

Factors influencing the physical characteristics of pellets obtained by extrusion-spheronization

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Abstract

The objective of this work was to analyse the influence of the solubility of the drug and the filler on the physical characteristics of pellets prepared by extrusion/spheronization. Different formulations were prepared according to a statistical plan, using five different drugs and five different fillers selected according to their water solubility. The pellets were then obtained by a standardized extrusion/spheronization process and evaluated in terms of their physical characteristics by measuring the pellet size, density, porosity, mechanical strength, residual moisture after drying and shape. The results were first analysed by the analysis of variance to identify the main factors involved. The results were further assessed by canonical analysis and the significant influence factors were quantified in terms of regression equations. It can be concluded that the solubility of materials used (both drugs and fillers) plays an important role in the quantity of water required to form satisfactory pellets and on the physical characteristics of pellets. Quantitative relationships were identified between (a) the extrusion force required to provide extrudate, which would form pellets and the natural log of the filler solubility; (b) the quantity of the pellets in the size range 1–1.4 and the solubility of both the filler and the drug; (c) the apparent pellet density and both the level of drug and filler plus the solubility of the filler; (d) the pellet porosity and the quantity of drug and the inverse function of the filler solubility; and (e) the mechanical strength of the pellets and the square root of the quantity of drug. © 2002 Elsevier Science B.V. All rights reserved.

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1. Introduction

The extrusion/spheronization process is an accepted method of producing pellets. This process

consists of five unit operations—blending, wet massing, extrusion, spheronization and drying—resulting in the formation of spherical pellets showing a homogeneous surface (Otsuka et al., 1994). Since these phases are strongly related to each other (Newton, 1994) the quality of the end product—pellets—is also strongly dependent on the process factors (Woodruff and Nuessle, 1972;

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