Barat FZE

BIOSIP 50L Detail Specification (with price)

NO:B10192-1 (Detail)

Date:06/07/2022

TO: Behestan Pharmaceutical Co.

Adress: Behestan Bldg., #10, Pardis St., Mollasadra Ave.

Tehran,1991915613

Phone: (+98 21) 887744200

Commercial ID : 10102165778

1) P/N: BIOSIP/50L
Qa: 1
Technical description;
BIO-SIP 50 LITERS IN SITU STERILIZABLE SKID MOUNTED BIOREACTOR WITH COMPACT MODULAR
CONTROLLER FOR MULTI PURPOSE CELL CULTURE mABS PRODUCTION.

The BIO SIP is an advanced modern designed fermentation system developed using state of
the art cultivation technologies. For trouble-free operation only high quality industrial
components are used. All possible product contact (wetted stainless steel) components are
made of stainless steel AISI 316L.

MODULAR BIO SIP BIOREACTOR, PILOT SYSTEMS WITH 50 LITERS STEEL VESSEL INCLUDE:
- Compact Controller Module with Industrial PLC 'Programmable Logic Controller' automation
- Integrated Gas Mixing system, Air, O2, CO2, N2
- Integrated Peristaltic pumps, 4 pcs.
- Thermo regulation temperature control 'wet part' heating/cooling
- Culture Vessel 20L with top mounted mixing system
    - Supply Unit for In situ steam sterilization
    - Skid mounted Vessels with rotating wheels

50 LITRES VESSEL:
Vessel Total volume: 50 Liters
Vessel working volume from 8/10L to 40/45L (suggested)
Vessel SIP in situ sterilizable by steam jacket and direct steam injection.

50L Vessel features:
SS Stainless steel made of AISI 316L,
Vessels H/D= 2:1 for cell cultures
Vessels design pressure; -1 / +4 barg,
Vessel design temperature: -5°C / +150°C
Head-plate ports;
1 x Level/Foam sensor,
1 x Pressure indicator,
1 x inoculation port,
1 x gas overlay inlet,
1 x Condenser, jacketed condenser
1 x gas exhaust filter 0.2 micron with housing
1 x stirrer assembly mechanical seal with stainless steel shaft and 2 x Marine / Pitched impellers,
1 x safety valve
1 x spare port (optional spray ball CIP)

Upper side wall:
4 x re-sterilizable 3-way valves inlets with manual valves for liquids additions acid/base, anti-foam, inoculation and feeding
1 x connection for Sparger gas inlet, ring sparger type
1 x jacket inlet water (temperature regulation)

Low side wall ports available:
4 x DN25 Ingold ports for pH, pO2, Temperature, and spare sensor (optional Biomass or other)
1 x TK port for Sampling with re-sterilizable manual valves for repeated use,
1 x jacket outlet water (temperature regulation)

Bottom valve:
1 x Harvesting re-sterilizable automated valve for product harvesting / transferring.

Vessel Jacket:
Jacket for water Inlet and Outlet for temperature regulation,
Safety valve for vessel jacket

Mixing system:
Top mounted Agitation system with Mechanical seal, working range 50 – 800 rpm,
Agitator height with stirrer shaft made of stainless steel AISI 316L,
2 x Marine / Pitched blade impellers, 0.45 vessel diameter
All impellers are removable and height adjustable

Inlet Gas system:
Aeration via Ring sparger and Overlay bypass,
SS Housing made of AISI 316L,
Absolute filter 0.2 micron for gas inlet

Outlet Gas:
Condenser for exhaust gases made of SS 316L, jacketed condenser for water circulation,
SS Housing made of AISI 316L,
Absolute gas filter 0.2 micron for gas outlet,

Sight Glass and illumination lamp

2. COMPACT MODULAR CONTROLLER with PLC 'Programmable Logic Controller'
Automation and BIO-FLEX Scada Software
Advanced Programmable Automation Controller combines embedded real-time/FPGA
technology.

Main Control Tower consisting of:
- Stainless steel housing installed on mobile skid
- Main switch (power supply for whole system; emergency stop function)
- Unit switch (power supply for fermenter)
- Industrial PLC NI hardware
    - HMI PC interface 15.6'' screen mounted on the control panel
    - LAN-Interface
    - Sub rack for:
    * Gas mix
    * Amplifier
    * Motor controller
    - Peristaltic Pumps
    - Temperature control
    - Main power connection: 220V/230V, 50/60Hz

3. Thermo regulation system:
Thermo regulation system, Wet part circuit working in the adjustable range +10°C / +60°C including all the necessary auxiliaries. The Wet part is equipped with electrical heating for water heat-up and cooling via tap or city water. (KBiotech Chiller is quoted as option).

