

## PRESS RELEASE

LEWA: Custom-designed system for low-pressure liquid chromatography (LPLC)

### **Reproducibly precise flow**

*LEWA EcoPrime® supports a linear gradient for the chromatographic purification of biopharmaceutical materials*

LEWA has provided metering pumps and complete systems for chromatographic separation processes on an industrial scale for years. These solutions are popular due to their exact, reproducible metering accuracy, wide adjustment ranges, and high product quality. LEWA's chromatography systems are generally not standard solutions, but are designed precisely in accordance with their conditions of use and customer requirements.

Low-pressure chromatography (LPLC) is the most important step in the biopharmaceutical industry for obtaining biomolecules in the required purity. Over the past few years, fermentation yields have increased significantly. The consequence has been that vaccines, monoclonal antibodies, or recombinant proteins occur in higher concentration in downstreaming for the purification. The result is that the requirements for process chromatography are significantly higher; systems must not only be very reliable, but also be capable of handling larger volumes significantly more quickly. Operators are also more and more frequently expressing the need for a linear gradient (linear concentration drop) in order to elute the molecule from the chromatography column in a reproducible manner.

The new LEWA EcoPrime makes it possible to provide this linear gradient in a much broader range of mixtures. While traditional systems often work linearly only over a range between 20 and 70 percent of the mixing range, EcoPrime offers a linear gradient between 0.5 and 99.5 percent – at an accuracy of 0.5 percent.

Since the validation of processes required in the pharmaceutical industry is only possible within a narrow range of process parameters, the high reproducibility of configurable parameters offers advantages. This increases reliability while significantly reducing the time required and costs for validation. Additional economic advantages of this new system solution result from its wide range of performance and simultaneously minimized pulsation with which broad ranges of metering flow can be covered with only a single system configuration.

The basis of EcoPrime is the ecodos hygienic series of metering pumps used in thousands of installations. This mature pump technology has been enhanced with the modern LEWA intellidrive drive concept.

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LEWA intellidrive works with servo motors that drive the pumps much more precisely; software permits adjustment of the flow rate characteristics, permitting nearly pulsation-free operation. The advantage of this technology: intellidrive provides higher precision with minimal residual pulsation, so chromatographic purification can be operated with great repeatability with the EcoPrime system solution and adapted better to the specific conditions of the process. An adjustment range of up to 1:150 can be implemented without problems.

The most important properties of LEWA EcoPrime and its benefits for the operator:

- Precise flow rate: Precision means a more exact modeling of the process, reliability in validation – ensuring a higher yield.
- Larger dynamic range: The operator has a wide flow range for process adjustment: For the smallest system "Platform 500", from 0.04 to 5.64 l/min (corresponding roughly to 1:150). The largest system "Platform 3000" covers 0.15 to 33.1 l/min.
- Minimal pulsation: A low pulsation ensures that the chromatography medium will suffer less damage.
- Lowest holdup volume: The design of the bubble trap reduces the holdup volume of the system and thus the residence time of the gradient and the product. LEWA developers have thereby achieved a better peak symmetry and a lower level of backmixing, increasing product yield.
- Low-shear purification: The structurally low-shear purification with a diaphragm pump ensures that the biomolecule (the active material) is not damaged or changed.

The user interface has been kept very simple (basis: Wonderware). The operator can store 10 recipes, and each recipe can be constructed of up to 20 freely definable sequences – adapted individually to the process.

EcoPrime can be used both as a buffer dilution skid or – connected directly to a column – as a standalone chromatography system. Thanks to its design and high performance, a process-specific selection can be made from the four available EcoPrime platforms. It can be used in research as well as in process development and optimization (laboratory) and in production itself. Communication is possible using different protocols with all SCADA and process control systems.

EcoPrime meets the requirements of FDA CFR 21 Part 11. LEWA provides the entire documentation – including original certificates – in order to ensure pharmaceutically appropriate traceability of all materials used.

For many ecodos pumps already installed by customers, an upgrade with LEWA intellidrive to EcoPrime functionality is possible.

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**Figure 1:**

LEWA EcoPrime – custom-designed systems for process chromatography (LPLC).



**Figure 2:**

Purification process with the LEWA EcoPrime system in a cleanroom.

Images and digital text files can be found at [www.lewa.de/presse](http://www.lewa.de/presse) or [www.lewa.com/press](http://www.lewa.com/press)

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- Gasodorierung

### Key industries:

- *Oil & Gas*
- *Chemicals & Petrochemicals*
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- *Personal Care*
- *Food & Beverages*
- *Plastics*
- *Cleaning & Detergents*
- *Energy & Environment*
- *Gas Odorization*

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