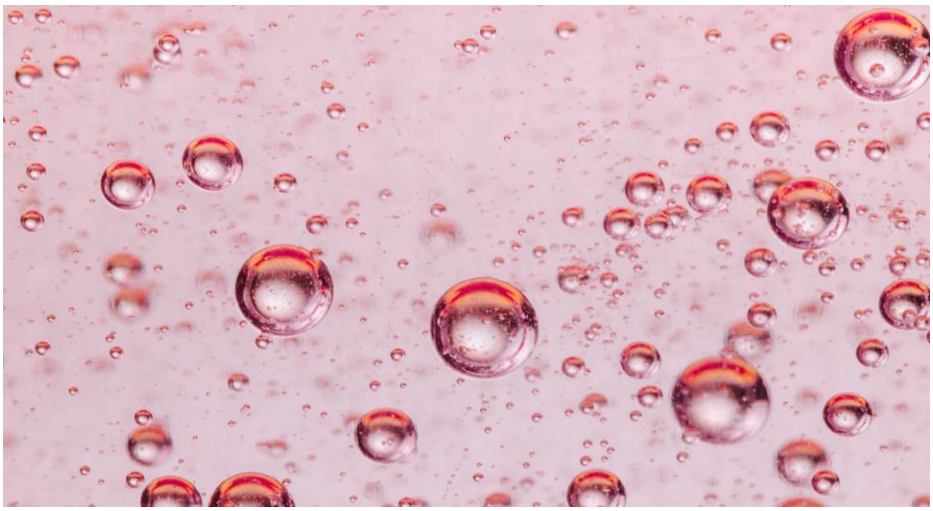
NovaUCD

Technology Licensing Opportunity

Formulation of Poorly Soluble Drugs

- Encapsulation of room temperature ionic liquid-based drug by an immiscible polymer for formulation of poorly water-soluble drugs



Opportunity:

API-based ionic liquids (API-ILs) present an exciting new paradigm for the formulation of poorly soluble drugs. They have the potential to generate more soluble and hence more bioavailable active pharmaceutical ingredient (API) forms than high-energy solid forms while also eliminating physical and polymorphic stability issues that present challenges for amorphous solid dispersions (ASDs) and have precluded the uptake of higher energy metastable crystalline APIs for commercial applications.

However, the problematic physical properties of RT API-ILs that are often viscous oil from a processing perspective remains an unresolved challenge if they are to be routinely incorporated into commercial oral solid dosage forms. It has also been shown that formulating liquid drugs in mesoporous silica can severely hinder the bioavailability of the API by as much as 50% in comparison to the equivalent free liquid, as a result of incomplete desorption from the solid carrier.

UCD and TCD research teams have developed a solution to improve formulation of poorly soluble drugs. This addresses the difficulties associated with current liquid phase formulations and processability of API-ILs by developing something that more closely resembles the materials used in oral solid dosage (OSD) manufacturing by spray drying a room temperature API-IL into a polymer carrier.

To enable high-loading of ionic liquid API without the ASD-(API-IL) solid solution, which would be expected to exhibit the poor physical properties and melting point depression associated with the ionic liquid component of the solid solution, low solubility or immiscible polymers are used to microencapsulate the API-IL in place of formation a single-phase dispersion, in a spray drying operation.

FUNDERS: Science Foundation Ireland sfi For what's next

Value Proposition:
Method to improve formulation of poorly soluble drugs.

Markets:
Pharmaceutical sector involved in the development and formulation of poorly soluble drugs.

Lead Inventors:
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IP Status/Publication:
Patented 2020
UK Patent Application No. 2012897.1.

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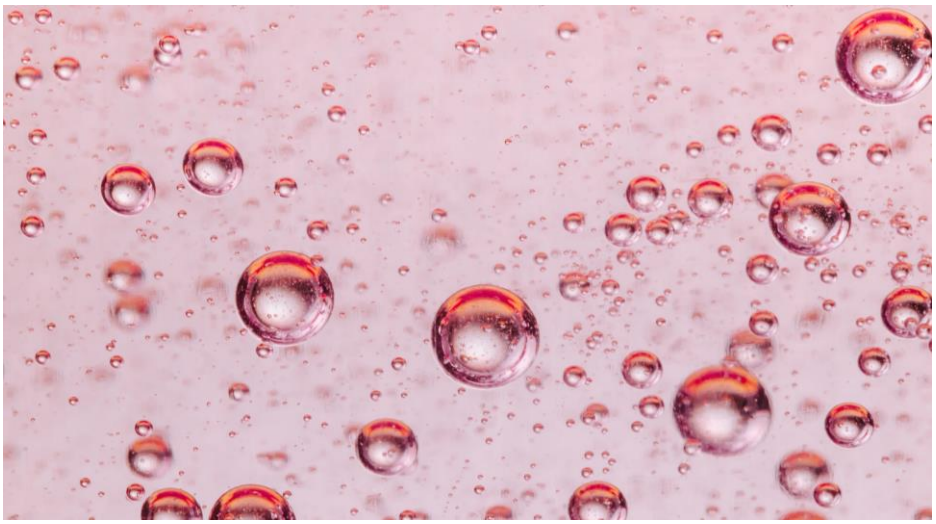

Key Features/Advantages:

- Immiscibility between the components allows the favourable material properties of the polymer to be conserved and to merely act as a vehicle for containing the API-IL in a more favourable form with respect to downstream processing.
- Eliminates the limitations of ASDs by making use of a seemingly unrelated class of compounds, ionic liquids. The molecular structures of many APIs already exhibit properties that are favourable for forming ionic liquids without the need for further modification.
- Solutions of the API-IL were found to be stable for up to 2 years, indicating that they have the potential to offer thermodynamic stability upon release, avoiding *in vivo* recrystallisation issues that can limit the bioavailability of ASDs and some high-energy crystalline forms.
- This method improves the immiscibility between drug and polymer. In the current state-of-the-art for improving the water solubility of drugs, strong interactions are favourable for stabilising a high energy solid form of the drug.
- It utilises high aqueous solubility and even fully miscible ionic liquids for OSD applications. Ionic coformer selection/design can enable thermodynamic stability of API-ILs both within the OSD and potentially on release *in vivo.*

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