



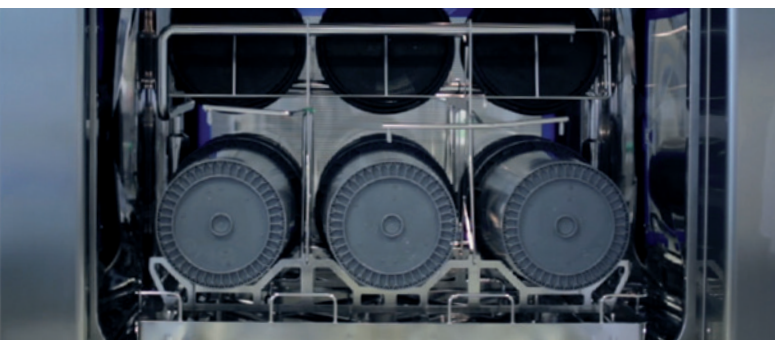
Hamo PG-800
Hamo PG-1300

cGMP compliant Cleaning Equipment (Pharma Grade)

Hamo PG-800/PG-1300

Unique solutions

Hamo Cleaning equipment for industrial and life sciences fields are special cleaning equipment designed to process critical components such as, fermentation containers, big bottles, glassware, components of filling and packing-machines, mixers, cones, palettes, boxes, tableting-tools, and other parts from the pharmaceutical, diagnostic, cosmetic and food industries.



Maximum Flexibility

Hamo Cleaning equipment are available in various sizes, to accommodate many different sizes of goods:

Hamo PG-800

Chamber usable dimensions W x D x H, mm (inches): 800 x 800 x 1000 (31,5 x 31,5 x 39,4)

Hamo PG-1300

Chamber usable dimensions W x D x H, mm (inches): 1300 x 1300 x 1000 (51,2 x 51,2 x 39,4)

Chamber

The polished chamber (with only three openings) and tubing are designed to fully drain. The chamber ceiling and the chamber are designed with slopes to achieve a quick and full emptying.

On request the chamber is equipped with internal lighting, to monitor the process during cleaning.

Glass-Doors

The units are executed in a single door-version, or as double-door if wash load shall be introduced through the machine into an higher classified room («Bio-Seal» room separation).

The doors are made out of double-walled hardened glass, with surrounding inflatable silicon- or EPDM-seals.



Load- and Unloading

By means of an external transport trolley the machines are loaded and unloaded. Automated systems with feed- in and feed-out roller conveyors are also available.

Dosing Pumps

Up to four detergents or additives are dosed (monitored by a flow-meter) into the machine; the dosing volume set values are part of the wash-cycle setting; the pumps are integrated in the machine.

Utilities

All media-supplies (except drain) are from above:

- The electrical and pneumatic supply
- Up to 3 separate water supplies
- Up to 4 additives/detergents
- Clean-air supply (eg for blow out of water inlet piping)

Service Friendliness

The machine concept allow easy access through doors to the control cabinet, to the dosing systems, the sensors, and the water-sample-probes.

Energy Efficiency

Hamo machines are built according the latest technologies to reduce the loss of energy and the use of resources. The double walled chamber are asbestos and chlorine free insulated, which reduces the heat loss to a minimum. The innovative pump and spray system reduces the use of water to an absolute minimum.

Safety

The machines are built to the latest safety guidelines: Main switch and safety circuits, pressure monitoring of the pneumatic supply, door-opening only if chamber temperature is below safety level, dripping pan with alarm, etc.

Machine Documentation

The machine is shipped with a detailed machine documentation according CE, containing eg:

Manual, spare part list, lay-out, P&ID-plans, data-sheets, CE-conformity declaration, electrical-diagram, pneumatic diagram etc.



Process-Safety / Reproducibility

Control

The machine is controlled via a modern Control-system (Siemens) which stands for reliability and flexibility. The visualization (HMI) runs on a touch screen.

The cleaning cycles are individually configured to be adapted to the soiling and the specific requirements of the wash-load.

The integrated user management on the software allows easy configuration of the access-levels of each user-group. Specific user-group have different access-rights; therefore configuration or changes on cleaning-processes can only be made by authorized personal.

