Strategy for Detecting Residual Host Cell Proteins Using Aptamers

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BRIEF DESCRIPTION

A proposal for the use of aptamers (nucleic acids that are selected for high-affinity binding to target ligands) for the detection of HCPs in recombinant biopharmaceutical products.

BACKGROUND

Recombinant proteins are typically produced in host cells. Host Cell Proteins (HCPs) are process-related impurities that arise from the host cells during the normal course of recombinant protein production. Removal and clearance of HCPs through a purification process must be demonstrated before product can be released for use in the clinic. HCPs are currently detected using polyclonal antibodies in a sensitive immunoassay format. This process of anti-HCP antibodies is time consuming, expensive, and variable. Therefore, a better HCP detection reagent, one that recognizes all or nearly all potential HCPs, would be highly desirable to give better quantitative meaning to the HCP immunoassay results.

DESCRIPTION

Researchers at the University of California, Santa Barbara propose using aptamers (nucleic acids that are selected for high-affinity binding to target ligands) for the detection of HCPs in recombinant biopharmaceutical products. Specifically, the method uses next generation sequencing (NGS) to identify aptamers for binding to all targets in the mixture in parallel, and uses the aptamer arrays to measure the actual binding simultaneously of all aptamers to all targets in the mixture. Because aptamer generation is not dependent on immune recognition, they have the potential to detect all HCP species without depleting any targets. This strategy works as an “all-in-one” detection process leading to lower costs and increased reliability in targeting the HCPs.

ADVANTAGES

- Detect all HCP species
- Decrease cost
- Reliability

APPLICATIONS

- Biopharmaceuticals
- Pharmaceuticals

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OTHER INFORMATION

KEYWORDS

HCP, Host Cell Proteins, Antibodies, Aptamer, Biopharmaceutical, indpharma, Biotech

CATEGORIZED AS

- **Biotechnology**
  - Health
- **Medical**
- Other

RELATED CASES

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PATENT STATUS

Country	Type	Number	Dated	Case
United States Of America	Issued Patent	11,007,849	05/18/2021	2014-310

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