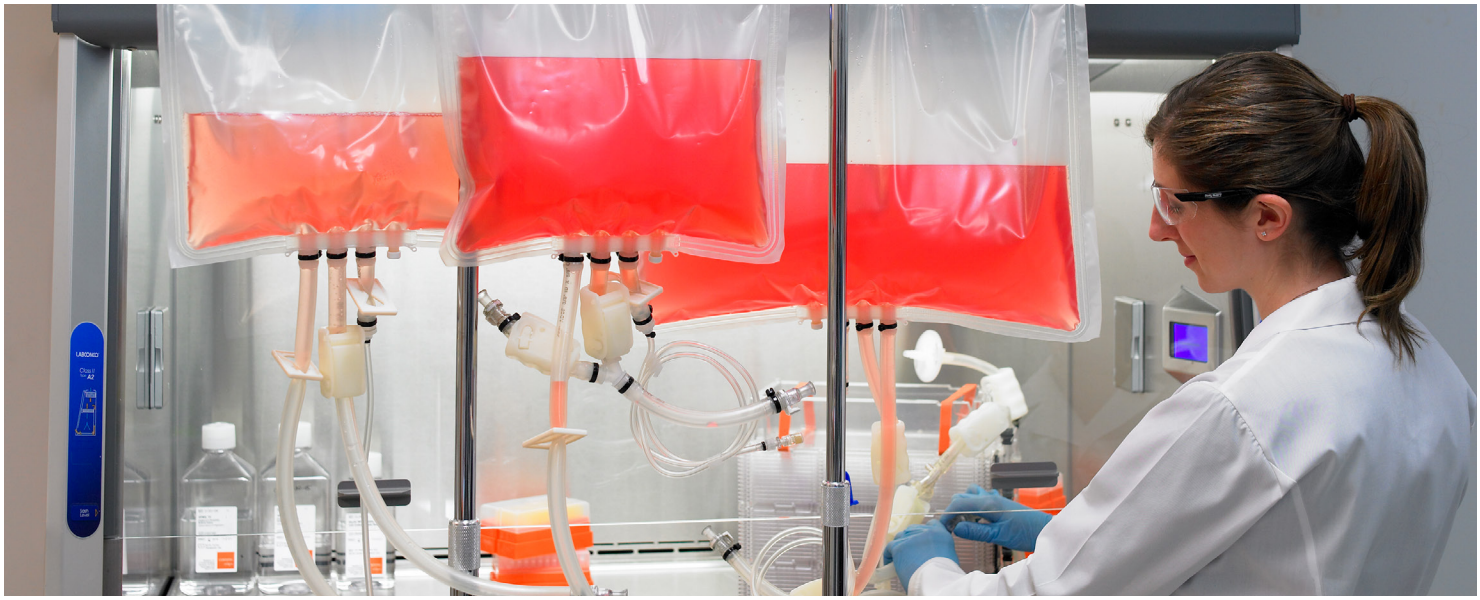
Corning® Media Manufacturing Services

Corning can support you from the lab bench to the production line so you can focus on what matters most.

CORNING



Are you looking for a steady supply of media to help accelerate your journey from the bench to the production line and bring life-changing pharmaceuticals to market? Corning's media and customized sterile solutions ensure consistent, repeatable results. Corning is ready, willing, and able to provide you with quality media – available when and where you need it. As a leader in cell culture products, we are committed to providing you with the knowledge, expertise, and hands on support to deliver what's next. We're ready when you are.

Corning® Media Capabilities

- Manufactured according to ISO 13485 and 21 CFR 820 requirements.
- Separate production for animal and non-animal products
- High quality water tested to the chemical and physical properties found in the USP and EP monographs for sterile Water for Injection (WFI)
- Sterility Assurance Level (SAL) of 10^{-3}
- Customer audits welcomed

Standard, Custom Configured, or Completely Customized

Flexibility to meet your exact requirements

With over 100 years of experience in research, product development, and manufacturing, Corning Life Sciences is uniquely positioned as a partner who can deliver an extensive portfolio of standard products as well as customized solutions. Corning also has classical media, buffered salt solutions, cell culture reagents, and other media supplements available. Please contact your local Corning Account Manager for more information.

Custom Products and Sterile Solutions Designed to Meet Functional Needs

Our custom sterile solutions support your research, development, and production needs for the following and more:

- Mammalian cell culture, insect cell culture, and microbial biopharmaceutical manufacturing
- Monoclonal antibody production
- Cell culture process development
- Tissue and cell culture manufacturing
- Drug discovery and high throughput screening (HTS)
- Vaccine manufacturing

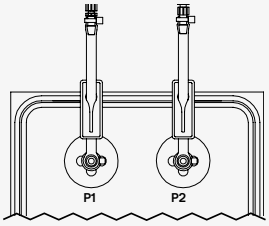
Our products can be customized to your specific application with flexibility and quality.

