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Development and optimization of the coating processes of lysozyme loaded pellets for oral delivery

Yousif H-E.Y. Ibrahim, Katalin Kristó, Géza Regdon jr., Tamás Sovány

Institute of Pharmaceutical Technology and Regulatory Affairs, Faculty of Pharmacy, University of Szeged, Szeged, Hungary



Increasing attention has been raised towards biopharmaceutical drugs in the last two decades as a result of known advantages compared to the small drug entities [1]. The design space of lysozyme loaded pellet production was optimized in the frame of raw material attributes by applying a special granulation chamber (Opulus®, Hungary) to take the encountered thermal shocks generated by the mechanical stress during the production steps into account as prescribed by [2]. The aim of the present work is to optimize the consecutive coating process in a manner to preserve pellet quality. The coating processes were performed based on 23 full factorial design with a center point. The effects of atomizing pressure, drying air temperature and drying air pressure were set as investigated factors, and pellet properties were set as optimization parameters. It was found that pellets demonstrated good thermal stability at the applied coating temperatures. Atomizing pressure was found as main factor affecting enzyme activity, moisture content, hardness, and release behaviour. Also, it is recommended to increase spheronization time to improve sphericity and then film homogeneity. In addition, increasing coating thickness is crucial to prevent premature drug release. Based on the biological activity and release pattern, the optimization of the coating process was successful, and the delivery system may be utilized for treating GI infections or as adjuvant regimen for controlling inflammatory bowel disease.

References

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Supervisors: Katalin Kristó, Géza Regdon jr., Tamás Sovány