



## IV. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

January 19-21, 2022 - Szeged, Hungary

DOI: [10.14232/syrptbrs.2022.46](https://doi.org/10.14232/syrptbrs.2022.46)

### Effect of Process Conditions and Parameters on Low-Dose Drug Uniformity Formulated as Pellets

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Multiparticulate delivery systems (MPDSs) such as pellets are well-known advantageous over the other conventional solid dosage forms such as tablets, regarding the dose accuracy and delivery effectiveness. The extrusion and spheronization technique represents the highly recommended method regarding the loading capacity and possibility to acquire the required properties such as roundness and content uniformity [1]. Drugs with low doses may encounter uneven distribution within the whole powdered mixture to be processed; accordingly, mixing steps in both dried form and wetted conditions should carefully be evaluated. Moreover, the environmental condition during the production should be carefully monitored [2]. The aim of the study is to investigate the effect of material attributes such as particle size, crystallinity, and deformability on prepared pellet quality. The other goal is to study the effect of the homogenization mixing process parameters on the content uniformity (in both dried and wetted systems). Also, the process parameters of the wet-kneading in the high shear granulator will be thoroughly monitored by applying a specially designed chamber supplied with sensors having the ability to precisely and continuously measure the distribution of the pressure, temperature, and relative humidity (RH). Furthermore, a full factorial design with a center point will be adopted to study the effect of the various critical process parameters and material characteristics on the quality of the targeted pellets.

#### References

1. Y. H-E.Y. Ibrahim, et al., JDDST 66, 102714 (2021)
2. A ,Hamad ,et al., PloS One, 12(6), e0178772 (2017)