




Recombumin[®]

Formulate with confidence

Recombumin[®] a versatile stabilizer for challenging drug and vaccine formulations

- Protects against surface adsorption enabling stable liquid formulations and improved dose control
 - Allows reformulation from lyophilized to simple liquid formulations without compromising stability
 - Reduced unwanted immunogenicity through prevention of aggregation and oxidation
 - Possibility to bring valuable yet initially unstable drug candidates to market
 - Commercially validated in marketed products
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Overcoming formulation challenges of biotherapeutics

The expanding field of vaccine and biotherapeutics gives promise for improvement of treatments against several diseases. Despite advancements in protein engineering many of these therapies continue to face *ex vivo* instability challenges (physical and chemical instability) which are a source of dosage form inefficacy and undesirable immunogenic responses.

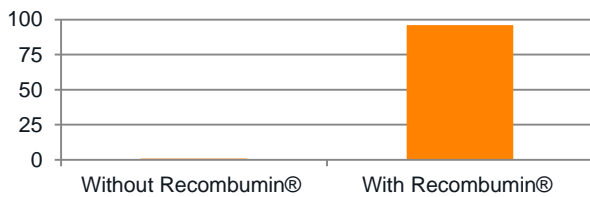
Albumedix' Recombumin®, provide drug formulators with a versatile and effective stabilizer when working with hard-to-formulate drug candidates such as high-concentration biotherapeutics, highly potent drugs and instable therapeutic peptides. By utilizing the many properties of Recombumin®, drug developers can overcome these critical formulation challenges.

Protection against surface adsorption

Recombumin® acts to prevent drug adsorption due to its adsorption to both hydrophobic and hydrophilic surfaces, where it remains attached over time. Surface coverage is typically achieved through a single layer of Recombumin®, where as little as only 1-2 mg Recombumin® is needed to cover 1 m² of surface.

Here exemplified by prevention of drug depletion due to surface adsorption of the protein TGF-β3.

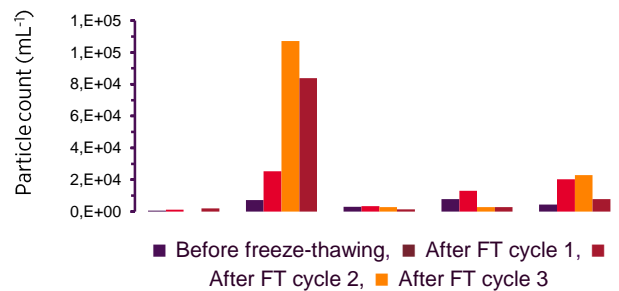
HPLC recovery-% of TGF-β3



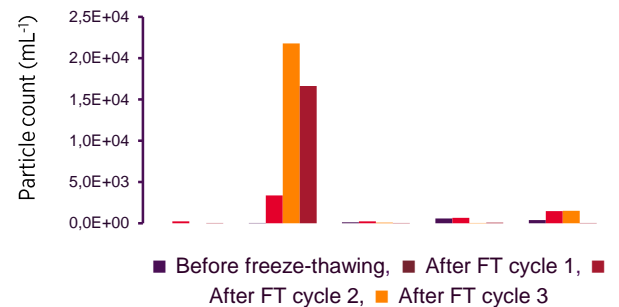
Prevention of aggregation

Recombumin® possesses two important properties for the prevention of biotherapeutics aggregation: It binds promiscuously using both ionic and hydrophobic interactions protecting otherwise exposed surfaces eligible for aggregation. By dispersing uniformly throughout solution Recombumin® affords an insulating quality which minimizes unwanted protein-protein interactions. Its properties in this respect are here illustrated by the prevention of aggregation of the peptide insulin as seen by MFI.

1- to 10-μm particles



11- to 100-μm particles



Prevention of oxidation

Recombumin has high antioxidation capacity due to a free thiol group and several methionines. These enable Recombumin® to protect biopharmaceuticals against modification through oxidation by scavenging when in formulation. Here illustrated by the lowered degree of oxidation as the Recombumin® concentration increases seen for the malaria vaccine The ability of Re candidates MSP2 3D7 and MSP2 FC27. Analyzed by tryptic digest and LC/MS for methionine and cysteine oxidation by H₂O₂ stress.

