State-of-the-Art GMP-Compliant Container Cleaning in Pharmaceutical Production

PH 880.2:
Cleaning machinery for containers, drums and other large-sized components used in pharmaceutical production

Belimed
Infection Control

Installation with two laterally reversed PH 880.2 cleaning machines

Based on innovation and experience

As one of the leading companies operating in the area of decontamination and infection control, for over 40 years Belimed has been developing, producing and marketing innovative cleaning, disinfection and sterilization systems in the health care, pharmaceutical industry and laboratory sector.

By an ongoing process of developing products and additional development based on customer needs, in line with the most recent guidelines and directives, Belimed has ensured that its products meet current and future market requirements, thus meeting the evermore stringent demands applicable to cleaning efficacy processes.

Cleaning methods are an essential process element in pharmaceutical research and production industries. This is typically shown by the multifaceted requirements of sanitisation and validation, to ensure repeatability of the process at any time. The objective of completely removing any product contamination from all components must be accomplished by adhering to an extremely stringent validated procedure. These stringent demands encompass all machine parts that may come into contact with the processed products, i.e. containers, drums, bins, kegs, funnels, tubes, drying trays, pumps and filling line components.

With its newly developed PH range of GMP washers for the pharmaceutical industry, Belimed has set new standards of engineering in automated cleaning process machinery. Modular design and the highest level of quality are at the core of these products. Due to the implementation of GMP, GAMP and FDA requirements plus a large number of innovative technical solutions, Belimed machines exemplify a benchmark standard in the pharmaceutical industry. Intelligent engineering ensures self-cleaning of the machines, which helps avoid any product carry-over.

Belimed has placed a high priority not only on the build quality of its product, but also the after sales support. With regionally based engineering support for installation, planned preventative maintenance, plus its support service offices for spare parts, documentation and validation, Belimed can provide all its customers with after sales backup throughout any of its products' life cycle.

Loading rack for drums

Loading rack for bins

Loading rack for pallets

The right solution for all fields of application

Designed as a cleaning system for containers, drums, pallets and other large-sized vessels, the PH 880.2 is part of an extensive model range (PH 820.2, PH 840.2, PH 860.2 and PH 880.2). The tailored operational sequences for professional pharmaceutical processes maximises efficient throughput.

Based on standardised technical design and years of Belimed's experience in automatic cleaning, the PH washer range covers a wide range of cleaning requirements and features harmonised construction characteristics throughout the various models. The PH 880.2 combines highest possible component standardisation with the necessary design flexibility to achieve best possible adaptation of the machine to the requirements of the production process.

Flexible loading systems

Depending on process requirements and the types of the washing items, various methods of loading and unloading the wash chamber are possible. Individual customer requirements may thereby be taken into account.

Manual loading and unloading system

- by forklift, etc.
- by means of transfer cart and separate loading rack

Automatic loading and unloading system

- by means of loading and unloading platforms with telescopic drive for insertion and withdrawal of washing items with loading racks
- by means of loading and unloading platforms using roller conveyors
- with buffer areas
- by means of swivel-type loading platform to change transport direction
- by means of automated guided vehicle (AGV)
- by means of fully automated transport systems with FDA-compliant transport belts
- with automatic recognition of washing items and loading status monitoring
- with automatic opening of containers on top and bottom

Scope

For cleaning and drying of

- containers
- drums
- bins
- trolleys
- pallets
- machine parts
- and much more

Design options

- flexible chamber sizes
- single- or double-door operation
- above-floor-level loading
- floor-level loading
- automatic loading and unloading by means of transport system
- internal cleaning system via connection coupling
- container internal cleaning system
- chamber with guide rails for loading racks or with deposit points for forklift loading
- application-specific loading racks
- variable tank equipment
- integration into barrier technology with gas-tight divider walls
- machines with customised dimensions

GMP-compliant cleaning of containers, drums and other large-sized vessels

FDA-compliant transport belts for the flexible transport of containers and pallets and other large-sized vessels

Pharma-adapted design

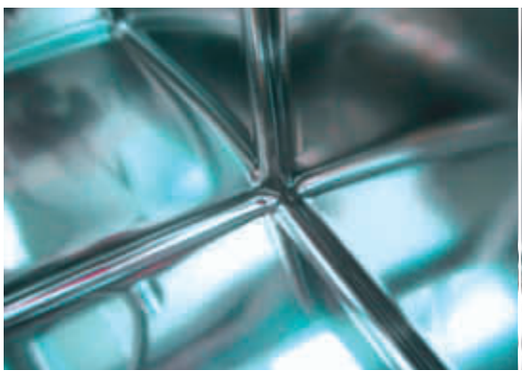
Design that incorporates customer requirements and at the same time meet the latest FDA, GMP and GAMP guidelines represents the main focus in the development of the PH 880.2.

