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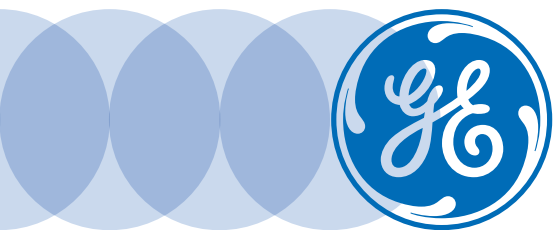
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First published Mar. 2014

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29-1051-75 AA 03/2014



HyClone™ buffers and process liquids

◀ upstream ▶ downstream 🧩 single-use 📦 services

Imagination at work.

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Proven capabilities

GE Healthcare Life Sciences HyClone cell culture products deliver validated solutions from small scale to large manufacturing. We help to optimize your process and secure your product by supplying integrated solutions for the biopharmaceutical market.

Buffers and process liquids

GE Healthcare HyClone buffers and process liquids complement our broad range of solutions for cell culture and bioprocessing. Our extensive formulation experience includes:

- Acetic acid
- Ammonium sulfate
- Citrate
- Dextrose
- Di-Sodium hydrogen phosphate
- Dulbecco's phosphate buffered saline
- EDTA
- Ethanol
- Earle's balanced salt solution
- Glucose
- Glycerol
- Glycine
- Hank's balanced salt solution
- HEPES
- Histidine
- Hydrochloric acid
- Isopropyl alcohol
- MES
- Non-ionic surfactants
- Phosphate buffered saline
- Phosphate / sodium chloride
- Phosphoric acid
- Potassium phosphate
- Propylene glycol
- Sodium acetate
- Sodium bicarbonate
- Sodium chloride
- Sodium citrate
- Sodium hydroxide
- Sodium phosphate
- Sodium phosphate dibasic
- Sodium phosphate / sodium chloride
- Sucrose
- Tris
- Tris / hydrochloric acid
- Urea
- WFI quality water

Customization and collaboration

In addition to a broad portfolio of classical formulations, we offer an extensive range of customization services. Our Rapid Response Production (RRP) program manufactures up to 200 L of your custom prototype formulation, typically within seven working days of request. Use our RRP service to expedite the development and testing of custom buffers and process liquids for your biopharmaceutical manufacturing process.

Scalability and delivery systems

Continuity in biotherapeutic and vaccine production supply

Our manufacturing facilities are designed to meet stringent regulatory requirements, while serving the global bioproduction market. With facilities around the world, we are able to provide buffers and process liquids in lot sizes and delivery systems suitable for your application.

Buffers and process liquids are produced in traditional stainless steel tanks or in single contact manufacturing systems. We also offer dedicated animal-derived component free (ADCF) mixing systems where appropriate.

For preblended powdered buffers, our pin mill powder manufacturing facility offers a high level of quality and consistency. Additionally, we offer liquid preparation technical support for hydration at your facility.



Traditional stainless steel tanks

- Up to 10 000 liter batch capacity
- Closed system sterile filling
- US and UK production sites

Single contact manufacturing systems

- Up to 10 000 liter batch capacity
- ADCF film contact surface

Powder manufacturing

- > 6000 kg powder manufacturing batch capacity
- Dedicated ADCF powder facility
- Wide range of powder delivery systems
- Global production capabilities in US and Singapore

Cost-effective

By combining our large-scale production capabilities with efficient packaging options, buffers and process liquids can be delivered to your facility when you need them, allowing your resources to focus on your core capabilities: manufacturing and delivering vaccines and biotherapeutics.

Flexible packaging

Containment of critical solutions

Buffers and process liquids can be packaged in single-use containers.

Standard shipping configurations for single-use containers include:

- Corrugated shippers for single-use container volumes in the 500 mL to 20 L range.
- Bottom-drain drums for single-use container volumes in the 50 to 200 L range.
- UN liquid-rated drums for single-use container volumes in the 20 to 200 L range.
- Palletized bins for single-use container volumes in the 250 to 1000 L range.

Customized shipping containers

We have a wealth of experience in providing buffers and process liquids in large-volume delivery systems. These systems have been extensively tested for product integrity and comply with internationally recognized transportation requirements. Additionally, we work with clients to customize delivery systems that support ease of use in your facility.



Customer-focused solutions

Requirements for buffers and process liquids often entail unique formulations, volumes, packaging, quality control testing, and delivery schedules. We have met these unique requirements in numerous situations, including the following examples.

Case study: US pharmaceutical company

- Multiple buffer formulations (10 +)
- Custom single-use containers ranging from 20 L to 200 L
- Annual volume range from 64 000 L in year one to 795 000 L in year seven
- Shipped from Logan, Utah to Northeastern US

Case study: West European pharmaceutical company

- Multiple custom buffer formulations (10 +)
- Customer-specified quality control testing
- Custom 1 000 L single-use containers delivery systems
- Collapsible, returnable shipping/storage containers
- Annual volume range from 105 000 L in year one to 419 000 L in year four
- Manufactured and shipped locally from the UK



Stability testing support

Committed to quality...every step of the way

With rigorous quality management systems, we consistently meet internationally recognized regulatory requirements and customer expectations throughout our collaborative process. As one of the leading suppliers of cell culture and bioprocessing products, we provide innovations and advances in cell culture that continually expand our knowledge and expertise.

Stability testing support

- Our analytical laboratory supports your stability testing requirements
- Our stability of process liquids data sheet provides summary stability test data for model formulations
- Our data sheet library provides detailed stability testing protocols and results

Leachable and extractable testing support

- Leachable and extractable data is available for our high performance film
- Custom leachable and extractable testing is evaluated upon request

Quality systems

Our robust vendor management program enables sourcing from qualified and audited raw material suppliers.

- Multiple, qualified raw material sources for risk mitigation and contingency planning purposes
- Raw materials meeting our quality, USP, EP, and/or JP requirements

Improved performance through quality management

- Meeting your documentation and regulatory requirements
- Consistent procedures and raw materials, for lot-to-lot equivalence across global manufacturing sites
- Animal-derived component free (ADCF) manufacturing segregation with single-use liquid management systems
- Single-use advantages alleviate cleaning, validation, and cross-contamination concerns
- EudraLex Annex 1 aligned manufacturing capabilities

Validated and documented processes

Products manufactured following:

- Medical device current good manufacturing practices (cGMP) 21 CFR 820
- ISO 13485 (2003) for medical devices
- ISO 9001:2008



A history of innovation

We strive to be the leading supplier of quality solutions for challenges faced in the biopharmaceutical industry and cell culture-based research. Our commitment to provide the most innovative tools to facilitate advanced research and bioproduction is the foundation for all HyClone cell culture buffer and process liquids products.

For more than 45 years, our product experts have remained dedicated to the advancement of science through

the support of cell culture in academic research and bioprocessing environments.

As a global manufacturer of sera, liquid and powdered media as well as process liquids that support research and the production of biopharmaceuticals, our products continue to meet the high quality standard of the industry.

