Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

APS8&APSD8 TECHNICAL DOCUMENT

APS8&APSD8 技术文件

1. SYSTEM DESCRIPTION 系统描述

Blow-fill-seal (BFS) technology is an automated process by which ampoules are formed, filled, and sealed in a continuous operation. All these procedures are completed in a single time under aseptic conditions, and the whole cycle is completed within 12 to 14 seconds.

吹灌封技术即吹瓶（Blow）-灌装（Fill）-封口（seal），简称 BFS。该技术是通过在一台设备连续运行的工艺中，完成对塑料安瓿的成型、液体的灌装，将灌装好的塑料安瓿瓶进行封口，所有这些工序都是在无菌条件一次性完成的，整个循环，在 12~14 秒以内完成。

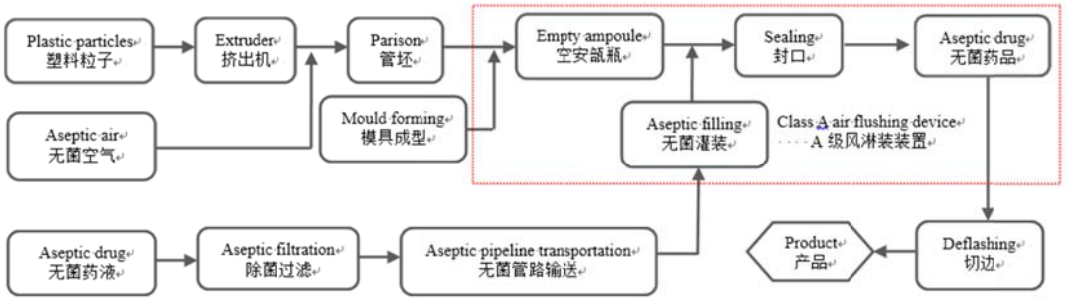
As the container is formed, filled and sealed on a single machine, the whole process is completed under the protection of aseptic laminar flow air, and all process media (liquid medicine, air, etc.) are sterilized and filtered, so the possibility of the product being polluted by the production environment is very low. During the whole process, the opening time of the container is exposed to the air in the production environment for less than 1.5 seconds, so the BFS aseptic filling process has become the first choice for products that need to be protected from particle and microbial contamination.

由于容器是在一台单机上成型、灌装并封口，整个工艺过程在无菌层流空气的保护下完成，所有的工艺介质（药液、空气等）均经除菌过滤，因此产品受到生产环境 污染的可能性非常低；在整个工艺过程中容器开口时间暴露于生产环境空气中不足 1.5 秒，故三合一无菌灌装工艺成为了需要防止微粒及微生物污染的产品的首选

2. PROCESS DESCRIPTION 工艺描述

The following picture show the major phases of BFS machine。

下图为 BFS 设备主要工序。



Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

Process **工艺步骤**	**Description** **描述**
Extrusion 挤塑 	High temperature screw extrusion: the thermoplastic material is continuously extruded into tubular shape by high-speed rotating screw, overhanging plastic tube (called parison), and the parison washed by sterile air is through the forming mould. The temperature of plastic hot melt and extrusion is 170~230 degrees, and the pressure is 350bar. It is the aseptic extrusion and heat removal process. **高温螺杆挤塑：**用高速旋转螺杆将热塑性材料连续挤压成为管状，悬垂的塑料管（称为管坯），由无菌空气冲洗的管坯穿过成型模具。塑料热融和挤出的温度为 170~230 度，压力 160-260bar,是经过实证的无菌挤出和去热源工艺。 Parison sealing and cutting: when the parison reaches an appropriate length, the main mould closes and seals the bottom of the parison, the cut-off knife cuts the parison. The top of the parison is positioned by the opening holder, and sterile air continues to protect the opening parison in the mould. 管坯**封口切断：**当型坯达到适当长度时，主模合模把管坯底部密封，切刀切断管坯，管坯顶部被开口保持架定位，无菌空气继续保护模具中敞开的管坯。
Blowing 吹瓶 	Aseptic air blowing: the mould is quickly transferred to the blow blowing/filling station, and the aseptic air supplied in the grade A air shower protects the blowing, filling and sealing station. Lower the filling needle into the parison until it is sealed against the mould. The plastic material is then molded into containers by vacuum and/or sterile compressed air according to the mould shape. **无菌气体吹瓶：**模具被快速转移到吹瓶/灌装工位，A 级风淋装置中供应的无菌空气对吹瓶、灌装和封口工位进行保护。降低灌装针，使其进入管坯，直至与模具形成密封。再通过真空和/或无菌压缩空气按照模具的形状，把塑料原料成型容器。

Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

Process **工艺步骤**	**Description** **描述**
Filling 灌装 	Container quantitative filling: the measured liquid medicine is immediately filled into the container, and sterile air is exhausted. Air and liquid medicine are filtered through a filter before entering molded or forming containers. The pipeline which the liquid medicine passes through should conduct CIP and SIP before filling to ensure the safety of the liquid medicine. **容器定量灌装：**通过计量的药液立即被灌装在容器里，并排出无菌空气。空气和药液在进入已经成型或正在成型的容器之前都经过过滤器过滤。药液经过的管路在灌装之前进行在线 CIP 和在线灭菌 SIP，确保药液安全性。
Sealing 封口 	Sealing of the ampoule head: after filling, the plastic between the top of the mould and the opening holder is in a state of semi-melting, and then the sealing mould is closed to form the top of the container and make the ampoule sealed. **瓶体头部封口：**灌装结束后，模具顶部和开口保持架之间的塑料处于半融化状态，接下来密封模具合闭，形成容器的顶部，并使瓶子密封。
Outfeeding and cutting **出瓶和切边** 	Outfeed, transferring and deflashing: after sealing, the mould is opened, the finished ampoule after forming, filling and sealing is sent out of the machine to start the next cycle. **出瓶传送切边：**密封后，模具打开，已经完成成型，灌装并密封的瓶子被送出机器，接着开始下一个循环. Deflashing system: the deflashing system is placed in the general area. It needs two times of handover from the filling room to general area. The handover area is recommended to be placed in the buffer room to avoid contamination of the clean area caused by cross-domain of different areas. **切边系统：**切边系统放置在一般区域，从灌装间进入一般区经过两次交接完成，交接区域建议放置在缓冲间，避免不同区域跨域造成的洁

Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

Process **工艺步骤**	**Description** **描述**
	净区域的污染。 切边机构采用液压油缸驱动，高度冲击板料，将成品从框架分离形成成品块。

Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

3. THE MAIN TECHNICAL PARAMETER 设备主要技术参数

设备型号 APS8

Specification 产品规格	Extrusion Heads 挤出头数	Mould Cavity 模具腔数	Total Cavity 总腔数	Capacity 产能/时
100mL	8	8	8	1850
250mL	8	8	8	1700
500mL	8	8	8	1550

设备型号 APSD8

Specification 产品规格	Extrusion Heads 挤出头数	Mould Cavity 模具腔数	Total Cavity 总腔数	Capacity 产能/时
100mL	8	2x8	16	3300
250mL	8	2x8	16	3000
500mL	8	2x8	16	2800

The capability of the whole compact line can be adjusted, and the test is subject to the distribution of WFI after the machine running in normal condition.

注：上述规格对应的准确产能依据买方药品特性以及瓶型而定，整机产能可调，测试以设备正常运行后以分装注射用水（WFI）为准。

APS8&APSD8 Blowing -Filling-Sealing System 吹灌封一体机	
Qualified rate 产品合格率	99%
Product weight deviation 产品克重控制偏差	±0.10g/piece
Ampoule thickess deviation 产品容器壁厚控制偏差	±0.10mm
Filling accuracy 灌装精度	100mL~500mL：±0.5%

Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

Overall dimension 主机外形尺寸（不含轨道）	See the layout drawing 见平面图
Weight 主机设备重量	APS8: 约 11000kg APSD8: 约 13000kg
Power 主机装机功率	APS8: 约 120kW APSd8: 约 140kW
N2 or Pure Air 氮气（非必须） 或者洁净压缩空气	Pressure 压力：4.2-6.0bar 耗量： Consumption is determined according to the pharmaceutical process.(用量根据药品工艺定)
Cooling Water 冷却水	Pressure 压力：2.5-3.5bar Temperature 温度：7-12℃（可调） Flowrate 流量： APS8：1.75m³/h APSD8：2m³/h
City water 软化水/城市用水	Pressure 压力：2-3.5bar Temperature 温度：12-25℃ Flowrate 流量： APS8：1m³/h APSD8：1.5m³/h
Compressed air 干燥压缩空气	Pressure 压力：6-8bar Flowrate 流量： APS8：60m³/h APSD8：100m³/h
Vacuum 真空	Pressure 压力：-0.075MPa（min） Flowrate 流量：63m³/h （the machine has been configured the vacuumsystem 设备自带真空泵）
Liquid CIP/SIP inlet 药液 CIP/SIP 进口	APS8： Liquid 药液：max.1bar，max.800L/h Pure steam 蒸汽:2.7-3.4bar，60kg/h，125℃（40min） Clean liquid 清洗介质：2m³/h，2-3bar（40min） Pure air 无菌压缩空气：0.5m³/min（20min）

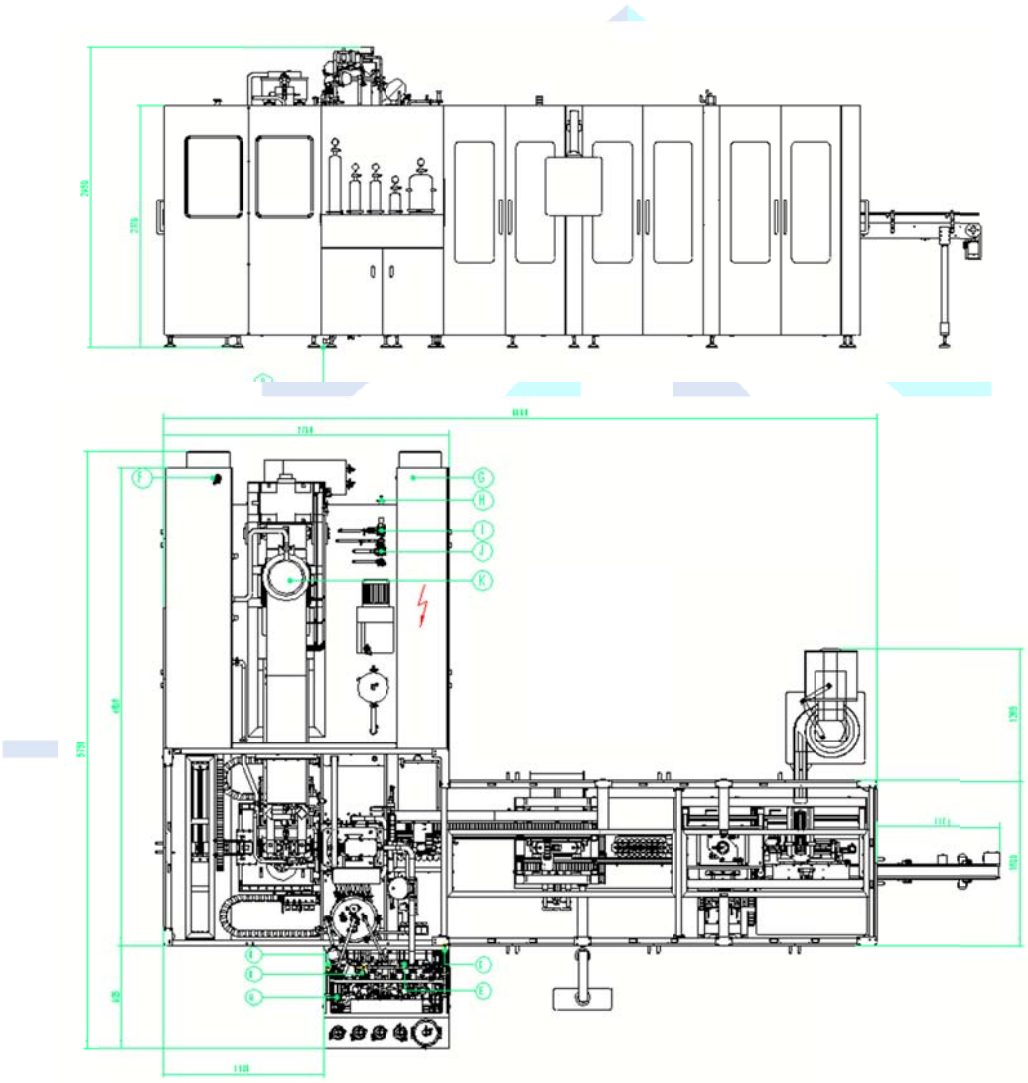
Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

