Characterization of the Physical Properties of the New Excipient Base Part 1: Scanning Electron Microscopy (SEM) Imaging

SUMMARY: Scanning Electron Microscopy (SEM) was used to compare the physical characteristics of two compounding excipients. PCCA UniFlow™ showed smoother, more uniform particles with less agglomeration. These features suggest improved flowability and content uniformity for compounding tablets and capsules.

Introduction:

When compounding solid dosage forms, such as tablets and capsules, the excipients used in the formulation play a pivotal role in enhancing flowability, compressibility and stability of the powder blend, ultimately ensuring uniformity of content in the final product. Understanding the physical characteristics of the excipients at a microscopic level provides crucial insights into their functionality during the compounding process.

Scanning Electron Microscopy (SEM) is a powerful tool used to visualize the surface morphology, size and shape, texture and agglomeration of materials, allowing compounding pharmacists to evaluate and compare excipient performance across different formulations.

The physical characteristics of the new excipient base, PCCA UniFlow™, were evaluated and compared to a commonly used compounding excipient: Microcrystalline Cellulose (MCC) NF (PH-105). The objective of this study was to identify potential differences that could influence flowability, compressibility and stability leading to potential differences in content uniformity.

Methodology:

The two excipients were provided by PCCA and the study was conducted by Particle Testing Authority (Norcross, GA). A portion of the powder from each sample was mounted on a carbon adhesive substrate and sputter-coated with gold for electrical continuity. The samples were imaged using a JEOL JSM-IT700HR field emission scanning electron microscope at increasing magnifications: 100x, 500x and 3,000x. Figure 1 illustrates the principle of SEM by showing the path of the electron beam and the key components involved in generating and detecting SEM images.

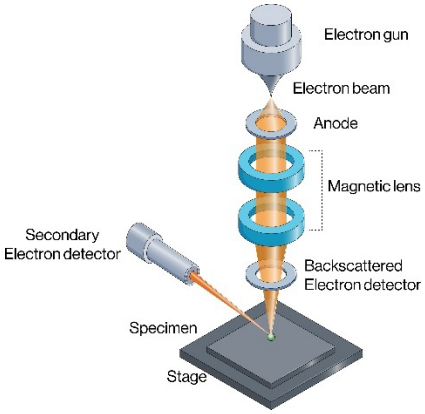

Figure 1. Scanning Electron Microscopy (SEM) instrumentation and principle diagram (*adapted from* Shutterstock illustration ID: 2491721153).

Results and Discussion:

High-resolution, grayscale SEM images were taken for the two excipients at increasing magnifications (100x, 500x and 3,000x), as shown in Figure 2. Samples were compared according to three different parameters: surface morphology; size and shape; texture and agglomeration (Table 1).

MCC NF (PH-105) is a purified, partially depolymerized form of cellulose that exhibits a distinct morphology of fibrous or rod-like particles. As observed in Figure 2, elongated and angular particles dominate, and there is visible agglomeration likely due to interlocking shapes. At high magnifications, the texture appears porous or rough.

In contrast, PCCA UniFlow shows relatively uniform particles with smoother surfaces, and a moderate surface texture, not highly porous. There is limited agglomeration as particles are more discrete and less clumped. As such, the new excipient base is expected to provide superior flowability and content uniformity, making it an ideal excipient for compounding solid dosage forms (Table 1).

Characterization of the Physical Properties of the New Excipient Base Part 1: Scanning Electron Microscopy (SEM) Imaging

Table 1. Comparison of the physical characteristics of PCCA UniFlow and MCC NF (PH-105) according to morphology, size and shape, texture and agglomeration; and predicted implications on the flowability and content uniformity of the powder samples.