4. PERISTALTIC PUMPS:
Pumps: built-in, assignable, peristaltic pumps
n.4 controlled speed Peristaltic pumps for acid / base / anti-foam / nutrient, work range 0-150/200mL/min

ALL PUMPS HAVE:
Totalizer and with calibration mode.
Each pump with direct/reverse mode and fully configurable,
Interchangeable tubing are also available.

5. GAS MIXING:
Gassing Additive Flow
- Gassing module designed for microbial fermentation and cell culture.
Gas mixing with n°5 Mass flow controller for Air, Overlay, O2, CO2, N2 automated gas control with PLC automation and Bioflex Software.

Individual gas flow range 0.01 to 0.2 VVM.

6. SENSORS AND CABLES:
- pH sensor and cable included, working range 0-14pH units, precision 0.01pH, Hamilton ARC sensor
- Optical pO2 sensor and cable included, working range 0-100%, precision 0.1%, Hamilton ARC sensor
- Temperature probe and cable included, working range 0-150°C, precision 0.1°C,
- Level/Foam sensors and cable included, height adjustable, working range 0-100%, precision 0.1°C,
- Pressure sensor, work range -1 /+5 Barg, precision 0.1 Barg, H+S
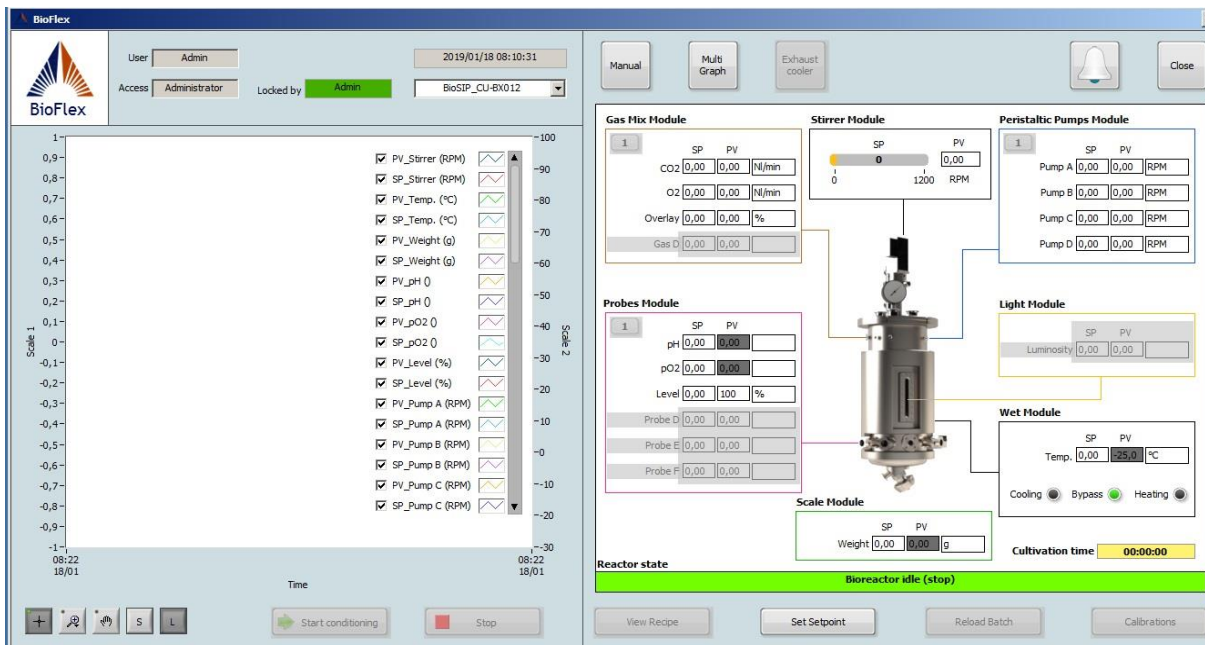

7. SOFTWARE BIO-FLEX ;

BIO-FLEX is a software especially designed for R&D, scale up purpose and production process, with high flexibility for batch, feed batch and continuous cultures, open interface for third party sensors such like (pCO2, Biomass, Gas analysers and other) Including feed batch strategies (pH STAT, DO STAT, Turbido-stat, exponential equations), perfusion, graphics visualization and historian, off line data input, feeding profiles, data batch records and more.

