the Modul™ P (rotary tablet press)

OBJECTIVES OF THIS PHD

– Process parameters

- *Related to the external lubrication system*
 - Spray time, pressure, flow rate lubricant (puff box / microdosing unit: 2 positions: High & Low)
- *Related to the tableting process*
 - Main compression force, tableting speed / punch speed

– Responses

- *Process parameters*
 - Ejection force, scrape-off force
- *Tablet quality*
 - Disintegration time, dissolution time, tensile strength ($\approx$ hardness)

FORMULATIONS

- Filler / API (90/10)

- Filler

- MCC
 - Lactose
 - Mannitol

- API

- Caffeine
 - Metoprolol tartrate

- Lubricant

- Magnesium stearate (MgSt)
 - Sodium stearyl fumarate (Pruv®)

EXTERNAL LUBRICATION SYSTEM

Tested formulations on the Styl'One Evolution

- Tablettose 80 (lactose) – Caffeine (90/10)
- Pearlitol SD200 (mannitol) – Caffeine (90/10)
- Pearlitol SD200 (mannitol) – Avicel PH102 (MCC) (80/20)
- Tablettose 80 (lactose) – Metoprolol (90/10)

Die filling issue

Lubricant: MgSt

FORMULATION:
TABLETTOSE 80 –
CAFFEINE 90/10

EL

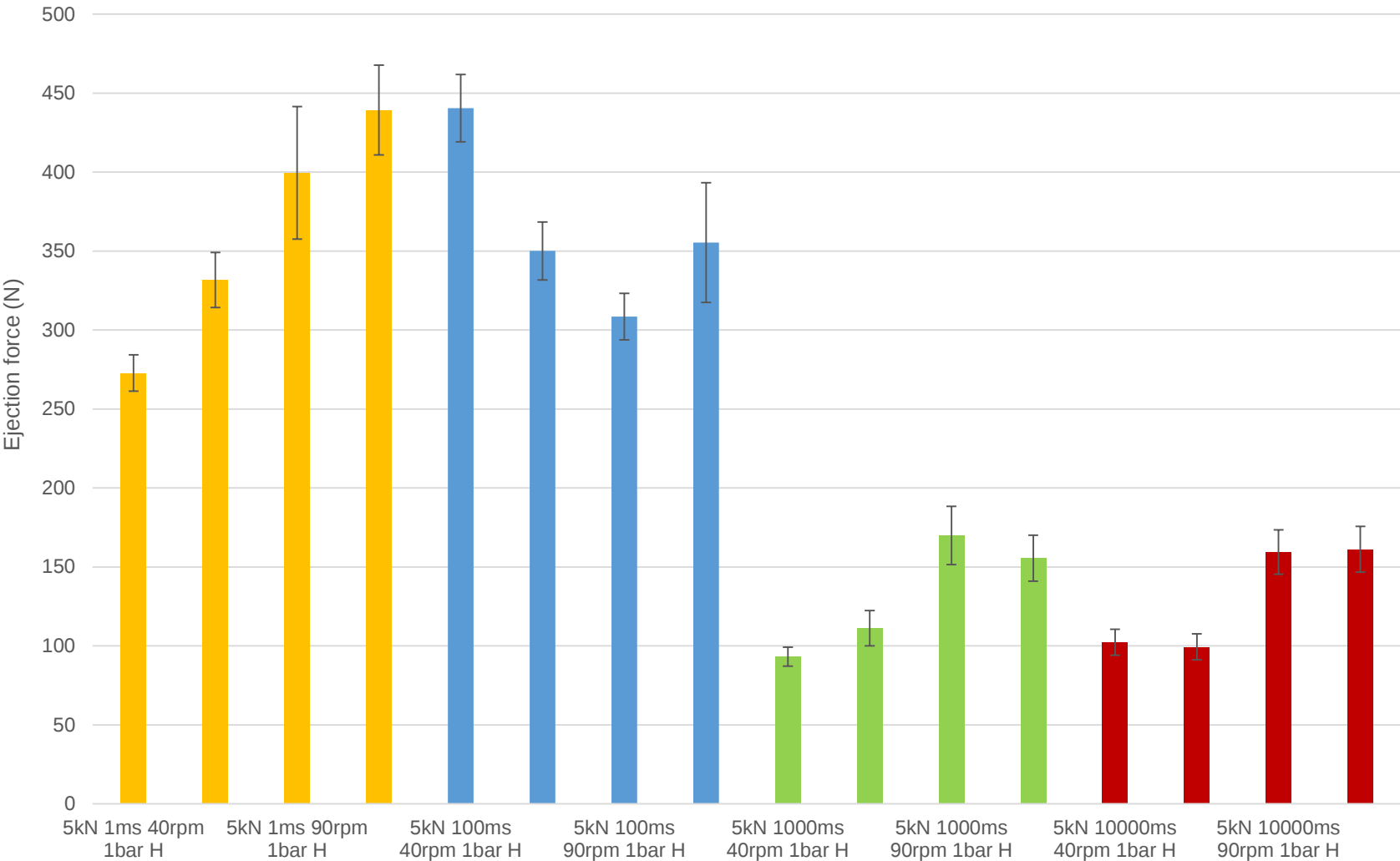
SETTINGS

- Punches Natoli, flat faced round, 10 mm
- Used cycle Courtoy Modul P - Euro B
- Asymetrical compression Penetration depth upper punch: 3,15 mm
- Overfill 2 mm
- Pre-compression force 2 kN
- Tablet weight 325 mg
- Forced feeder
 - Paddle: small spaghettis
 - Feed shoe speed / paddle speed: 20 %

