AN INVESTIGATION OF CORRELATION BETWEEN THE LENGTH OF THE EXTRUDATES AND SPHERONIZATION
PARAMETERS ON QUALITY OF PELLETS OBTAINED BY THE EXTRUSION-SPHERONIZATION PROCESS USING STARCH 1500®

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INTRODUCTION

Extrusion spheronization process has gained considerable attention since its invention in 1960. The unique advantages of this process make it suitable for developing immediate release dosage forms of active pharmaceutical ingredients (APIs) by extrusion spheronization pellets with 100% drug loading without binder, using different process parameters. Generally at high drug loading, the formulation requires a strong binder. The presence of a binder in the formulation increases the plasticity of the wet mass and reduces the friability of the resulting pellets. This is particularly true for extrusion with high drug loading in which the concentration of pharmaceutical excipients cellulose is low [1].

In 1979, Reynolds removed the requirement of capacity or adhesion type binder in the process [2]. Funck et al. [3] showed that low levels of excipients such as PMC, starch, HPMC, PVP, and sodium carboxymethyl cellulose were used to produce spheres with high drug loading using extrusion spheronization cellulose (MCC). However, a slight increase in the concentration of these binders in the formulation greatly affected the mechanical properties of the extrudates. According to the authors, the wet mass with high consistency and low plasticity could be obtained, but not easily spheronized [4].

The objective of this study was to find a correlation between spheronization conditions and extrudate length to physical properties of pellets. Different lengths of extrudates were obtained with different spheronization conditions of starch 100® as a binder. Five different spheronization conditions (selected based on a factorial design) were used to spheronize extrudates of different lengths. Relationships between extrudate length and spheronization conditions with physical properties of pellets were evaluated.

EXPERIMENTAL

2.1. Design of Experiment

API powder was mixed with 10% w/w of Starch 1500®, 10% w/w of Avicel PH102® and 1% w/w of hibiscus root extract to provide a binder content of approximately 20% w/w. The binder content in the powder mixture was adjusted to obtain appropriate density, diameter and friability of the extrudates. The binder content in the powder mixture was adjusted to obtain appropriate density, diameter and friability of the extrudates.

The geometric mean pellet diameter was significantly influenced by spheronization speed, spheronization time and interaction between spheronization speed and spheronization time. This implied that the relationship between spheronization conditions and friability is similar for similar process variables with a similar range of values. Extrudate length did not influence the friability significantly. This implied that the relationship between spheronization conditions and friability is similar for similar process variables with a similar range of values.

REFERENCES