Imperial College London

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 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 different payloads and delivery vehicles to remain stable over a range of temperatures and conditions in solutions. These include formulations in solution that remain stable for at least 50 days at 20-25 ^{o}C to 365 days at 2-8 ^{o}C. Developed formulations can also enhance payload solubility, can be surface modified and 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 formulations enabling enhanced stabilisation 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, and decreasing aggregation propensity.

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. Depending on desired applications, the stability of formulations ranges from at least 50 days at 20-25 ^{o}C to 365 at 2-8 ^{o}C, both in solution. Additional desirable properties can be enhanced including, but not limited to: reduced cytotoxicity, surface charge modification, cellular uptake, encapsulation efficiency, and solubility.

Intellectual property information

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Benefits

- Stabilises a range of payloads, antibodies and RNA-based systems, small molecule drugs, and delivery vehicles
- Allows pharmaceuticals to be stored in solution under refrigerator condition or 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
- Enhance solubility
- Reduce aggregation
- Enhance encapsulation efficiency
- Can be surface-modified for drug targeting
- Can be used for co-delivery applications

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