



南京百帕斯制药设备科技有限公司
Nanjing BioPAS Pharmaceutical Equipment Tech.Co.,Ltd

Pharma Integrated Solution & Turnkey Project

www.am-biopas.com

Pharmaceutical Machinery

Integrated Bioproduction Solution

Pharma Turnkey Project

About BioPAS

BioPAS Pharmaceutical Equipment Technology Co., Ltd. has been dedicated to pharmaceutical industries from their foundation and the main products are bioreactor (fermenter), disc centrifuge, and compounding system etc. The company has been granted as Chinese high technological innovated enterprise. Its name means providing core equipment and integrated solutions for pharmaceutical production.

Based on our expertise and engineering practices, we can help the customer to design the whole pharmaceutical production line, such as vaccine production, injection liquid production, syrup/oral liquid /suspension production, veterinary/agrochemical production, etc. We can configure the necessary equipment according to GMP regulations and the process, complete the fabrication and establishment, commissioning to real production, submit all the engineering documents and validation files. The customer can be free of headache about the different party coordination and save the project time schedule.

All the machines have been fine fabricated and strictly tested good before dispatch. The workshop of BioPAS has been equipped with automatic welding machines, endoscope detector and all kinds of tools and sensors. We can execute FAT in our workshop with necessary facilities such as pure water and steam.

We have already implemented different projects overseas and have a lot of experience on delivery and good understanding and communication with the owner, which ensures that we can succeed in the pharmaceutical project especially abroad erection and project management.

Different with the others, we prefer to help the customer to finalize the real production, instead of supplying machines only. Which means we can give you all the supports such as process development and accompany production.

Our Characteristics and Commitment

- Based on our expertise of pharmaceutical equipment you can be ensured the quality and fast delivery.
- Follow ASME BPE guideline for equipment fabrication and ISO 9001:2008 quality system.
- Provide full set of engineering & fabrication documents, including traceable materials and welding records.
- Customize the equipment based on the individual process and GMP regulations, module design which can be fast installed and flexible use.
- Built test lab with sufficient test tools and condition, which can execute FAT test and sterility test.

Pharmaceutical Production Turn-Key Project

More customers realize that EPC/Turn-Key Project can give them a better solution covering all the aspects of pharmaceutical projects, which is actually very sophisticated and needs interdisciplinary expertise. Even the customer can be very aware of the budget and can have good management on time schedule, which is very important for product launch. BioPAS can provide the integrated solution which is consistent with ISPE guidelines.



Project Consultant

We can provide consulting service for pharmaceutical project. Such as feasibility study, concept design, detailed design, which can meet the budget of the customer and latest GMP requirements.

Compounding System & Pipeline Engineering

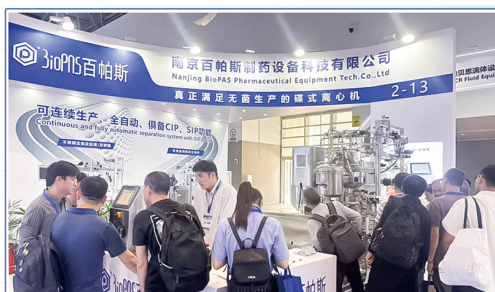
Provide compounding system for the pharmaceutical plant, including pure water/WFI system and pipeline engineering. All the contact parts are SS 316L and the valves are international brands.

Fermentation & Bioreactor

The section includes media preparation, bioreactors, buffer tanks, inactivation tanks, viral production, concentration, centrifuge, formulation tanks and all kinds of mixers and filters.

Commissioning & Qualification

We offer the commissioning & validation service which can support the customer to finalize the project as designed and meet the GMP regulations. It includes risk assessment of plant assets, commissioning and qualification of equipment, CSV and etc.

