

Ionic liquids with excipients as stabilisers for payloads in solution

Proposed use

This technology covers a formulation strategy, presenting different formulations that can enhance the stability of payloads and delivery vehicles, with formulations also maintaining potency and stability of the pharmaceutical payloads in solution, without requiring cold storage. The formulation design allows the payload to remain stabilized for at least 50 days at 20-25 °C in solution. These formulations can also be surface modified and can be used for co-delivery applications.

Problem addressed

The majority of biomolecules in aqueous solution are prone to hydrolysis. To avoid this, pharmaceuticals are generally manufactured via lyophilisation or spray-drying, removing water and drying the active ingredients. Removal of water molecules results can reduce the molecular mobility of the active ingredient and slow down the degradation pathways. Lyophilised biomolecules require frozen storage to be preserved and shipped, and need to be rehydrated prior to administration. However, under exposure to temperatures above 4°C, uncontrolled pH conditions, or the presence of water upon rehydration, the active ingredient is prone to aggregation and degradation.

Eliminating drying and the need for cold storage would reduce the cost and technological challenges associated with this process and simplify distribution across the globe. This would also address the issue of cold-denaturation, and would ensure distribution of functional pharmaceutical formulations, including vaccines, particularly in the developing world, where low-temperature storage is not readily available. One strategy to enhance the stability of payloads is using a delivery vehicle, such as a nanoparticle. However, the majority of delivery vehicles, still require delicate storage conditions to maintain their integrity, as well as payload stability.

Technology overview

This technology introduces ionic liquids with excipients as stabilising agents for different payloads and delivery vehicles. Through their stabilising hydrogen bonding and electrostatic interactions, these excipients work to reduce the molecular mobility of the payload, delaying structural changes. For short-term storage the matrix components include different biocompatible ionic liquids with water, and formulations of ionic liquids with different excipients, including sugars, amino acids, polyols, and surfactants at specific ratios to ensure stability of the payload in solution. For select formulations, including neutral lipid nanoparticles, formulations remained stable for at least 50 days in solution at 20-25 °C.

Intellectual property information

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Benefits

- Stabilises a range of payloads, antibodies and RNA-based systems, as well as small molecule drugs
- Allows pharmaceuticals to be stored in solution at room temperature, without requiring frozen storage
- Reduces costs and technological challenges resulting from frozen storage of pharmaceuticals
- Enables long-term preservation of sensitive vaccines and increase shelf-life of pharmaceuticals
- Can be surface-modified for drug targeting
- Can be used for co-delivery applications

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