Job-Report / Load-Documentation

cGMP and state of the art quality methods request the documentation of the cleaning processes and their critical parameter.

The job-report and /or the load-documentation can therefore be printed by a local printer or saved as PDF-file.

PDVS and Process-Monitoring-Options

The PDVS (Process Data Validation System) for Water-Temperature, the drying temperature as well for the dosing-flowmeters for two detergents are installed default on the standard machine.

Process-independent and redundant measuring probes monitor the critical parameters with alarm.

Optionally the PDVS can be extended to more parameters, such as eg conductivity in tank, pH-measurement, pump-pressure measuring, and two more detergent-volumes or temperatures.

Calibration

Machines working in a qualified environment have to be maintained and calibrated on a regular base.

The components in HAMO machines allow easy maintenance and quick calibration in accordance with the latest regulations.



Execution PG (Pharma Grade)

Technical Execution / Tubing / Components

The machine are designed, built and documented according the latest requirements of the pharmaceutical industry, such as EHEDG, FDA, cGMP and GAMP.

As for example:

- Chamber and welding surface quality $RA \leq 0,8 \text{ mm}$; all radius minimal 30 mm electropolished
- All piping sanitary/aseptic execution (Tri-Clamps) according ISO 11864-3
- All membrane valves without dead legs; membranes made out PTFE/EPDM



Drying

The drying air is pre-filtered H8 and is – just before entering the chamber and the wash-system- again filtered via a filter HEPA H13 (Filter-monitoring system optionally available).

Qualification Support Package

Hamo can offer the customer a full qualification support package in the form of extensive professional support-documentation as well as with qualification-services. This service results in a massive reduction of time and cost for IQ, OQ and PQ as well as for calibration and maintenance.

Based on specific requirements the following documentation is available:

- CE Documentation 'as built'
- Material certificates 2.1 / 2.2 / 3.1
- Calibration certificates
- FS/DS (HDS & SDS)
- IQ & OQ documents
- Weld logs

Regulation / Quality Assurance

Design and manufacturing are by a quality system ISO 9001 and a team with high quality experience. The manufacturing process is guided by reviews and milestones which guarantee the requirements of FDA, EMA, cGMP as well GAMP.

IQ/OQ and FAT/SAT

During factory acceptance test, based on the standard FAT protocols the machines are checked on conformity according the URS/FS. Trained Hamo personal set up, install, start-up, calibrate the equipment; also they can execute installation qualification (IQ) and operational qualification (OQ) as well they can support any performance qualification (PQ).

