

ABSTRACT

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Title of thesis: Lyophilization of polymeric nanoparticles

Lyophilization is a widely used drying method with extensive application possibilities in the drug preparation. Its importance in pharmacy is growing because it is one of the important methods of stabilizing active substances, especially proteins. A detailed understanding of the properties of the drug and the physicochemical phenomena of the individual phases of lyophilization is a basic prerequisite for the preparation of a safe, effective and stable drug. Biomedical nanoparticles as drug carriers are the type of the dosage forms in which lyophilization is also used.

A series of lyophilization experiments were performed using trehalose, mannitol, dextran and xylitol as cryo and lyoprotectant. The parameters assessed were particle size, PDI, appearance and lyophilisate reconstitution. The properties of nanoparticles prepared by nanoprecipitation from PLGA polymer were evaluated. Furthermore, experiments were performed to validate the deep-freezing method as an alternative method to lyophilization for long-term storage of nanoparticles. The nanoparticles were stored in 5% solutions of trehalose, mannitol, dextran and xylitol at -70°C . Stability was assessed based on changes in nanoparticle size and PDI over 4 months. The diploma thesis includes dissolution tests in which curcumin was used as a model drug. The effect of lyophilization and freezing of nanoparticles on the percentage of released curcumin was evaluated.

We have come to the conclusion that the most suitable excipient in terms of suitability for lyophilization, release of the active substance from nanoparticles and for maintaining stability during deep freezing is trehalose. The use of a 5% solution proved to be the most effective.

Keywords: PLGA, nanoparticles, lyophilization, stability, dialysis