BATCH SIZE	BASE PRODUCT	UNIT VOLUME	COMPONENTS
▪ Liquid batch size (100 to 7,800L) - Animal (100 to 6,000L) - Non-animal (100 to 7,800L) ▪ Powder lots	▪ Standard media ▪ Sera ▪ Buffers/Salt solutions ▪ Water ▪ Reagents	▪ Liquid in bottles 10 mL to 2L ▪ Liquid in bags 1L to 200L ▪ Powder mass units g/kg	▪ Bags and bottles ▪ Raw materials ▪ Product formulation ▪ Testing specifications ▪ Labeling ▪ Packaging

Standard Bag Offerings

Our standard bag sizes include: 1L, 5L, 10L, 20L, 50L, 100L, 200L and are composed of a single-layer co-extruded film with metallocene catalyzed polyethylene as the product contact layer. Our standard bags are available off the shelf and have a quick turnaround around time to keep your work on track.

1 Liter Capacity

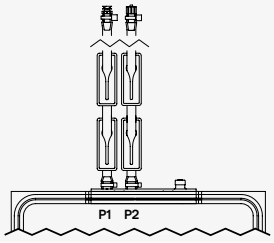


Bag Design	Film	Dimensions
04.108	Metallocene	10.5" x 7.25"

Tubing/Connector Specifications

- P1 3" length 1/4" I.D. x 3/8" O.D. PCMGS tubing; slide clamp; female Luer with 1/4" barb and cap
- P2 3" length 1/4" I.D. x 3/8" O.D. PCMGS tubing; slide clamp; male Luer with 1/4" barb and cap

5 Liter Capacity

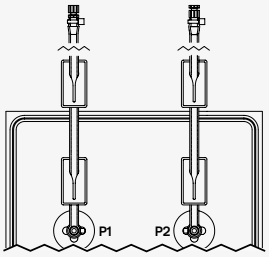


Bag Design	Film	Dimensions
04.107	Metallocene	16" x 11.75"

Tubing/Connector Specifications

- P1 30" length 1/4" I.D. x 3/8" O.D. PCMGS tubing; slide clamps; female Luer with 1/4" barb and cap
- P2 30" length 1/4" I.D. x 3/8" O.D. PCMGS tubing; slide clamps; male Luer with 1/4" barb and cap

10 Liter Capacity

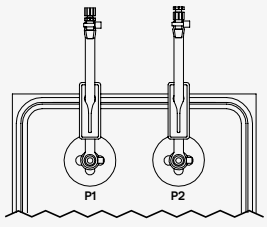


Bag Design	Film	Dimensions
04.101	Metallocene	18.25" x 17"

Tubing/Connector Specifications

- P1 24" length 1/4" I.D. x 3/8" O.D. PCMGS tubing; slide clamps; female Luer with 1/4" barb and cap
- P2 24" length 1/4" I.D. x 3/8" O.D. PCMGS tubing; slide clamps; male Luer with 1/4" barb cap

20 Liter Capacity

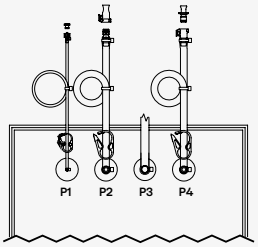


Bag Design	Film	Dimensions
04.102	Metallocene	25" x 19"

Tubing/Connector Specifications

- P1 24" length 1/4" I.D. x 3/8" O.D. PCMGS tubing; slide clamps; female Luer with 1/4" barb and cap
- P2 24" length 1/4" I.D. x 3/8" O.D. PCMGS tubing; slide clamps; male Luer with 1/4" barb and cap

50 Liter Capacity

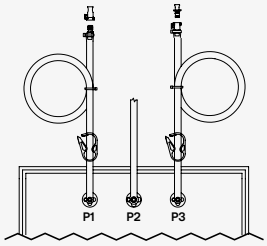


Bag Design	Film	Dimensions
04.118	Metallocene	37.5" x 21.5"

Tubing/Connector Specifications

- P1 3' length 1/8" I.D. x 1/4" O.D. chemically resistant, heat sealable, flexible tubing; pinch clamp; male Luer with 1/8" barb and cap
- P2 3' length 3/8" I.D. x 5/8" O.D. chemically resistant, heat sealable, flexible tubing; pinch clamp; male MPC with 3/8" barb and plug
- P3 Fill line
- P4 3' length 3/8" I.D. x 5/8" O.D. chemically resistant, heat sealable, flexible tubing; pinch clamp; female MPC with 3/8" barb and plug

