

Method for Excipient-free Lyophilization of Drugs for Respiratory Treatment

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Categories:

- Chemical Engineering
- Pharmaceuticals

Keywords:

- Excipient
- Excipient-free
- Lyophilization
- Micelle
- Pharmaceuticals
- Polymer lung surfactants

Researchers at Purdue University have developed an excipient (cryoprotectants)-free method of lyophilization of aqueous polymer micelle suspensions. Lyophilization is a pharmaceutical manufacturing method that provides drugs with improved shelf lives and reconstitution characteristics. Excipients like binders and glidants are typically added to the active pharmaceutical ingredient to improve formulation or release properties of the drug, and cryoprotectants may be added for lyophilized drug forms. However, excipients can be determinantal to the pharmacological properties of a drug formulation in certain cases. In a formulation of polymer lung surfactants (PLS), excipients negatively impact the air-water surface-mechanical properties of the formulation. The Purdue researchers' method allows excipient-free production of a PLS comprised of poly(ethylene glycol) (PEG)-based block copolymer micelles, which can be used to treat acute respiratory distress syndrome (ARDS) and other respiratory problems. The Purdue researchers' method allows use of lyophilization for production of PLS, providing shelf-stable, easily reconstituted, and effective drugs.

Technology Validation: In vivo therapeutic efficacy of a lung surfactant (in improving the compliance of injured lungs) correlates with the high-surface-pressure-generating (surface-tension-reducing) capability of the surfactant. For this reason, the initial screening of candidate lung surfactant materials can be conveniently accomplished with in vitro evaluation of the surface pressure-area (σ) vs. surface area (A) relationship. The researchers have confirmed that the surface pressure and also nanostructural characteristics of PLS are unchanged after the lyophilization treatment.

Related Publications: Seyoung Kim, Daniel J. Fesenmeier, Sungwan Park, Sandra E. Torregrosa-Allen, Bennett D. Elzey, and You-Yeon Won. "Pulmonary Pharmacokinetics of Polymer Lung

Surfactants Following Pharyngeal Administration in Mice", *Biomacromolecules* 23(6), 2471-2484, 2022 (DOI: 10.1021/acs.biomac.2c00221).

H. C. Kim, M. V. Suresh, V. V. Singh, D. Q. Arick, D. A. Machado-Aranda, K. Raghavendran, Y.-Y. Won, "Polymer Lung Surfactants", *ACS Applied Bio Materials* 1(3), 581-592, 2018 (DOI: 10.1021/acsabm.8b00061).

Advantages:

- Powder or liquid formulation for aerosolized delivery
- Low surface tension at the air-water interface that helps maintain the surfactant property of PLS
- Low/no toxicity

Applications:

- Formulating of drugs for treating acute respiratory distress syndrome (ARDS)
- Treatment of NRDS

People:

- Won, You-Yeon (Project leader)
- Fesenmeier, Daniel James
- Kim, Seyoung
- Park, Sungwan

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