	APSD8： Liquid 药液：max.1bar，max.1450L/h Pure steam 蒸汽:2.7-3.4bar，90kg/h，125℃（40min） Clean liquid 清洗介质：3m³/h，2-3bar（40min） Pure air 无菌压缩空气：1m³/min（20min）
Extrusion 挤出机能力	APS8： LDPE:160 Kg/h PP:160 Kg/h APSD8： LDPE:160 Kg/h PP:160 Kg/h
Suitable Sizes of bottle 配置安瓿瓶规格	The suitable scope of the machine: size 100-500mL LVP bottle, it can be realized after adding relevant change parts 100-500mL. The Buyer provide the samples or drawing, the related filling volume information. 整套设备适应范围：(100-500mL)输液瓶规格，在增加相应的规格件后可实现(100-500mL)。买方提供以上规格样品或图纸，提供每种规格对应的分装量。

4. APS BLOW-FILL-SEAL MACHINE DESCRIPTION 设备简介

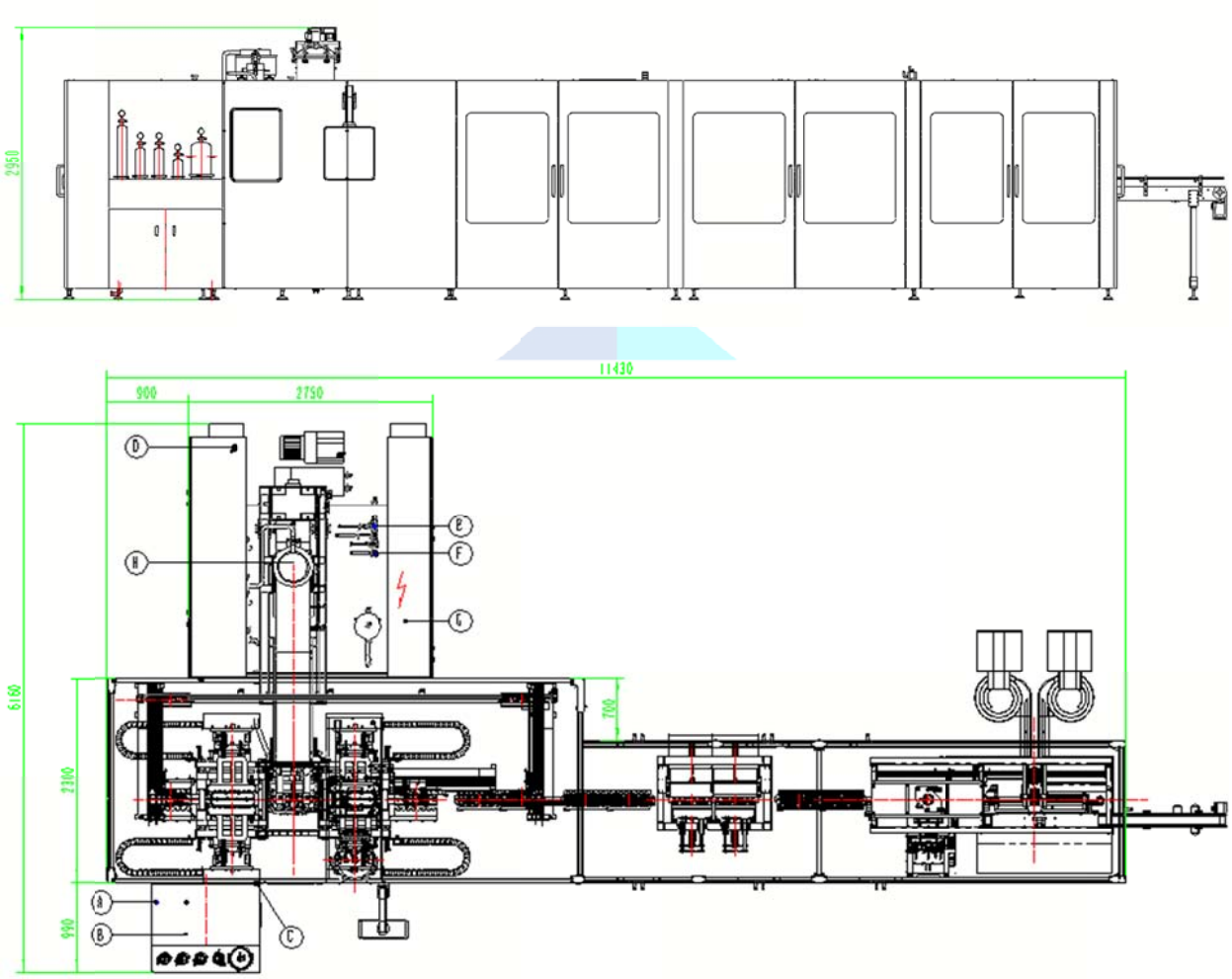
BFS is short for Blow-Fill-Seal machine. It's a fully-automatic machine which can blow the thermoplastic material into container, then finish filling and sealing in continuous operation under A Grade environment.

