

## NEWS RELEASE

### Malvern's light scattering supports formulation development for Novozymes' recombinant albumins

**29 November 2011, Malvern, UK:** Scientists from Malvern Instruments and from biological ingredients and technology developers, Novozymes Biopharma, have successfully completed the first phase of extensive collaborative studies. These have involved the application of Malvern's light scattering technologies in evaluating the formulation stability of two of Novozymes leading recombinant albumin products – Albucult® and Recombumin® – which are used in the manufacture of human therapeutics.



The teams applied the resolving and detection capabilities of size exclusion chromatography light scattering (SEC-LS) and dynamic light scattering (DLS) offered by Malvern's Zetasizer Nano system to monitor the stability of these Novozymes products. These results have now been published as a series of application notes that are freely available on the Malvern Instruments website;

[www.malvern.com/labeng/industry/protein/novozymes.htm](http://www.malvern.com/labeng/industry/protein/novozymes.htm)

Mark Perkins, Customer Solution Specialist from Novozymes explained: "When developing an active pharmaceutical ingredient it is important to design a formulation that offers long term stability over a range of storage conditions. Liquid formulations allow easy and economical product handling during manufacture and convenience for the end user, but some proteins prove difficult to formulate in this way. Recombumin and Albucult have been designed to aid in the development of liquid formulations of unstable APIs, and a detailed understanding and confirmation of their stability under a variety of conditions is essential. The Malvern systems have proved highly effective in this application, allowing us to further demonstrate the stability and purity of our products and how this may be translated into improving liquid biopharmaceutical formulations."

**More...**

**Malvern's light scattering supports formulation development for  
Novozymes' recombinant albumins.../2**

Malcolm Connah, Product Marketing Manager, Malvern Instruments said: "Malvern is delighted to be working with a company so active in this important area of biopharmaceutical development. We look forward to seeing Recombumin and Albucult helping in the delivery of drugs and vaccines that are challenging to formulate."

Novozymes' animal-free, recombinant albumin (rAlbumin) range helps pharmaceutical drug and medical device manufacturers deliver safe and affordable product improvements in a variety of applications. Further information can be found at: [www.biopharma.novozymes.com](http://www.biopharma.novozymes.com)

Dynamic Light Scattering using the Zetasizer Nano can be applied to predict the stability of a protein formulation, as well as monitoring how the protein responds to thermal stress. This information is useful in the design of production processes and sample handling recommendations. Further information can be found at: [www.malvern.com/zetasizer](http://www.malvern.com/zetasizer)

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**Notes follow...**