PURDUE INNOVATES | Office of Technology Commercialization

Rapid Purification of Biopharmaceuticals by Crystallization

A rapid, cost-effective biopharmaceutical crystallization method reduces active pharmaceutical ingredient production time twenty-fold and replaces high-cost chromatographic purification.

Purdue University researchers have devised a fast method of biopharmaceutical crystallization for use in the pharmaceutical manufacturing industry. Crystallization of biopharmaceuticals is an important process of purification and manufacturing of active pharmaceutical ingredients (API). Slow growth kinetics is the rate limiting step for many contemporarily used protein crystallization methods. This bottleneck in addition to high cost chromatographic purification of the protein crystals that form exemplify the need for a faster, less expensive biopharmaceutical crystallization method.

Researchers at Purdue University have developed a faster crystallization method that significantly reduces protein batch purification times by modulating solvent addition and mixing speed during the crystallization process. This production process was tested by producing active lysozyme in powder form at a rate of 20 g/day. Batch production times were reduced 20 fold over contemporary crystallization methods. This methodology produced spherical lysozyme particles that were a few hundred microns in diameter and exhibited properties useful for purification and downstream processing. This process could be optimized for antibodies, pharmaceuticals, enzyme catalysts, and any other protein powder production significantly increasing productivity of API production.

Advantages:

-Faster biopharmaceutical crystallization

-Good bulk flow properties

-Chromatographic separation replacement

Potential Applications:

Technology ID

2019-NAGY-68435

Category

Biotechnology & Life Sciences/Bioprocessing & Biomanufacturing

Pharmaceuticals/Drug Delivery & Formulations

Pharmaceuticals/Pharmaceutical Manufacturing & Methods

Authors

Zoltan Nagy

Joseph A Oliva

Kanjakha Pal

Further information

Joe Kasper

JRKasper@prf.org

Nathan Smith

nesmith@prf.org

View online

-Biopharmaceutical manufacturing

Lysozyme production

TRL: 3

Intellectual Property:

Provisional-Patent, 2018-10-25, United States | Provisional-Patent, 2018-10-29, United States | PCT-Patent, 2019-10-02, WO | NATL-Patent, 2021-04-09, United States | DIV-Patent, 2024-09-06, United States

Keywords: Biopharmaceutical crystallization, active pharmaceutical ingredients, API manufacturing, protein crystallization, lysozyme production, faster crystallization method, solvent addition modulation, mixing speed modulation, purification time reduction, chromatographic separation replacement, enzyme catalysts, antibodies