Of particular importance is the crevice- and dead-leg-free design of the wash chamber with radius corners: this design negates the problem of cross-contamination by soil deposits lodged in the machine.

Characteristics

- The maintenance-friendly, integrated technical and service compartment not only contains the machine control, but also provides space for all media connections as well as storage of additive containers.
- Machine casings are finished with oil-smoothed stainless steel panels.
- Horizontal sliding glass doors with inflatable seals and soil-proof electric linear or friction wheel drives enable visual checking of the washing process, thus attaining an optimal level in ease of maintenance and operational safety.
- Hygienically ideal bottom sump integrated into the wash chamber
- Wash chamber and tank interior are produced from mirror finish stainless steel featuring radius corners (radius R20). All chamber weld seams are ground and polished (Ra ≤ 0.8 µm).
- All product-contacted surfaces (chamber ceiling, chamber floor and piping) are sloping and crevice free.
- No dead legs, no screw and bolt connections inside the chamber
- Gears for automatic loading and unloading outside the chamber
- High-level safety within the piping system is provided by a pneumo-sanitary flange system according to DIN 32676, clamp secured by two bolts.
- Complete self-draining recirculation pump in 3A2 standard; 5,5 kW
- Controlled tank heating system via a heat exchanger in pharmaceutical execution (Ra ≤ 0.8 µm)
- Pneumatically actuated solenoid valves

Detail of wash chamber with radius corners



Patented pneumatic connection coupling

Internal cleaning via high-performance rotating spray head with rotation control

PH 880.2 with high-performance self-rotating spray nozzle for effective internal cleaning of containers

Cleaning system

Particular attention was paid to optimise the washing liquid pressure and solution distribution between internal and external product cleaning, with especial consideration to any delicate items being processed.

- External cleaning by means of rotating spray arms (oscillating), placed vertically in wash chamber corners. The monitored gears of the spray arms are located outside the chamber conforming to GMP.
- Container internal cleaning by means of a high-performance self-rotating spray nozzle for effective removal of product residues on the inside of the tanks.
- Internal cleaning of hollow bodies (e.g. drums) is effected by direct injection via the loading rack. A high-efficiency, patented connection coupling enables leak-free and constant pressure supply of the cleaning system. This results in higher wash jet pressure and thus shorter wash cycles.

Materials and components

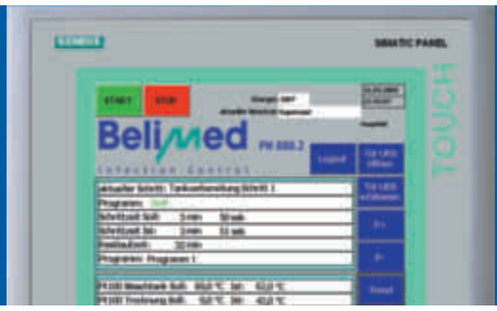
The selected materials and components from approved manufacturers meet even the highest requirements in terms of quality and long life cycle.

- Media-contacted components such as chamber, tank, piping and pumps are manufactured of 316L stainless steel.
- Frame and panels are manufactured of 304 stainless steel.
- Components are FDA certified.
- Seals are made of EPDM.
- Optional material certificates 3.1.

Options are available for specific material requirements.

GMP-rinse and drying

Cleaning, rinsing and drying are accomplished by means of a single-pipework system. As an option, final rinse may be effected by direct connection with the supply line (GMP final rinse). A powerful drying system and the tight connection coupling ensure optimal drying results even without optional compressed air purging. The system consists of prefilter, fan, heater and a HEPA filter H13 as the final element in the air stream. The access opening for qualification of the filter integrity (DEHS Challenge Test) has been placed ergonomically.