100 Liter Capacity

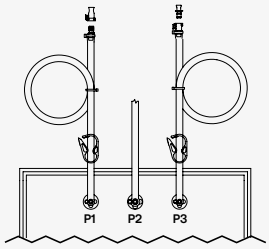


Bag Design	Film	Dimensions
04.105	Metallocene	42.5" x 30"

Tubing/Connector Specifications

- P1 5' length 3/8" I.D. x 5/8" O.D. chemically resistant, heat sealable, flexible tubing; pinch clamp; male MPC with 3/8" barb and cap
- P2 Fill line
- P3 5' length 3/8" I.D. x 5/8" O.D. chemically resistant, heat sealable, flexible tubing; pinch clamp; female MPC with 3/8" barb and plug

200 Liter Capacity



Bag Design	Film	Dimensions
04.109	Metallocene	56" x 37.5"

Tubing/Connector Specifications

- P1 5' length 3/8" I.D. x 5/8" O.D. chemically resistant, heat sealable, flexible tubing; pinch clamp; male MPC with 3/8" barb and cap
- P2 Fill line
- P3 5' length 3/8" I.D. x 5/8" O.D. chemically resistant, heat sealable, flexible tubing; pinch clamp; female MPC with 3/8" barb and plug

If the size options above do not meet your specifications, a customized bag can be created to fit your workflow. We have other size options available along with an assortment of connectors and tubing to choose from. Contact your local Corning Account Manager for more information.

Select your tubing connectors and configuration

Choose your Luer locks, MPC connector, and tubing to specifically match your needs.

Luer locks

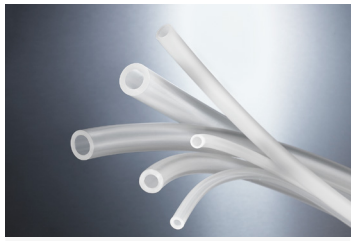
Suited for:
- Drawing samples
- Supplement addition
- Inoculation of culture

Features
- Smaller ID tubing

MPC Connectors

Suited for:
- Quick connections
- Sterile transfers

Features
- Typically has a larger ID tubing than Luer lock



Tubing

Platinum-cured medical grade silicone (PCMGS) tubing
- Compatible with peristaltic pumps
- Chemically resistant, heat sealable flexible tubing
- Compatible with tube welder

Filled Bag Options (ready-to-use)

If you are interested in classical formulations in a ready-to-use, pre-filled format, please see our options below.

	Cat. No.	Media Description	Bag Size	Design Ref No.
Classical Media and Buffers	15-013-LX	DMEM [+] 4.5 g/L Glucose, sodium pyruvate; [-] L-glutamine	10L	4.101
	15-013-LB	DMEM [+] 4.5 g/L Glucose, sodium pyruvate; [-] L-glutamine	20L	4.102
	10-013-LX	DMEM [+] 4.5 g/L Glucose, L-glutamine, sodium pyruvate	10L	4.101
	10-013-LB	DMEM [+] 4.5 g/L Glucose, L-glutamine, sodium pyruvate	20L	4.102
	15-013-LB	DMEM [+] 4.5 g/L Glucose, sodium pyruvate; [-] L-glutamine	20L	4.102
	10-040-LX	RPMI 1640 [+] L-glutamine	10L	4.101
	10-040-LB	RPMI 1640 [+] L-glutamine	20L	4.102
	15-040-LB	RPMI 1640 [-] L-glutamine	20L	4.102
	21-031-LX	DPBS [-] calcium and magnesium, 1X	10L	4.101
	21-031-LB	DPBS [-] calcium and magnesium, 1X	20L	4.102
Specialty Media	46-060-LB	Tryptic Soy Broth (TSB), animal-free, liquid	20L	4.121
High Quality Water	25-055-LB	Water, cell culture grade, tested to USP sterile WFI specifications	20L	4.102
	25-065-LB	Water, cell culture grade, tested to USP and EP sterile WFI specifications	20L	4.102
	25-055-LG	Water, cell culture grade, tested to USP sterile WFI specifications	100L	4.105
	25-065-LG	Water, cell culture grade, tested to USP and EP sterile WFI specifications	100L	4.105
	25-055-LH	Water, cell culture grade, tested to USP sterile WFI specifications	200L	4.109
	25-065-LH	Water, cell culture grade, tested to USP and EP sterile WFI specifications	200L	4.109

Cell Culture Grade Water

Cell culture grade water is high quality water suitable for use as a solvent in the preparation of cell culture media and other reagents for sensitive applications. Our bioprocess container selections are suitable for large-scale applications such as cleaning and upstream and downstream reagent preparation. Cell culture grade water goes through a wide array of testing which includes testing to the chemical and physical properties found in the USP and EP monographs for sterile Water for Injection (WFI).

