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Sullivan et al.

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[54] **PARTIALLY LYOPHILIZED FRUCTOSE-1,6-DIPHOSPHATE (FDP) FOR INJECTION INTO HUMANS**

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[21] Appl. No.: **705,773**

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Related U.S. Application Data

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[51] **Int. Cl.**[6] **A61K 31/70**

[52] **U.S. Cl.** **514/23**

[58] **Field of Search** 514/23

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[57] **ABSTRACT**

A method is disclosed for preparing a partially lyophilized (freeze-dried) powder or solidified cake containing fructose-1,6-diphosphate (FDP), a naturally-occurring intermediate in glycolysis. Preferably, about 10% to 25% residual water (by weight) is left in the powder or cake. This high moisture content does not degrade or limit FDP's stability or shelf life, and it provides for faster, less expensive processing. The methods disclosed herein also allow direct lyophilization inside a vial or other sealed container that will hold the lyophilized FDP, to avoid any need for milling, handling, or other treatment under conditions that might endanger its sterility. Lyophilized FDP can be used to create emergency injection kits which also contain aqueous solutions for mixing, and syringes and needles for injection. These kits can be carried in ambulances, police cars, firetrucks, etc., and can be stored at nursing homes, swimming pools, and in the homes of people suffering from various conditions such as heart disease or sicle cell anemia. These kits will allow rapid (even pre-diagnostic) injection of FDP into people suffering medical crises such as heart attacks, severe blood loss, suffocation, etc.

18 Claims, 6 Drawing Sheets

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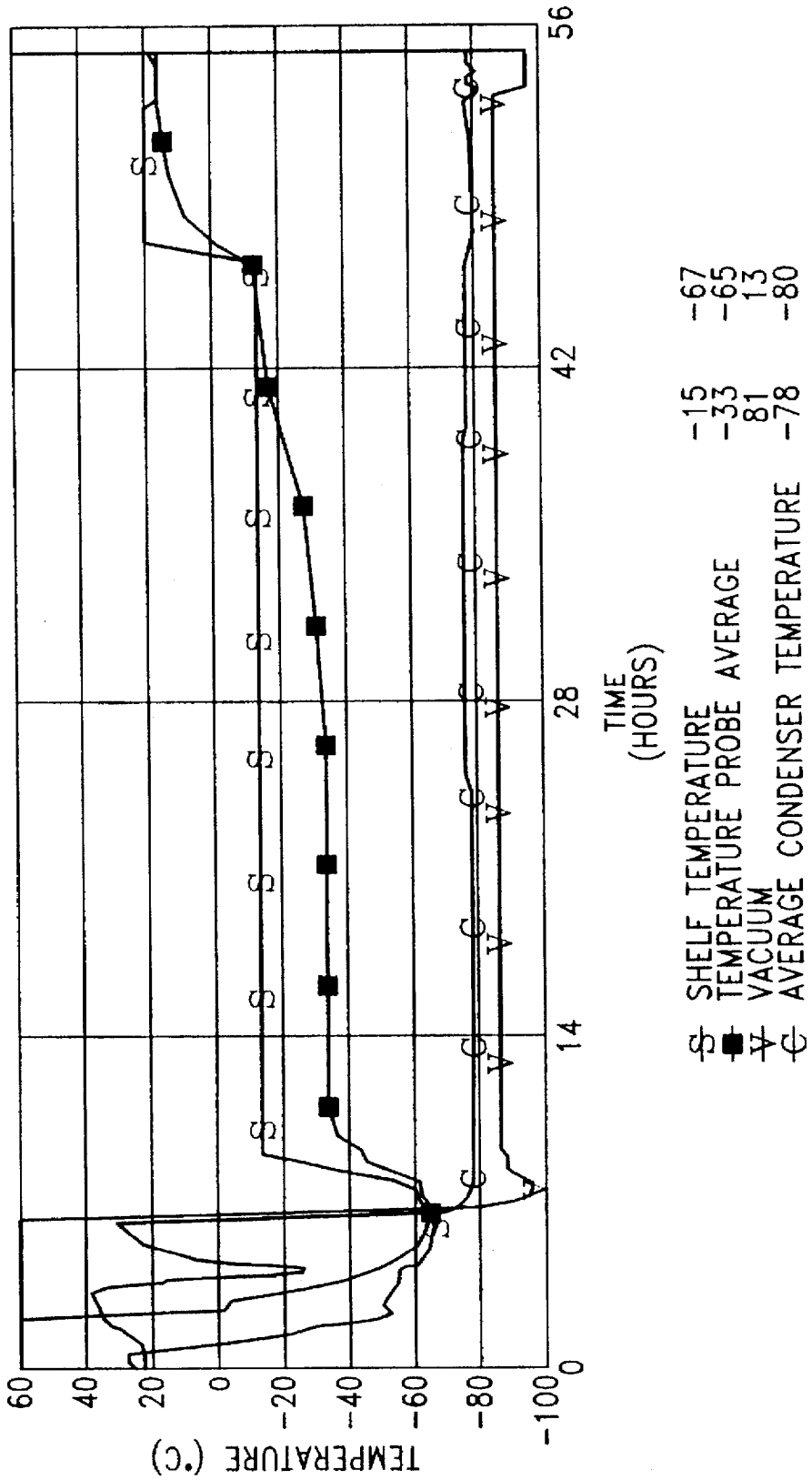