Siemens Touch Panel MP 277 colour

Reliable process guidance

Intuitive operation

The modern, touch-screen-equipped graphic control panel (Siemens MP 277, 10,4" colour or Allen-Bradley PanelView Plus 1000) enables simple and concise operation.
All essential process data are displayed.

The machine control unit is either a Siemens S7-300 or a Rockwell Allen-Bradley CompactLogix PLC. As an option, both control systems may be linked to a higher level management system via Profibus or Ethernet (standard with the Allen-Bradley) for further data processing. The 21 CFR Part 11 compliance is reached by the Siemens Audit Trail Option. The software is in compliance with the guidelines under GAMP4.

For enhanced operational safety, control and power sections are separated and contained in separate control cabinets. For ease of service and maintenance, the control section is located in the service compartment door.

Process monitoring

Reproducibility of cleaning results is ensured by permanent monitoring of all process-relevant parameters. For this purpose, various sensors for measurement of the cycle data is available:

- Detergent concentration, with flow and conductivity measurement
- Pressure monitoring of all cleaning and rinsing cycles
- Temperature monitoring by means of PT-100 sensors, class A
- Conductivity monitoring of final rinse
- Drying with air stream monitoring
- Differential pressure monitoring of the sterile filter
- Validation connection for independent readings recorde

Batch documentation

A batch record containing all sensor-detected process data may be printed or transmitted in data format to an external PC or network.

Qualification

The optional Belimed technical documentation contains comprehensive and concise information to be directly applied in the qualification process:

- Documentation (DQ, IQ, OQ, FAT, SAT)
- Manufacturer certificates (2.1 / 2.2 / 3.1)
- Welding documentation
- Video endoscope inspection of the piping system
- X-ray testing of weld seams
- Dye-penetrant testing of weld seams
- Cleaning test using Riboflavin

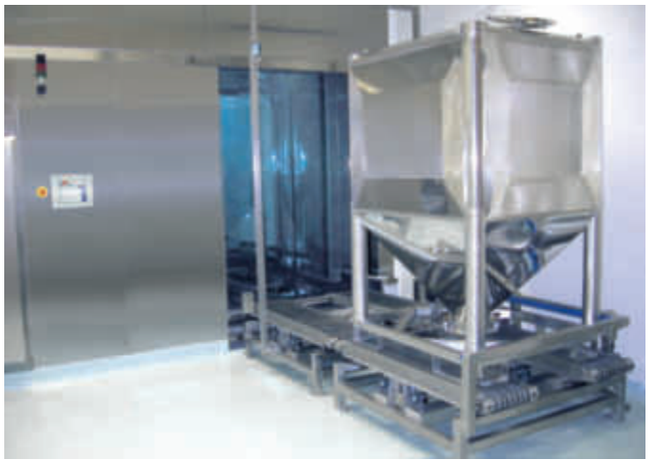
The documentation is also available ISPE baseline Volume 5 compliant (IT, FT, FAT, FCT).

The Belimed technical documentation contains comprehensive information to be directly applied in the qualification process.

Technical data

Type	PH 880.2S	PH 880.2M	PH 880.2L
Usable chamber dimensions H x W x D (mm)	1800 x 1000 x 1700	1800 x 1300 x 1700	2100 x 1600 x 2000
Installation outer dimensions without container cleaning system H x W x D (mm)	2700 x 3100 x 2360	2700 x 3400 x 2360	3000 x 3700 x 2660
Installation outer dimensions with container cleaning system H x W x D (mm)	4500 x 3100 x 2360	4500 x 3400 x 2360	5000 x 3700 x 2660
Chamber volume (litres)	3060	3978	6720
Loading height (mm)	500 / floorlevel	500 / floorlevel	500 / floorlevel
Door design	sliding glass door	sliding glass door	sliding glass door
Door opening	horizontal	horizontal	horizontal
Number of doors	1 or 2	1 or 2	1 or 2
Base frame height (mm)	100	100	100
Depth of floor recess with floor-level loading (mm)	300	300	300
Water connections			
Cold water	DN 25 2–3 bar	DN 25 2–3 bar	DN 25 2–3 bar
Hot water	DN 25 2–3 bar	DN 25 2–3 bar	DN 25 2–3 bar
DI water (AP)	DN 25 2–3 bar	DN 25 2–3 bar	DN 25 2–3 bar
WFI water	DN 25 2–3 bar	DN 25 2–3 bar	DN 25 2–3 bar
Outlet	DN 70	DN 70	DN 70
Electric connection	3N 400 V / 50 Hz	3N 400 V / 50 Hz	3N 400 V / 50 Hz
Exhaust air connections			
without container cleaning system	DN 200	DN 200	DN 200
with container cleaning system	DN 350	DN 350	DN 350
Steam connection	saturated steam DN 50; 2,5 bar	saturated steam DN 50; 2,5 bar	saturated steam DN 50; 2,5 bar

