ALFA WASSERMANN

Separation Technologies

Promatix 1000™

Laboratory Ultracentrifuge

From Virus to Vaccine

Bioprocess Downstream Processing Using Density Gradient Ultracentrifugation

Ultracentrifugation has been recognized for decades as a simple preparative method for small scale processing of a diverse range of biological products including viruses, virus like particles (VLPs) and nano-particles.

Continuous flow ultracentrifugation allows scale up of these laboratory preparations to enable ultracentrifugation to be used in large scale manufacture of human therapeutic products.

The Promatix 1000™ Laboratory Ultracentrifuge completes the Alfa Wassermann range of scalable continuous flow ultracentrifuges enabling laboratory researchers to use this powerful purification technology for production process development.

Promatix 1000™

Research and Development

PKII Ultracentrifuge

Pilot Plant Scale Up

eKII

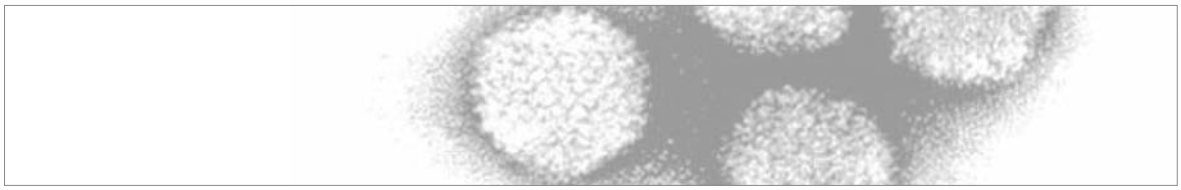
cGMP Vaccine Manufacture

cGMP Manufacture

cGMP manufacture of viral vaccines, VLPs and subcellular components using continuous flow ultracentrifugation is possible using the eKII system. The eKII core technology uses industrial design to meet the needs of manufacturing for robustness, cleaning, data security and serviceability.

The KII ultracentrifuge has been used in global vaccine manufacture for 40 years and has been continuously supported by the Separation Technologies Group of Alfa Wassermann to ensure reliability and minimize downtime making the ultracentrifuge a very cost effective option for vaccine manufacture.

Alfa Wassermann | Separation Technologies



Alfa Wassermann Separation Technologies (AWST) is the leader in ultracentrifugation solutions for process development and industrial scale manufacturing, exploiting 40 years of industry-leading continuous flow ultracentrifugation experience of its parent, Alfa Wassermann, Inc. (AWI).

The bioprocess industry has relied on Alfa Wassermann continuous flow ultracentrifuges to efficiently and reliably purify viruses in the development and manufacture of life-saving vaccines and other bioproducts.

40 years of industry-leading
continuous flow ultracentrifugation

History | Continuous Flow Ultracentrifuges

The Promatix 1000™ Laboratory Ultracentrifuge completes the Alfa Wassermann range of scalable continuous flow ultracentrifuges. Continuous flow zonal ultracentrifugation was a major development of Dr N.G. Anderson and co-workers in the AEC-NIH Molecular Anatomy Program at Oak Ridge National Laboratories. In 1967 this technique was made available commercially by Electro Nucleonics Inc (now Alfa Wassermann). Since then the worlds leading pharmaceutical manufacturers are utilizing the KII ultracentrifuge to produce purified Influenza vaccine on a large scale as well as Meningitis, Rabies, and Hepatitis B vaccines.

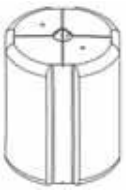
Alfa Wassermann's KII and PKII continuous flow ultracentrifuges meet all the demands of cGMP manufacturing for viral vaccines and viral vector gene therapy products. Alfa Wassermann's experience has led to the development of a sophisticated and robust ultracentrifuge suitable for running upward of 3000 operational hours a year.

Promatix 1000™ Product Handling

A versatile BioPurification system, the Promatix 1000™ Laboratory Ultracentrifuge is fully automated with hands free sample preparation and modular control sequences to perform the following steps:

> System Purge
> Gradient Load
> Acceleration to speed
> Product Load
> Product Concentration Banding
> Deceleration from speed
> Fractionation
> Sanitization

Rotor Assemblies for Density Gradient Centrifugation

Rotor Type	Application	Parameters	Capacity with Core	Dimensions
 PX3-55	For separation using isopycnic banding techniques with viral particles, virus like particles, nano-spheres. The basis of separation is the difference in buoyant densities of the particles being separated.	At 35 000 rpm Rmax: 90 500 xg Rmin: 74 600 xg K factor: 40	55 ml	Diameter: Max: 130 mm Min: 110 mm Path Length: 11 mm
 PX3-120	For separation using isopycnic banding techniques with viral particles, virus like particles, nano-spheres. The basis of separation is the difference in buoyant densities of the particles being separated.	At 35 000 rpm Rmax: 90 500 xg Rmin: 74 600 xg K factor: 40	120 ml	Diameter: Max: 130 mm Min: 110 mm Path Length: 11 mm
 PX3-230	For separation using isopycnic banding techniques with viral particles, virus like particles, nano-spheres. The basis of separation is the difference in buoyant densities of the particles being separated.	At 35 000 rpm Rmax: 90 500 xg Rmin: 74 600 xg K factor: 40	230 ml	Diameter: Max: 130 mm Min: 110 mm Path Length: 11 mm

Rotor Parameters

The rotor assembly is composed of a tubular bowl and two end caps made of Titanium Alloy. These create the housing of the rotor assembly and contain within the rotor core. The core has four (or three) flow channels and when assembled into the rotor assembly forms the flow channels down which the process material flows during operation.

Maximum Speed and Centrifugal Force : 35 000 rpm, 90 500 xg

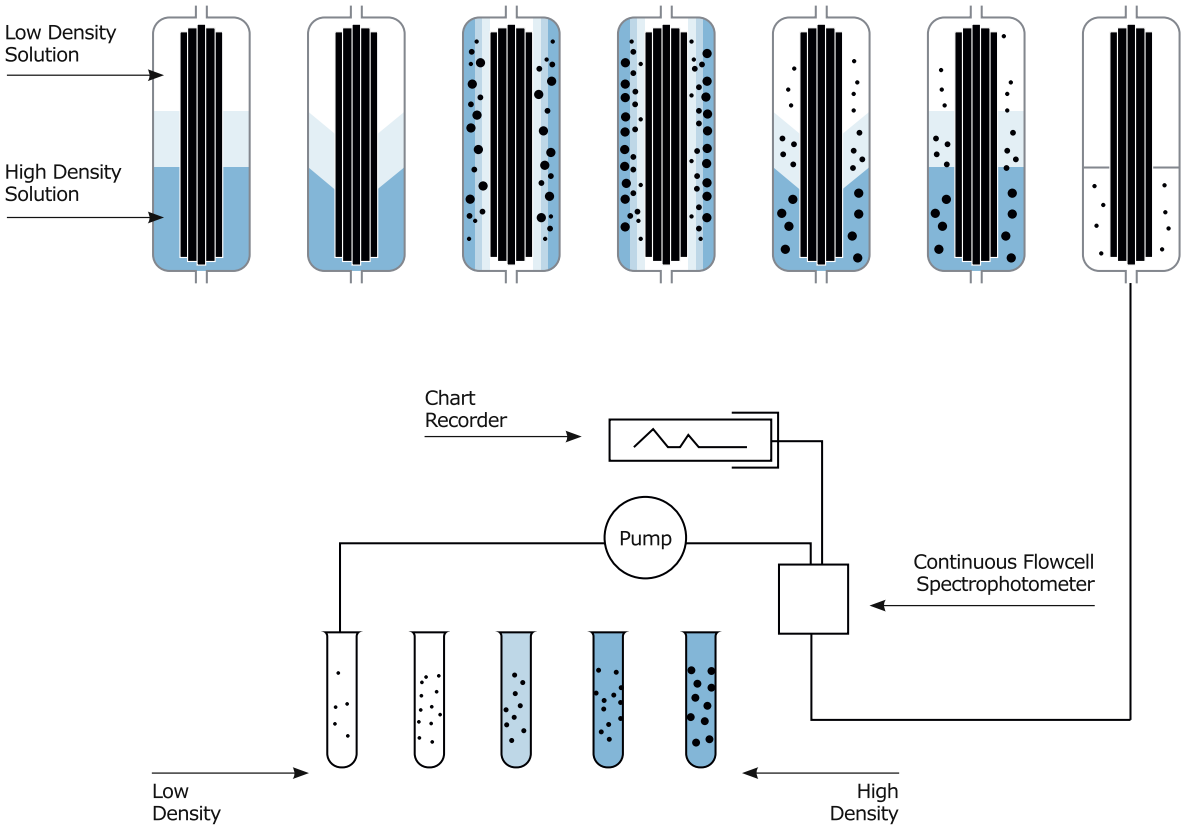
Flow Rate Range : 0 to 60 ml/min

Volume : 50ml to 10 liters

Residence Length (Core Length) : 165 mm

Zonal Density Gradient Reorientation

Step	Process
1	The density gradient is loaded into the rotor while it is at rest.
2	As the rotor is gradually accelerated, the gradient reorients itself vertically along the outer wall of the rotor assembly.
3	Once at operating speed sample fluid is pumped into the rotor on a continuous flow basis.
4	The sample particles sediment radially into the gradient of increasing density. They eventually band (iso-pycnically) in cylindrical zones where the gradient density equals a particle's buoyant density.
5	At the end of the run, the rotor is decelerated to rest.
6	The gradient reorients itself to the original position without disturbing the particle bands.
7	The banded particles are now ready to be unloaded. Fractions are collected using air or water pressure and a pump to control flow.



Parameters

Parameter	Specification
Drive and Speed	Electric Motor capable of 35 000 rpm +/- 100 rpm
Rotor Temperature	10 – 30°C
Process Flow Rates	Up to 60 ml/min
Rotor / Core Material	Rotor - Titanium Alloy, Core – Noryl®
Interface Language	English
Electrical Supply	32A, 1pH 230V
Sound Emissions	Low sound level suitable for laboratory installations
Environmental Conditions	10 to 25°C, RH 85%
Space Requirements	850 x 1280 x 1750 mm (D x W x H)
System Weight	477kg
Regulations	CE and ISO 13485 : 2003 Registered Company
Rotor Handling	Integrated Rotor Lift and Rotor Clamp for assembly
Interfaces	Fraction collection pump and fraction collector
Cleaning	Software configurable Integrated CIP and rinse cycles.

Services

The Separation Technologies Service Support Group of Alfa Wassermann has continuously supported the KII ultracentrifuges in GMP production and R&D environments for over 40 years. Highly trained Field Service Engineers are available globally to support Ultracentrifuge users.

Separation Technologies Service Team provides support 7 days a week providing maintenance, emergency callout support, and operator training programs. cGMP equipment and process validation support are provided for the entire process from FAT, SAT, IQ, OQ and PQ. Product purification, gradient development testing, and application support is provided for all new processes in development.

ДИА•М
современная лаборатория

Диаэм, Москва ■ ул. Магаданская, д. 7, к. 3 ■ тел./факс: 8 (800) 234-0508 ■ sales@dia-m.ru

С.-Петербург spb@dia-m.ru
Новосибирск nsk@dia-m.ru
Воронеж vrn@dia-m.ru
Йошкар-Ола nba@dia-m.ru
Красноярск krsk@dia-m.ru
Казань kazan@dia-m.ru
Ростов-на-Дону rnd@dia-m.ru
Екатеринбург ekb@dia-m.ru
Кемерово kemerovo@dia-m.ru
Нижний Новгород nnovgorod@dia-m.ru

мобильное приложение

www.dia-m.ru