

Determination of Solid-State Acidity of Chitin-Metal Silicates and Their Effect on the Degradation of Cephalosporin Antibiotics

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Abstract: It was of interest to determine the solid-state acidity of chitin metal silicate co-processed excipients and to correlate this acidity to the chemical stability of cefotaxime sodium in the presence of the aforementioned excipients. The solid-state acidities of chitin aluminum silicate, chitin magnesium silicate and chitin calcium silicate were determined by reflectance spectroscopy using structurally different dye molecules. The chemical stability of cefotaxime sodium was assessed at 50°C in a slurry 4% (w/v) in the pH range 6.6-10.5 and in the solid-state in the Hammett acidity range 6.1-7.8. The solid-state acidity was found to be reproducible since one or more structurally different dye molecules gave reliable solid-state acidity values. A significant discrepancy in pH stability profile of cefotaxime sodium between the solid-state and the slurry system was observed. Furthermore, chitin aluminum silicate showed minimum drug stability in the solid-state, close to where the maximum drug stability in the slurry was observed. This unexpected effect might be ascribed to the catalytic properties of chitin aluminum silicate. The slurry method was not able to predict efficiently the solid-state surface acidity and stability of cefotaxime sodium. Moreover, the solid-state chemical stability might be influenced by factors other than the solid-state acidity.