吹塑、灌装、密封（简称吹灌封）设备是一台可连续操作，将热塑性材料吹制成容器并在 A 级空气洁净度的气流条件下完成灌装和密封的全自动机器。



Layout drawing APS8 设备外形图

Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0



Layout drawing APSD8 设备外形图

4.1. Vacuum infeed 真空上料

Raw material in-feed via the vacuum feeding machine, it can achieve the linkage function with main machine. When the raw material level low, aotumatically start sucking and infeed, when the raw material level high, automatically stop feeding.

通过真空上料机实现自动上料，与系统保持联动控制，能做到料位低位时自动吸入，高位时自动停止。

4.2. Extrusion station 挤出工位

Extruder is a kind of mechanism that converts loose plastic particles into molten plastic in high temperature, high pressure and closed environment by directly driving screw through motor.

挤出机是通过电机直接驱动螺杆在高温高压及密闭的环境中把松散的塑料颗粒转换成熔融塑料的一种机构；

The cast aluminum heater with internal water cooling device and PID control technology are equipped on the screw to provide accurate control of three-stage extrusion temperature for the extruder. The West temperature control module PID controls the temperature of 17 temperature control points, and the temperature control machine precisely controls the plasticizing temperature of the screw segment of the extrusion system.

在螺杆上配备内带水冷装置的铸铝加热器和 PID 控制技术为挤出机提供 3 段挤出温度精确控制；

West 温度控制模块 PID 控制 17 个温控点温度，温控机精确控制挤塑系统挤塑系统螺杆段塑化温度。

Core control parameters: extrusion temperature control ±1℃; extrusion tube thickness control ± 0.1mm;.

核心控制参数：挤出温度控制±1℃；挤出壁厚控制±0.1mm；

4.3. BFS mould shifting and locking 移模锁模部件

4.3.1 Mould carriage movement 模架移动

Adopt the rotating oil cylinder to let the mould carriage part reciprocate the movement in the position of extrusion and filling and sealing through the drive of swing arm.

采用旋转油缸、通过摆臂驱动，或者通过直线油缸将模架部分在挤塑位置和灌封位置往复运动。

Mould carriage movement is controlled by displacement sensor and position control card, which ensures that the repetition accuracy of mould carriage movement is ±0.02mm. the mould carriage moves at high speed during the moving process without impact.

模架移动采保证模架移动的重复精度在±0.02mm，模架在移动过程中高速移动，且没有冲击。

Core control parameters: mould shifting speed 1.2s; parallelism of linear guide of mould shifting is 0.02mm; linear guide relative level 0.02mm, repetition accuracy of mould carriage movement is ±0.02mm. ，no impact.

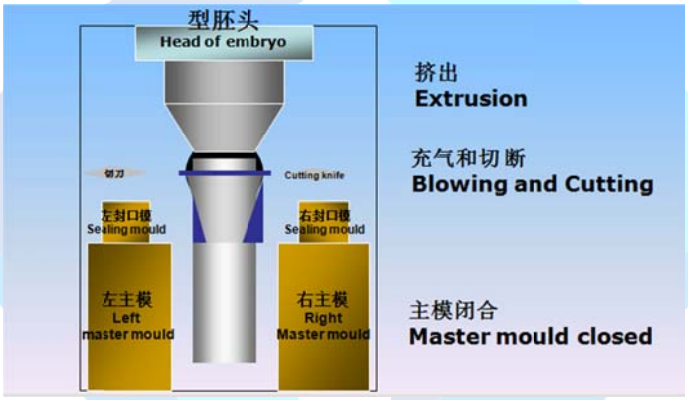
核心控制参数：移模速度 1.2s；移模线性导轨平行度 0.02mm；线性导轨相对水平度 0.02mm，重复定位精度±0.02mm 移模无冲击。

4.3.2 Opening and closing action of master mould 主模开合模动作

The linear hydraulic cylinder is used to drive the mould to close the mould, and the cylinder is controlled by proportional regulating valve. The displacement sensor is used to accurately locate the mould position, and opening and closing action curve is controlled to ensure that the mould moves forward at high speed and closing at low speed.