Subject to modification



The PH 880.2 ensures a GMP-compliant container cleaning

Belimed AG
6300 Zug
SWITZERLAND

www.belimed.com

AUSTRIA
Belimed GmbH
Grüne Lagune 1
8350 Fehring
Tel. +43 3155 40 699 0
Fax +43 3155 40 699 10
info@belimed.at

BELGIUM
NV Belimed SA
Rue de Clairvaux 8
1348 Louvain-La-Neuve
Tel. +32 10 42 02 40
Fax +32 10 42 02 49
info@belimed.be

CHINA
Belimed Medical Equipment
(Shanghai) Co., Ltd
CaiLun Road 780,
5th floor, Room H
ZhangJiang Hi-Tech Park
201203 Pudong, Shanghai
Tel. +86 21 513 709 98
Fax +86 21 513 709 96
info@belimed.cn

FRANCE
Belimed SAS
Parc GVIO
330 Allée des Hêtres, Hall E
69760 Limonest
Tel. +33 4 37 41 63 03
Fax +33 4 37 41 63 04
info.pharma@belimed.fr

Branch Office
Belimed SAS
ZAC Saumaty Séon
19 rue Gaston Castel
13016 Marseille
Tel. +33 4 96 15 22 10
Fax +33 4 96 15 22 19
info.sud@belimed.fr

Branch Office
Belimed SAS
Parc Espale
1, av. Pierre Pflimlin
68390 Sausheim
Tel. +33 3 89 63 65 40
Fax +33 3 89 63 65 41
info@belimed.fr

GERMANY
Belimed Deutschland GmbH
Edisonstrasse 7a
84453 Mühldorf am Inn
Tel. +49 8631 9896 0
Fax +49 8631 9896 300
info@belimed.de

Branch Office West
Belimed Deutschland
GmbH
Emil-Hoffmann-Strasse 27
50996 Köln
Tel. +49 2236 9642 0
Fax +49 2236 9642 200
info.west@belimed.de

NETHERLANDS
Belimed B.V.
Energieweg 8
6658 AD Beneden-Leeuwen
Tel. +31 487 59 11 00
Fax +31 487 59 15 90
info@belimed.nl

SLOVENIA
Belimed d.o.o.
Kosovelova cesta 2
1290 Grosuplje
Tel. +386 1 7866 010
Fax +386 1 7866 011
info@belimed.si

SWITZERLAND
Belimed Sauter AG
Zelgstrasse 8
8583 Sulgen
Tel. 0848 55 88 11
Fax +41 71 644 86 00
contact@belimed-sauter.ch

UNITED KINGDOM
Belimed Limited
Unit 4 Newbuildings Place
Dragons Green Road
Shipley
West Sussex, RH13 8GQ
Tel. +44 1403 738 811
Fax +44 1403 730 830
info@belimed.co.uk

USA
Belimed, Inc.
2284 Clements Ferry Road
Charleston, SC 29492
Tel. +1 843 216 7424
Fax +1 843 216 7707
info@belimed.us

OTHER COUNTRIES
Medical & Lab
Belimed AG
Dorfstrasse 4
6275 Ballwil
SWITZERLAND
Tel. +41 41 449 78 88
Fax +41 41 449 78 89
info@belimed.ch

OTHER COUNTRIES
Pharma
Belimed Sauter AG
Zelgstrasse 8
8583 Sulgen
SWITZERLAND
Tel. +41 71 644 85 00
Fax +41 71 644 86 00
info@belimed-sauter.ch

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