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Gastro-resistant Pellets of Didanosine obtained by Extrusion and Spheronization: Assessing the Production Process

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SUMMARY. The aim this work was develop gastro-resistant pellets of didanosine as well as study the impact on the pellets properties, regarding the way as the binder was added and drying process used. The pellets formation was accompanied by analysis of morphological parameters and didanosine dissolution. In the most cases, pellets showed diameter around 1.0 mm and shape parameters acceptable. The variations of the process did not interfere significantly in pellets size. In turn, drying in fluid bed favored the dissolution of didanosine, in contrast to binder addition on powder form that impaired. In another hand, this last resulted in the best aspect factor (about 1.1). Gastro-resistant pellets showed adequate dissolution, compatible with this type of dosage form. The variables of process studied enabled obtain pellets with characteristics of shape and dissolution just slightly different, indicating flexibility of the formulation for production of gastro-resistant pellets of didanosine.

KEY WORDS: Didanosine, Extrusion, Gastro-resistant dosage form, Pellets, Spheronization.

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