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Influence of external lubrication of hard capsules on their hygro-mechanical properties, in-process tribo-charging and aerodynamic performance of DPI

T. Wutscher[1,2], M. Stankovic-Brandl[1], S. Zellnitz[1], M. Kobler[3], F. Buttini[1,4], V. Chierici[4], L. Andrade[5], V. Daza[5], A. Mercandelli[6], S. Biserni[6], S.Ecenarro Probst[7], L.Canalejas[7] and A.Paudel[1,2]

[1] Research Center Pharmaceutical Engineering, Graz, Austria

[2] Institute of Process and Particle Engineering, Graz University of Technology, Graz, Austria

[3] MEGGLE Excipients and Technology, Wasserburg, Germany

[4] University of Parma, Parma, Italy

[5] Laboratorios Liconsa, Guadalajara, Spain

[6] MG2, Bologna, Italy

[7] Qualicaps Madrid, Spain

Introduction

Hard capsules are often coated with an external lubricant to improve their flow properties during filling and prevent sticking to each other during processing and storage. The external lubrication can impact mechanical strength, surface roughness and tribocharging behaviour of a capsule. This study investigates potential connection among the mechanical properties of capsules coated with different external lubricants, storage humidities (RH), the charging behaviour during capsule filling and the delivered fine particle dose (FPD) from a capsule based DPI.

Material and Methods

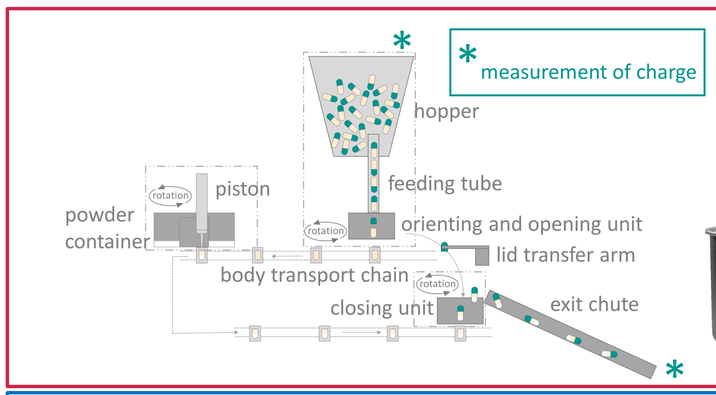
HPMC & gelatin (QG) capsules with **different lubricants** stored at 11%, 22%, 51% RH

(without lubricant [w/o], sodium lauryl sulfate [SLS], carnauba wax [CW], magnesium stearate [MgSt])

Water content
Karl-Fischer Titration

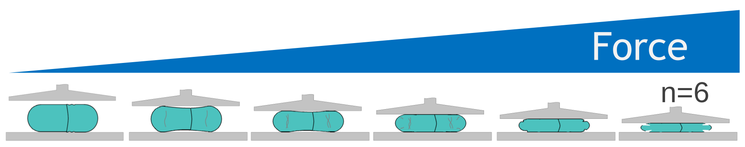
In-process charging
Keithley Electrometer + Faraday Cup

Elasticity + Plasticity
Anton Paar Rheometer



Filling at 21°C
22% RH and 51% RH
cph 1500

n=30



n=6

Aerodynamic performance
Fast Screening Impactor

Flow rate: 60 L/min
Aspiration time: 4 s
Device: RS01 Plastiape
Device Resistance: 0.33 kPa 0.05L/min
Pressure Drop: 4 kPa
n=3

Results and Discussion

- Water content increased for all capsules with increased storage RH, independent of lubricant type.
- Elasticity was not influenced by lubricant type but by capsule material (gelatin capsules were more rigid).
- RH had minor effect on elasticity at 11% and 22% RH storage, but larger effect at 51% RH (more dominant for HPMC capsules).
- Tribo-charging is affected by the presence of external lubrication but not by the type of lubricant.
- Lubricated gelatin capsules charged low and delivered higher FPD compared to unlubricated capsules.
- Lubricated HPMC charged low and delivered lower FPD compared to unlubricated capsules.
- FPD was influenced by both the external lubrication present and the type of lubricant used.

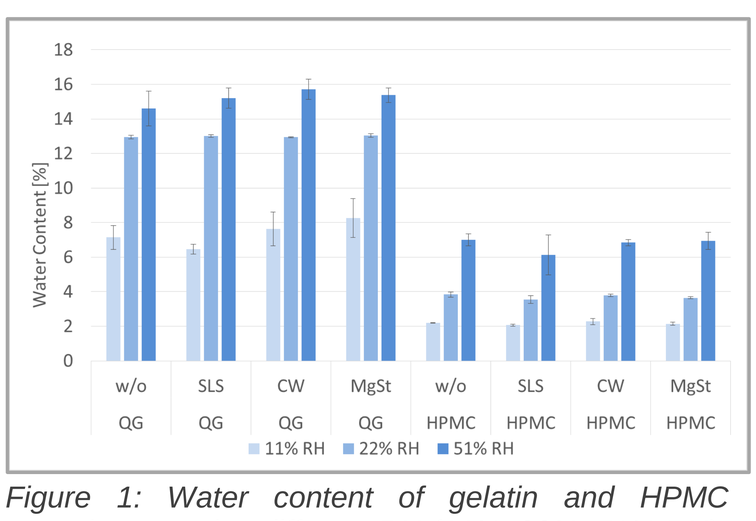


Figure 1: Water content of gelatin and HPMC capsules stored at different RH (11%, 22%, 51% RH).