FIG. 1

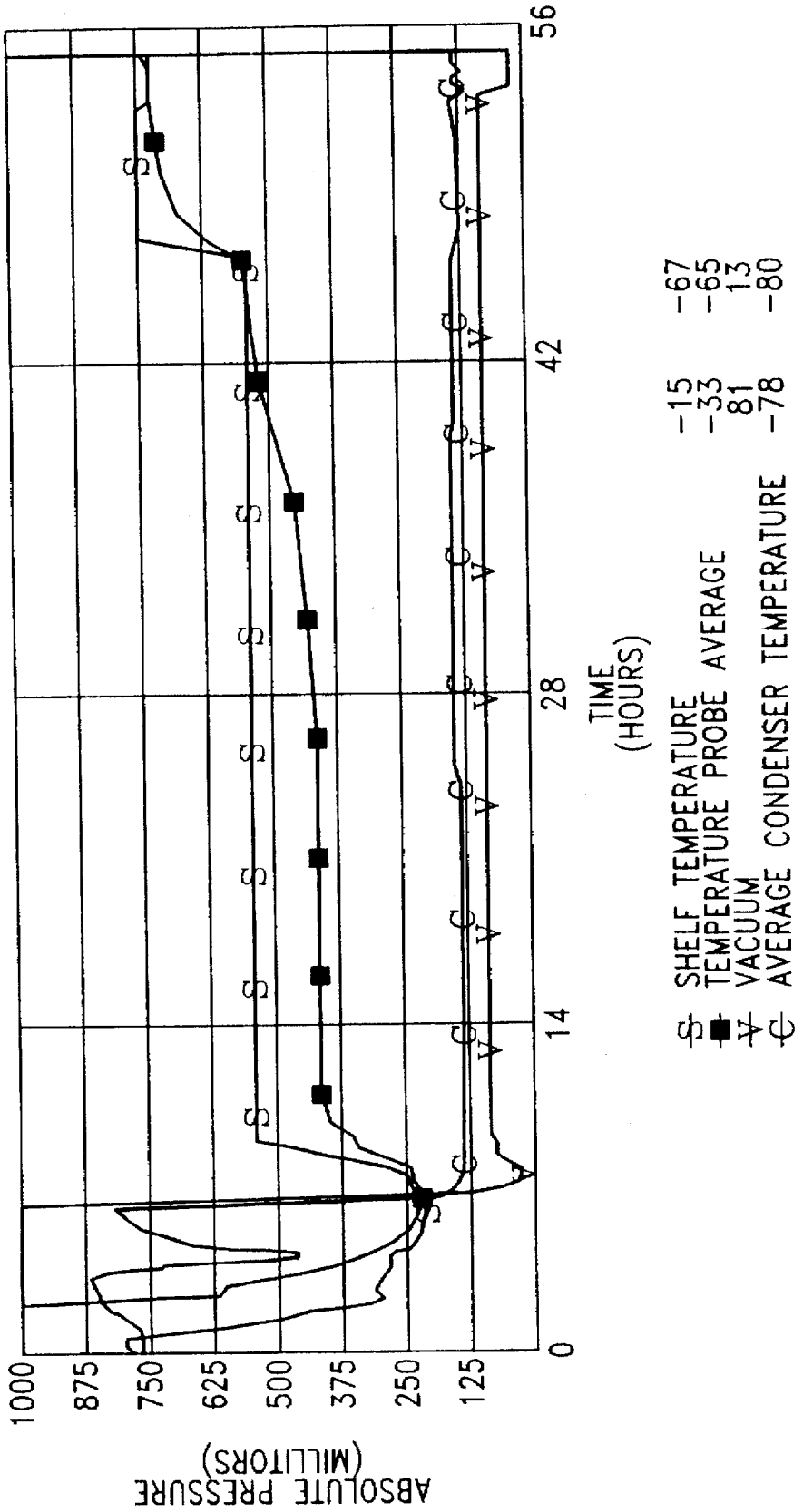

FIG. 2

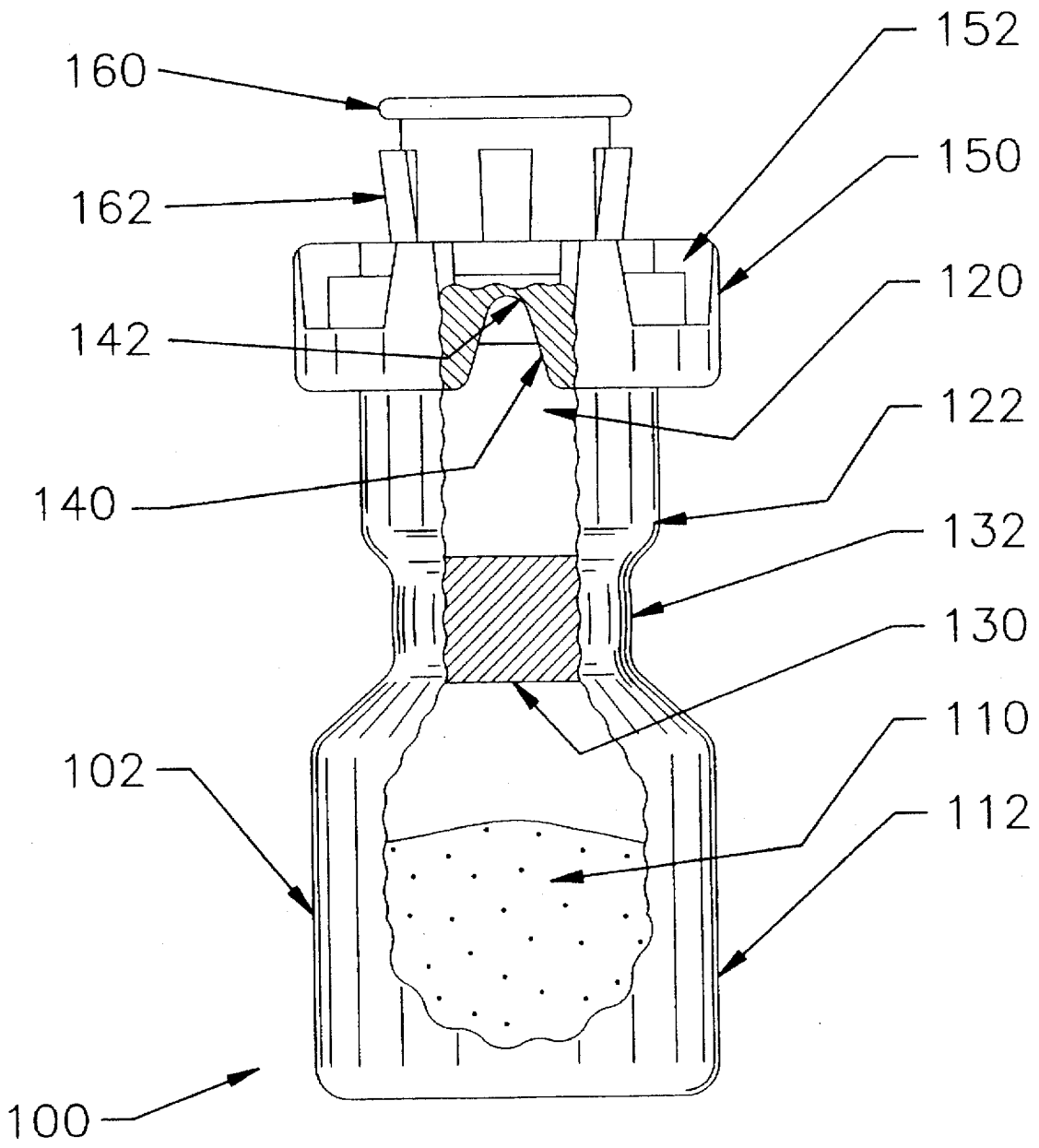

FIG.3

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