采用线性液压油缸驱动动模板带动模具进行合模动作，油缸采用比例调节阀控制，位移传感器精确定位模具位置，开合模动作曲线控制，保证模具高速前进，低速合模。

Master mould closed 主模闭合



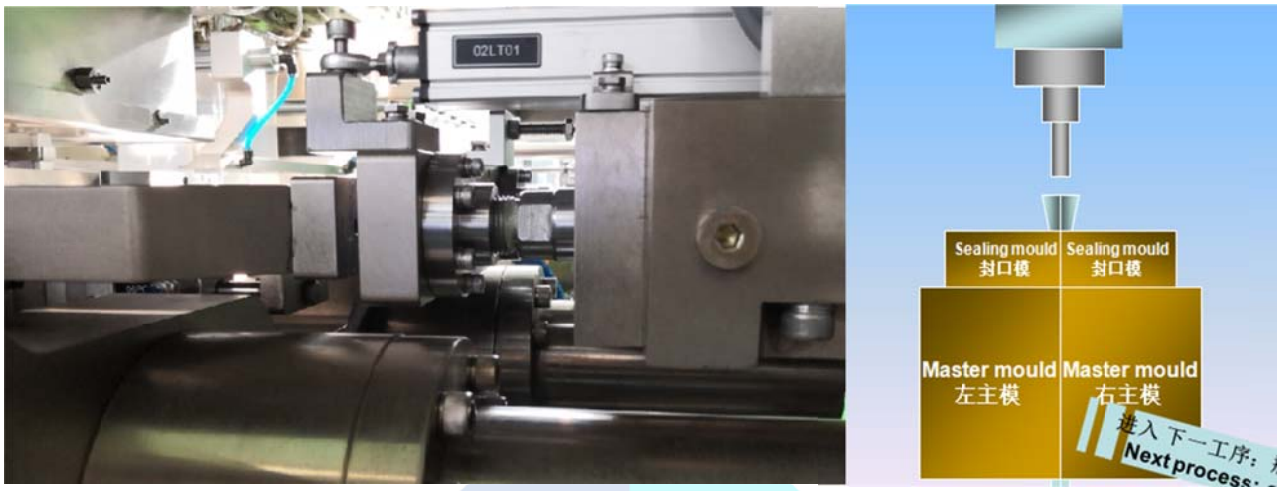
4.3.3 Opening and closing action of sealing mould 封口模开合模动作

The duplex linear hydraulic cylinder is used to drive the mould to close the mould, and the cylinder is controlled by proportional regulating valve. The displacement sensor is used to accurately locate the mould position, and opening and closing action curve is controlled to ensure that the mould moves forward at high speed and closing at low speed.

采用双联线性液压油缸驱动封口模具进行合模动作，油缸采用比例调节阀控制，位移传感器精确定位模具位置，开合模动作曲线控制，保证模具高速前进，低速合模。

The pushing plate action of three-point sliding rail positioning and sealing mould can effectively avoid the phenomenon of raising head for the sealing mould closing caused by the original two-point sliding rail positioning.

三点滑轨定位封口模具推板动作，有效的避免原有两点滑轨定位带来的封口模具合模翘头现象



Sealing mould closed 封口模闭合

4.3.3 The feeding action 取料机构

The feeding action adopts servo hydraulic linear oil cylinder. When the feeding rod descends to the middle position, there is the feeding plate. When it descends to the low position, the feeding rod breaks away from the plate. The feeding plate holds the plate for cooling and it is conveyed to the deflashing station.

取料动作采用伺服液压线性油缸动作，取料杆下降到中位有取料板取料，下降到低位取料杆脱离板料，取料板夹持板料进行冷却，由传送夹传送至切边工位。

4.4. Filling stestem 灌装系统

The filling system adopts time-pressure method for filling. The servo drives the filling head to move down. The filling system is equipped with buffer tank. The buffer tank adopts Mettler Toledo weighing module to control the liquid level of tank and uses pressure transmitting module to control the filling pressure of tank. It is equipped with high precision and high frequency air replenishing/exhaust valve to ensure the constant pressure of filling buffer.

灌装系统采用时间-压力法进行灌装，伺服驱动灌装头下降，灌装系统配置有缓冲罐，缓冲罐采用 Mettler Toledo 称重模块控制罐体液位高度，采用压力变送模块控制缓冲罐体灌装压力，配置高精度高频补气排气阀门保证灌装缓冲恒定压力。

◆**Waste ampoule** identification function: the equipment is equipped with waste ampoule

identification function, the product is not filled and deflashed due to unqualified forming and will be rejected directly.

废瓶识别功能：设备配置有废瓶识别功能，对于成型未达到要求的产品不进行灌装和切边，直接剔废。

◆**Grade A shower device:** BFS equipment adopts the fan to suck the clean air in the clean room. The air passes through the coarse efficiency filter and HEPA filter and enters the filling area. The air pressure chamber adopts the flow equalizing membrane for supply to reduce the disturbance inside the chamber, which can provide grade A shower for the filling needle and non-sealed ampoule body ensuring the sterility of product. The static pressure chamber of the filling system is equipped with air speed detection and differential pressure detection, at the same time, dust particles, plankton and sedimentation bacteria detection can be selected as required.

A 级风淋装置：BFS 设备采用风机抽取洁净房间洁净风，通过初效过滤器，高效过滤器送风至灌装区域等风压箱，风压箱体送风采用均流膜送风，减少箱体内流体的扰动，给灌装针和未封口的瓶体部分 A 级风淋，保证产品的无菌性。灌装系统静压箱体内配置有压差检测，同时可根据可以要求选

配尘埃粒子。

Core control parameters: differential pressure, dust particles, plankton, sedimentation bacteria meet grade A requirements.

核心控制参数：压差、尘埃粒子、浮游菌、沉降菌符合 **A 级要求。**

◆Filling head 灌装头

The problem of drug bubbles can be solved better by using a tangential intake pipe. All the control elements are outside and easy to maintain. The diaphragm is controlled by high frequency solenoid valve switching vacuum/compressed air.

采用切斜的进液管，更好的解决药液气泡问题。全部控制元件在外面，维护简单。采用高频电磁阀切换真空/压缩空气来控制膜片。

4.5. Mould 模具

Mould: including three parts: ampoule body mould, sealing mould and holder. Each part has separately-adjusted cooling water and vacuum pipeline. The mould is made of imported copper alloy, after heat treatment, it has the advantages of non-deformation, high hardness, high strength, anti-rust and good polishing performance, and long service life. Its own cooling and vacuum channels are connected to the cooling and vacuum system of the equipment to ensure consistent temperature of the products and moulds.

