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Room temperature stabilization of human serum albumin by vacuum foam drying

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The purpose of this study was to investigate the process of vacuum foam drying (VFD) as an alternative technique to lyophilization and to study usefulness of lyoprotectants for the storage stability of human serum albumin (HSA). Various grades pluronic surfactants were screened and optimized for their foamability during vacuum drying. For the assessment, HSA was formulated with sugars alone or in combination with stabilizers, which were vacuum foam dried and stored at 25°C. Comparative process efficiency was determined using lyophilization of composition optimized in VFD. The lyophilization cycle parameters were adjudged from the freeze drying microscopy using Lyostat2® and electrical impedance using Lyotherm2®. Protein content of the resulting formulations was analyzed by high-performance liquid chromatography. FTIR analysis of the products showed protein secondary structure-stabilizing effects during the VFD. In particular, sucrose-sodium phosphate monobasic mixture provided an interesting alternative to pure saccharide formulations due to their high glass transition temperatures and increased ability to maintain a low melting transition temperature in the anhydrobiotic state. Inhibition of the sucrose crystallization in solutions under vacuum resulted in highly amorphous sucrose. Changes in the endothermic melting transition studied by DSC indicated reduced sucrose molecular mobility with increased amount of sodium phosphate. Our data suggest that sucrose and phosphate as additives seem to protect HSA better during VFD than the lyophilization. This technique with sugar-phosphate composite glass preserves HSA for the period of two years without the need of refrigeration. VFD will help in saving lot of capital investment on processing and storage facilities particularly for distribution of thermolabile products to the underdeveloped regions of our globe.

Biography

Ashok A Hajare has completed his Ph.D. at the age of 41 years from Bharati Vidyapeeth College of Pharmacy, Pune, India. He is the Head, Department of Pharmaceutical Technology, a premier Pharmacy Institute in Maharashtra State. He has published more than 35 papers in reputed journals and serving as an editorial board member of reputed.

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