



November 1, 2019

Re: Precipitation in Allergy Extracts

Dear Healthcare Professional:

In response to your recent inquiry, glycerinated or non-glycerinated allergenic extracts are essentially saturated solutions and precipitation is a phenomenon common to all manufacturers. The precipitate is inherent to the product and some antigens are more prone to precipitation than others. We make every effort to ship clear extracts but have no control over precipitation that can occur during shipping or storage after arrival.

Potency, composition, and protein contents are not affected by precipitate. Precipitate has been characterized as an agglomeration of protein and/or carbohydrates that form sediments. This is an industry recognized allergenic extract characteristic and has been shown to cause no risk or potency issues with the product. Post market surveillance has shown that precipitation poses no risk to patient safety as there have been no adverse events reported. Additionally, each batch of extract produced is sterility tested to ensure added safety for your patients.

In summary: (1) precipitate is common to allergenic extracts; (2) potency appears to be unaffected by the occurrence of precipitate; and (3) there have been no adverse events associated to precipitated extracts. However, HollisterStier Allergy allows return of precipitated extracts.

Should additional discussion or further clarification be necessary, please contact Customer Technical Service at 1.800.495.7437.

Sincerely,

Megan Steeber
Customer Service Representative
HollisterStier Allergy

A Jubilant Pharma Company

OUR VALUES



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