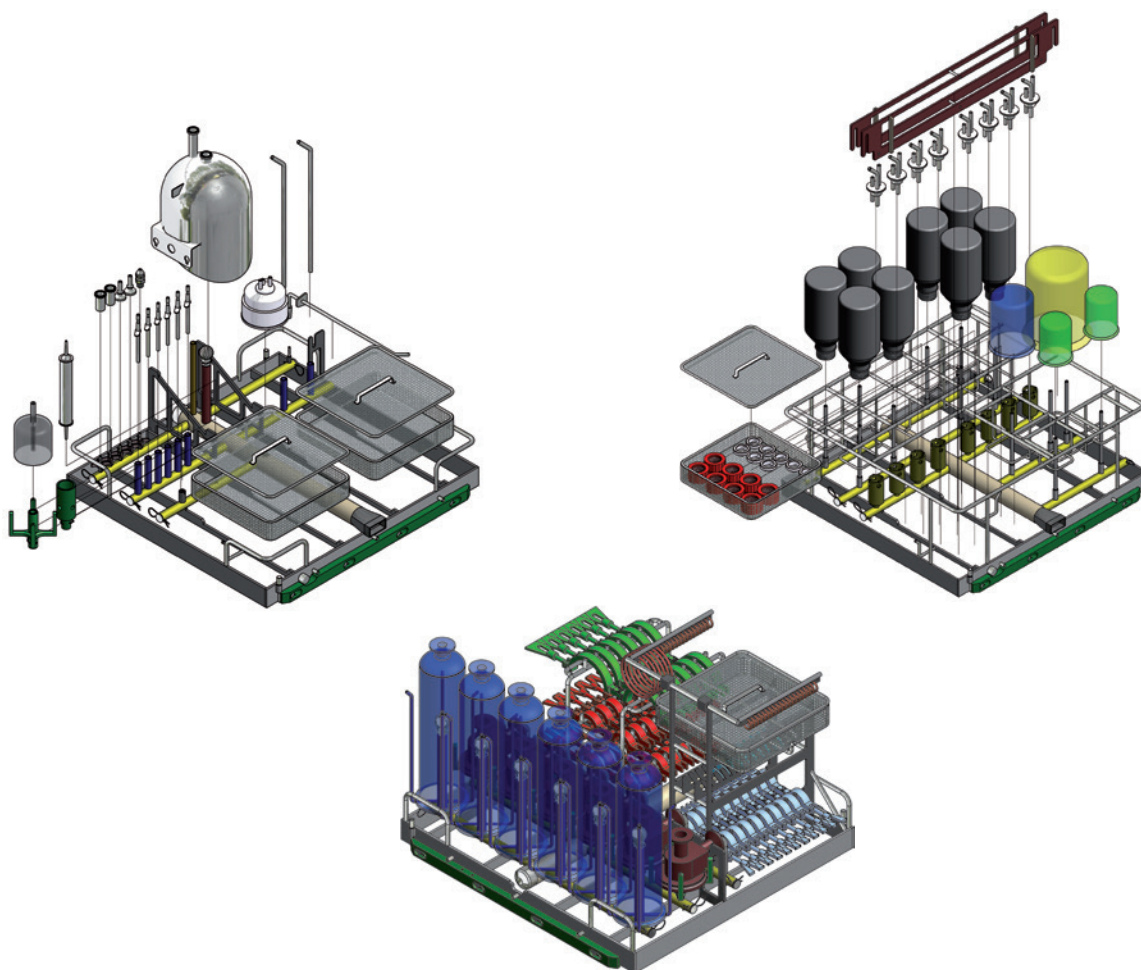
Customized Racks / Application Laboratory

Racks

Hamo have specialized personnel with long experience in pharmaceutical cleaning capable of developing customized racks.

This experience paired with intense cooperation with our customers, allow innovative and creative solutions.

All racks are completely in stainless steel 316L, electro polished and are delivered with the requested documentation and the necessary certificates.



Application Laboratory

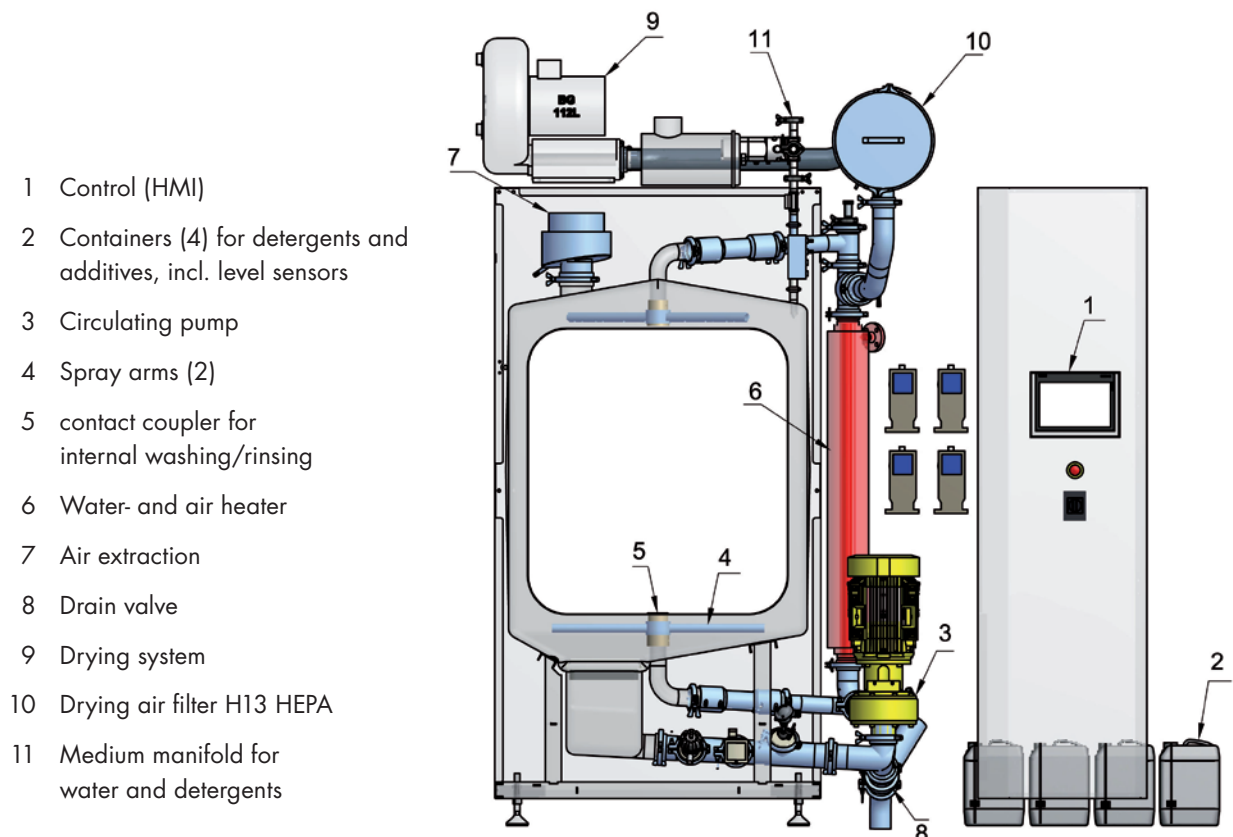
New cleaning cycles are developed in the application laboratory.

