PHARMA SOLID KNOWLEDGE REPORT

SYNTEGON
PROCESSING & PACKAGING

Commissioning of TPR Tablet Presses

A robust and efficient tableting process is key – not only because it is requested by the FDA. All is based on a reliable product and process understanding. It should begin with a systematic approach from the development and pre-defined objectives. Based on sound science and process knowhow and enhanced process understanding, a higher process capability and a better product quality will be achieved.
Main steps in the commissioning of new products on a compression machine are:

Formulation check (customer data)
- Product flowability
- Particle size and distribution
- Moisture content (LOD)
- Bulk density
- Tests considering customer feedback like abrasiveness, low melting point, etc.

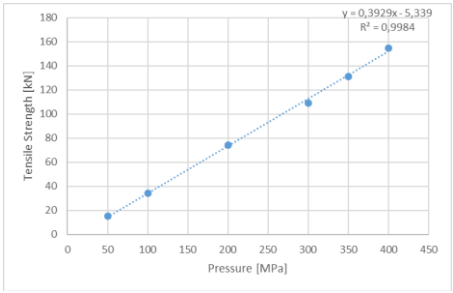
Tablet ability check on FlexiTab (single punch)
- Possibility of making tablets
- Check tablet appearance
- Ejection force
- Check tablet profile pressure/force vs. hardness
- Check for the comfort zone of the tablet for compression

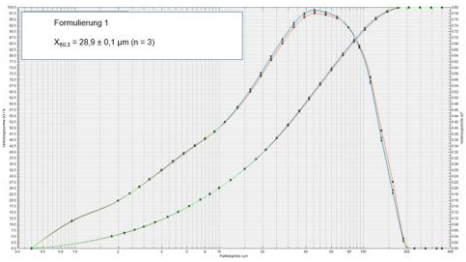
Rotary machine test
- Configure the machine setting based on profile study
- Set parameters gained from tablet profiling study
- Fine-tune the parameters WHT tablet attributes
- Stabilize the product with process parameters
- Check maximum possible output for the product within acceptance criteria
- Different paddle geometries (rectangular or round) offer flexibility to handle challenging powders with different product flowabilities

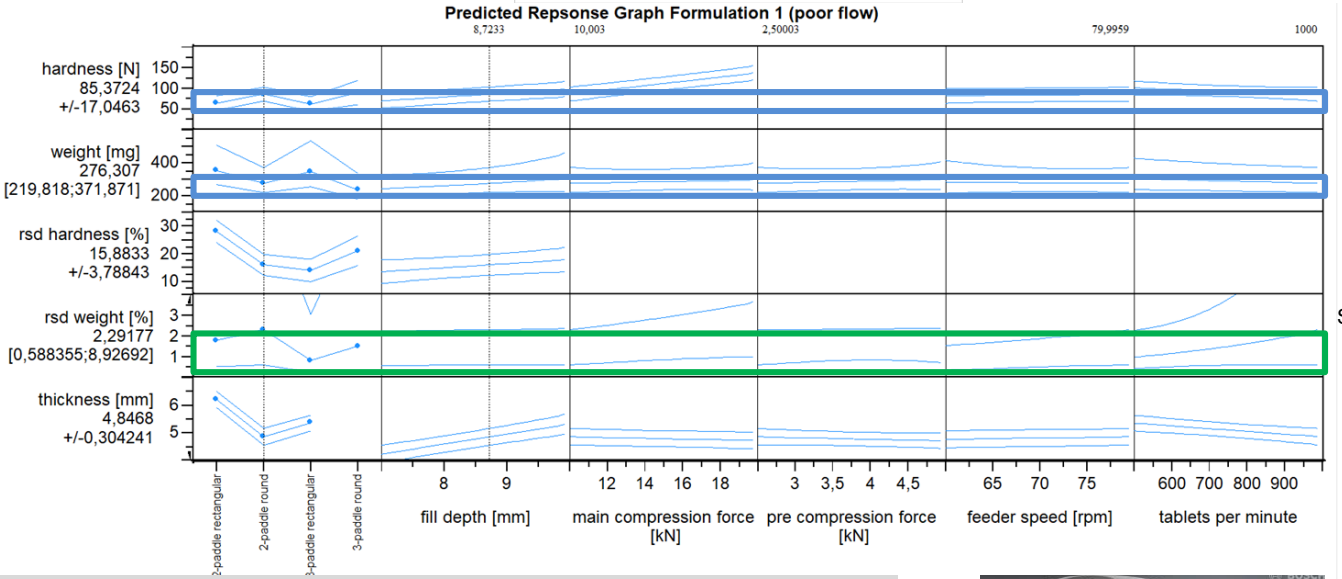
Analysis and optimization
- Check collected samples for Weight, Hardness and Thickness
- If necessary, also check disintegration time and content uniformity
- Analysis of important parameter information collected from DAQ

Examples how to deal with difficult products

Formulation 1: Poor Product Flowability
- Very small particle sizes tend to form interparticular bonds due to the larger specific surface area
- The flowability of the formulation is very poor (powder flow stops and has to be stimulated by mechanical support)
- Linear compression profile







