Abstract

DIRECTLY COMPRESSIBLE HIGH FUNCTIONALITY GRANULAR MICROCRYSTALLINE CELLULOSE BASED EXCIPIENT, MANUFACTURING PROCESS AND USE THEREOF

An improved excipient comprising substantially homogeneous particles of a compressible, high functionality granular microcrystalline cellulose based excipient is provided. The improved excipient comprises microcrystalline cellulose, a binder and a disintegrant, and is formed by spraying a homogeneous slurry of the components. The excipient provides enhanced flowability/good flow properties, excellent/high compactibility, and increased API loading and blendability as compared to the individual components, and as compared to conventional excipients formed from the same materials. The improved excipient has strong intraparticle bonding bridges between the components, resulting in a unique structural morphology including significant open structures or hollow pores. The presence of these pores provides a surface roughness that is the ideal environment for improved blending with an API.

Figure 1