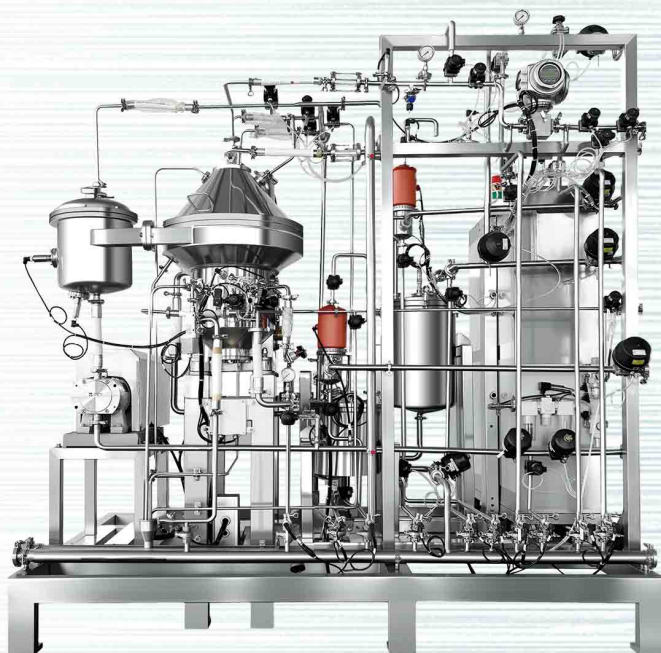


Best practice

Highlight Product

Disc centrifuge

- 1.The ultra-high separation efficiency can meet the needs of pharmaceutical or food process for closed, automatic, and continuous production. It can achieve a high yield above 90% and a high water throughput over 10000 L/H.
- 2.BPS series can comply with GMP requirements of biopharmaceuticals, with fully automatic clean in place (CIP), and fully automatic sterilization in place (SIP).
- 3.The drum body is made of high-strength stainless steel, and materials in contact with the product are stainless steel 316L. The surface finish of the product contact is $Ra \leq 0.4\mu m$.
- 4.We have rich experience on configuring centrifuge according to different separation products. It can be widely used for protein separation, vaccine separation, animal cell separation, fermentation broth concentration and clarification, probiotic concentration, etc.



Parameter

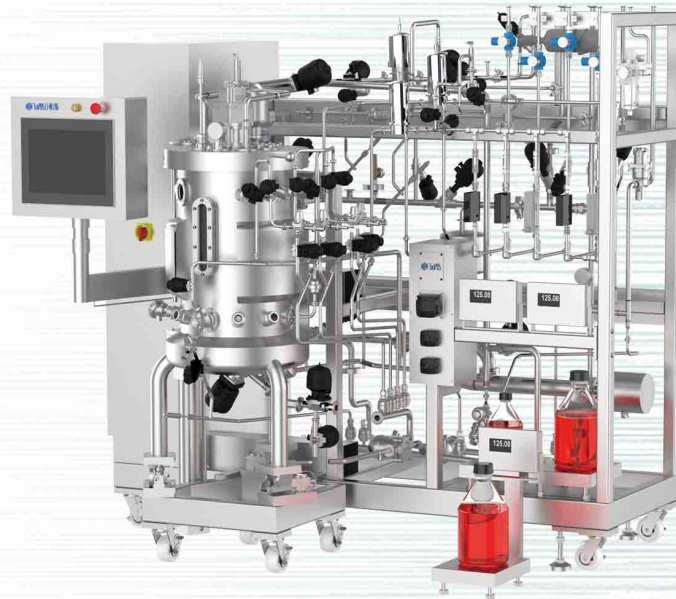
Item	BPS-L204	BPS-L305	BPS-L209
Rotating speed	11000r/min	8500r/min	7300r/min
Full drum volume	2.5L	5.5L	14L
Separation factor	$\geq 14000g$	$\geq 12100g$	$\geq 12000g$
Water throughput	500L/H	5000L/H	10000L/H
Motor	3.0kw	7.5kw	15.0kw

Highlight Product

Based on advanced infrastructure of manufacturing automation, and the characteristics of mammalian cell culture and microbial fermentation process, BioPAS has developed bioreactor and fermenter with cutting edge technology. The products are suitable for cell culture and microbial fermentation from pilot production to commercial production such as monoclonal antibody, vaccine or recombinant protein.

