Chemical Dilution Skids DATASHEET
Version 2.2

SUNCOMBE
CIP, BIOWASTE & PROCESS SOLUTIONS

Chemical Dilution Skids

The Biotech, Pharma and Critical Application cGMP Validatable Caustic, Base or Acid Chemical Dilution, Heated, Control and Delivery System

Overview

These skid mounted systems provide a robust and repeatable method of diluting, heating, controlling and delivering caustic, base and acid chemical solutions.

Skids comprise all the necessary water storage tanks, heaters, pumps, valves, pipework and related components and instrumentation to dilute, heat, control and delivery the solutions. Type, quantity and physical sizes of components are determined during the design phase of each project to suit the required application.

System construction and components are suitable for sanitary use in pharmaceutical, biotech and other hygienic applications.

Systems include a user-configurable recipe based control system to suit a wide range of applications and are pre-assembled and fully tested with operating utility supplies in our works to minimise risk and optimise installation and validation time on-site. Systems comply with all applicable regulatory standards and are accompanied by a comprehensive suite of documentation covering all aspects of installation, operation and maintenance. Extended documentation packages can be supplied to meet specific validation needs.

Constructed to cGMP, a lifecycle approach is adopted (DQ, FDS, HDS, SDS, FAT, SAT, IQ & OQ), with validation being key to every stage of the development process, including Factory Acceptance Testing (FAT), SAT and Qualification. All functions of the equipment would be fully wet and dry tested and test results would be documented in the FAT protocol.

Applications

- ✓ Dilution
- ✓ Heating
- ✓ Control
- ✓ Delivery
- ✓ Chemical Routing
- ✓ Water Delivery
- ✓ and many more in Pharmaceutical, Biotech and other Critical process industries.

GMP Construction

- ✓ FDA approved components with no threads and triclamp connections
- ✓ ASME BPE 316L no dead legs, fully drainable, material & weld traceability
- ✓ Control and instrumentation to GAMP5
- ✓ Repeatable, validatable client configurable sequences
- ✓ Riboflavin proof of coverage

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Welcome

Since our foundation in 1961, Suncombe has pioneered the development of innovative solutions for Cleaning In Place, BioWaste decontamination, GMP Washers, GMP skids, Sanitary Tanks and Vessels. The business continues to be privately owned and managed day to day by Dave Adams and Steve Overton.