	Cell Culture Grade Water	
Specification	**USP (25-055)**	**USP & EP (25-065)**
Mycoplasma	Tested negative	Tested negative
LM (plating efficiency)	Pass	Pass
Oxidizable Substances	Pass	Pass
Total Organic Carbon (before packaging) USP <643>	<500 ppb	<500 ppb
Water Conductivity (packaged water) USP <645>	✓	✓
Water Conductivity (before packaging) USP <645>	✓✓	✓✓
Endotoxin USP <85>	≤0.025 EU/mL	≤0.025 EU/mL
Sterility USP <71>	Pass	Pass
Particulate Matter USP <788>	≤25 particles/mL that are ≥10 µm in size	
	≤3 particles/mL that are ≥25 µm in size	
RNase	-	-
DNase	-	-
Protease	-	-
Acidity-Alkalinity	-	Tested in accordance with EP
Chlorides	-	Pass
Nitrates	-	≤0.2 ppm
Sulfates	-	Pass
Ammonium	-	≤0.2 ppm
Calcium & Magnesium	-	Pass
Residue on Evaporation	-	≤3 mg (0.003%)

✓ Meets USP requirements ✓✓ Meets USP temperature/conductivity requirements

cGMP Lot Manufacturing

Our products may be customized to meet your formulation, packaging, and specification needs. Please reach out to your local Corning Account Manager to learn more.

- Our products are manufactured according to ISO 13485 and 21 CFR 820 requirements.

The product is filled in a cleanroom with environmental monitoring and validated systems and utilizes cGMP raw materials and high quality water for all cleaning and formulation.

Batch Sizes	100L to 7,800L
Formats	Liquid or powder
Container Types	Bottles (10 mL to 2L) and flexible containers (bags) (1L to 200L) - Bottles can be divided into standard bottle with plug seal and standard bottle with septum cap
Lead Times	12 weeks from purchase order (based on raw material availability)
Intended Use Options	For Further Manufacturing Use
Documentation	Certificate of Analysis (CoA), additional Manufacturer's Declarations based on needs
Testing	As requested; standard testing includes sterility, endotoxin, appearance, osmolality, and conductivity

Pilot Batch Manufacturing

We can provide pilot batches ideal for development and testing purposes prior to cGMP scale-up. A summary of quality control tests performed on liquid pilot batches is available for endotoxin, appearance, pH, osmolality, and conductivity. There is no environmental monitoring, but we utilize cGMP raw materials and WFI for all cleaning and formulation and single use end point filtration for filling – sterile filtered.

Batch Sizes	5L to 100L
Formats	Liquid Only
Container Types	Bottles (10 mL to 1L) and bags (1L to 20L) Bags must have a female MPC
Lead Times	6 weeks from PO for in stock raw materials
Intended Use Options	RUO
Documentation	Summary Analysis

Manufacturing process overview

Formulation
- Weigh and dispense
- Formulate
- Sterilize

Aseptic Fill
- Bottle fill
- Flexible container fill
- Finish

Quality Control and Quality Assurance
- Release testing
- Records review
- Release

IN-PROCESS MONITORING

By partnering with Corning, you'll have a team dedicated to meeting your needs, along with:

- Flexible Supply Agreements
- Global Distribution Network
- Global Supply Chain
- Customization
- Corning Innovation

How to Purchase: For specific availability in your region and purchasing options, terms and conditions of sale, customer/product support, and certificates, visit **www.corning.com/how-to-buy**.

Warranty/Disclaimer: Unless otherwise specified, all products are for research use or general laboratory use only.* Not intended for use in diagnostic or therapeutic procedures. Not for use in humans. These products are not intended to mitigate the presence of microorganisms on surfaces or in the environment, where such organisms can be deleterious to humans or the environment. Corning Life Sciences makes no claims regarding the performance of these products for clinical or diagnostic applications. *For a listing of US medical devices, regulatory classifications or specific information on claims, visit www.corning.com/resources.

Corning's products are not specifically designed and tested for diagnostic testing. Many Corning products, though not specific for diagnostic testing, can be used in the workflow and preparation of the test at the customers discretion. Customers may use these products to support their claims. We cannot make any claims or statements that our products are approved for diagnostic testing either directly or indirectly. The customer is responsible for any testing, validation, and/or regulatory submissions that may be required to support the safety and efficacy of their intended application.

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