Profos AG has officially launched EndoTrap® HD, the much-anticipated new addition to the company's innovative system for removing lipopolysaccharides (LPS), also known as endotoxins, from aqueous biological solutions. While previous EndoTrap® versions (EndoTrap® red and EndoTrap® blue) were targeted primarily at applications in research and academia, EndoTrap® HD extends this endotoxin removal system to actual biomanufacturing processes, where it can be used in both early and late steps in the manufacturing process for drugs and vaccines.

EndoTrap® HD LPS Removal System Meets Challenges of Biomanufacturing Processes

Because endotoxins induce unwanted pathophysiological effects in humans, contamination of drugs and vaccines with LPS must be kept to a minimum if pharmaceutical products are to be marketed successfully. Profos addresses this issue with EndoTrap® HD, an endotoxin removal system specially optimized for use in the biomanufacturing process. Endo-

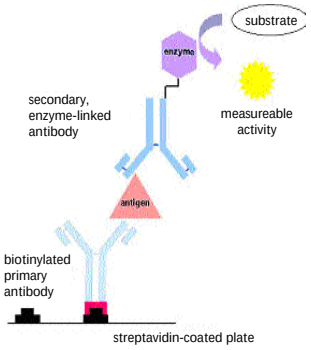
EndoTrap® HD endotoxin removal system.

Trap® HD is an affinity chromatography system based on highly specific protein ligands that capture endotoxins from acqueous biological solutions. After endotoxins are captured and proteins elute, the ligand can then be regenerated and reused up to ten times with no loss in efficiency.

EndoTrap® HD features a robust and chemically defined matrix, high LPS capacity, and excellent chromatographic characteristics. Profos also says that EndoTrap® HD virtually eliminates many of the limitations of other LPS clearance systems like ultrafiltration, ion exchange chromatography and two-phase extraction. The system's dimensionally stable affinity matrix, specific LPS capture capabilities, a broad pl range for target proteins, a broad pH/buffer range, and its compatibility with commonly-used buffer additives and high salt conditions ensure that EndoTrap® HD can be used in both early and late steps in the biomanufacturing process.

Although ligand leakage is low with EndoTrap® HD, Profos has also announced immediate availability of its EndoTrap Leakage ELISA, an acronym for Enzyme Linked ImmunoSorbent Assay. The ELISA addresses the fact the ligand leakage in minute amounts is unavoidable and that regulatory agencies may require accurate and repeatable testing for such leakage. The EndoTrap ELISA uses a two-step sandwich enzyme-linked immunosorbent assay for the quantitative determination of the EndoTrap® HD ligand in biological acqueous solutions (see diagram).

According to Dr. Stephanie Steck, Profos' International Product Manager, EndoTrap® HD is the next step in the Profos quest to become a global market leader in the field of endotoxin removal systems and high-quality endotoxin-free products. "With our products "EndoTrap® blue" and "EndoTrap® red", which both are established on the global markets for endotoxin removal, we have successfully been serv-



Principle of EndoTrap® Leakage ELISA

ing the needs of our customers – especially in academia and research," said Steck. "But we observed an increasing demand for a specific endotoxin removal system for large scale purification processes. With our new product "EndoTrap® HD" we are convinced we have created a product that fully satisfies our customers' requirements." ■

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