模具：包括三个部分：瓶体模、封口模和保持架。每部分都有单独调节的冷却水和真空管路。模具采用进口铜合金制造，经过热处理工艺后，具有不变形、高硬度、高强度、防锈及良好的抛光性能，使用寿命长。其本身带有冷却和真空通道与设备的冷却和真空系统相连，保证产品及模具温度一致。

Mould temperature is controlled by self-excited temperature-controlled water valve, which can automatically adjust the water inlet and outlet of mould to ensure the cooling temperature of product and reduce the generation of waste sheet.

Core control parameters: mould processing control, flatness 0.015mm, verticality 0.02mm, parallelism 0.02mm, constant temperature control of mould.

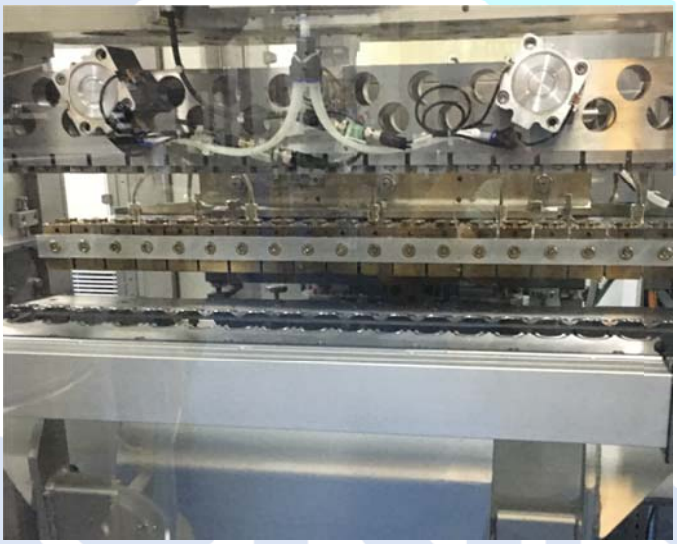
核心控制参数：模具加工工艺控制，平面度 0.015mm，垂直度 0.02mm，平行度 0.02mm，模具温度恒温控制

4.6. Cutting system 切边系统

切边机构采用伺服电缸传送，采用气缸驱动切边机构，高度冲击板料，将瓶顶部和底部废料去除。

4.7. 焊盖机构

瓶子通过伺服电缸传送至焊盖工位，整盖斗将盖子整理，输送至焊盖加热板，加热板将瓶子和盖子加热，然后将瓶子与盖子焊接。



4.8. CIP/SIP system CIP/SIP 系统

BFS equipment has CIP/SIP unit. All valves of CIP/SIP system adopt Gemu pneumatic diaphragm valve and Festo valve terminal automatic control. After the operator has installed the sterilization cup, the system will automatically complete the CIP/SIP program.

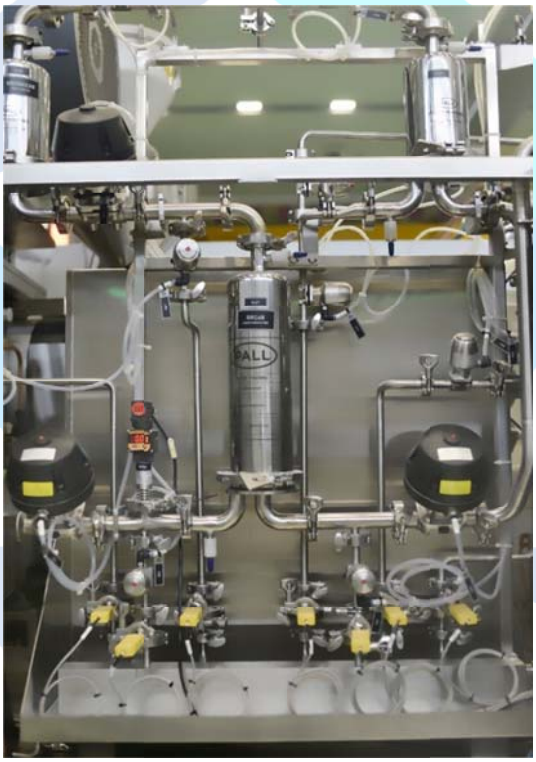
BFS 设备具有 CIP/SIP 单元，CIP/SIP 系统采用所有阀门采用 Gemu 气动隔膜阀，采用 Festo 阀岛自动控制。操作人员安装好灭菌杯以后系统自动完成 CIP/SIP 程序。

The cold point of the system is designed with temperature monitoring to ensure that all points of the system reach the sterilization temperature. System piping shall be designed in accordance with ASME BPE standards. Horizontal piping shall be designed with slope and drainage piping shall be designed with low point. The piping shall meet 3D requirements.

系统冷点设计有温度监测，保证系统所有点都达到灭菌温度。系统管路设计按照 ASME BPE 标准执行，水平管路设计有坡度，管路低点设计有排放管路，管路满足 3D 要求。

System pipeline construction shall be performed according to ISPE GEP standard, and material certification, welding seam report, argon gas protection record, welding sample report and endoscopic inspection report shall be provided.