Bioreactor/Fermenter

1. Working volume: 20L-5000L
2. Fully automatic design: Including CIP/SIP, process parameter control
3. Stirring: A variety of stirring forms (magnetic stirring/ double-end shaft seal) are optional to meet different production needs
4. Boosted control system follow with ISA 88 standard, friendly HMI and easy operated. It contained recipe management and electronic batch records, which meet 21 CFR Part 11
5. Can offer fixed bed bioreactor as optional; different ventilation strategies such as microbubbles and bubble-free aeration are available



Parameter

Stirring	Speed: 10~800rpm continuously variable speed
pH Control	Range: 2~12pH; Control accuracy: ± 0.02 pH
DO Control	Can be associated with speed; Range: 0~150% Control accuracy: $\pm 5\%$
Temperature Control	Range: cooling water temperature +5~55°C; Accuracy: $\pm 0.2^\circ\text{C}$;
Foam Control	Electrode detection, peristaltic pump automatically replenishes defoaming agent
Ventilation	Automatic adjustment, MFC control; Range: 0.1-3VVM
Tank Pressure	Automatic adjustment, pressure gauge display; Range: 0~0.20MPa

Highlight Product

Benchtop bioreactor

1. Working volume: 2L/5L/10L/20L
2. Tank material: Borosilicate glass or PES for the body. SS316L for other contacting parts and SS304 for other non-contacting parts
3. HMI: Full-color all-in one touch industry computer IPC with web remote access function
4. Stirring: Internationally renowned servo motor for controlling of stirring speed, various replaceable impellers (Ruston, marine, cell lift)
5. Flexible control system, friendly HMI and easy operated. It is scalable and can control one or multi bioreactors
6. Optional for different culture mode, such as suspension culture, microcarrier culture and fibra-disk carrier culture



Parameter

Work Volume	2L,5L,10L,20L
Temperature Control	PID control, control accuracy: $\pm 0.2^{\circ}\text{C}$, Temperature control range: 5-65 $^{\circ}\text{C}$
Gas Control	Four gas control system (Air/O ₂ /N ₂ /CO ₂)
DO Control	Mettler/Hamilton Control range: 0-150% Control accuracy: $\pm 5\%$ Can be controlled in conjunction with speed, ventilation and feeding
pH Control	Mettler/Hamilton Control range: 2-12pH Control accuracy: $\pm 0.02\text{pH}$ Can be controlled in conjunction with acid-base feeding pump or CO ₂
Peristaltic Pump	Imported peristaltic pump can realize timing, quantitative and precise feeding or function feeding The working mode can be customized Feeding can be done at intervals or continuously during the cycle
Stirring	Top-mounted mechanical stirring or magnetic stirring Imported servo motor, PID control, Stirring speed range: 20-1200rpm, Accuracy : $\pm 1\text{rpm}$

Highlight Product

Sterile Compounding System

1. Working volume: 15L-5000L
2. Compact and flexible functions which are suitable for liquid preparation and mixing/dispensing
3. Fabrication of tanks follows ASME BPE guideline and $Ra \leq 0.4\mu\text{m}$, magnetic stirring/double end shaft seal is preferred to ensure no contamination
4. CIP/SIP fully automatic design and automatic tank pressure. It can realize the automation of the whole process, which saves the manpower and reduces the probability of incorrect operation
5. The SKID is module equipped and fast delivery for the project



PROCESSING AND QUALITY CONTROL



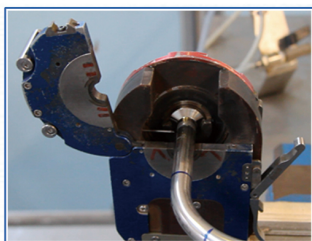
Slope Control



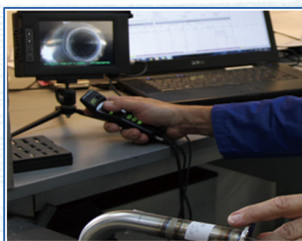
Finish Test



Coverage Test



Pipe Welding



Endoscopy



Empty Check



ADD: No.190, East Bianzhong Road, Chengqiao Street,
Liuhe District, Nanjing, China

TEL: +86 025-68520566

WEB: www.am-biopas.com

E-mail: panda@anmantech.com

Mobile(WhatsApp): +86 13899382662
+86 18756617868

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