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Influence of different sugar cryoprotectants on the stability and physico-chemical characteristics of freeze-dried 5-fluorouracil plurilamellar vesicles

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Abstract:

Lyophilization increases the shelf-life of liposomes by preserving it in a dry form as lyophilized cake to be reconstituted with water immediately prior to administration. Aiming at increasing stability and availability of 5-Fluorouracil liposomal products, 5-Fluorouracil Stable Plurilamellar Vesicles were prepared. Freeze dried liposomal dispersions were prepared with or without cryoprotectants. The cryoprotectants used were glucose, mannitol or trehalose in 1, 2 and 4 grams per gram phospholipids. The results showed that lyophilized cake of liposomes without cryoprotectants was compact and difficult to reconstitute, in comparison with fluffy cakes which reconstituted easily and quickly when using cryoprotectants. The percentage of 5-Fluorouracil retained in liposomes freeze-dried without cryoprotectants was $18.29\% \pm 0.96\%$ and the percentage of 5-Fluorouracil retained in stable plurilamellar vesicles was $31.22\% \pm 0.62\%$ using 4 grams trehalose as cryoprotectant per gram of lipid. Physico-chemical and release stability studies showed superior potentials of the lyophilized product after reconstitution in comparison to dispersion product. It may be concluded that all tested sugars have cryoprotectant effects that stabilized liposomes in the freeze dried state, where trehalose offered the most superior cryoprotectant effect for freeze dried 5-fluorouracil liposomes.

Keywords:

5-Fluorouracil . Trehalose . Release stability . Stable plurilamellar vesicles . Cryoprotectants

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