Bioflex software is able to monitor and control 1 to 12 bioreactors simultaneously.

Bioflex software allows the full control of each Bioreactors systems with data acquisition and exporting. You can set all cultivation parameters in a Recipe that can be easily modified and duplicated including real time Cascade control, setting of process values and Synoptic display. Other key functionalities include single and group calibration of pumps, probes and sensors for the best accuracy in reading process parameters.

Bioflex Software features include:
•Password protection and different access levels.
•Control via local HMI-PC and remote Desktop, Laptop,
•Recipe configuration database.
•Logical and intuitive programming of all operational menu's
•Data export via csv-files to USB or direct exchange via OPC interface (OPC optional)
•Web-based remote service
•Remote access with client via Ethernet port

8. Bioreactor In situ Sterilization description:
The BIOSIP 50L Bioreactors enable full and empty sterilization by steam.
KBiotech Bio-STEAM Steam generator is quoted as optional.

The steam sterilization sequence / cycle is carried out automatically by the BIOSIP Controller

Software as follow;
Steam inlet valve is automatically open/closed
Bottom valve is automatically open/close
Sterilization cycle, automated
Peripherals sampling and liquid additional valves are manually open/closed

9. Documentation:
- Documentation includes a general arrangement of the whole package
- Operating and Maintenance Manuals in English languages
- Information for the safe installation of the equipment.
- List of spare parts
- CE and PED pressure vessel certificate

10. Services:
- Packaging for the BIOSIP 20L Bioreactors complete units
- On-line technical assistance and support via remote web access

KBiotech ensure that all equipment is designed and manufactured to current international current legislation and directives as applicable. All machine, control panel and operator-machine interfaces labelling will be in the English language.

Infrastructure
KBiotech will provide details of all installation requirements such as utilities connections to be available at the customer premises.

Utilities
KBiotech will submit his detailed requirements for electrical power as part of his offer.

Guarantees
KBiotech equipment include 1 Year warranty period.

1.After-sales service department
All after-sales service will be provided by KBiotech international after-sales department.
We include remote diagnostic system for online after sales assistance provided by KBiotech technical department.

Remote access "TeamViewer":
We include the supply of the remote access "TeamViewer" to provide real-time online support for assistance, maintenance and support.

TOTAL NET PRICE AS ABOVE LISTED: 207.000,00 EUROS / price for one 50L bioreactor

Ancillaries;

1) Packaging is included

2) Shipping costs, not included, to be billed aside

3) Online installation and training support; Price; 1.000,00 Euros / day

4) Installation and training at your premises including travel expenses and onsite labor; Price; 10.000,00 Euros (to be confirmed)

5) IOQ protocols and execution for 50L BioSip bioreactors; Price; 7.500,00 Euros

6) Level 1 GMP + CFR21 part 11 package documentation for 50L BioSip Bioreactors; Price; 25.500,00 Euros

Options, not included in the above prices;

2) Integrated CIP cleaning system with centrifugal pump, 2 x reagents bottles 2L, flexible CIP pipe, conductivity probe, 1 x spray ball, PLC automation and Bioflex Software CIP sequences.
Price; 26.500,00 Euros

3) Load cells for vessel weight monitoring and control with PLC and Bioflex software feedback control.
Price; 8.800,00 Euros

4) Steam generator to work in a GMP environment with 50L bioreactor
Price;18000 Euros

5) Turbidity biomass probe Hamilton Dencitee DN25 x 120mm length with PLC and Bioflex software feedback control.
Price; 12.200,00 Euros

6) Online O2 and CO2 Gas analyzer exhaust gas monitoring with PLC and Bioflex software feedback control.
Price; 9.200,00 Euros

7) PC workstation 22" large screen including Bioflex software installation to control 50L bioreactor; Price; 1.600,00 Euros

8) 50L Bioreactor start-up kit, Price; 1.850,00 Euros

NOTE: The described prices for the described items are excluding VAT, custom duties and local taxes in charge of the

Ancillaries; Shipping costs not included, to be quantified or you to organize the goods collection.
Delivery time; approx. 20/24 weeks from PO and first deposit payment receipt.