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Development of stable lyophilized formulation for adenoviral vectors

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Introduction: Adenoviral vectors are far from being commonly established in clinic use because of the complexity to preserve their activity. Currently, the formulations are based on Tris buffer with glycerol that allows long-term storage at -80ºC. This ultra-low temperature creates significant inconvenience for storage, transport and practical clinic use. In addition, an extensive dilution may be required before administration to reduce toxic effects of glycerol. So, enhancing the thermostability has long been recognized as the target for improving the impact of viral vectors on world health.

Aim: Identification of a suitable combination of excipients which will allow the storage of Adenovirus type 5 vector at higher temperatures and the maintenance of infectivity at an acceptable level. Design a lyophilization process that makes more controllable and reproducible formulation with enhanced stability by limiting the loss of infectivity.

Methodology: This goal requires a global approach that starts by analyzing the factors that influence stability of viral preparations prior to and during freeze-drying, and the major mechanisms responsible for inactivation during storage. Furthermore, there are other parameters that affect stability such as: virus concentration, pH, aggregation and residual water. It is crucial to control them during the process by Dynamic Light Scattering (DLS) and coulometric Karl Fischer titration, as well as verify the functional titer at different points of the process to assure well-design. A battery of formulations has been developed to test its effectiveness in terms of liquid stability at 4ºC, freeze-dry impact and stability of lyophilized powder during storage.

Results & Conclusion: A formulation stable until 24 hours in liquid at room temperature has been identified. Selected lyophilization process reduced less than a half the activity and it is maintained until 6 months at 5°C and -20°C. This formulation is being submitted to a 2-years stability program at -20°C, 5°C and 25°C.

Biography

López Ortiz L has a degree in Biotechnology from Universitat Autonoma de Barcelona and MSc in Pharmaceutical and Biotechnological Industry - Universitat Pompeu Fabra in Barcelona. Currently, she is finishing her Industrial PhD in the pharmaceutical company Reig Jofre Laboratories in Barcelona in collaboration with Universitat Autonoma de Barcelona.

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