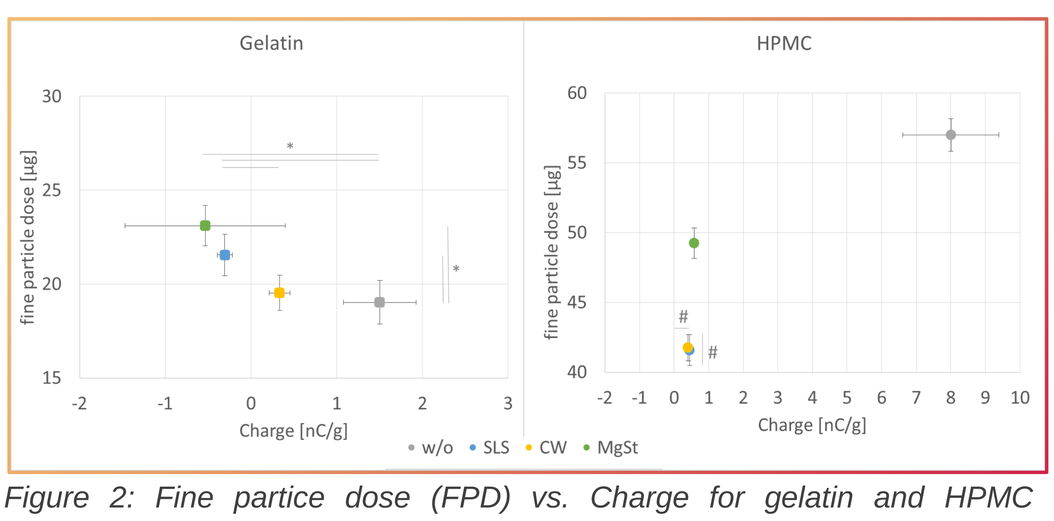


Figure 2: Fine partice dose (FPD) vs. Charge for gelatin and HPMC capsules.

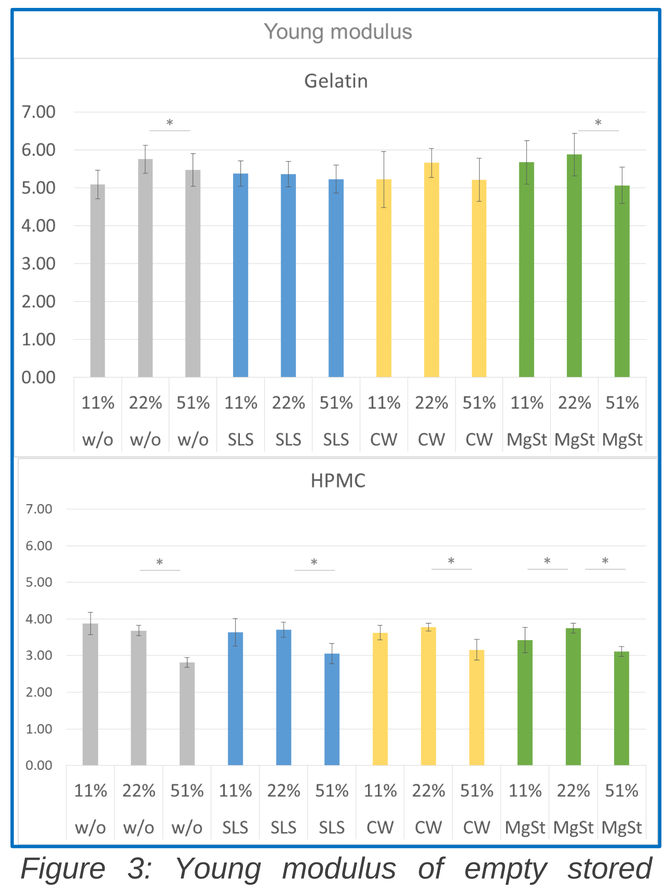


Figure 3: Young modulus of empty stored gelatine and HPMC capsules.

Outlook

- Further work will attempt to reveal whether the observed differences in the FPD as a consequence of lubricant type may be more related to the lubricant chemistry, lubricant homogeneity on the capsule surface or piercing properties of the differently lubricated capsules.

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