Powder Samples	Morphology	Size and Shape	Texture and Agglomeration	Flowability and Content Uniformity
PCCA UniFlow	Predominantly rounded, uniform particles	Consistent, moderately-sized particles	Smooth particles, low agglomeration	Superior (*predicted*)
Microcrystalline Cellulose NF (PH-105)	Predominantly fibrous, irregular particles	Inconsistent and broad size range	Rough/porous particles, moderate agglomeration	Inferior (*predicted*)

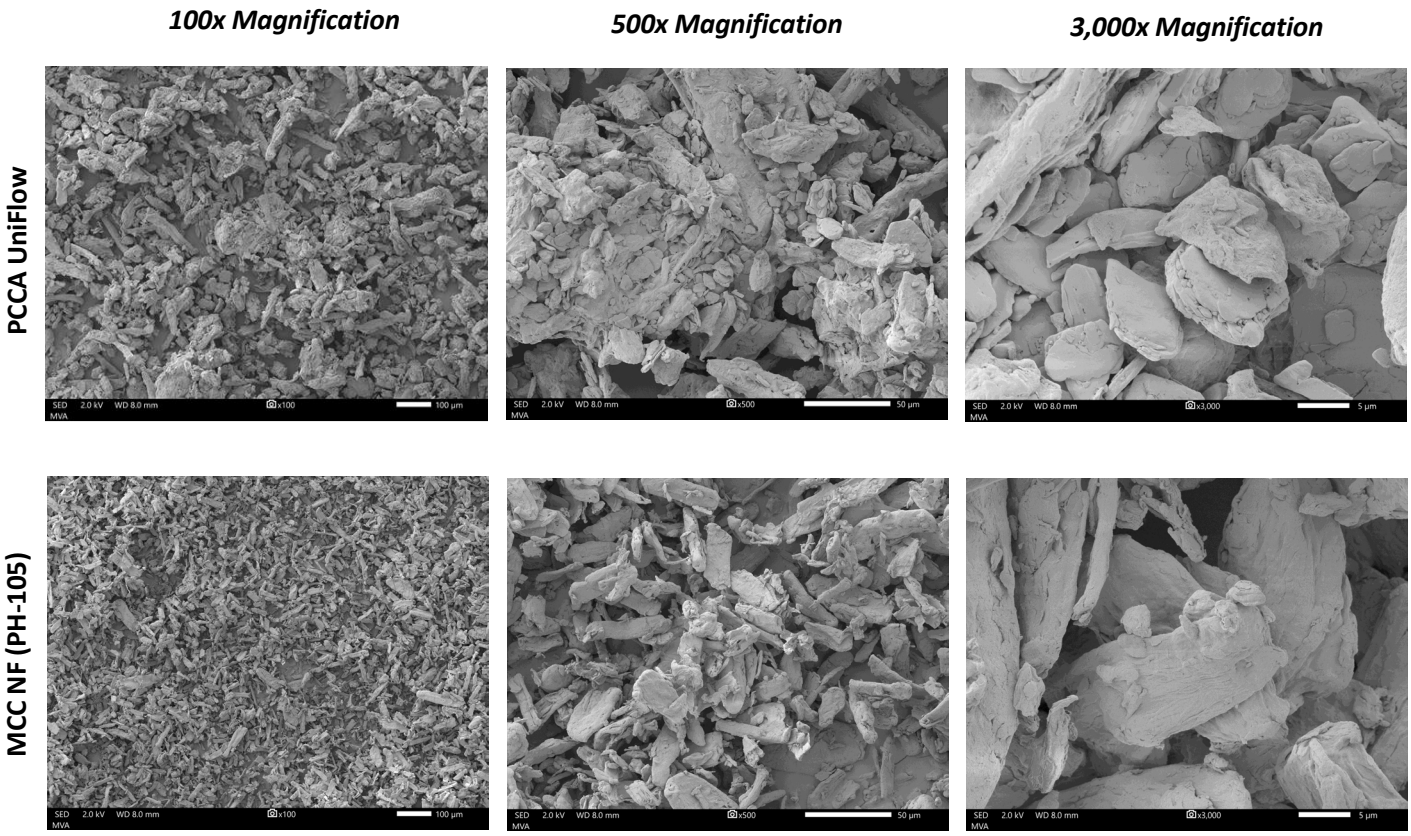

Figure 2. Powder samples for PCCA UniFlow and MCC NF (PH-105) imaged using a field emission scanning electron microscope at increasing magnifications (100x, 500x and 3,000x).