In October 2007, Pharmatec, a Bosch Packaging Technology company, was selected by a Russian customer to undertake the detailed planning of preparation equipment for basic fractionation, as well as fractionation equipment for albumin and immunoglobulins. In March 2008, the company received the contract to produce this equipment and further installations. In addition, the preparation equipment for the thawing of blood plasma, was also delivered by Pharmatec.

**Blood plasma fractionation**

Blood plasma fractionation requires the separation of plasma phase proteins using physical and chemical procedures. The critical parameters in this process are temperature, alcohol concentration and pH-value. The first step in blood plasma processing is a gentle thawing process, while maintaining strict temperature control. The plasma fractions are then separated by means of filtration, centrifugation and other procedures.

**Plant technology and main equipment**

The core components of the supplied equipment are special preparation and buffer vessels for thawing, storage, mixing, precipitation and reaction. Designed pipe systems and operator-friendly transfer panels ensure an optimal product flow. A further pipe system provides all processing equipment and installations with the required media and energy. At the heart of the fractionation equipment are fourteen process vessels with a capacity of up to 17 cubic meters. Each vessel rests on weighing cells, is equipped with measuring technology to determine product flow, temperature and pressure, and also has its own temperature control. The preparation equipment, as well as the pipework with product contact is made of high quality stainless steel. All pipes with product
contact and high-purity media contact, as well as all fixtures, are cGMP compliant, and all welding has been carried out observing the 3D rule.

**High level automation**
Pharmatec installations ensure that all important parameters are monitored by a powerful control and process visualization system. The control system ensures registration and documentation of all process-relevant data, steps and parameters.

**Testing and cleaning**
An important aspect of quality-oriented pharmaceutical production is an integrated cleaning system (CIP). Pharmatec uses high-performance cleaning concepts which are designed for customer specific needs. Two CIP plants were supplied for cleaning the equipment, each comprising two stainless steel vessels (capacity: 1–2 cubic meters). All preparation and cleaning programs are product-specific and were tested at Pharmatec in Dresden for thawing and basic fractionation processes.

**One-stop solution**
Well thought-out configuration and flexible orientation towards the customer’s requirements enabled Pharmatec to supply the preparation equipment for the basic fractionation as well as the additional, separately commissioned thawing installation on schedule in November 2008.

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Blood plasma (circa 55% of the human blood)

Thrombocytes and white blood cells

Red blood cells