

PRESS RELEASE

Number 16

WACKER at BIO 2009: Proprietary ESETEC[®] and DENSETEC[®] Fermentation Technologies Produce High Yields

Munich/Jena, May 18, 2009 – Taking place from May 18 to 21 in Atlanta (GA, USA), BIO 2009 is an ideal venue for Wacker Biotech GmbH – a full-service contract manufacturer of biopharmaceutical actives – to showcase its proprietary ESETEC[®] and DENSETEC[®] technology platforms for the production of pharmaceutical proteins (biologics). ESETEC[®] provides a simple and cost-effective way of producing high yields of, for example, antibody fragments, which are increasingly used as active ingredients for therapeutic applications. The novel technique produces up to 40 times more antibody fragments than is the case via conventional methods. Combined with WACKER's patented DENSETEC[®] high-cell-density fermentation process, ESETEC[®] yields increase further by as much as 50 percent.

Wacker Biotech's collaboration with pharmaceutical-sector customers has included projects in which its proprietary ESETEC[®] and DENSETEC[®] fermentation technologies were used to produce high antibody-fragment yields. The ESETEC[®] technology permits the highly efficient extracellular production of proteins and antibody fragments. It utilizes high-expression plasmids and an *E. coli* host strain that can transfer proteins in their native, that is, correctly-folded conformation across the outer membrane into the culture broth. Exhibiting highly stable performance during fermentation, the patented *E.*

coli K12 strain is routinely used in commercial-scale fermenters with capacities up to 4.5 m³. Yields of protein actives exceeding 10 g/l have thus been achieved. Additionally, extracellular secretion streamlines product purification, which enhances cost-efficiency. What's more, fermentation yields are not constrained by the limited space within the periplasm. Compared to periplasmic expression systems, therefore, up to 40 times more antibody fragments have been produced.

Combining the ESETEC[®] technique with a special *E. coli* high-cell-density fermentation process called DENSETEC[®] increases antibody-fragment yields by another 50 percent. Under strictly monitored and reproducible conditions, high cell dry weights of well over 50 g/l and optical densities far exceeding 100 can be obtained with this process. Due to its extremely high space/time yield, the process has already been able to generate product yields exceeding 12 g/l. Wacker Biotech's high-cell-density fermentation and optimized purification processes have made it possible to isolate over 0.3 kg of hyperpure active protein from 100 liters of culture broth. For customers, this means high product yields from lower reactor volumes, and reduced purification costs.

By combining its proprietary ESETEC[®] and DENSETEC[®] technologies, Wacker Biotech can efficiently produce active pharmaceutical proteins with optimal space/time yields. WACKER has developed an antibody-fragment expertise platform that extends to purification and, if required, PEGylation. In doing so, WACKER has positioned itself as a microbial antibody expert and as a preferred production partner to pharmaceutical and biotech firms.

WACKER is substantially boosting capacity at its Jena site in order to cope with a growing need for high-efficiency biologics production processes and to meet rising customer demand. A new building for process development and quality control was completed back in December 2008. A second extension at the Jena site will double the production area in the existing GMP plant and include a brand-new downstream purification site. This extension is expected to come fully on stream in early 2010. It will enable Wacker Biotech to provide customers with sufficient capacity for commercial production of biopharmaceuticals right at the advanced development stage.

About Wacker Biotech

Wacker Biotech GmbH is a full-service contract manufacturer of biopharmaceutical products based on microbial systems. Its service portfolio ranges from molecular biology and process development, through GMP-compliant production of clinical test samples and actives, to commercial market supply and comprehensive analytical services. Above all, Wacker Biotech offers proprietary technologies that satisfy market needs for cost-efficient production and very high quality. Jena-based Wacker Biotech is a wholly-owned WACKER subsidiary.

For further details, visit the following website:

<http://www.wacker.com/biologics>



Preparing samples in the molecular genetics lab: Wacker Biotech GmbH in Jena, Germany, produces actives (known as “biologics”) for pharmaceutical companies. Wacker Biotech observes the latest principles of quality by design (QbD) throughout process development, which necessitates a detailed understanding of the products and processes (photo: Wacker Chemie AG).

Note:

You can download pictures at:

<http://www.wacker.com/pressreleases>

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The company in brief:

WACKER is a globally-active chemical company with some 15,900 employees and annual sales of around €4.3 billion (2008). WACKER has 27 production sites and over 100 sales offices worldwide.

WACKER SILICONES

Silicone fluids, emulsions, rubber and resins; silanes; pyrogenic silicas; thermo-plastic silicone elastomers

WACKER POLYMERS

Polyvinyl acetate and vinyl acetate copolymers in the form of dispersible polymer powders, dispersions and solid resins used as binders for construction chemicals, coatings, adhesives, paints, plasters and nonwovens

WACKER FINE CHEMICALS

Fine chemicals, biologics and other biotech products, such as cyclodextrins and cysteine

WACKER POLYSILICON

Polysilicon for the semiconductor and photovoltaics industries; solar wafers

Siltronic

Hyperpure silicon wafers and monocrystals for semiconductor devices