



**SUNCOMBE**  
CIP & PROCESS ENGINEERS

# Solution Preparation



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## About Us

Suncombe is the UK's largest supplier of Cleaning in Place and Hygienic Processing Systems. We are experts in our field and have the resource and technology to manage any Cleaning in Place and Hygienic Processing project.

We can provide standard or bespoke fully packaged units and skids, as well as taking on your full project requirements. All of our units are environmentally friendly, incorporate the latest technologies and are built in house to your industry standards.

## Introduction to Solution Preparation Systems and Formulation Systems

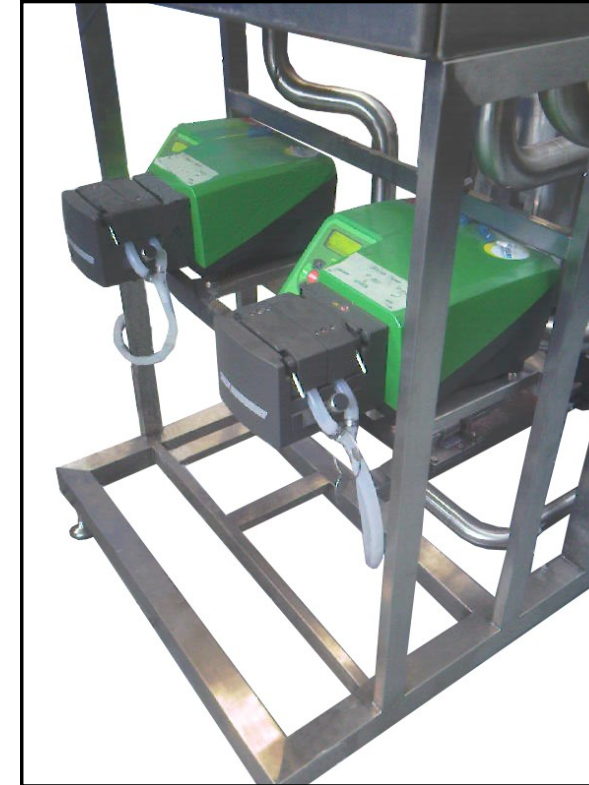
Suncombe have been manufacturing Solution Preparation Systems and Formulation Systems for in excess of 45 years. Solution preparation requires detailed design to ensure that the formulation and preparation of your Solutions are carried out in an exacting controlled and contained manner. Our engineers and designers pay exacting attention to ensure the precise, efficient and safe operation of your Solution Preparation Systems and Formulation Systems.

## Modelling

Utilising Industry Standard Autocad 3D tools, the solutions are extensively modeled to provide a virtual model of the solution, which is reviewed and updated to provide an immediate indication of any optimization and developments



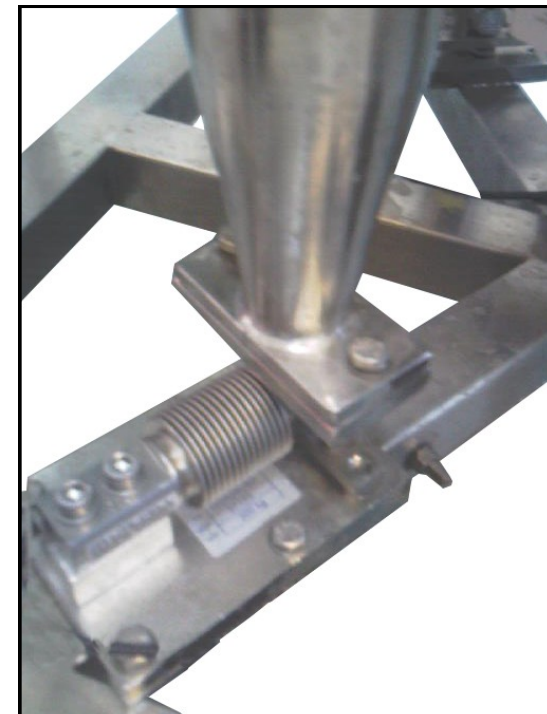
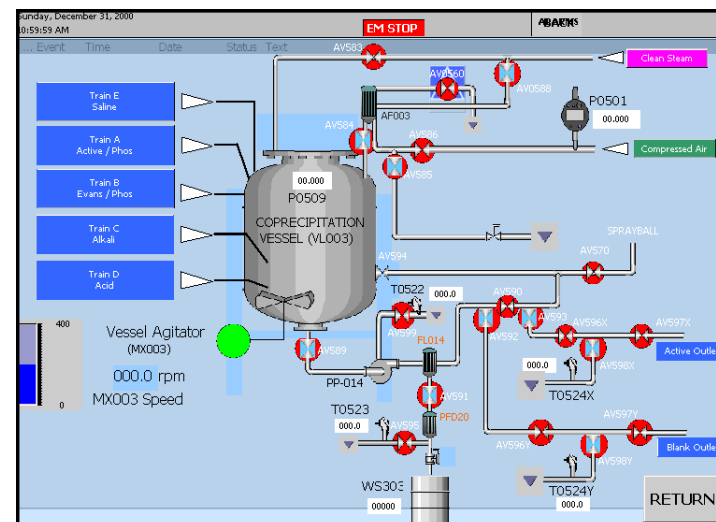
Solution Preparation Vessel