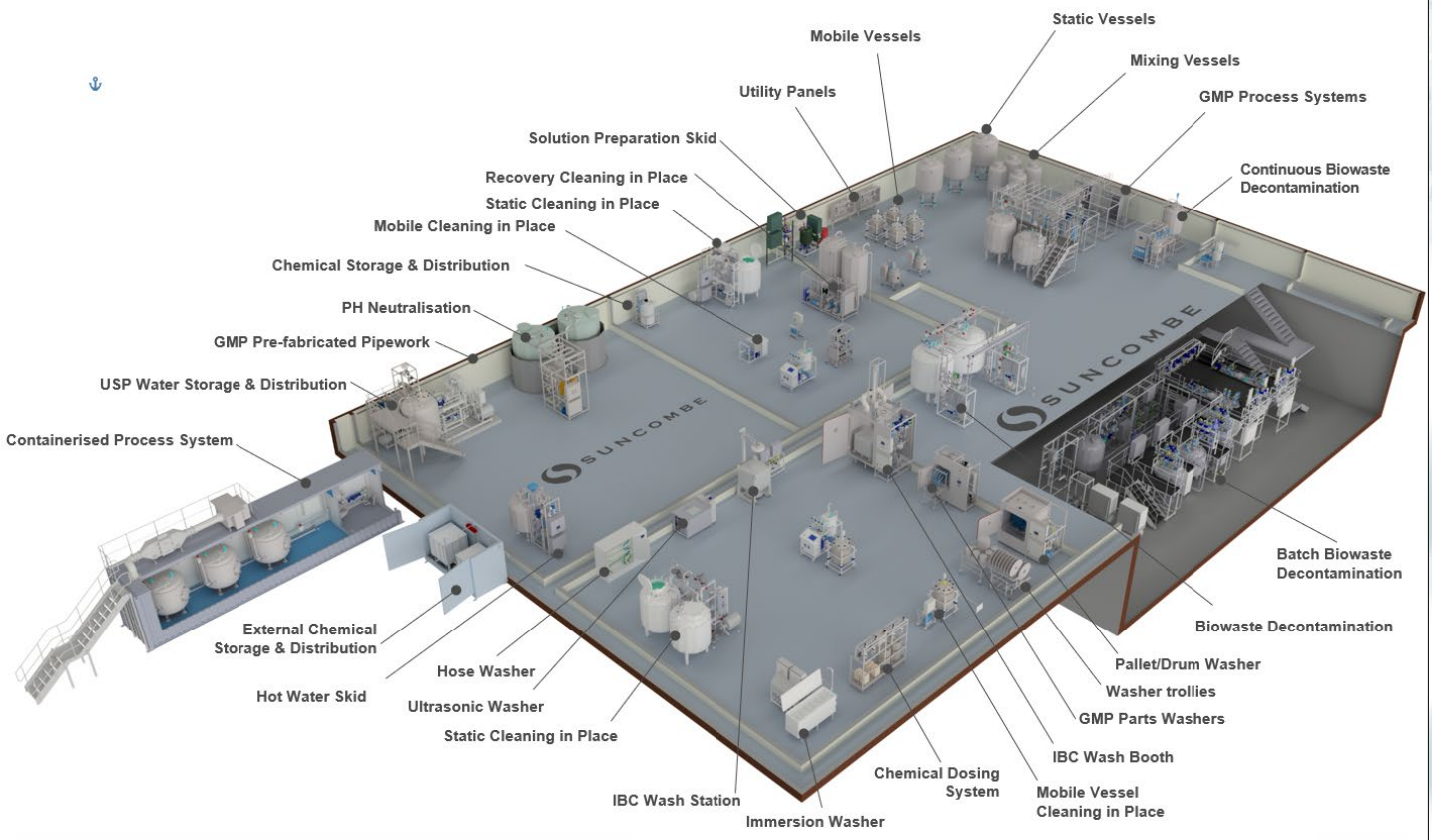
Supporting Dave and Steve is a close-knit, dedicated, highly motivated and long-standing team encompassing a wealth of technical experience and knowledge in all relevant disciplines, including design, manufacture, testing, installation, validation, documentation and after-sales support. All of our work is carried out across our own facilities, just off the M25 in north London.

The team employ the very latest techniques, standards and best in class solutions. Having such a strong team allows us to offer the ability to carry out all of our work in-house, under our direct control and

Our policy is to re-invest much of our profits into continuous development of our staff and our facilities, together with Research and Development to provide the optimum technical solutions for our clients requirements.

