Blood plasma
Complete solutions for process plant

GEA Process Engineering
GEA Diessel
From blood plasma to medication: all production steps from a single source

The manufacture of pharmaceutical products from blood plasma by plasma fractionation requires process conditions that are extremely kind to the product. These products are manufactured, as far as possible, under sterile conditions that require materials and processing of the highest quality. In addition, the process has to comply with a large number of national and international standards and statutory provisions.

Manufacturers, therefore, expect great precision in the manufacture and assembly of their process plant. Every detail of the design must comply with high quality standards to avoid production errors. Using high-performance processing equipment helps guarantee reliable production.

As a competent manufacturer of complete plant for the pharmaceutical industry, GEA Diessel offers you a full service to meet every specification. From the planning, development and installation of your new process plant all the way to qualification and maintenance – our experienced engineers will work with your project team to develop innovative and efficient process technologies for your very individual blood plasma processing applications.

GEA Diessel supplies plant and components for:
- fractionation
- concentration
- pre- and post-virus inactivation
- purification
- buffer production, storage and distribution

Processing of blood plasma

<table>
<thead>
<tr>
<th>Individual plasma donations</th>
<th>(deep-frozen)</th>
</tr>
</thead>
<tbody>
<tr>
<td>plasma pool</td>
<td>thaw</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>F VIII</th>
<th>vWF</th>
<th>Fibrinogen</th>
<th>cryoprecipitate</th>
</tr>
</thead>
<tbody>
<tr>
<td>F XIII</td>
<td>(hyper) immunoglobulins</td>
<td>Fraction I</td>
<td>supernatant + ethanol</td>
</tr>
<tr>
<td>α1-Inhib.</td>
<td>albumin</td>
<td>Fraction II/III</td>
<td>supernatant + ethanol</td>
</tr>
<tr>
<td>Fraction IV</td>
<td>Fraction V</td>
<td>supernatant + ethanol</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F IX</th>
<th>PPSB</th>
<th>Protein C</th>
</tr>
</thead>
<tbody>
<tr>
<td>F VII</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AT III</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F XI</td>
<td></td>
<td></td>
</tr>
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GEA Diessel offers you:
- consultancy
- engineering
- automation
- manufacture of process vessels
- skids / units
- installation
- qualification
- assistance with validation
- after-sales service
Valve ring

Performance and quality
Whatever it is you need your process plant for – the fractionation and manufacture of products from immunoglobulins, human albumins, Factor VIII, Factor IX or whatever – our wide range of plant concepts will provide the equipment you need to meet any requirements or conditions.

By using the latest components and valve technology and the most advanced manufacturing concepts for vessels and skids, we ensure that your plant manufactures your products economically and in a way that’s kind to the source materials too.

Essential process requirements
• gentle thawing of the plasma through precise temperature control and regulated stirring
• appropriate conditions for solid/liquid separation by centrifugation or filtration to separate the plasma fractions
• special filtration techniques to gain eluate for the manufacture of Factor IX
• exact temperature control for the precipitation of all fractions
• design free of dead-leg areas
• compliance with emission regulations when dosing the precipitation medium

Technologies used
• centrifugation and filtration for solid/liquid separation
• thermal and chemical inactivation procedure
• ultrafiltration/diafiltration
• nanofiltration
• chromatography

Everything automated
GEA Diessel provides for all important parameters to be monitored by a high-performance control system, with all processes being visualised. The control system automatically administers all parameters and records and documents all data, steps and parameters that are important to the process.

CIP / SIP
An essential part of a high-quality production of blood plasma is an integrated CIP/SIP system. GEA Diessel provides efficient cleaning and sterilisation processes to meet your individual demands and to ensure the correct cleaning media is delivered to the right place at the right time. We have a large range of cleaning options from mobile, independent cleaning systems up to diverse CIP satellites fed with conditioned cleaning solutions.
Blood plasma

Complete solutions for process plant

GEA Diessel specializes in planning, construction and qualification of sterile process plant for liquids in pharmaceutical and biotechnology industry. Our process systems are operational within the area of parenterals, fermentation, feed media, blood plasma and special liquids as well as clean utilities.

GEA Diessel has 80 years of expertise and know-how in plant and equipment technology and holds a decisive position in development of modern process technology today.