

AUSTAR

Multi-functional Fluid Bed Processor



AUSTAR

Formulation

AUSTAR is a technology-based pharmaceutical engineering solution provider with deep understanding of pharmaceutical industry regulations and processes. Integrating global high-quality resources and being committed to helping clients improve pharmaceutical process and operational effectiveness. Through boosting global drug safety and efficacy to protect and promote human health.

With the concept of “clients first”, we provide high-efficient and compliant fluid bed products and services with prominent performance to our clients all over the world by integrating with experience in formulation technology, automatic control technology, compliance consultation and validation. Our products are widely applied in pharmaceutical, food, and chemical industries.

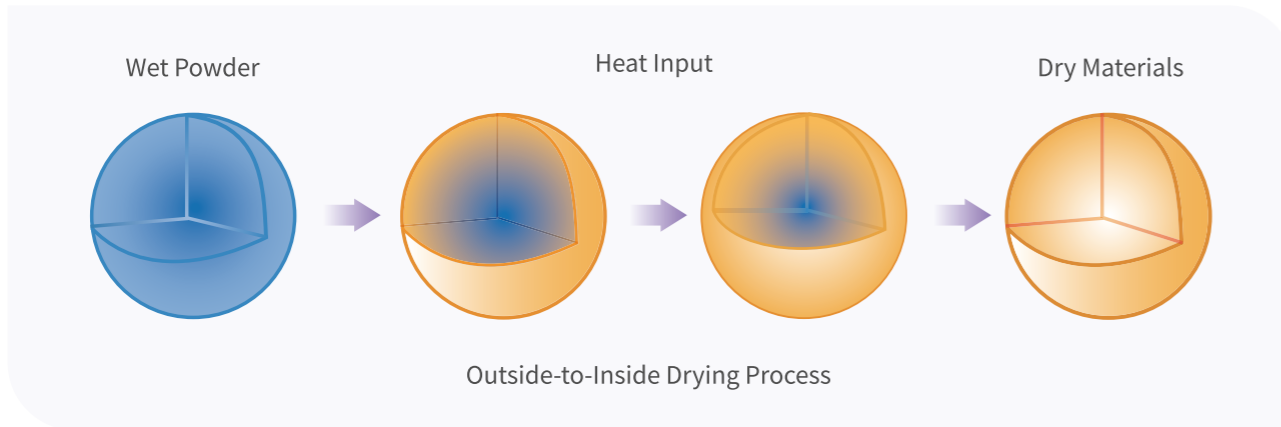
With rich experience in fluid bed process equipment technical cooperation and exchange as well as know-how design, we can integrate mixing, granulating, drying, and pellet coating processes in a perfect way.

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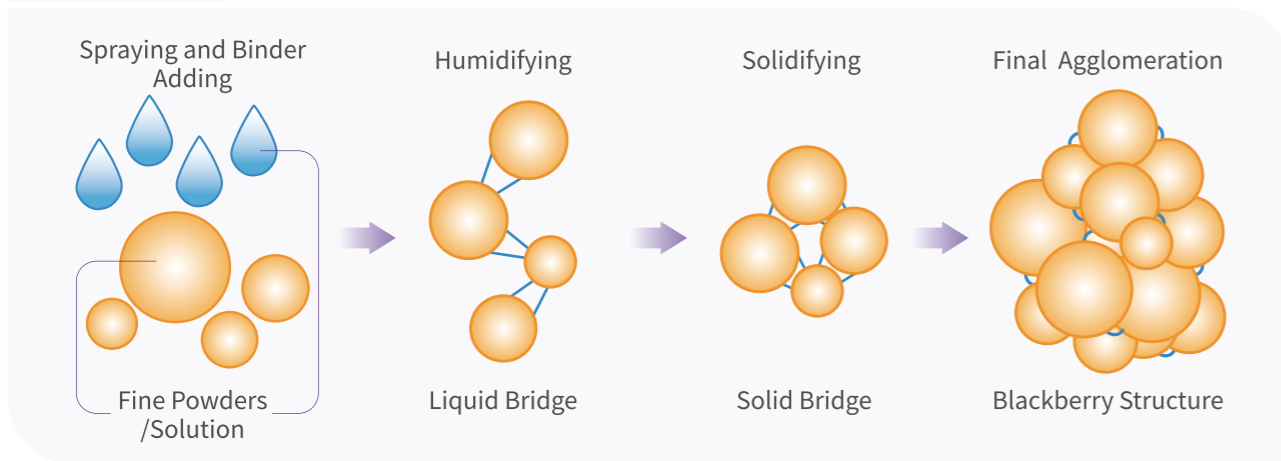
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AUSTAR innovative fluid bed technologies could be applied to drying, granulating and pellet coating processes.

