ROOM TEMPERATURE STABLE LYOPHILIZED PROTEIN

ABSTRACT

Stable lyophilized therapeutic protein compositions and their methods of manufacture are provided. Specifically, the use of water as a solid cake plasticizer and protein stabilizer is described. Also, the inclusion of a multicomponent stabilizer comprising a larger molecular entity and a smaller molecular entity is described. Also, the inclusion of post-drying annealing under certain conditions improves protein stability. Proteins are predicted to remain stable over 24 months at 25°C.

[No Figure]