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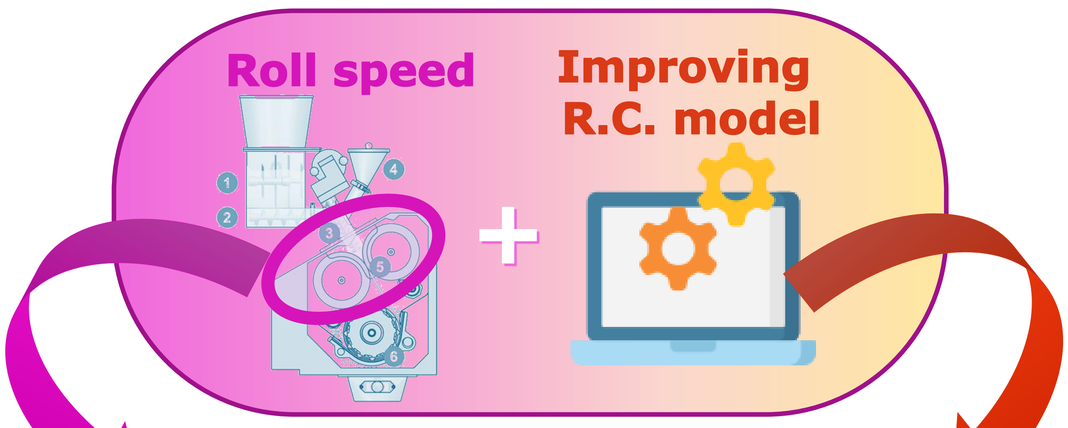
MODIFIED ROLLER COMPACTION MODEL TO ACCOUNT FOR ROLL SPEED EFFECT ON POWDER COMPACTION IN DRY GRANULATION PROCESS

ROLLER COMPACTION (R.C.)

Widely used in Pharm. Indus. [2]

→ Facilitate **blend homogeneity**
→ Facilitate **processability**
→ Ease of **control**
→ Ease of **scalability**



MODELLING OF KEY PROCESS PARAMETERS

Understanding dependency of process parameters [8,9]

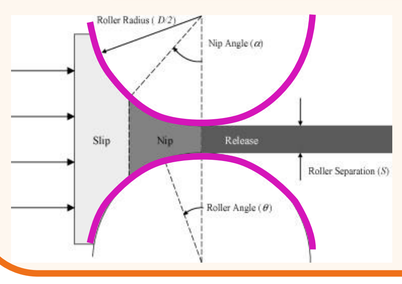
→ **Predict & control final tablet properties** : hardness, dissolution rate

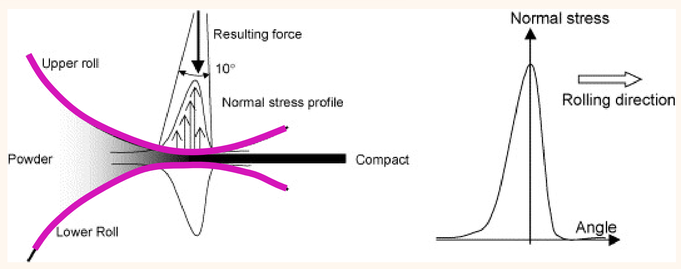
BACKGROUND

Sousa et al. [1] MODEL

$$\rho_R = \rho_0 P_{max}^{1/K}$$

ρ0 : preconsolidation density
K : compressibility constant





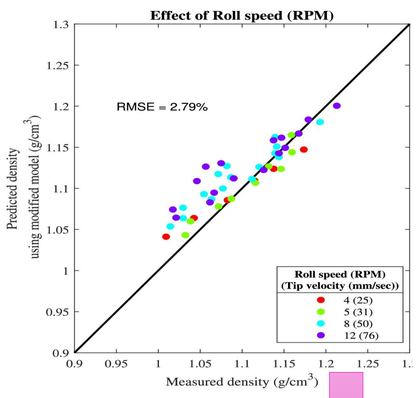
Sousa et al. derives **Johanson [11] model Density calc.** from the **peak pressure** at **minimum roll gap** → Estimation of **ribbon density** at **infinite time** compaction **w/o considering kinetics** of **compaction** → **Overprediction** of **density** at **higher roll speed**

WHAT'S NEW WITH THE PROPOSED MODIFIED R.C. MODEL ?