Our Clientele

Our Equipment



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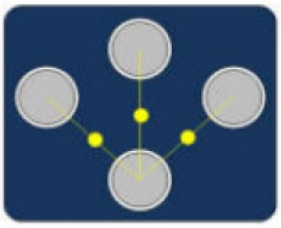
Key Features	Benefits
Sanitary 316L stainless steel construction and components	Caustic and chemical are maintained at the highest sanitary standards complying with ASME BPE offering guaranteed surface finishes with diaphragm valves, full material traceability, weld maps and tables and welding dossier.
Variable Duty Delivery Pump	316L Stainless Steel Heavy Duty Sanitary Pumps with Variable Speed Drive to allow speed control to vary the delivery flowrate and pressure from the recipe, complete with PID loop and automatic impellor casing drain valve
Siemens PLC and 12" colour HMI with options for additional HMIs	Control hardware is industry standard and supported worldwide by Siemens. Ethernet interface included for transfer of critical operating variables to other systems. Designed to enable integration to third party equipment or higher level control system. Versions also available with remote I/O for control by clients control system.
Suncombe SmartCIP™ software	Control software specification has been developed and proven over many years for process applications and includes a wide range of user or administrator configurable parameters to enable customised cleaning recipes, including water flow, pressure, time, temperature, chemical concentration and many more. User passwords, Active Directory, Audit Trails, Electronic batch reports for local or network storage are possible. User interface screens and process visualisation is simple, intuitive, clear and comprehensive. Remote access options are possible if required. Software complies with FDA 21CFR and EU GMP regulations.
Vessel/s	316L Stainless Steel Pressure vessel with heated 0.2µm Vent Filter, bursting disc, sanitary construction with riboflavin tests. Water storage or chemical make-up vessels.
Steam, hot water/oil or electric water heating options	Solutions can be heating energy may be derived from most convenient and cost-effective source available.
Heated Solution Preparation	Heated solutions can be batch made up in vessel or using In-Line Heating validated method
USP Water	1, 2 or 3 water inlets for Soft Water, Purified Water and Water for Injection. Water can either fill vessel or bypass vessel for direct application.
Continuous monitoring of key parameters	Process is highly repeatable and validatable.
Variable chemical dosing	Delivery of 1, 2, 3 or 4 chemicals is controlled.
In-line or batch chemical dosing	Chemical solutions can be batch made up in vessel or using optional In-Line Dilution validated method with flowmeter. Option for conductivity concentration verification.
Return	Skid prepared to accept return of fluids
Plug 'n' Play	Fully integrated with comprehensive in-house testing to ensure fast start up on site
Caustic/Chemical Distribution	A single outlet is included. Options available for up to 10 separate outlets for feeding to different items. Each outlet can be a single or double valve for isolation. Distribution can also be via flowplate/splitter panel.  Typical flowplate/splitter panel
Solution Cooling	Coolers can be added for colder rinses
Air Purge	Includes air purge facility to evacuate all water from the pipework
Fully Drainable	Automatic valves to fully drain entire skid including pump casing
Instruments	Sanitary instruments of Endress and Hauser/Mettler Toledo or equivalent with full material and calibration certification.

Our Sustainability Operations

Sustainability of Suncombe Equipment

As a company, we recognise the importance of sustainability and the need to minimise our environmental impact. All Suncombe equipment has been re-developed for sustainability purposes and incorporates techniques and methodologies to minimise impact on the environment, including technologies that reduce energy consumption, emissions, and waste, as well as adopting practices that promote sustainability and reduce the environmental impact of operations.

Social Responsibility

Our company philosophy is one of Social Responsibility and under this banner we are fully committed to the need to balance economic growth with environmental stewardship and social responsibility.

Overall, Suncombe demonstrates a commitment to sustainability and environmental responsibility in our operations and products. For further details Suncombe have produced Sustainability and Lifecycle White Papers available **on request**

Here are some of the ways we achieve this:

- ✓ Efficient use of resources: Suncombe uses energy-efficient technologies in our equipment, which helps to reduce energy consumption and carbon emissions.
- ✓ Waste reduction: Suncombe strives to reduce waste throughout our operations, from manufacturing to product disposal. We use sustainable materials and designs that minimise waste and maximise product lifespan.
- ✓ Recycling: Suncombe promotes recycling and reusing of materials to reduce waste. We also recycle our own equipment where possible.
- ✓ Compliance with regulations: Suncombe adheres to environmental regulations and standards set by governing bodies, ensuring that our operations do not harm the environment.
- ✓ Green initiatives: Suncombe invests in research and development of new, sustainable technologies and processes to further reduce our environmental impact.
- ✓ Lifecycle Considerations: The company emphasizes the entire lifecycle of our equipment, from design and manufacturing to use and disposal. We strive to select materials and components that are environmentally friendly and can be recycled or disposed of responsibly. Featuring design with margin, upgrading and future-proofing extends the equipment lifecycle.