系统管路施工按照 ISPE GEP 标准执行，提供材质证明，焊缝报告，氩气保护记录，焊接试样报告，内窥检查报告。



4.9. Hydraulic system 液压系统

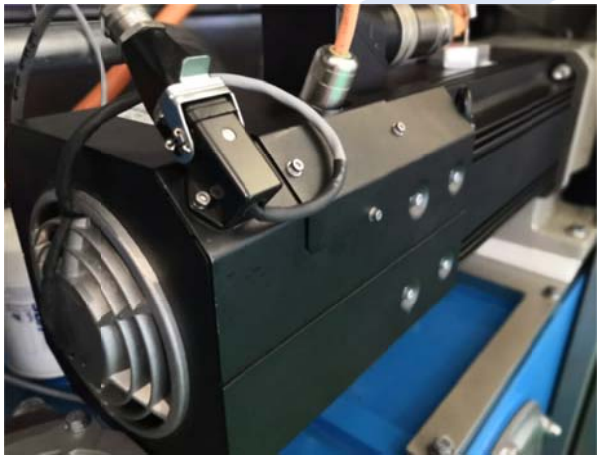
The hydraulic system includes hydraulic oil tank, overflow valve, accumulator, control valve set, servo-driven low pressure pump head and motor driven high pressure pump head, heat exchanger,

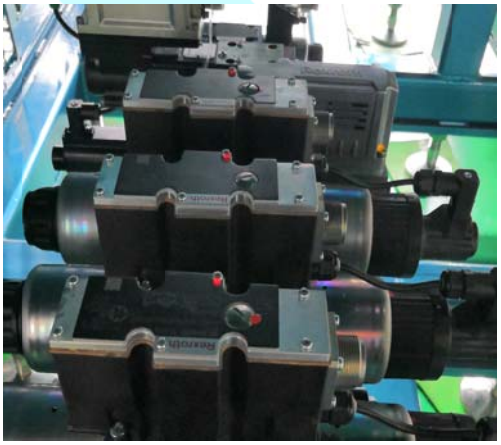
etc. The main components are internationally renowned brands. Servo low pressure pump controls the flow and minimizes energy consumption.

液压系统包含液压油箱、溢流阀、蓄能器、控制阀组、伺服驱动低压泵头和电机驱动高压泵头、换热器等部分组成。主要元件均采用国际知名品牌。伺服低压泵控制流量，最大限度降低**能耗**！

The hydraulic system adopts servo pump, the pump is PID adjusted according to the outlet pressure, and the proportion curve of mould shifting, mould locking, mould opening and mould closing action is controlled, which can effectively reduce the impact of equipment and reduce the energy consumption of the hydraulic pump station by 30%. Nickel-plated oil cylinder is without the risk of paint peeling, more in line with the requirements of pharmaceutical GMP.

液压系统采用伺服泵，泵根据出口压力做 PID 调节，移模、锁模开合模动作比例曲线控制，有效的减少设备冲击，同时减低液压泵站能耗 30%；
镀镍油缸无油漆脱落的风险，更加符合制药 GMP 的要求





4.10. Pneumatic&Cooling&Vacuum system 气动冷却真空系统

- Pneumatic system: pneumatic system is divided into compressed air system and aseptic compressed air system, the system consists of filter, valve, pneumatic valve terminal and solenoid valve. Compressed air system is to complete the pneumatic action, sterile air system is to complete the air supply of product forming and CIP/SIP.

  气动系统：气动系统分为压缩空气系统和无菌压缩空气系统，该系统由过滤装置、调节阀、气动阀岛及电磁阀构成。压缩空气系统完成气动动作，无菌空气系统完成对产品成型用气和 CIP/SIP 气源的供应

- Cooling system: the cooling system is divided into two independent loops: chilled water system and cooling water system. The chilled water system is used to cool the reducer, hydraulic system and mould of the extruder system. The cooling water system cools the extruder scrap holder, the extruder parison bottom sealing holder, the take-out holder and the extruder screw barrel.

  冷却系统：冷却系统分为两个独立回路：冷冻水系统和冷却水系统。冷冻水系统用于冷却挤出机系统减速机、液压系统、模具。冷却水系统冷却挤出机废料夹、挤出机封底夹、取料夹和挤出机螺杆筒体。

- Vacuum system: the vacuum system includes vacuum pump, vacuum reserve tank, vacuum valve which can be independently controlled by each branch and a vacuum module of analog quantity. Provide vacuum source for product forming.

  真空系统：真空系统包括真空泵、真空储备罐、各支路能独立控制的真空阀和一个模拟量的真空模块。为产品成型提供真空源。

All utilities should be tested. When the test value fails to meet the requirements of the set value, the system will alarm and stop.

所有的供应工程介质均应该进行检测，当检测值未达到设定值要求时，系统报警停机。

4.11. Control system 控制系统

The control system of equipment is mainly composed of the main motion controller, microcomputer touch screen, valve terminal, temperature controller, servo controller, frequency converter, servo card and other control components. The control system design conforms to the requirements of Part 11 and GAMP5.

设备控制系统主要由主运动控制器、微机触摸屏、阀岛、温控仪，伺服控制器、变频器、伺服卡及

其他控制元件组成。控制系统设计符合 Part 11 和 GAMP5 要求。

4.10.1 Data backup and recovery 数据备份与恢复

- V the database can be backed up manually. The backup database contains the backup of historical data 、log records and alarm records.
  数据库可通过人工备份的方式进行，备份的数据库中包含历史数据、日志记录和报警记录；
- The backup database has been encrypted and cannot be opened without permission;
  备份的数据库已做加密处理，在不具备权限的情况下不能将数据库打开；
- The data in the database can choose a period of time to print PDF documents for backup;
  数据库中的数据可选择一段时间打印生成 PDF 文档进行备份；
- The data in the database can choose batch number to print PDF document for backup;
  数据库中的数据可选择批号打印生成 PDF 文档进行备份；
- The printed PDF document is consistent with the data in the original database;
  打印生成的 PDF 文档与原始数据库中的数据一致；
- After system failure or other abnormal conditions recovery, data can be restored, and ensure the authenticity, consistency and integrity of data.
  在系统失效或者其他不正常条件下恢复后，数据可恢复，并确保数据的真实、一致和完整性。

4.10.2 Authorization 权限

User group 用户组	Authorizations 权限			
	User administration 用户管理	Monitor 监控	Maintenance 维护	Operate 操作

Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

User group 用户组	**Authorizations 权限**			
	User administration 用户管理	**Monitor 监控**	**Maintenance 维护**	**Operate 操作**
Administrators 管理员	√	√	√	√
Supervisors 主管	×	√	√	√
Maintenance 维修	×	×	√	√
Operators 操作员	×	×	×	√

Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

5. TECHNICAL DOCUMENT TO BE PROVIDED 提供的技术文件

One set of hardcopy of all documentation provided by Truking in English and Chinese dual language, using the metric system. Drawing symbols comply with IEC and ISO standards.