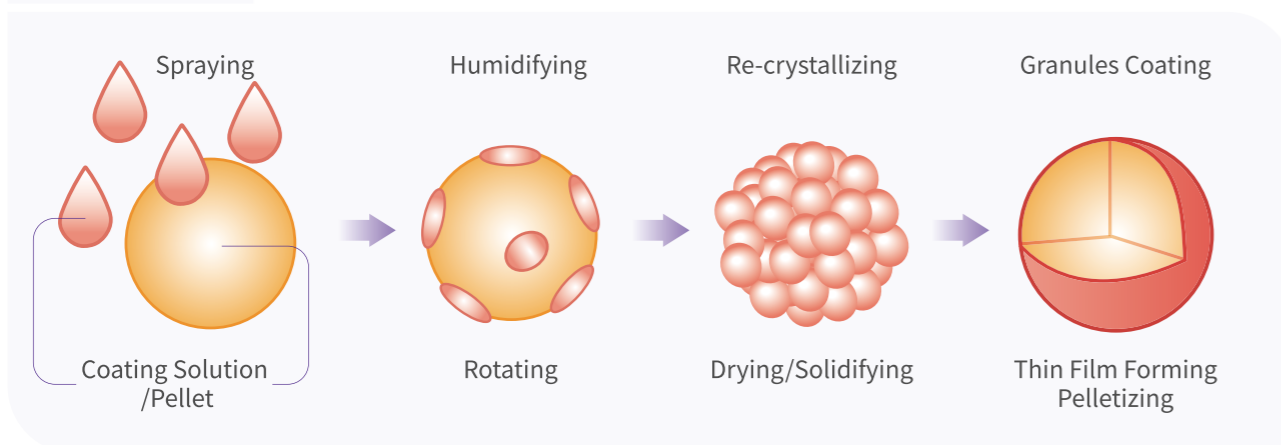
Drying



Granulating



Pellet Coating



Working Principle

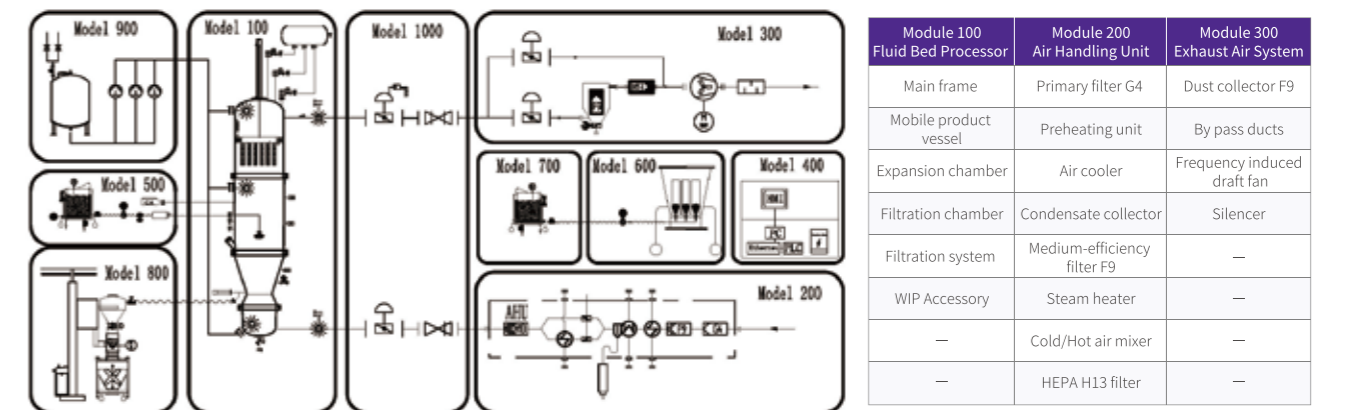
After the inlet air being handled in handling unit, the process air flows through the specially designed rotational flow bottom plate into product vessel, fluidizes the product thoroughly and keeps it in constant motion. After product mixing, granulating by agglomeration, or pellet coating inside product vessel, high drying rate can be realized by high-efficiency heat exchange.

