PHARMA BIOS®

BIOREACTOR

Bioreaction Engineering

Pharmabios®
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COMPANY PRESENTATION / BIOREACTORS

Pharmabios® is a company focused on the design and manufacturing of high technology equipment for the pharmaceutical and biotech branch. It is also a supplier for engineering services on these fields.

The **Pharmabios®** bioreactors are specially designed for the scale-up and manufacturing of biological pharmaceutical products. They are equipped with all the necessary components to carry out the bioreaction.

WORKING PRINCIPLE:

The **Pharmabios®** bioreactors are designed to work in "batch" mode, with the following operational steps:

Load of the culture media: The required media volume is added to the bioreactor.

Inoculum addition: The inoculum is added to the bioreactor.

Bioreaction: The bioreaction is performed, where the temperature, optical density, pH and dissolved oxygen are controlled.

Bioreactor unloading: The product is unloaded to process it in the downstream steps.

CIP: Automated cleaning of the bioreactor and its piping and components.

SIP: Bioreactor sterilisation.

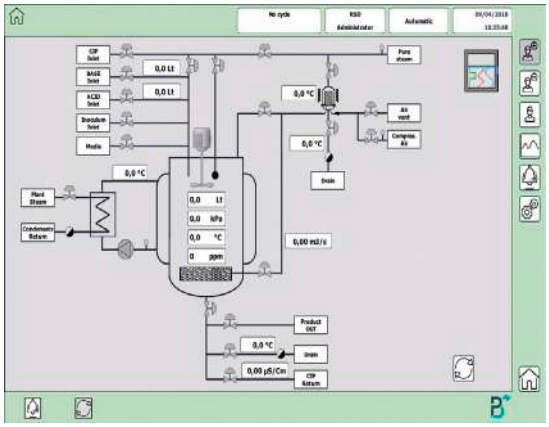
PHARMABIOS® EQUIPMENT:

General features: Finish of the product-contact parts Ra ≤ 0.5 µm., mechanically polished. Valves in product-contact are diaphragm valves with diaphragm in EPDM. The design minimises the use of connections and welds. Components in product-contact suitable for the pharmaceutical industry. Design carried out in order to minimize the number of connections and welds, dead legs comply with the standard L < 3D, product contact components designed for the pharmaceutical industry.

Supporting frame: All the components including the bioreactor are supported on a stainless steel 304L frame.

Control system: The equipment is controlled by means of an electrical cabinet which contains all the necessary components for the equipment performance. The control system is composed of a touch screen HMI (SCADA) type and a Siemens PLC.

Included documentation: User and maintenance manuals, quality certificates of the components, welding certificates, manuals/data sheets of the components, CE marking DS/DQ/FAT protocols to be executed in our facilities.



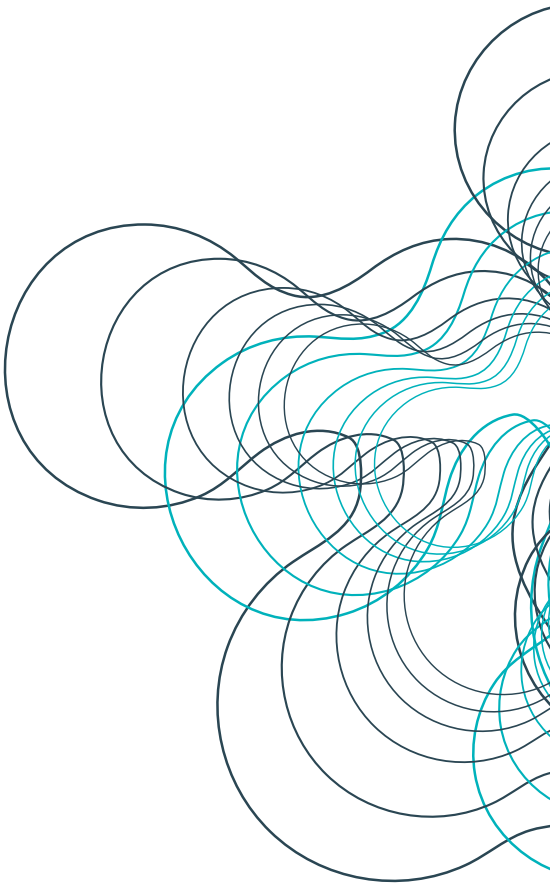
In PHARMABIOS®
we adapt ourselves to the
customer needs, offering
custom-made solutions.

THE ADVANTAGES OF THE PHARMABIOS® DESIGN:

- A complete quality documentation, including FDS protocols, DQ & FAT (IQ/OQ) as option.
- A very versatile control system that allows the configuration of any options to carry out the culture in optimal conditions.
- A high quality equipment, with GMP design and compliant with all the current international normatives (21 CFR Part 11, GAMP 5, ASME BPE and ISPE recommendations).
- Customised technical consultancy.
- Possibility of customisation, tailor-made.
- High range components, with recognised brands.
- Sanitary connections, ASME BPE.

OPTIONS:

- Heating system using resistances.
- Setup for anaerobic growth (N2 addition, CO2, ...).
- Control system upgrade.
- Load cells.
- Interface with other equipment or components.
- Functioning of the bioreactor in continuous mode.
- Extra copies for documentation.
- 6-channel graphic register.
- Supplementary instruments.



TECHNICAL SPECIFICATIONS:

MODEL	BIO-50	BIO-100	BIO-500	BIO-1000	BIO-2000
Bioreactor volume (l)	50	100	500	1000	2000
Dimensions (length x height x width)	1.500 x 1.500 x 2.000	2.000 x 2.000 x 2.500	2.500 x 2.500 x 2.500	3.000 x 2.500 x 3.000	3.500 x 3.000 x 3.500
PLC/Touch screen	Siemens S7-1200, Siemens, con Tia-portal				
Utilities required					
Electrical consumption (kW)	2	3	4	6	11
Clean steam (flow rate / pressure)	15 kg/h / 3-8bg	30 kg/h / 3-8bg	50 kg/h / 3-8bg	80 kg/h / 3-8bg	100 kg/h / 3-8bg
Purified water (flow rate/pressure)	0.5 m3/h / 2bg	1 m3/h / 2bg	1.5 m3/h / 2bg	2 m3/h / 2bg	3 m3/h / 2bg

Do you have some special requirements to fulfil?

We adapt ourselves to your process in order to provide you the tailor-made solution which suits best to your needs.