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Effect of Processing Conditions and Material Attributes on the Design Space of Lysozyme Pellets Prepared by Extrusion/Spheronization

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The formulation of macromolecular drugs such as proteins into stable solid dosages represents a challenging goal as a result of the mechanical attrition and thermal stress involved during their production [1].

This study aimed to investigate the impact of the material attributes and processing parameters on the quality of the prepared pellets containing a macromolecular drug. Spray-dried and lyophilized lysozymes were used as a model protein, crystalline and spray-dried mannitol were involved as conformation stabilizers [2] and microcrystalline cellulose served as pellet former. The experiments were conducted according to 2³ full factorial design. Kneading was performed in the high shear granulator equipped with seven temperature and relative humidity (RH) sensors (Opulus, Hungary). The obtained granules were extruded at different rates, and the extrudates were spheronized at a fixed rate.

The dried samples were investigated for the enzyme activity and physical properties. It was found the material attributes have a potential effect on biological activity and pellet properties, as they demonstrated different thermal responses upon the applied mechanical stresses; lysozyme showed considerably good stability towards the applied mechanical stress and generated heat. It was concluded that the instrumented chamber represents a novel means for the online monitoring of temperature and RH%. Besides, screening of the formulation excipients is a key factor for the successful production of multiparticulates containing protein.

References

1. Kristó et al., Eur. J. Pharm. Sci. 95, 62–71 (2016)
2. Sovány et al., Chem. Eng. Res. Des. 106, 92–100 (2016)

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