

European Pharma Congress August 25-27, 2015 Valencia, Spain

Preliminary studies of formulation development of an oral lyophilisate

Paloma Florez Borges, Pilar Perez Lozano, Encarna Garcia Montoya, Montserrat Minarro, Josep R Tico, Enric Jo and Josep M Sune Negre University of Barcelona, Spain

Oral lyophilisates are solid preparations intended either to be placed in the mouth or to be dispersed (or dissolved) in water before administration. They are obtained by freeze-drying (lyophilisation), involving division into single doses, freezing, sublimation and drying of usually aqueous, liquid or semi-solid preparations. They combine the advantages of both solid and liquid forms, particularly useful in the case of patients with dysphagia. The presence of metastable state and the glass transition temperature (Tg) are two important aspects when formulating a freeze drying product. Therefore, thermal analysis studies (differential scanning calorimetry, DSC) were performed in order to determine Tg for each excipient separately, the active substance used as model and also the combinations among them. We have studied two common excipients used in freeze drying formulations: the saccharide mannitol (MNT) - in concentrations from 2-7% - and the water-soluble polymer polyvynilpirrolidone (PVP)-in concentrations from 1-5%. Only MNT presented metastable state. Three out of nine formulas studied (with the active substance) did not presented metastable state, with a Tg ranging from -27 to -32°C. It was also seen that increasing the concentration of PVP resulted in a slight decreased of Tg.

Biography

Paloma Florez Borges has a Master's degree in Research, Control and Development of Medicinal Products (University of Barcelona, UB) and currently is a PhD student at the Department of Pharmacy and Pharmaceutical Technology (UB) and a production technician responsible for the liquids manufacturing section at Reig Jofre Group (Spain). Has worked as a Associate Professor (2010-2011) at the Department of Pharmacy and Pharmaceutical Technology at UB. He has published two research articles.

pflorezb@gmail.com

Notes: