



Adeno-Associated Virus
(AAV) Suspension Platform
AcceleratorSM Integrated Solutions

Contents

Introduction: AAV Drug Products	3
1. Cell Seeding	4
2. Cell Culture – Growth	5
3. Cell Culture – Production	6
4. Clarification	7
5. Concentration 1	8
6. Prefiltration	9
7. Affinity Chromatography	10
8. Neutralization	11
9. IEX Chromatography	12
10. Concentration 2	13
11. Bulk Filtration	14
Additional Resources	15
Equipment List	16

Illustrations and recommendations are based upon a typical process and may be subject to change based upon your individual process requirements.

AAV Drug Products

An Introduction to Today's AAV Manufacture

Over the past years we've witnessed the approval of several gene therapy products, and these much-anticipated therapies are beginning to deliver on their promise and have a radical impact on patient health. Gene therapies represent a new medical paradigm and their progress is the result of decades of research, acquired best practices, and hard lessons learned. Despite an increasing number of gene therapy drugs in development and clinical trials every year, this industry is still in its early stages. While this evolving industry is able to benefit from the experience already gained in the field of recombinant antibodies, manufacturers today are facing new issues and challenges throughout the drug marketing journey – from development and manufacture, right through to the regulatory approval of AAV-based therapies

Plan for Speed in AAV Development

In process development, speed to market and costs are critical considerations. Selecting the most suitable production system that results in fast production, high yields, and a high ratio of full-to-empty AAV capsids is key. Several producers are currently entering the market using transfection and adherent cells because it presents a fast route to market. There are however limitations to transfection-based manufacture, as typical AAV titers currently reach plateau at around 10^3 - 10^5 viral genomes per cell. Where higher yields are needed, alternative approaches are required. Developing suspension cultures or using stable producer cell lines can deliver long-term benefits for yield, scalability and cost but the additional development required may extend the time to market.

Increase Capacity and Quality in AAV Manufacture

The viral vector manufacturing capacity is estimated to be 1 – 2 orders of magnitude lower than what is needed to support commercial supply requirements both today, and in the future. All parts of the industry are therefore focused on what is needed to achieve sustainable increases in capacity. In addition to scaling out manufacturing capacity through existing and new manufacturing centers, the development of manufacturing practices that can increase productivity are ongoing. This includes optimizing cell lines and refining plasmid constructs, as well as enhancing process recovery in downstream processing. Current downstream recovery is typically only 20% and maximizing yield while meeting both product and impurity specifications provides an immediate opportunity to improve downstream processing. Recently elaborated practices in the empty-full capsid separation using scalable chromatographic methods, paired with an increasing understanding of purification conditions for different AAV serotypes, are fostering AAV recoveries and thus capacity of high-quality AAV drug product. These advances see chromatographic methods displacing older methods such as ultracentrifugation as the industry increasingly adopts scalable methods which are better suited to the industrialization of these processes.

Gain Regulatory Approval for AAV Drug Products

Moving AAV products into the highly regulated production environment puts a spotlight on the rising expectations in drug reviews as the understanding in industry and regulatory bodies is building. The much-needed regulatory framework is rapidly developing and is now supported through multiple guidance documents. Part of the challenge to obtain regulatory approval is paired with analytical constraints: viral titer, quality and impurity assays require lengthy offline processes and come with limited sensitivity. A series of next generation analytical tools are being developed and promise real-time monitoring and process analytical technology (PAT) implementation. With several approved gene therapies and hundreds of products in the pipeline, the industry knowledge is building at pace. At the same time, the regulatory framework is rapidly developing which is increasing confidence in interpreting guidelines and builds regulatory maturity in both industry and regulators. The continued connection of academia research, industry investment and regulatory commitment comes with great potential for streamlining AAV manufacturing and allows new, high-quality AAV therapeutics to reach patients.

1. Cell Seeding

When adapted for growth in suspension cell culture, cell lines for the production of viral vectors may be prepared in small volumes using shaker flasks or small glass stirred tank bioreactors. As processes scale-up to support late-stage clinical trials and production, seeding volumes also increase and batch turnaround times and process reliability increase in importance. Utilizing single-use technology throughout the seed train minimizes contamination risks, maximizes productivity and allows for seeding of production bioreactors with larger volumes at the targeted cell density.

Equipment

Allegro™ STR Single-Use Stirred Tank Bioreactor

The Allegro STR bioreactor family combines our bioprocess engineering expertise, cell culture know-how and our drive for quality into a series of single-use bioreactors. These deliver consistent and scalable cell culture performance across the range, with working volumes as low as 10 L.

Part Number (PN): STR50-230W

[Discover more](#)



Input

Allegro® 2D Standard Systems
PN: 7190-1397P

Allegro 3D Standard Systems
PN: 7190-1374W

Allegro Bioprocessing Workstations
PN: LGRTBDC, LGRTSDC, LGRTPE20L,
LGRTLPE20L, LGRTRDC

Bottle
PN: 7414-0972X

Transfer Sets
PN: 7292-1381X



Supporting

Allegro STR Bioreactor Biocontainer Bags
PN: 6412-0726H



2. Cell Culture – Growth

Additional resources 

Rocking platforms and stirred tank bioreactors are well characterized and have long been used for the commercial production of monoclonal antibodies and recombinant proteins. This heritage, coupled with user and regulatory familiarity, highlights the knowledge-base that enables the control of culture conditions that are optimized to achieve productive and reproducible processes at all scales.

Equipment

Allegro STR Single-Use Stirred Tank Bioreactor

The Allegro STR bioreactor range simplifies scale-up and grows with your process to meet demand. A working volume of 500 L is common for the production bioreactor, but this can also be used as a step in the seed train and to support larger scale production and volumes up to 2000 L.

PN: STR500-230W

[Discover more](#)



Input

Allegro 2D Standard Systems
PN: 7190-1397U

Allegro 3D Standard Systems
PN: 7190-1376T

Allegro Bioprocessing Workstations
PN: LGRUFBK, LGRTBDC, LGRTSDC,
LGRDCE, 215-19658-B4N,
LGRTP20L, LGRTLPE20L, LGRTRDC

Allegro Plastic Totes
PN: LGRPTTE500L, LGRPTTL500L,
LGRPTTEL500L

Emflon® II Filters
PN: 7090-1388M

Transfer Sets
PN: 7292-1381X, 7292-1382M

Output

Allegro STR Bioreactor
Sampling Manifolds
PN: 7190-1397G



Supporting

Allegro 3D Standard Systems
PN: 7190-1374W

Allegro STR Bioreactor Biocontainer Bags
PN: 6412-1189Q

3. Cell Culture – Production

Low shear, but effective mixing in suspension bioreactors supports rapid delivery of transfection agents to achieve high transfection yields and the production of high-quality vectors. These well characterized and scalable control parameters ensure robust and repeatable processes as production volumes increase and deliver consistent vector quality to downstream processing.

Equipment

Allegro STR Single-Use Stirred Tank Bioreactor

The Allegro STR bioreactor family delivers the critical controls necessary to assure consistent high quality and controls process risk with intuitive operation from installation to recovery.

PN: STR500-230W

[Discover more](#)



Input

Allegro 2D Standard Systems
PN: 7190-1397U

Allegro 3D Standard Systems
PN: 7190-1376T, 7190-1374W

Allegro Bioprocessing Workstations
PN: LGRTTBSC, 215-19658-B4N,
LGRUFBK, LGRTBDC, LGRTSDC,
LGRDCE, LGRTPE20L,
LGRTLPE20L, LGRTDC

Allegro Plastic Totes
PN: LGRPTTE500L, LGRPTTL500L,
LGRPTTE50L, LGRPTTEL500L

Emflon II Filters
PN: 7090-1388M

Transfer Sets
PN: 7292-1381X, 7292-1382M

Output

LevMixer® System
PN: LMG403, LM650JCMA-B4N,
7403-1352U

Transfer Sets
PN: 7292-1381X

Supporting

Allegro STR Bioreactor Biocontainer Bags
PN: 6412-1189Q

Allegro STR Bioreactor Sampling Manifolds
PN: 7190-1397G

4. Clarification

The removal of cells, cell debris, and other insoluble impurities reduces the particulate burden on downstream operations. The simplest and most economic technology used to clarify the cell culture is filtration. Low yield is a common challenge in this step, especially for the higher cell densities common to suspension processes. Finding the right combination of depth filter sheets and membrane sheets is therefore essential to optimizing both yield and performance. Our experienced technical team can help you achieve both by optimizing test protocols and process parameters, aiding selection of the best filter materials and size.

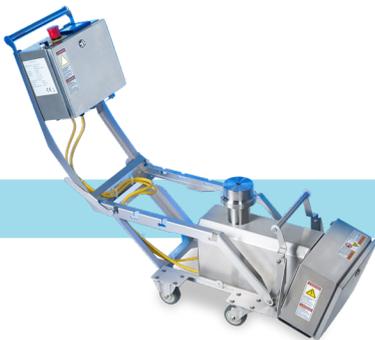
Equipment

Stax™ Depth Filters

Placed into a chassis, our single-use Stax capsules eliminate the use of stainless steel housings which require costly cleaning and cleaning validation.

PN: 7008442, 7008225, 7008602

[Discover more](#)



Input

Allegro 3D Standard Systems
PN: 7190-1374Y, 7190-1376R

Allegro Bioprocessing Workstations
PN: LGRKPCBKHD, LGRUFBK,
LGRTBDC, LGRTSDC, LGRTDCPE

Allegro Plastic Totes
PN: LGRPTTE500L, LGRPTRL500L,
LGRPTTE200L, LGRPTRL200L,
LGRPTTEL200L, LGRPTTE200L,
LGRPTRL200L, LGRPTTEL200L,
LGRPTTEL500L

LevMixer System
PN: 7403-1352U, LMG403,
LM650JCMA-B4N

Transfer Sets
PN: 7292-1381A



Supporting

Allegro MVP Single-Use System
PN: 9430-1413Q, LGRMVPAPE, CBG401A

Stax Depth Filter Vent Bottle
PN: 7090-0936X

Stax Depth Filters Chassis
PN: SXPSC10W

Output

Allegro 3D Standard Systems
PN: 7190-1376T

LevMixer System
PN: 7403-1356W, LMG403,
LM1000JCMA-B4N

Transfer Sets
PN: 7292-1381X

5. Concentration 1

Additional resources 

Ultrafiltration (UF)/diafiltration (DF) using tangential flow filtration (TFF) membranes concentrates the target molecule and exchanges buffers to support downstream chromatographic purification. Achieving high yield is a common challenge with TFF, but our technical experts can work with you to optimize your UF/DF unit operation based on experience and thorough testing.

Equipment

ÄKTA readyflux[†] XL Single-Use Filtration System

The ÄKTA readyflux XL system supports a broad flow-rate range and combines a single-use flowpath with a low hold-up volume to minimize cross-contamination and maximize yields. Multiple filtration-control features provide versatility for use in all ultrafiltration operations.



Input

LevMixer System

PN: 7403-1356W, LM1000JCMA-B4N, LMG403

Allegro Bioprocessing Workstations

PN: LGRTBDC, LGRTPE20L, LGRTLPE20L, LGRTRDC, LGRTSDC, LGRTDCPE

Allegro Plastic Totes

PN: LGRPTTE200L, LGRPTTL200L, LGRPTTEL200L

Allegro 2D Standard Systems

PN: 7190-1397U

Allegro 3D Standard Systems

PN: 7190-1374Y, 7190-1376R

Transfer Sets

PN: 7292-1381A

Supporting

ÄKTA readyflux XL Flow Kit TriClamp

PN: 29403627

Allegro MVP Single-Use System

PN: CBG401A, LGRMVPPE

Cadence[®] Single-Use Tangential Flow Filtration (TFF) Modules

PN: 7443-1437P, CSUM100T250

LevMixer System

PN: 7403-1350S

Transfer Sets

PN: 7292-1381A

C10 Manifold with TriClamp ready for ÄKTA readyflux XL

UNICORN[†] Workstation License

Output

Allegro 3D Standard Systems

PN: 7190-1376V

Allegro Plastic Totes

PN: LGRPTTE1000L, LGRTRLPT1000L, LGRPTTEL1000L

LevMixer System

PN: 7403-1350S, LM50JCMA-B4N, LMG403,

Transfer Sets

PN: 7292-1381A

6. Prefiltration

Additional resources 

Reducing bioburden through a suitable grade 0.2 µm or 0.45 µm filter is usually the next step in this process and is essential for maintaining stability and quality of the drug intermediate. The optimal filter used here can vary based on the titer and volume of material, fouling properties of the fluid, and processing time requirements. Excessive bioburden and propagation of contaminants can be easily controlled in the downstream process through strategic positioning of a well-selected filter.

Equipment

Fluorodyne® EX EDF Membrane in Kleenpak Capsules

Fluorodyne EX Grade EDF membrane in Kleenpak capsules are built for biopharmaceutical use with their durable and compact design. Using Fluorodyne EX grade EDF filters promotes higher protein transmission and a sterile cell harvest. Its prefiltration layers and bacterial retention performance combine to deliver efficient purification in intermediate and final biological process solutions.

PN: 7090-1437X

[Discover more](#)



Input

Allegro 2D Standard Systems
PN: 7190-1397S

Allegro Bioprocessing Workstations
PN: LGRTBDC, LGRTPE20L,
LGRTLPE20L, LGRTRDC

LevMixer System
PN: 7403-1350S, LM50JCMA-B4N,
LMG403

Transfer Sets
PN: 7292-1381X



Supporting

Allegro MVP Single-Use System
PN: LGRUFBK, LGRMVAPE, LGRKPCBKHD,
9430-1413G, 9430-1413Q

Output

Allegro 2D Standard Systems
PN: 7190-1397S

LevMixer System
PN: 7403-1350S, LM50JCMA-B4N,
LMG403

Transfer Sets
PN: 7292-1381X

7. Affinity Chromatography

Relying on the unimpeded interaction between the viral particles and an immobilized ligand, affinity chromatography can be an effective purification step and can achieve high specificity and high binding capacity to deliver an economic and scalable purification step. Often the challenge is the ability of affinity chromatography to capture the viral particles. When there are many serotypes, and a lack of a universal structural element to bind to, this can be overcome by structuring ligands to target specific viral serotypes.

Equipment

ÄKTA ready† Single-Use System

ÄKTA ready is a single-use liquid chromatography system built for process scale-up and manufacturing. The systems use disposable flow paths and prepacked columns that enable flexibility and speed in bioprocessing.



Input

Allegro 2D Standard Systems
PN: 7190-1397S

Allegro 3D Standard Systems
PN: 7190-1376R, 7190-1374W,
7190-1374Y

Allegro Bioprocessing Workstations
PN: LGRTBDC, LGRTPE20L,
LGRTPLE20L, LGRTRDC

Allegro Plastic Totes
PN: LGRPTTE200L, LGRPTRL200L,
LGRPTTEL200L, LGRPTTE50L,
LGRTTBSC

LevMixer System
PN: 7403-1350S, LM50JCMA-B4N,
LMG403

Transfer Sets
PN: 7292-1381L



Supporting

Transfer Sets
PN: 7291-1399Y

Resin (Suggested Capto† AVB)

ÄKTA ready Low Flow Kit

UNICORN Workstation License

Output

Allegro 3D Standard Systems
PN: 7190-1374Y, 7190-1376T

Allegro Plastic Totes
PN: LGRPTTE500L, LGRPTRL500L,
LGRPTTEL500L, LGRPTTE200L,
LGRPTRL200L, LGRPTTEL200L

LevMixer System
PN: 7403-1350S, LM50JCMA-B4N,
LMG403

Transfer Sets
PN: 7292-1381L

8. Neutralization

The neutralization and dilution step in AAV manufacture will often occur in single-use mixers. Viral constructs can be very fragile, with special buffer solutions needed to keep them stable. Carefully selected mixing technology also enables sensitive mixing at lower speeds.

Equipment

Supor EKV Membrane in Kleenpak Capsule

Validated sterilizing grade membranes for the most cost-effective filtration of a wide range of liquids such as buffers, tissue culture media, and others.

PN: 7090-1437Z

[Discover more](#)



Input

Allegro 3D Standard Systems
PN: 7190-1374W

Allegro Bioprocessing Workstations
PN: LGRUFBK, LGRTBDC

Allegro Plastic Totes
PN: LGRPTE50L, LGRTTBSC

LevMixer System
PN: 7403-1350S, LM50JCMA-B4N,
LMG403

Transfer Sets
PN: 7292-1381X

Output

LevMixer System
PN: 7403-1351N, LM100JCMA-B4N,
LMG403

Transfer Sets
PN: 7292-1381X



Supporting

Allegro MVP Single-Use System
PN: LGRMVPAPE, LGRKPCBKHD,
9430-1413G, 9430-1413Q

9. IEX Chromatography

Purity has a direct impact upon the potency, efficacy and safety of the therapy. Reliably reducing DNA and host cell proteins (HCP) increases product safety and the removal of empty capsids increases potency to reduce the risk of undesirable dose related side effects. The challenge of large-scale manufacture is to ensure the percentage of empty capsids is minimized, and the empty/full ratio is always controlled. Adsorptive membrane chromatography provides an effective option for polishing of gene therapy products.

Equipment

ÄKTA ready Single-Use System

ÄKTA ready minimizes the risk of cross contamination and reduces downtime between batches, and between products, to improve process economy and productivity.



Input

Allegro 3D Standard Systems
PN: 7190-1374Y

Allegro Plastic Totes
PN: LGRPTTE200L, LGRPTTL200L, LGRPTTEL200L

LevMixer System
PN: 7403-1351N, LM100JCMA-B4N, LMG403

Transfer Sets
PN: 7292-1381L

Output

Allegro 3D Standard Systems
PN: 7190-1376R, 7190-1374Y

LevMixer System
PN: 7403-1350S, LMG403, LM50JCMA-B4N

Transfer Sets
PN: 7292-1381L

Allegro Plastic Totes
PN: LGRPTTE200L, LGRPTTL200L, LGRPTTEL200L



Supporting

Mustang® Q XT Ion Exchange
Chromatography Capsules
PN: XT5000MSTGQP1V, XT5000B100,
XT5000H100, XT5000T100

Transfer Sets
PN: 7291-1399Y

ÄKTA ready Low Flow Kit

UNICORN Workstation License

10. Concentration 2

A second phase of concentrating the target molecule into the final concentration buffer is an optional step using TFF membranes.

Equipment

ÄKTA readyflux Filtration System

The automated system uses gamma-irradiated single-use flow kits including single-use flow path, pumps and sensors for pressure, conductivity, temperature, flow and pH. These allow a wide variety of control modes and help users to tailor the filtration controls to different processing requirements.



Input

Allegro 2D Standard Systems
PN: 7190-1397P, 7190-1397U

Allegro Bioprocessing Workstations
PN: LGRTBDC, LGRTSDC, LGRTPE20L,
LGRTLPE20L, LGRTRDC

LevMixer System
PN: 7403-1350S, LM50JCMA-B4N,
LMG403

Transfer Sets
PN: 7292-1381L



Supporting

Cadence Single-Use Tangential
Flow Filtration (TFF) Modules
with Omega™ Membrane
PN: CSUM100T010

Transfer Sets
PN: 7292-1381L

Bagkart[†] Bag Trolley

ÄKTA readyflux Flow Kit Plus TriClamp

UNICORN[†] Workstation License

Output

Allegro 2D Standard Systems
PN: 7190-1397P

Allegro 3D Standard Systems
PN: 7190-1374Y

Allegro Plastic Totes
PN: LGRPTTE200L, LGRPTTL200L,
LGRPTTEL200L

Transfer Sets
PN: 7292-1381L

11. Bulk Filtration

Manufacturing for clinical purposes requires the production of highly pure and biologically active vectors that meet regulatory requirements. A final sterilizing grade (0.2 µm) filtration step ensures the removal of any potential bacterial contamination before product is stored, frozen and sent for final filling. The knowledge that a filter is integral post-processing contributes to confirmation that a final drug product is sterile and gives assurance for patient safety prior to bulk filling. Ensuring data integrity when conducting filter integrity testing is a must to comply with the latest regulations for electronic audit trails.

Equipment

Palltronic® Flowstar V Filter Integrity Test Instrument

The Palltronic Flowstar V integrity test instrument ensures accurate filter integrity testing with a further reduction in test time, full compliance with 21 CFR Part 11, advanced automation capabilities, and simplified network integration, saving the user time while improving process efficiency.

PN: FFS05

[Discover more](#)



Input

Allegro 2D Standard Systems
PN: 7190-1397P



Supporting

Supor EKV Membrane in Mini Kleenpak Capsules
PN: 7090-1388G

Supor EKV Sterilizing-Grade Filter Cartridges

Emflon II Filters

Additional Resources

Process Description	Format	Title	Link
Cell Seeding	Poster	Scaling-Up and Industrializing the Production of Viral Vectors and Cells for Therapeutic Use	▶
Cell Culture	White Paper	Choice of Upstream Bioreactor Technologies for Industrial Scale Viral Manufacturing	▶
Cell Culture	Webinar	Gene Therapy Upstream Processing: Adherent v Suspension Cost Modelling and Perspectives	▶
Concentration 1	Poster	Optimizing the Clarification of Viral Vector Culture for Gene Therapy	▶
Prefiltration	White Paper	Understanding Single-Pass Tangential Flow Filtration and the New Era of Bioprocessing	▶
IEX Chromatography	White Paper	Scalable Purification of High Yield Adeno-Associated Virus and Lentivirus Gene Therapy Vectors Using Membrane Chromatography	▶
Overall Process	Webinar	Scalable, Single-Use Solutions for Purification of Viral Vectors	▶



Equipment List

Step No.	Process Description	Product	Part Number	Link
1	Cell Seeding	Allegro 2D Standard Systems	7190-1397P	▶
1	Cell Seeding	Allegro 3D Standard Systems	7190-1374W	▶
1	Cell Seeding	Allegro Bioprocessing Workstations	LGRTBDC, LGRTSDC, LGRTPE20L, LGRTLPE20L, LGRTRDC	▶
1	Cell Seeding	Bottle	7414-0972X	
1	Cell Seeding	Transfer Sets	7292-1381X	
1	Cell Seeding	Allegro STR Single-Use Stirred Tank Bioreactor	STR50-230W (EU), STR50-110NW (US)	▶
1	Cell Seeding	Allegro STR Bioreactor Biocontainer Bags	6412-0726H	▶
2	Cell Culture – Growth	Allegro 2D Standard Systems	7190-1397U	▶
2	Cell Culture – Growth	Allegro 3D Standard Systems	7190-1376T, 7190-1374W	▶
2	Cell Culture – Growth	Allegro Bioprocessing Workstations	LGRUFBK, LGRTBDC, LGRTSDC, LGRTRDCPE, 215-19658-B4N, LGRTPE20L, LGRTLPE20L, LGRTRDC	▶
2	Cell Culture – Growth	Allegro STR Bioreactor Biocontainer Bags	6412-1189Q	▶
2	Cell Culture – Growth	Allegro STR Bioreactor Sampling Manifolds	7190-1397G	▶
2	Cell Culture – Growth	Allegro STR Single-Use Stirred Tank Bioreactor	STR500-230W (EU), STR500-110NW (US)	▶
2	Cell Culture – Growth	Allegro Plastic Totes	LGRPTTE500L, LGRPTRL500L, LGRPTTEL500L	▶
2	Cell Culture – Growth	Emflon II Filters	7090-1388M	▶
2	Cell Culture – Growth	Transfer Sets	7292-1381X, 7292-1382M	
3	Cell Culture – Production	Allegro 2D Standard Systems	7190-1397U	▶
3	Cell Culture – Production	Allegro 3D Standard Systems	7190-1376T, 7190-1374W	▶
3	Cell Culture – Production	Allegro Bioprocessing Workstations	LGRTTBSC, 215-19658-B4N, LGRUFBK, LGRTBDC, LGRTSDC, LGRTRDCPE, LGRTPE20L, LGRTLPE20L, LGRTRDC	▶
3	Cell Culture – Production	Allegro STR Bioreactor Biocontainer Bags	6412-1189Q	▶
3	Cell Culture – Production	Allegro STR Single-Use Stirred Tank Bioreactor	STR500-230W (EU), STR500-110NW (US)	▶
3	Cell Culture – Production	Allegro STR Single-Use Stirred Tank Bioreactor Sampling Manifolds	7190-1397G	▶
3	Cell Culture – Production	Allegro Plastic Totes	LGRPTTE500L, LGRPTRL500L, LGRPTTE50L, LGRPTTEL500L	▶
3	Cell Culture – Production	Emflon II Filters	7090-1388M	▶
3	Cell Culture – Production	LevMixer System	LMG403, LM650JCMA-B4N (EU), LM650JCMA-B4A (US), 7403-1352U	▶
3	Cell Culture – Production	Transfer Sets	7292-1381X, 7292-1382M	

Equipment List

Step No.	Process Description	Product	Part Number	Link
4	Clarification	Allegro 3D Standard Systems	7190-1374Y, 7190-1376R, 7190-1376T	▶
4	Clarification	Allegro Bioprocessing Workstations	LGRKPCBKHD, LGRUFBK, LGRTBDC, LGRTSDC, LGRTDCPE	▶
4	Clarification	Allegro MVP Single-Use System	9430-1413Q, LGRMVPAPE (EU), LGRMVPAPA (US), CBG401A (EU), CBG402A (US)	▶
4	Clarification	Allegro Plastic Totes	LGRPTTE500L, LGRPTTL500L, LGRPTTE200L, LGRPTTL200L, LGRPTTEL200L, LGRPTTE200L, LGRPTTL200L, LGRPTTEL200L, LGRPTTEL500L	▶
4	Clarification	LevMixer System	7403-1356W, 7403-1352U, LMG403, LM650JCMA-B4N (EU), LM650JCMA-B4A (US), LM1000JCMA-B4N (EU), LM1000JCMA-B4A (US)	▶
4	Clarification	Stax Depth Filter Vent Bottle	7090-0936X	▶
4	Clarification	Stax Depth Filters	7008442, 7008225, 7008602	▶
4	Clarification	Stax Depth Filters Chassis	SXPSC10W	▶
4	Clarification	Supor EAV Membrane in Kleenpak Capsules	7090-1437W	▶
4	Clarification	Transfer Sets	7292-1381A, 7291-1381B, 9430-1413S, 7292-1381X	
5	Concentration 1	ÄKTA readyflux XL Flow Kit TriClamp	29403627	
5	Concentration 1	ÄKTA readyflux XL Single-Use Filtration System	29609298	
5	Concentration 1	Allegro 2D Standard Systems	7190-1397U	▶
5	Concentration 1	Allegro 3D Standard Systems	7190-1374Y, 7190-1376R, 7190-1376V	▶
5	Concentration 1	Allegro Bioprocessing Workstations	LGRTBDC, LGRTPE20L, LGRTLPE20L, LGRTRDC, LGRTSDC, LGRTDCPE	▶
5	Concentration 1	Allegro MVP Single-Use System	LGRMVPAPE (EU), LGRMVPAPA (US), CBG401A (EU), CBG402A (US)	▶
5	Concentration 1	Allegro Plastic Totes	LGRPTTE200L, LGRPTTL200L, LGRPTTEL200L, LGRPTTE1000L, LGRTRLPT1000L, LGRPTTEL1000L	▶
5	Concentration 1	C10 Manifold with TriClamp ready for ÄKTA readyflux XL	7445-1418W	
5	Concentration 1	Cadence Single-Use Tangential Flow Filtration (TFF) Modules	7443-1437P, CSUM100T250	▶

Equipment List

Step No.	Process Description	Product	Part Number	Link
5	Concentration 1	LevMixer System	7403-1356W, 7403-1350S, LM50JCMA-B4N (EU), LM50JCMA-B4A (US), LM1000JCMA-B4N (EU), LM1000JCMA-B4N (US), LMG403	▶
5	Concentration 1	Transfer Sets	7292-1381A	
5	Concentration 1	UNICORN Workstation License	29128116	
6	Prefiltration	Allegro 2D Standard Systems	7190-1397S	▶
6	Prefiltration	Allegro Bioprocessing Workstations	LGRTBDC, LGRTPE20L, LGRTLPE20L, LGRTRDC	▶
6	Prefiltration	Allegro MVP Single-Use System	LGRUFBK, LGRMVPAPE (EU), LGRMVPAPA (US), LGRKPCBKHD, 9430-1413G, 9430-1413Q	▶
6	Prefiltration	Fluorodyne EX EDF Membrane in Kleenpak Capsules	7090-1437X	▶
6	Prefiltration	LevMixer System	7403-1350S, LM50JCMA-B4N (EU), LM50JCMA-B4A (US), LMG403	▶
6	Prefiltration	Transfer Sets	7292-1381X	
7	Affinity Chromatography	ÄKTA ready Low Flow Kit	28930182	
7	Affinity Chromatography	ÄKTA ready Single-Use System	29032038	
7	Affinity Chromatography	Allegro 2D Standard Systems	7190-1397S	▶
7	Affinity Chromatography	Allegro 3D Standard Systems	7190-1376R, 7190-1374W, 7190-1374Y, 7190-1376T	▶
7	Affinity Chromatography	Allegro Bioprocessing Workstations	LGRTBDC, LGRTPE20L, LGRTLPE20L, LGRTRDC	▶
7	Affinity Chromatography	Allegro Plastic Totes	LGRPTTE200L, LGRPTTL200L, LGRPTTEL200L, LGRPTTE50L, LGRTTBSC, LGRPTTE500L, LGRPTTL500L, LGRPTTEL500L, LGRPTTE200L, LGRPTTL200L, LGRPTTEL200L	▶
7	Affinity Chromatography	LevMixer System	7403-1350S, LM50JCMA-B4N (EU), LM50JCMA-B4A (US) LMG403	▶
7	Affinity Chromatography	Resin (Suggested Capto AVB)	N/A	
7	Affinity Chromatography	Transfer Sets	7292-1381L, 7291-1399Y	
7	Affinity Chromatography	UNICORN Workstation License	29128116	

Equipment List

Step No.	Process Description	Product	Part Number	Link
8	Neutralization	Allegro 3D Standard Systems	7190-1374W	▶
8	Neutralization	Allegro Bioprocessing Workstations	LGRUFBK, LGRTBDC	▶
8	Neutralization	Allegro Plastic Totes	LGRPTTE50L, LGRTTBSC	▶
8	Neutralization	LevMixer System	7403-1350S, 7403-1351N, LM50JCMA-B4N (EU), LM50JCMA-B4A (US), LM100JCMA-B4N (EU), LM100JCMA-B4A (US), LMG403	▶
8	Neutralization	Transfer Sets	7292-1381X	
8	Neutralization	Supor EKV Sterilizing-Grade Filters	7090-1437Z	▶
8	Neutralization	Allegro MVP Single-Use System	LGRMVPAPE (EU), LGRMVPAPA (US), LGRKPCBKHD, 9430-1413G, 9430-1413Q	▶
9	IEX Chromatography	Allegro 3D Standard Systems	7190-1376R, 7190-1374Y	▶
9	IEX Chromatography	Allegro Plastic Totes	LGRPTTE200L, LGRPTTL200L, LGRPTTEL200L	▶
9	IEX Chromatography	LevMixer System	7403-1351N, 7403-1350S, LM100JCMA-B4N (EU), LM100JCMA-B4A (US), LMG403, LM50JCMA-B4N (EU), LM50JCMA-B4A (US)	▶
9	IEX Chromatography	Transfer Sets	7292-1381L, 7291-1399Y	
9	IEX Chromatography	ÄKTA ready Single-Use System	29032038	
9	IEX Chromatography	ÄKTA ready Low Flow Kit	28930182	
9	IEX Chromatography	Mustang Q XT Ion Exchange Chromatography Capsules	XT5000MSTGQP1V, XT5000B100, XT5000H100, XT5000T100	▶
9	IEX Chromatography	UNICORN Workstation License	29128116	