Customized cleaning processes will be (on request together with the customer) tested and documented.



Technical Data

HAMO	PG-800	PG-1300
External Dimension mm (inches)		
Width	1800 (70,9)	2300 (90,6)
Height	2950 (116,2)	2950 (116,2)
Depth	1300 (51,2)	1700 (66,9)
Usable Dimension mm	800 x 800 x 1000	1300 x 1300 x 1000
W x D x H (inches)	(31,5 x 31,5 x 39,4)	(51,2 x 51,2 x 39,4)
Regulations	CE EHEDG, FDA, EMA, cGMP as well GAMP FDA 21 CFR part 110: Food FDA 21 CFR part 210/211: Pharma FDA 21 CFR part 177: non ss-parts FDA 21 CFR part 11: Electronic records	
Certificates	Material certificate 2.1, 2.2, 3.1	
Material	Stainless steel in contact with wash media AISI 316L / 1.4401 / 1.4404 / 1.4435 electro polished	
Electric	3x 400V, 50 Hz	
Water	3 different water (eg Tap water, Demi, Osmose, WFI etc)	
Pneumatic	6–8 bar, oil free	
Steam	Saturated steam 2–8 bar	
Drain	min 50 l/min gravity	



Your Competence-Center for Cleaning Technology



Amsonic CleanLine

Hamo/Amsonic offers a wide range of water-based and closed circuit A3 solvent based cleaning units that provide thorough cleaning processes for various industrial sectors:

Water-Based Precision Cleaning Equipment (Ultrasonic)

Amsonic CleanLine / AquaLine

High performance-Ultrasonic-Precision-Cleaning equipment



Hamo 200

Water-Based Spray Cleaning systems

Hamo 200

Compact spray-cleaning and drying equipment for various application

Hamo 210 / 420 / 840

Spray-cleaning equipment for life sciences application



Hamo PG 800

Pharma-Conform Spray Cleaning systems (cGMP)

Hamo PG 800 / 1300

Pharma-Conform (cGMP) Cleaning equipment in single or double door execution (Bio Seal)

Amsonic Hamo HPM

High pressure cleaning systems (>80 bar) for pharmaceutical application

Hamo T-BCC

Fully automatic Cleaning and Drying System for Bulk Containers, Barrels and Pallets



Amsonic 4000

Solvent-Based Precision Cleaning Equipment

Amsonic 4000 / 4100 / 4400

Solvent-based Ultrasonic equipment (Class A3)
Cleaning under vacuum, above or below flame-point

Detergents / Additives

Amsonic PreciClean / Hamo liquid

Water based detergents



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