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Title: Two-dimensional granule property measurement using hyperspectral imaging in continuous pharmaceutical wet granulation

Abstract:

In manufacturing of pharmaceutical oral solid dosage units, (wet) granulation remains an important production pathway to render powder formulations processible for downstream unit operations. The physics of these processes are however still not completely understood due to the complex multitude of mechanisms in these operations and the heterogeneous nature of the material after each unit operation. Model building of these processes requires detailed in-depth data collections of which the quality determines the quality of the model (Park & Choi, 2020).

Describing a granulation process outcome involves analyzing a distributed property in function of granule size instead of working with average values. Recently, a novel data collection method was composed based on hyperspectral imaging, capable of processing a population of granules, in order to measure size and a chemical composition property of individual granules (Ghijs et al., 2021). The primary target was the analysis of the semi-continuous fluid bed dryer of the ConsiGma[™]-25 granulation line. Initially, the technique was also used for a study on the smaller ConsiGma[™]-1 for obtaining moisture content and size distribution data of dried granules (Ghijs, 2020).

Recently, the technique was applied in data collections of the ConsiGma[™]-25 dryer itself, in which formulation composition and dryer and granulator process settings were varied to assess the effect on the drying process. The outcomes of the granule size and moisture content / compositional property distributions after the process and their relation to process input and process settings will be discussed.

References

- Ghijs, M. (2020). *Modelling and experimentation on fluid bed drying of granules in the context of pharmaceutical continuous wet granulation*. Universiteit Gent. Faculteit Bioingenieurswetenschappen.
- Ghijs, M., Vanbillemont, B., Nicolaï, N., De Beer, T., & Nopens, I. (2021). Two-dimensional moisture content and size measurement of pharmaceutical granules after fluid bed drying using nearinfrared chemical imaging. *International Journal of Pharmaceutics*, 595(January), 120069. https://doi.org/10.1016/j.ijpharm.2020.120069
- Park, M. S., & Choi, D. H. (2020). Application of mechanism-based modeling to predict drug quality during the pharmaceutical unit operations of granulation and compression: a review. *Journal of Pharmaceutical Investigation*, *50*(5), 445–467. https://doi.org/10.1007/s40005-020-00489-6