Addition and Dispensing Pumps

High Accuracy Load Cell

Operator Interface Mimic



## Processes

Mixing – mixing solutions can be included for most formulations and can incorporate simple agitation, low to high shear mixing and milling, homogenization, recirculation mixing, powder incorporation, de-aeration and other techniques to create the target product.

Dosing, Metering, injecting, fogging and other incorporation techniques provide a user-friendly automated formulation can be employed together with load cells, flow devices and other instrumentation to ensure the correct combination.

Vacuum treatment, Deaeration, Sparging and Blanketing, Mixing, Filtration and Holding, Powder Handling, Powder Discharge.

Integration of Upstream utility and ingredient systems

Integration of Downstream filling/coating systems, waste handling.



## Equipment

- Industry standard valves, pumps and instruments
- ASME BPE standard interconnecting pipework
- Mixing Vessels, reactors, Mobile Vessels
- Powder Handling Equipment, Loss in Weight Hoppers, Hoists
- Containment Facilities

## Trialing and Testing

Factory acceptance testing is carried out on all of our systems to allow us to demonstrate the correct operation of our solutions and allow our clients to witness and document the systems, providing a documentation trail and allowing leverage into future validation efforts.

## Validation

From the initial stages of tendering to the handover, the entire Life Cycle of the project is carried out in a formal, documented manner. Following the GAMP framework the design documents include DQ, FDS, HDS, SDS, FAT, SAT, IQ and OQ. Manufacturing complies with validation requirements and includes qualifications, certification, maps, log, schedules and lists.

All of the documents are developed under our change control system and are submitted against a Supplier Document Index to ensure traceability throughout the design process and approval of all major aspects.

## Continuous/Batch Operation

Whether In-line or batching systems are preferred, Suncombe have the experience and knowledge to work in co-ordination to provide the optimum solution.

## Single Source

The Suncombe organization offers the facility to provide a full encompassing solution, allowing you to pass responsibility to a single project team, who take responsibility for the design, manufacture, automation, testing and finally handover and acceptance of your system.

## Automation Systems

In order to provide a fully controllable and traceable Preparation System, the Suncombe solutions are available with a number of different levels of Automation.

Our automation systems also provide our clients with automated information management which is designed to meet their data acquisition and validation objectives

Suncombe automation systems have been developed in-house over the last 45 years to cater for the requirements of the Biopharma industries and provide a consistent and measurable batch control.

The base level system normally used for Preparation is the ControlSuite#3, which is a mid-level PLC driven system, complete with a Touch Panel HMI operator interface.

Advanced HMI graphics and Faceplates are included to facilitate an effortless operator interface

The separate parts of the solution preparation are split into stages or phases and are accurately controlled and monitored to provide the repeatability and validity required.

The HMI provides the Operator Interface for recipe setup and operation and in addition provides a comprehensive facility for diagnostics and equipment maintenance.

The base unit is supplied with a single HMI interface with remote interfaces available as required. The Suite#3 provides a real time printed record of the batch and an option can be included to record and store these onto a paperless chart recorder compliant with 21CFR11 requirements.

Barcode Reader  
Used for ingredients monitoring



Batch Records

Batch Header Information	
Batch	FGH1234
Start	04/09/2008 08:48:00
End	04/09/2008 08:51:00
Product	
Operator	
Desalt Solution (kg)	24.5
Purified Water (kg)	96.0