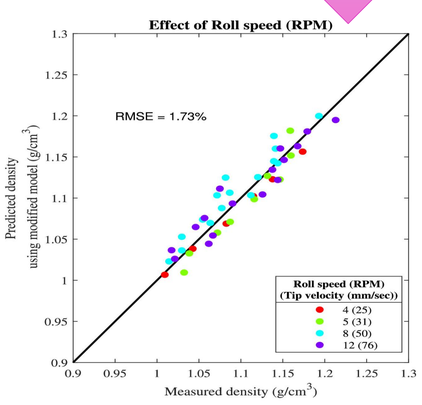
VALIDATION USING LITERATURE DATA

47-point data: 25 for calibration / 22 for validation

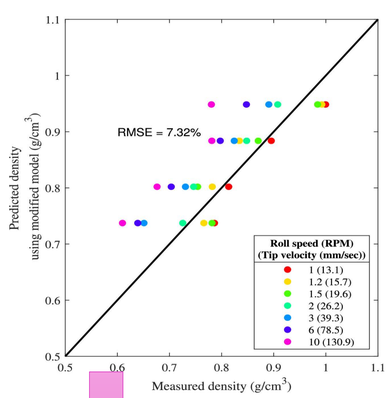
Nesarikar et al. [18]



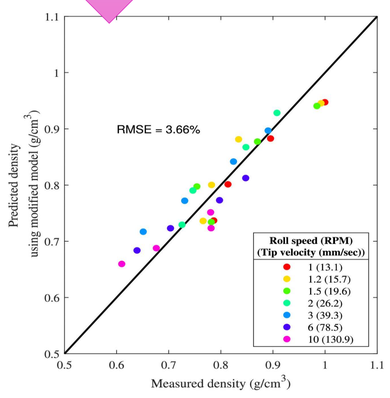
- 1.29% RMSE



Lück et al. [8]



- 3.67% RMSE



MODEL IMPROVEMENT

Ribbon density depends on compaction residence time of compaction
(t_{res} = nip angle / angular velocity)

$$\rho_R \neq \rho_R^{\infty} = \rho_0 P_{max}^{1/K}$$

and

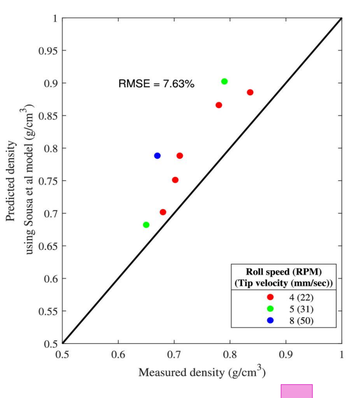
$$(\rho_R - \rho_0) = (\rho_R^{\infty} - \rho_0)\left(1 - e^{-t_{res}/\tau}\right)$$

τ is a material property dependent characteristic time of compaction

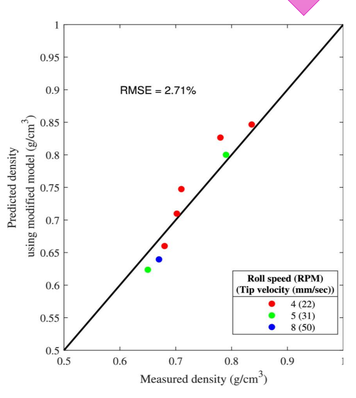
Reduction of Root Mean Square Error (RMSE) of ribbon solid fraction

INDUSTRIAL CASE STUDY

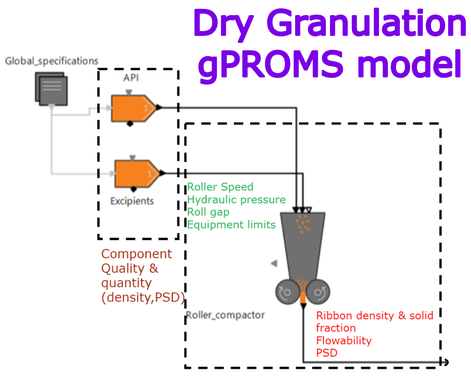
Styl'One uniaxial compaction simulator
Alexenderwerk WP120 roller compactor
GeoPyc1365 ribbon density measurement



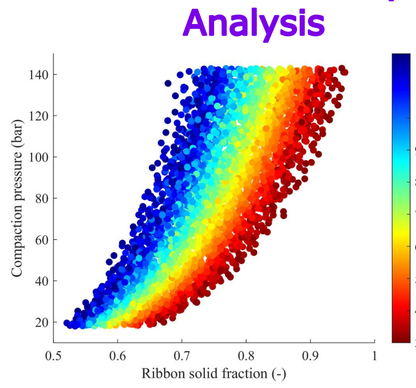
- 6.02% RMSE



Dry Granulation gPROMS model



Global Sensitivity Analysis



CONCLUSION & PERSPECTIVES

NEW MODIFIED MODEL:

1. **First time Kinetics aspects** considered → **Roll speed** = **Critical factor** influencing **ribbon density**

2. **Robust exploration** of **Design Space** for:
→ **Process optimization**
→ **Scale up**
→ **Transfer**

3. **Integrated in gPROMS environment** as **real-time decision-making tool**

NEXT STEPS:

Integration of **feeder screw speed** & configuration effects

Further understanding of **kinetics aspects sensitivity** with regards to **API & Formulation**

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Dublin 2024

Compaction Simulation Forum
CONNECTING SCIENTISTS AND COMPRESSION TECHNOLOGY

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