Abstract

Preformulation is an important step in the rational formulation of an active pharmaceutical ingredient (API). Micromeritics properties: bulk density (BD) and tapped density (TD), compressibility index (Carr's index), Hauser's ratio (H), and sieve analysis were performed in order to determine the best excipients to be used in the formulation development of omeprazole magnesium enteric coated tablets. Results show that omeprazole magnesium has fair flow and compressibility properties (BD 0.4 g/mL, TD 0.485 g/mL, Carr's index 17.5%, Hauser's ratio 1.2, and sieve analysis time 5 minutes). There were no significant drug excipient interactions except change in colour in all three conditions in the mixture of omeprazole and aerosil 200. Moisture content loss on drying in all three conditions was not constant and the changes were attributed to surrounding environment during the test time. Changes in the absorption spectra were noted in the mixture of omeprazole and water aerosil only in the visible region of 350–2500 nm. Omeprazole magnesium alone and with all excipients showed no significant changes in omeprazole concentration for a 30-day period. Omeprazole magnesium formulation complies with USP standards with regards to the fineness, flowability, and compressibility of which other excipients can be used in the formulation. Omeprazole magnesium powder did not change when subjected to stressful conditions of higher temperatures and relative humidity.

Keywords: Micromeritics properties, Bulk Density (BD) and Tapped Density (TD), Compressibility index (Carr's index), Hauser's ratio (H), sieve analysis, drug excipient interactions, fineness, flowability and compressibility.

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