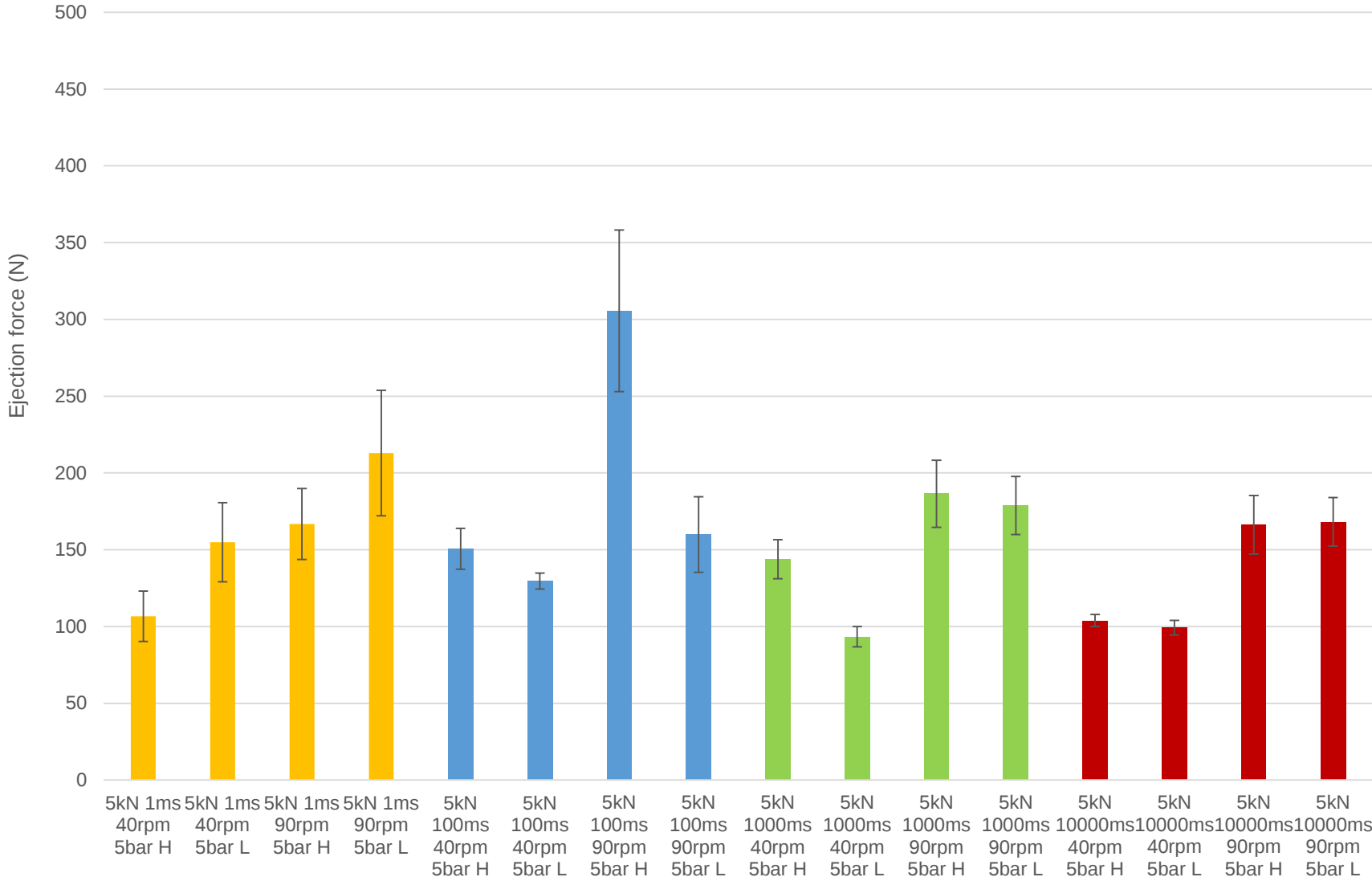
EL – TABLETTOSE 80 – CAFFEINE 90/10

– 5 kN

Overview Ejection force (N)
5kN 1bar



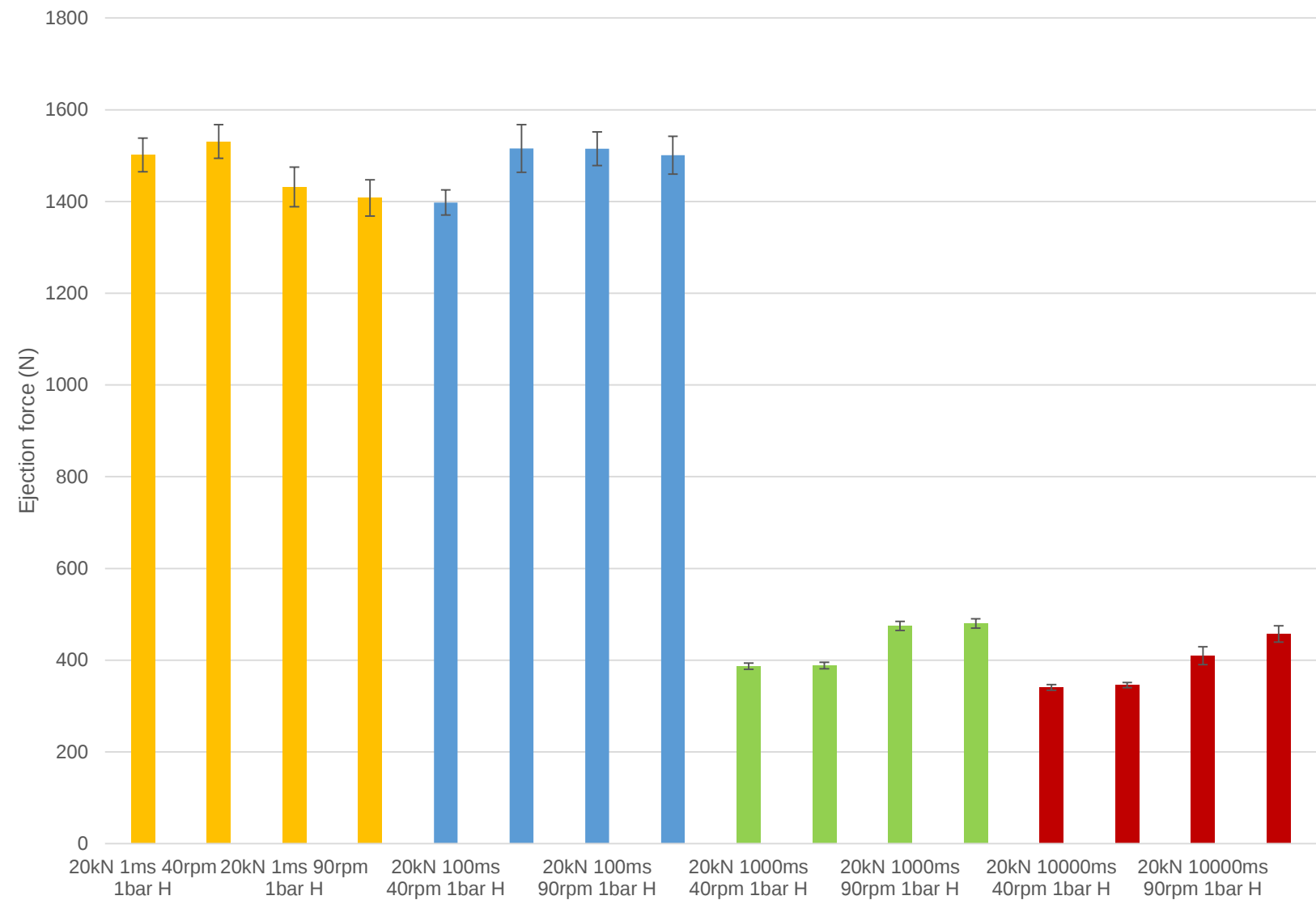
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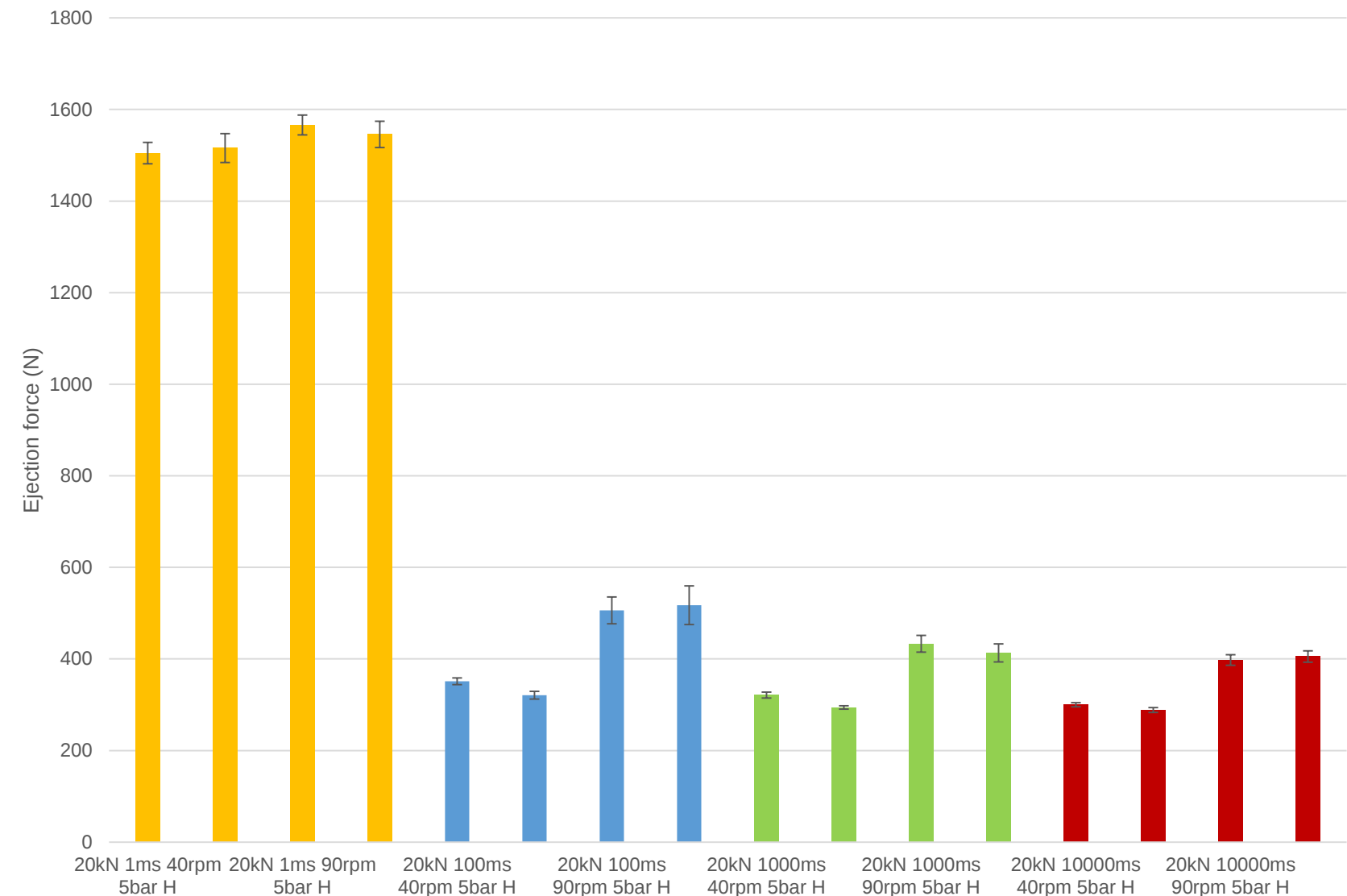
EL – TABLETTOSE 80 – CAFFEINE 90/10

– 20 kN

Overview Ejection force (N)
20kN 1bar



Overview Ejection force (N)
20kN 5bar



EL – TABLETTOSE 80 – CAFFEINE 90/10

- MODDE 11 software (Umetrics, Umea, Sweden) used for analysis
- Responses
 - **Ejection force**
 - %RSD Ejection force
 - %RSD Main compression force
 - %RSD Tablet weight
 - Tablets until SS is reached
 - **Hardness**
 - **Disintegration**

FORMULATION:
PEARLITOL SD200 –
AVICEL PH102 80/20

