Human blood plasma

Fractionation at exact target temperatures

The clear plasma phase of human blood contains about five percent valuable pharmaceutical substances with important medical applications, e.g. for controlling bleeding or for treating infections or malnutrition. However, a very narrow temperature range makes it particularly difficult to separate the individual substances from the remaining phase. Using sophisticated technologies, GEA centrifuges safely keep temperature tolerances, at the same time ensuring highest product quality as well as highest plant efficiency.

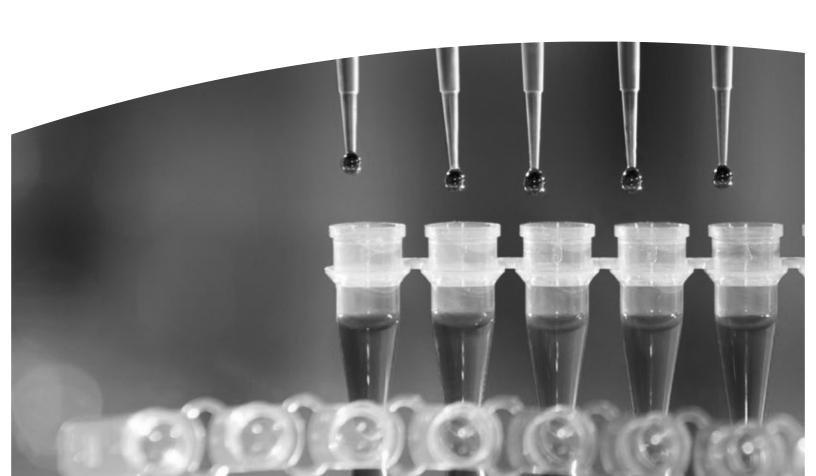
Maximum-safety cooling system

The permitted temperature range for processing blood plasma and plasma components is merely $+2\,^{\circ}\text{C}$ to $-7\,^{\circ}\text{C}$ and must be maintained under all circumstances so as not to render the sensitive product unusable. To ensure maximum safety, a direct cooling system is integrated into GEA chamber centrifuges for blood plasma fractionation. Using ethanol/water at up to $-20\,^{\circ}\text{C}$

temperature as a refrigerant, the system cools the machine bowl during operation so that the processed solids are always kept exactly at the pre-selected temperature and iso-electrical value, at no greater tolerance than +/- 1°C.

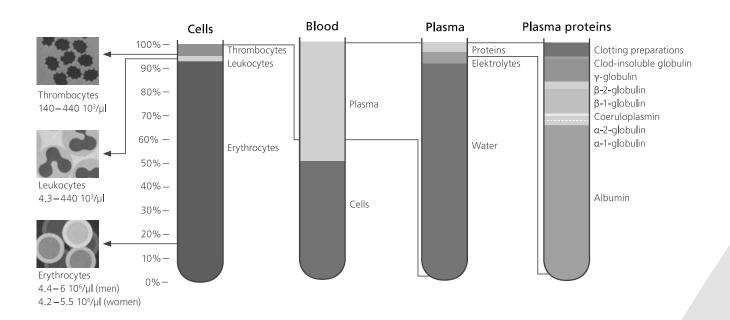
One machine type for all fractionation cycles GEA centrifuges for blood plasma fractionation can be applied to all the different steps of the Cohn fractionation process, presenting a particularly economical solution to facilitate efficient plant management as well as future changes in processes or capacities.

In preliminary steps, substances such as cryoprecipitate and the prothrombin complex (PPSB) can be separated from the fresh plasma. In further steps, the remaining plasma undergoes several chemical cycles at changing settings for temperature,



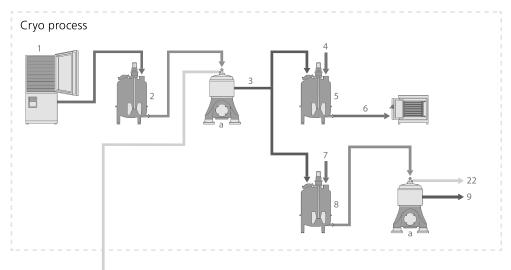
alcohol concentration and pH in order to deliver individual fractions such as fibrinogen, gamma globulin, alpha and beta globulin and albumin.

