

38. Title: Stabilization of biotherapeutics at high temperature

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Keywords: Biotherapeutic proteins, Thermal stability, Protein storage

Domain: Life Sciences (Biotech)

Summary:

A lot of instabilities are associated with protein biotherapeutics which includes aggregation, fragmentation, oxidation, reduction, truncation, etc. Existing technologies address chemical instability of proteins by using various excipients and cryoprotectants that stabilize the parenteral formulations of proteins. However, thermal degradation is not addressed, and proteins still need to be preserved at low temperatures which is very energy intensive and prohibitive.

The present technology is a dendron-based formulation that confers thermal stability to proteins enabling storage at high temperature conditions (upto 55 °C). A class of biocompatible dendrons are used as excipients to enhance the stability of protein drugs at temperatures higher than present storage temperatures. Both physical and chemical instabilities occurring at high temperatures conditions have been addressed. The formulation is applicable for various biotherapeutics such as monoclonal antibodies, cytokines, growth factors, hormones, interferons, interleukins, anticoagulants, bone morphogenetic proteins, antigens, and enzymes. It has been tested at lab-scale for monoclonal antibody IgG1.

Advantages:

- » Proteins can be stored at high temperature storage conditions (up to 55°C)
- » Reduced cost for protein storage
- » Increased shelf-life of proteins

Applications: Pharma and drugs

Scale of Development: Production at lab-scale, In vitro studies and characterization has been done

Technology Readiness Level: 4

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