The filter of fluid bed processor will retain the products and return them to product vessel. At the same time, the process air flow passes through the filter, exits from the top of fluid bed, and is vented after being filtered by air exhaust system.

Product Features

1. High degree of flexibility (25%-90%working volume)	2. Higher drying efficiency
3. Automatic online discharging and less residues	4. Rapid and easy replacement of filter cartridge
5. High containment solution which could achieve OEB5/OEB4	6. Easy cleaning
7. 10/12bar pressure shock resistance system	8. PAT available for process data analysis
9. Accurate control to CPP via excellent control system	10. Uniform and high efficient coating process
11. Qualified document system, DQ/IQ/OQ	12. Wide pellet coating capacity (Wurster coating, from 0.5-1200L)
13. High qualified document system	14. Data integrity of FDA, EU GMP complied control system
15. Special designed, series model and professional process team supports the scale up research from lab to commercial	

System Composition



Module 400 Control System	Module 500 Granulating System	Module 600 Pellet Coating System	Module 700 Solution Preparation System	Module 800 Powder Transfer System	Module 900 WIP System	Module 1000 Pressure Shock Resistant System
Electric cabinet/Pneumatic cabinet/HMI	Nozzles/Top spray gun	Spray gun	Preparation tank	Lifting device/Vacuum discharge system (Option)	Valves and pipes for cleaning system	Resistant buckle
Inlet air temperature/ Humidity control system	Peristaltic pump	Coating container	Binder solution tank	Mobile feeding chamber	Cleaning nozzles	Air inlet and exhaust system
Pressure differential monitoring system for bottom plate and filter bag	Mass flow meter	Peristaltic pump	—	Feeding valve	Valve station	Pressure monitor
Air flow and pressure monitoring system	Pressure meter	Mass flow meter	—	Discharge valve	Purified water buffer tank	—
Material temp online monitoring system	Flow meter	—	—	—	Detergent adding/ scale system	—

Standard Configurations

Top spraying system



The fluid bed processor is prepared for fitting top spray nozzle for granulating process. Height, position and spray angle of the nozzle can be adjusted.

Other spray systems (tangential spray, bottom spray) are available as options.

Rotational flow distribution plate



The bottom of product vessel is made of rotational flow plate. It minimizes the drying time of process and ensures an optimal distribution of inlet air in processor and generates an ideal product motion. At the same time, it minimizes the residual after discharging process. Pore size and clearance can be customized according to the products.

WIP system



The processor itself is automatically cleaned by cleaning nozzle.

The filters cannot be cleaned with a CIP system and need to be disassembled for cleaning.

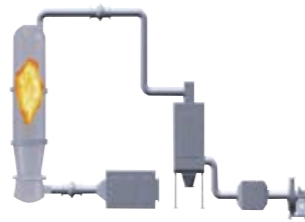
After cleaning, the filters will be assembled again and the cleaning results can be validated.