楚天提供一套中英文双语的纸质文件，使用公制计量单位，图纸的格式标准符合 IEC 及 ISO 的要求。

Documentation supplied with the equipment includes:

与设备一起提供的文件包括：

Document No. **分册**	**No.** **序号**	**Document** **文件**	**Abbreviation** **缩写**	**Note** **备注**
No.1: Design document 第一册：设计文件	1	Function Specification 功能描述	FS	
	2	Hardware design specification 硬件设计说明	HDS	
	3	Software design specification 软件设计说明	SDS	
	4	Main configuration list 主要配置清单	BOM	
	5	Layout drawing 外形图	OD	
	6	P&ID 管路和仪表流程图	P&ID	
	7	Electric Drawing 电气原理图	ECD	
No.2: Qualification Document 第二册：验证文件	1	Component Criticality Assessment 部件关键性评估	CCA	
	2	Risk assessment and recommended control measures 风险评估及建议控制措施	RA	
	3	Design Qualification 设计确认	DQ	
No.3:	1	Quality plan	QPP	

Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

Document No. **分册**	**No.** **序号**	**Document** **文件**	**Abbreviation** **缩写**	**Note** **备注**
Manufacturing and quality document 第三册：建造和质量文件		质量计划		
	2	Welding record, welding joint drawing, welder certificate, endoscopic photo 焊接记录，焊点图，焊工证,内窥镜照片		
	3	Pickling passivation report 酸洗钝化报告		
	4	Welding and passivation SOP files 焊接和钝化的 SOP 文件		
	5	Proof of material quality 材质证明		
	6	Measurement certificate 计量证书		
	7	Component specification 外购件说明书		
No.4: Operation and maintenance document 第四册：操作和维护文件	1	Operation manual (electrical) 操作手册（电气）	OM(EL)	
	2	Operation manual (mechanical) 操作手册（机械）	OM(ME)	
	3	Maintenance manual 维护手册	MM	
No.5: Supplier internal test 第五册：制造商内部测试	1	Supplier internal test 制造商内部测试	SIT	
No.6: Farctory Acceptance Test 第六册：工厂验收测试	1	Farctory Acceptance Test 工厂验收测试	FAT	
No.7: Site Acceptance Test	1	Site Acceptance Test 现场验收确认	SAT	

Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

Document No. **分册**	**No.** **序号**	**Document** **文件**	**Abbreviation** **缩写**	**Note** **备注**
第七册：现场验收确认				
No.7: Installation &Operation&Performance Qualification 第八册：安装, 运行, 性能确认	1	Installation &Operation&Performance Qualification 安装,运行,性能确认	IQ&OQ&PQ	

6. MAIN CONFIGURATION LIST 主要配置清单

序号	名称	品牌	产地	图片示例	品牌 LOG
1	人机界面 HMI	西门子 SIEMENS	德国 Germany		SIEMENS
2	空气开关 The circuit breaker	西门子 SIEMENS	德国 Germany		ABB
3	接触器 Contactor	西门子 SIEMENS	德国 Germany		ABB
4	逻辑控制器 PLC	西门子 SIEMENS	德国 Germany		SIEMENS
5	总气源处理 Main air source treatment	FESTO	德国 Germany		FESTO
6	阀岛 Valve terminal	FESTO	德国 Germany		FESTO

Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

序号	名称	品牌	产地	图片示例	品牌 LOG
7	液压阀 Hydraulic station	PARKER	美国 USA		Rexroth Bosch Group
8	各种气缸 Various cylinder	费斯托 FESTO	德国 Germany		FESTO
9	磁性开关 Magnetic switch	费斯托 FESTO	德国 Germany		FESTO
10	各种气动阀 Various pneumatic valve	盖米 GEMU	德国 Germany		GEMÜ
11	伺服、变频电机 Servo motor	西门子 SIEMENS	德国 Germany		SIEMENS
12	直线导轨 Linear guide rail	THK	日本 Japan		THK
13	直线轴承、端面轴承 Linear bearing, end bearing	易格斯 IGUS	德国 Germany		igus

Technical document **技术文件**	Equipment Name 设备名称	Aseptic Blow-Fill-Seal Machine 无菌塑料包装吹灌封设备
	Equipment Type 设备型号	APS8& APSD8
	Revision 文件版本	1.0

序号	名称	品牌	产地	图片示例	品牌 LOG
14	滑动轴承、拖链 Sliding bearing、 Drag chain	易格斯 IGUS	德国 Germany		igus
15	排气泵 Exhaust pump	富士 FUJI	日本 Japan		FUJI innovative spirit
16	电容开关 The capacitance switch	西克 SICK	德国 Germany		SICK
17	真空泵 Vacuum pump	BECKER	德国 Germany		BECKER
18	空气过滤器 Air filter	颇尔 PALL	美国 USA		PALL
19	压力变送器 Pressure transmitter	E+H	德国 Germany		Endress+Hauser
20	温度变送器 Pressure transmitter	E+H	德国 Germany		Endress+Hauser