

NEWS RELEASE



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FOR IMMEDIATE RELEASE
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ZirChrom Separations awarded Phase II SBIR grant for \$750,000 to study preparative LC of bio-molecules

ZIRCHROM Separations, Inc. (Anoka, MN) was just awarded a \$750,000 Phase II SBIR Grant (#2R44GM58354-02) from the National Institute of Health to produce preparative size zirconia microspheres for large-scale liquid chromatography of bio-molecules. Dr. Clayton McNeff, Vice President and Technical Director for ZirChrom, is the Principal Investigator conducting the research. The primary goal of the work is to bring to market a separation media that will enable the economical, one-step purification of monoclonal antibodies. Smaller scale separations indicate that high purity monoclonal IgG can be inexpensively purified from IgG growth media with greater than 95% yield of biological activity in a single chromatographic step.

Dr. McNeff explains, “there is a significant need for a rugged, simple and inexpensive method for the purification of antibodies. There are more monoclonal antibody-based drugs currently in phase II and phase III clinical trials than any other class of bio-pharmaceuticals. A majority of these therapeutics are being developed for patients with some of the most serious human diseases including cancer, AIDS and other immune-system disorders, such as multiple sclerosis, rheumatoid arthritis and heart disease. A widely used method for the preparative purification of antibodies involves the use of three LC columns, first a cation-exchange column, followed by an anion-exchange column and finally an affinity column as the final purification media. This purification protocol is extremely time-consuming, but the final product is adequately pure (>95%).”

“Purified antibodies obtained using a zirconia-based preparative column have a higher purity level, a much lower cost of production and higher recovery rate than the three column method. By reducing the antibody purification to a single step, a time savings of at least 66% is realized, which significantly lowers the overall antibody cost to the potential user, as purification costs make up at least 50% of the total cost of antibody production. Furthermore, the extreme stability of zirconia stationary phases makes the media sterilizable and cleanable thereby further reducing antibody production costs.”

Founded in 1995, ZirChrom manufactures a unique family of zirconia-based stationary phases made commercially available in the form of packed ZirChrom[®] analytical HPLC columns, ZirChrom[®] preparative HPLC columns and ZirChrom[®] guard columns. ZirChrom's packing chemistries cover all modes of modern HPLC including reversed-phase, normal phase, ion-exchange and size exclusion chromatography. Zirconia based materials have significant advantages over silica and alumina based stationary phases due to zirconia's extraordinary chemical (pH 1-13) and thermal (up to 150°C) stability. Unlike polymeric materials, zirconia based materials produce superior efficiency, give highly reproducible separations, exhibit selectivity similar to traditional bonded phase materials for easier method development.

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