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Biological Buffers For Diagnostics Manufacturers



SAFC Supply Solutions™
| Inspiring Science

www.safcsupplysolutions.com

SIGMA-ALDRICH®

Biological Buffers

Quality Systems You Can Trust

Unrivaled experience with biological buffers

SAFC® understands how important the right buffering systems are for protecting the integrity of your valuable proteins. For over 25 years we have been a primary manufacturer of high quality biological buffers, and have developed unrivaled scientific knowledge, analytical capabilities and technical support for these products in our industry.

Quality systems you can rely on

SAFC's buffer products are routinely used in diagnostics applications. To ensure manufacturing these products meet your strict regulatory requirements, we base our quality systems on ICH Q7A guidelines.

Consistency of products to help standardize your processes

SAFC's buffer manufacturing has implemented the use of Failure Mode and Effects Analysis (FMEA) to evaluate our processes. FMEA has allowed us to identify potential sources of variability in these processes and to put in place the necessary controls to ensure batch-to-batch consistency, to make sure that you get the same high quality product, time after time.



| ICH Q7A Section | SAFC Quality System |
|------------------------------------|---|
| Quality Management | <ul style="list-style-type: none">• Critical parameters identified via Failure Modes and Effects Analysis (FMEA) process and controls put in place• Critical deviations investigated by Material Review Board (MRB); non-critical deviations investigated by Manufacturing• Release based on QA review of Manufacturing, Packaging and QC |
| Personnel | <ul style="list-style-type: none">• Training curricula in place for Manufacturing, Packaging and QC |
| Buildings and Facilities | <ul style="list-style-type: none">• All critical equipment calibrated |
| Documentation and Records | <ul style="list-style-type: none">• Full change control, QA maintenance and issuance of master batch records and operating procedures via validated electronic document control system• QA maintains executed batch records in a controlled environment |
| Materials Management | <ul style="list-style-type: none">• ID testing performed on all incoming raw materials• Test minimum of three lots, then accept on Certificate of Analysis• Establishing specification agreements with vendors |
| Production and Process Controls | <ul style="list-style-type: none">• Verification of all critical steps by second person• Acceptable yields established based on statistical model |
| Laboratory Controls | <ul style="list-style-type: none">• Retention samples kept for all items |
| Validation | <ul style="list-style-type: none">• Cleaning verification protocol approved and executed• Retrospective review of equipment documented, system in place for Installation Qualification/Operational Qualification (IQ/OQ) of new equipment |
| Change Control | <ul style="list-style-type: none">• Formal quality agreements and change notification available in accordance with Q7A and IPEC guidelines |
| Rejections and Re-Use of Materials | <ul style="list-style-type: none">• Reprocessing/rework controlled by Material Review Board as per approved SOP's |
| Contract Manufacturers | <ul style="list-style-type: none">• Contract manufacturers evaluated via approved Vendor Qualification Program and are subject to full change notification |

World-class analytical capabilities for buffers

For our biological buffer products, SAFC® routinely assays for the following chemical parameters to verify their consistency:

- Purity
- Appearance
- UV Absorption
- Water Content
- Trace Metals

In addition, to ensure appropriateness for your specific processes, we can perform custom testing such as:

- Cytotoxicity
- Bioburden
- Endotoxin
- Nuclease/protease
- Specific trace impurity profiles

Capacity to meet your current and future needs

As one of the world's largest manufacturers of biological buffers, we have the capacity to meet your buffer needs, now and in the future.

Customization capabilities for powder and liquid buffers

Customized blending, packaging, testing and manufacturing options to meet your specific needs is routine for SAFC.

We manufacture custom sterile liquid buffers/salts/reagents solutions and concentrates under cGMP conditions and supply them in customized BIOEAZE™ disposable bag systems, in a wide range of volumes to 500 L.

Let us show you how custom solutions and concentrates from SAFC can accelerate your diagnostic manufacturing process and save you time and money through:

- Elimination of buffer preparations
- Elimination of cleaning validations
- Streamlining and controlling your supply chain
- Ensuring consistent results from consistent starting materials

Sample Buffer Listings

| Catalog Number | Description | Standard Batch Size (Kg) |
|----------------|------------------------------------|--------------------------|
| A0153 | Ada Disodium | 1,000 |
| A1925 | Ada Monosodium | 1,000 |
| A6659 | Ampso Free Acid | 800 |
| A1911 | Ampso Sodium | 500 |
| B9879 | Bes Free Acid | 1,000 |
| B2891 | Bes Sodium | 1,000 |
| B3876 | Bicine | 1,000 |
| B9754 | Bis-tris Free Base | 1,000 |
| B6032 | Bis-tris Hydrochloride | 500 |
| B6755 | Bis-tris Propane | 1,000 |
| C2632 | Caps | 500 |
| G2879 | Glycine Hydrochloride | 1,000 |
| G1002 | Gly-gly Free Base | 600 |
| G1127 | Gly-gly Hydrochloride | 100 |
| G4505 | Guanidine Hydrochloride | 1,000 |
| H3375 | Hepes | 1,000 |
| H7006 | Hepes Sodium | 1,000 |
| M8250 | Mes Free Acid | 1,000 |
| M0895 | Mes Potassium | 1,000 |
| M5057 | Mes Sodium | 1,000 |
| M1254 | Mops Free Acid | 1,000 |
| M9381 | Mops Sodium | 600 |
| P3768 | Pipes Disodium | 1,000 |
| P6757 | Pipes Free Acid | 1,000 |
| T5130 | Taps Free Acid | 500 |
| T1375 | Tes Free Acid | 1,000 |
| T0377 | Tricine | 1,000 |
| T1502 | Triethanolamine HCl | 1,000 |
| T1503 | Trizma Base Reagent Grade | 750 |
| T3253 | Trizma Hydrochloride Reagent Grade | 1,000 |