Equipment List

Step No.	Process Description	Product	Part Number	Link
10	Concentration 2	Allegro 2D Standard Systems	7190-1397P, 7190-1397U	▶
10	Concentration 2	Allegro 3D Standard Systems	7190-1374Y	▶
10	Concentration 2	Allegro Bioprocessing Workstations	LGRTBDC, LGRTSDC, LGRTPE20L, LGRTLPE20L, LGRTRDC	▶
10	Concentration 2	LevMixer System	7403-1350S, LM50JCMA-B4N (EU), LM50JCMA-B4A (US), LMG403	▶
10	Concentration 2	Transfer Sets	7292-1381L	
10	Concentration 2	ÄKTA readyflux Filtration System	29151000	
10	Concentration 2	Allegro Plastic Totes	LGRPTTE200L, LGRPTRL200L, LGRPTTEL200L	▶
10	Concentration 2	Bagkart Bag Trolley	29151500	
10	Concentration 2	Cadence Single-Use Tangential Flow Filtration (TFF) Modules with Omega Membrane	CSUM100T010	▶
10	Concentration 2	ÄKTA readyflux Flow Kit Plus TriClamp	29151600	
10	Concentration 2	UNICORN Workstation License	29128116	
11	Bulk Filtration	Allegro 2D Standard Systems	7190-1397P	▶
11	Bulk Filtration	Palltronic Flowstar V Filter Integrity Test Instrument	FFS05	▶
11	Bulk Filtration	Supor EKV Membrane in Mini Kleenpak Capsules	7090-1388G	▶
11	Bulk Filtration	Supor EKV Sterilizing-Grade Filter Cartridges		▶
11	Bulk Filtration	Emflon II Filters		▶

Scientific and Laboratory Services

The scientific and regulatory knowledge that supports the selection, adoption and ongoing use of critical process technology, coupled with analytical, imaging and measurement capabilities, creates a versatile and practical resource ready to respond to an ever-changing industry. Pall duplicates these laboratories across the globe and leverages their cumulative knowledge to deliver practical scientific and regulatory support to all process technologies to keep you moving forward.

Technical Services

The accessibility of local technical support networks minimize delays in your journey at all points. From the early stage of process development to on-site support for mature processes, Pall's technical support groups are there to help remove barriers to progress and to make your journey as rapid and stress-free as possible. Our knowledge of the technology and the process can be applied to everything from training to troubleshooting and consultancy. Our global team of technology experts are on hand to respond to your changing needs.

Advanced Separation Systems

Operating within the defined design space demands the monitoring and control of critical process parameters to assure product quality. Systems that control critical unit operations and that communicate with your existing process components can control process risks and maximize productivity by reducing operator involvement for many processes, Pall applies strong engineering and regulatory understanding to deliver compliant and qualified systems that safeguard and simplify your journey.

Process Development Services

Prior knowledge is a rare and valuable commodity, especially when preparing to take a new direction or when under pressure to deliver to a tight deadline. Take advantage of Pall's experience, process knowledge and technical know-how to help you achieve your goals. From the optimization of an end-to-end continuous process to establishing the right parameters for a single unit operation, our teams of scientists are ready to work with you and to generate the data you need to make the critical decisions necessary for success.

Validation Services

Arriving at your destination counts for nothing without the necessary paperwork to proceed to the next stage. Pall's Validation Services are committed to delivering the supporting data packages and analysis required to quantify process risk and to support regulatory submission. Our strengths include critical filtration technologies such as the performance validation of sterilizing grade filtration, and we are at the forefront of the evolving needs in the area of extractables and leachables for all product contact components. We combine the generation of data with interpretation and consultancy to deliver data packages that are ready for regulatory scrutiny and to ensure there are no barriers to progress.

Servicing and Maintenance

Our range of service packages keeps your equipment protected and well maintained, and includes itemized pay-as-you-go services, start-up care and training packages and a variety of post-warranty service plans that include priority response times, discounts for emergency repairs and flexible payment options. Pall service plans provide total peace of mind and worry-free support throughout the coverage period.



Corporate Headquarters
Port Washington, NY, USA
+1-800-717-7255 toll free (USA)
+1-516-484-5400 phone

European Headquarters
Fribourg, Switzerland
+41 (0)26 350 53 00 phone

Asia-Pacific Headquarters
Singapore
+65 6389 6500 phone

Visit us on the Web at www.pall.com/biotech
Contact us at www.pall.com/contact

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