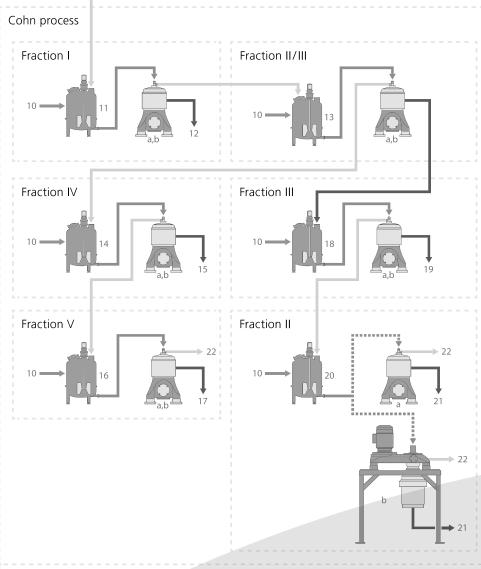
Thanks to extensive options for adjusting speed, separated particle sizes and discharge volumes, the same type of GEA centrifuge can cover all these steps at optimum performance.





HUMAN BLOOD PLASMA FRACTIONATION





Cryo process

- 1 Cold store
- 2 Thawing tank (temp. appr. 0°C)
- 3 Cryoprecipitate
- 4 Washing liquid
- **5** Washing tank (temp.appr. 0 °C)
- **6** Cryoprecipitate to freeze dryer
- **7** Buffer
- 8 Re-suspension tank (temp. appr. 0°C)
- 9 Factor VIII concentrate

Cohn process

- 10 Alcohol, pH, temperature
- 11 Protein precipitation (Alcohol content = 8 %, temp. = -3 °C, pH = 7.3)
- **12** Fraction I (Fibrinogen)
- 13 Protein precipitation (Alcohol content = 25 %, temp. = -5 °C, pH = 6.8)
- 14 Protein precipitation (Alcohol content = 40%, temp. = -5°C, pH = 5.9)
- **15** Fraction IV (- and Globulin to waste)
- 16 Protein precipitation (Alcohol content = 40%, temp. = -5°C, pH = 4.8)
- **17** Fraction V (Albumin)
- 18 Protein precipitation (Alcohol content = 8 %, temp. = -5 °C, pH = 5.1)
- 19 Fraction III (- Globulin to waste)
- 20 Protein precipitation (Alcohol content = 25 %, temp. = -6.5 °C, pH = 7.3)
- 21 Fraction II (- Globulin)
 - a Chamber bowl centrifuge
 - b hycon (two room concept with closed solids handling)

22 Waste



Maximum dryness of separated solids

Manufacturers need the fractionated solids to be as dry as possible, but without stress on the product. Based on decades of experience, GEA centrifuge technology ensures unsurpassable and reproducible quality of the product in terms of dryness, product integrity and preservation of product properties. Careful handling of the product is ensured by the hermetic inlet, which has been confirmed by CFD calculations.

Pre-configured skids with fail-safe GEA plasmacool unit State-of-the-art centrifuge models for blood plasma fractionation, such as GEA BKB 28 or the GEA BKI 45, are available preconfigured and pre-mounted on machine skids with integrated control units and connections. The latest addition to these skids is GEA plasmacool – a completely independent, dedicated cooling system for the centrifuge that ensures safe product handling at permitted temperatures.

Aseptic GEA hycon two-room concept

In addition to classic chamber centrifuges, the groundbreaking GEA hycon solution is also available for the blood plasma fractionation process. GEA hycon is a two-room system especially designed for aseptic production environments. It is equipped to operate fully automatically, avoiding the effort and risk of manual intervention.



GEA BKI 45 CENTRIFUGE SKID

The classic solution for all blood plasma fractionation stages is available on a pre-configured skid with an additional independent GEA plasmacool cooling unit to ensure a failsafe process.