

The assessment of the scale-up performance of the extrusion/spheronisation process

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Abstract

The ability to predict the spheronisation performance of a standard extrudate over a 125-fold range has been assessed in terms of spheroid quality produced. It has been found possible to predict the performance of a 25 kg batch on a 65.6 cm diameter production spheroniser from experiments (with a 22.9 cm diameter laboratory spheroniser). To achieve such prediction it is necessary to use a good quality extrudate and operate the spheroniser at rotational speeds which give the same linear peripheral velocity of the plate.

Keywords: Extrusion/spheronisation; Roundness; Scale-up

1. Introduction

The scaling up of any pharmaceutical formulation can present numerous problems, and considerable reliance is placed on past experience in overcoming such problems. Most pharmaceutical processes have a considerable body of knowledge which can aid scale-up, but the process of extrusion/spheronisation, first reported by Reynolds (1970) and Conine and Hedley (1970) is of recent usage and has considerably less literature than other solid dosage form processes, such as granulation, tableting, encapsulation and coating. While the literature contains information on for-

mulation factors, there is little reported work on the factors involved in the scaling-up process. To simplify the number of factors involved in an investigation, the variables due to scaling up the extrusion process were eliminated by processing a standard extrudate and evaluating only the scaling of the spheronisation stage.

2. Materials and methods

2.1. Materials

Equal parts of microcrystalline cellulose, Avicel PH 101 (FMC Corp., Philadelphia, USA), and lactose (extra fine Unigate, UK), formed the basis of the formulation, and were mixed with 12 parts distilled water as the binding fluid.

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