Required hardness range and weight

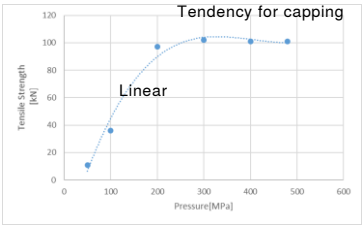
Stable and robust process range

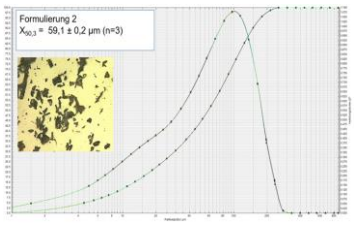
3-paddle-Feeder with rectangular blades result in the most robust process
- Distribution paddle leads to a constant powder flow to the filling and dosing blades
- Overlapping of filling and dosing paddles lead to a more efficient filling of the dies

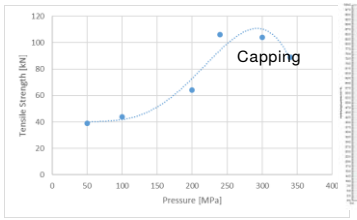
Commissioning of TPR Tablet Presses

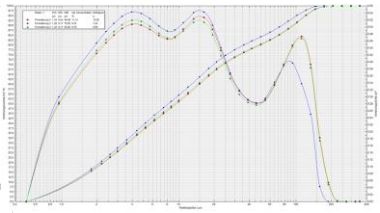
Formulation 2: Over-lubrication

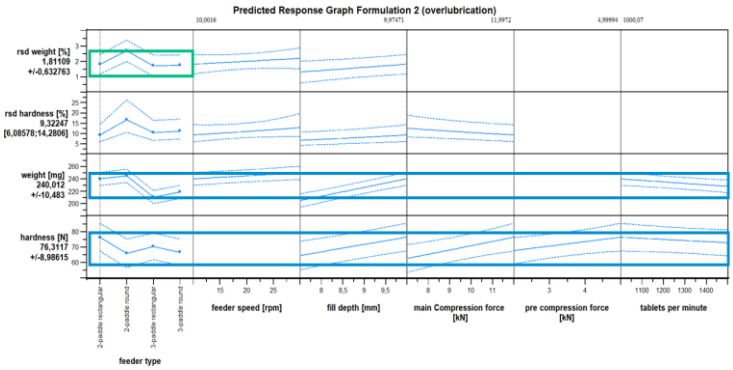
- Particle size distribution with a high proportion of fines
- However, the powder flow does not stop during the measurements
- Poor flowing product with limited linear compression profile



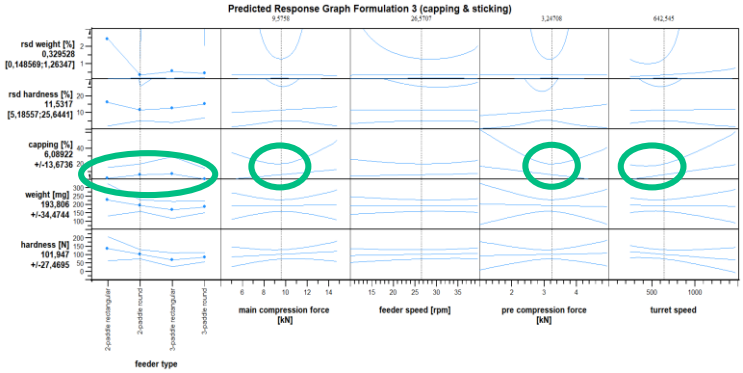








- Different feeder designs allow a smooth and gentle handling of the product to minimize / avoid over-lubrication effects
- Shortest residence time distribution (plug flow) is achieved with the 3-paddle feeder, having the paddle wheels on different levels each.
- Using APD (Automated Process Development, based on DoE) the optimum parameter setting can be identified



- Adjusting the pre-compression force and the compression zone supports air removal and reduces the capping effect.
- Different feeder designs allow a smooth and gentle handling of the product to prevent air trapping in the product
- Integration of data from capping test in the DoE model leads to reducing the percentage of capped tablets significantly.

Conclusion

APD function under development

- A robust and efficient tableting process is based on a product and process understanding
- The TPR portfolio can handle formulations with difficult properties
- Especially the unique TPR feeder design offers high flexibility to accommodate the whole range of challenging formulations
- Syntegon does support the process development, e.g. of very poor flowing products, materials with overlubrication or capping behavior
- Syntegon support covers both the formulation development and process design
- Results achieved in statistically planned and executed trials (DoE) lead to process optimization and problem solving

Your need is our passion!

You also have processes for optimization?
Please contact us. Our "Engineering Pharmaceutical Service" team will be available with all our experience of over 50 years:

Dr. Thomas Brinz
Head of Department Engineering Pharmaceutical Service
Phone: +49(7151)14-2160
Thomas.Brinz@syntegon.com

Syntegon Technology GmbH
Stuttgarter Straße 130
71332 Waiblingen
Germany
Mail packaging-ph@syntegon.com
Web www.syntegon.com

facebook.com/Syntegon
twitter.com/Syntegon
youtube.com/Syntegon
linkedin.com/Syntegon

03.2021