39. Title: PEGylation to enhance pharmacokinetic properties of proteins

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Keywords: Biotherapeutic proteins, Protein modification

Domain: Life Sciences (Biotech)

Summary:

PEGylation, the chemical linkage of polyethylene glycol (PEG) chains to a therapeutic protein/peptide, has been widely used as a post-production modification methodology to enhance the pharmacokinetic properties of proteins. It has been shown to increase solubility, decrease renal clearance, improve physical and thermal stability, increase proteolytic protection, increase circulating half-life, reduce immunogenicity and reduce toxicity. Several methods are available for pegylation of proteins, however they have a high reaction time, lengthy purification processes and low productivity.

The current technology provides an improved pegylation process which is able to remove all the multi-PEGylated impurities in the loading flow-through, simplifying the overall purification process and results in higher productivity, lower reaction times and improved resin utilization. The process can be integrated with any existing manufacturing process. The process is applicable for various cytokines such as interferons, growth factors, tumour necrosis factor, interleukins, and colony stimulating factors. It has been tested at lab-scale for granulocyte-colony stimulating factor.

Advantages:

- Higher productivity and reduction in the reaction completion time
- Reductions in manufacturing costs and facility size while improving consistency in product quality
- Easily adapted to continuous operations with benefits like increased productivity, higher equipment utilization and reduction in resin volume utilization compared to batch
- Can be integrated with any existing manufacturing process to offer an end-to-end integrated assembly from inclusion bodies to purified PEGylated product

Applications: Pharma and drugs

Scale of Development: Prototype developed and invitro testing don

Technology Readiness Level: 4

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