

PureCIP™ 313 Cleaning In Place System

Suncombe Ltd, Jade House, Lockfield Avenue, Brimsdown, Enfield, Middlesex, EN37JY, United Kingdom *T*+44(0)20-8443-3454 *F*+44(0)20-8443-3969 *E* info@suncombe.com *W* www.suncombe.com









GMP Process Systems

Biowaste Decontamination

Continuous Biowaste Decontamination

Batch Biowaste Decontamination Sunc

¢

PureCIP[™] 313 Cleaning In Place System

PureCIP[™] Cleaning In Place Systems Introduction

Suncombe PureCIP[™] Cleaning In Place Systems have been developed over the last 30 years for providing a robust, reliable means of supplying repeatable, validatable, controllable CIP cleaning. Every unit is specifically designed for its particular application and is developed by Suncombe CIP engineers together with the client personnel to provide the optimum cleaning system and a simple validation trail. The systems are based on standard modules with individual units custom designed and built - in-house - for your specific application. Automatically operated, the systems are used for cleaning tanks, Vessels, Vats, Fermenters, Mixers, Processors, Pipework, Valves, Isolators, Glove Boxes, Mills, Coaters, Filters, Pumps, Dryers, Tumblers, Fillers and many other applications. The standard system is designed for safe area and non-flammable fluids; ATEX versions are available if required.

Standards

Built to hygienic and sanitary standards and available to comply with ASME BPE, GAMP and 21CFR11, the PureCIP[™] Cleaning In Place Systems are supplied worldwide to the Biotech, Pharmaceutical, Medical, Healthcare, Personal Care and other critical processing industries.

Typical PureCIP™ 39172 Static Version

Cleaning Philosophy

Total loss cleaning philosophy is when the CIP fluids are used for the duration of a single clean and then discarded; this is the preferred method for critical applications. The PureCIP™s can recirculate the CIP solutions; there is an alternate method, which uses the CIP solutions as a single use and does not recirculate. This type of system is sometimes used where it is undesirable to allow the possibility of recontamination of the vessel or pipework by the recirculated product, or where installing return pipework to the CIP system is impractical. PureCIP[™] systems are designed to operate either method.

Typical Manufacturing Standards*

- Sanitary Construction, fully drainable, crevice free.
- T.I.G. Welding

*See Equipment Standards Datasheet for full details

Typical Equipment*

- 316 Stainless Steel pipework
- Sanitary Centrifugal Pump •
- Sanitary Valves, manual and air operated
- Steam heating
- **Calibrated Instruments**

*See Equipment Standards Datasheet for full details

Automation System*

The Integrated automation is designed to be operator friendly and simple to use whilst providing flexibility and optimisation. Reliable and robust, they have been developed over the last 20 years, they encompass all elements required to provide a controllable, repeatable automatic system. A range of automation levels are available, starting Versatile automation system allows you to build your own recipes from pre-commissioned steps in any order. The variables in each step can be individually configured. The system can either be run as a single pass, so that the wash liquid goes directly to drain after CIP or can be used in recirculation mode, so that the CIP recirculates the liquid for a pre-set time.

*See Automation Datasheet for full details





Two PureCIP™s in Construction

316 stainless steel contact parts, 304 non-contact parts,



Key Features

- 316L Stainless steel wetted parts .
- Sloping design and smooth, crevice-free construction
- EPDM, PTFE FDA-approved elastomers and tri-• clamp connections
- Enclosed head orbital welding to EN287/15614 •
- 316/304 stainless steel non-wetted parts
- 50 to 3000 litre storage vessels with double wall insulated construction to reduce electricity consumption and heat loss
- Atmospheric vents or heated vent filter options ٠
- **BioPharma Diaphragm valves**
- Certified surface finishes to 0.4 ra and optionally electropolished
- Large hygienic variable speed delivery pump
- **BioPharma instrumentation** .
- Fully self-draining including pump housing
- Steam heated using double plate or shell and tube heat exchangers
- One to four detergent dosing systems including dosing confirmation
- Fully adjustable cycle parameters including ٠ temperatures, pressures and times
- Conductivity controllers for detergent concentration and pure water.
- CIPSuite[™] Control Systems with a colour graphic ٠ operator interface for visualisation
- Password control •
- Up to 100 Fully configurable recipes
- In built troubleshooting and diagnostic ability
- USB port for connections to desktop printer ٠
- Desktop printer for printouts of operation
- Easy maintenance
- Final rinse recirculated or non-recirculated to eliminate possibility of cross-contamination between rinses.
- Can be fitted with stainless steel or clear covers
- ATEX versions available for solvent use and/or • aqueous use in zoned areas

PureCIP[™] 313 Cleaning In Place System Model





Common Options	
SIP/SOP Modules	Conductivity Sensors
Remote Control Panel	Validation Reports
Mobile or Static	21CFR11 Compliance
316 Stainless Steel Framework	access platform or step to pro- vide access to vessel top
Drain Cooler	Electrical Heating
Sampling Points	
Ribbon Printer	

LEAN Technology

Adopting LEAN principles, the washers were developed to minimise utilities and wash times, whilst ensuring the safety of the operators and the efficiency of the processing. Our automated systems are configured to incorporate LEAN principles including Overall Equipment Effectiveness, Energy Lean and minimise downtime maintenance.

Testing

All functions of the equipment would be fully wet and dry tested and test results would be documented in the 'Pre-Factory Acceptance Test' (FAT) protocol. Following successful completion of this protocol, the client will be invited to the FAT test, where all tests can be repeated or the pre-FAT tests results can be used.

Validation/ Documentation

The 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.

Time



Typical Cycle	
Pre-Rinse	Deliver water as a sin
Chemical Rinse	Deliver chemical — re
Inter-rinse Rinse	Deliver water as a sin
Final Rinse 1	Deliver water as a sin
Final Rinse 2	Deliver final quality wa
Air purge	Removes water from
Gravity Drain	System Drain

- ngle pass rinse
- ecirculate
- ngle pass rinse or recirculate
- ngle pass rinse
- ater as a single pass rinse
- pipework



PureCIP[™] 313 Cleaning In Place System Layouts with Multiple CIP Vessels

2 Tank version - Straight Orientation

1 Tank version

2 Tank version - 'L' Orientation





Part #	Dimensions					
	Vessel Capacity litres	Flowrate litres per minute	Width mm	Depth mm	Height mm	
1 Tank Version						
PureCIP [™] 313—750	750*	0—300	2500	1400	2500	
2 Tank Versions						
Straight Orientation						
PureCIP™ 313—750	750*	0—300	3800	1400	2500	
'L' Orientation						
PureCIP [™] 313—750	750*	0—300	2500	2800	2500	

*Dimensions shown with 750 litre vessels — 50 to 3000 litre storage vessels available









Height

PureCIP[™] 313 Site Layout Model