Inlet and exhaust air handling units



As a key part of fluid bed processor, the inlet air unit provides the process area with clean process air of constant quantity, temperature and humidity through three-stage filtration, dehumidification and heating, and accurate air quantity control. The air exhaust unit removes the dust from the exhaust air through pulse backflow filter F9 to meet clean environment requirements for exhaust system.

Pressure shock resistant system



When dust explosion happens inside the fluid bed, quick acting valve can quickly isolate processor from auxiliary equipment, which keeps the pressure and flame front within the processor chamber and there will be no leakage. This system applies to high containment production line for highly potent and active/hormone products.

Back flushing system



The filter can retain product particles inside processor chamber. The filter bags or stainless steel filter cartridges are cleaned during operation by blowing off with compressed air. One or multiple filtering bags are cleaned at one time, so that the surfaces of filtering bag keep efficient filtering operation during the whole process.

The filtering bag is mounted on a filter plate which can be automatically lifted and lowered for easy removal. Various filter materials can be selected as required.

The cleaning frequency of filter bag can be controlled according to differential pressure, and the frequency and time of pulse backflow can be separately set up.

Cartridge filter

The back flushing system cartridge filter F9 is used for effectively retaining micro quantity of dust in the air exhaust system to ensure that the dust concentration in the filtered air can meet the environment protection requirement.

The convenient replacement of filter cartridge and dust collection drum at the bottom can extremely alleviate the workload of the operators.

BIBO containment technology can realize the cartridge replacement and dust collection in a containment way. The technology is mainly used in the production facilities for highly potent active/hormone products.

Optional Configurations

Multiple solutions for material transfer according to users' requirements



After being processed in processor, by reversing air distribution plate, the products are discharged into buffer tank through the valve on the bottom of inlet air vessel under its own gravity, and then fall into the IBC bin finally after the milling process by integrated dry mill.



The product vessel is fixed and sealed by inflatable seals to processor, the charging and discharging can be realized with a mobile trolley, and dry milling is carried out by using a lifting device.



The charging and discharging of fluid bed processor are carried out by vacuum in a closed system.

Pressure shock resistant system

Organic solvent may be used during granulating or coating process, so an explosion-prone atmosphere will be created inside fluid bed. The inlet air handling unit, the processor and the controls are customized to ensure an explosion proof system, so that the complete system will be explosion proof.



Filter bag shaking system

Filter bag can be selected for filtering unit of the processor; dual-chamber or multi-chamber will be used, so that multiple filtering bags can shake alternately and the filter bags can be self-cleaned during the process to recover filtering efficiency. The filter bag is made of a kind of filtering cloth, which will not react with product or shed foreign matters, and have the static discharging function (being tested). Special production and testing reports will be provided about manufacturing material of filter bag and its electroconductivity to ensure GMP compliance and safety performance.



2 bar explosion venting system

If an explosion happens inside fluid bed because the static charges generated by dust friction cannot be led out smoothly or due to other reasons, the shock wave can be quickly guided through explosion venting pipe on the top or at the side of fluid bed to avoid damage to auxiliary equipment or operators in vicinity. The explosion venting membrane has passed ATEX certification to ensure reliable action.

Top spray granulation system

A binder solution tank with jacket insulation function and pneumatic motor-driven agitator will be used to maintain constant solution temperature and uniform binder content. A peristaltic pump will be connected with a GMP-complied flexible pipe and the binder solution will be sprayed uniformly on the surface of boiling materials inside fluid bed by a spray gun at a controllable speed to achieve granulating agglomeration. The solution spraying amount can be precisely measured by weight reduction method with a weighing module at the bottom of binder solution tank or a mass flow meter installed at the terminal of solution adding pipe.

Wurster bottom spray coating system

Wurster bottom spray coating system will be used together with spray gun with accurate flow control and good atomization effect to realize fountain type and orderly flow of the materials under the uniform and regular air distribution, so that uniform coating of pellets can be achieved to obtain the products of good uniformity. If the process requires large weight gain or large batch quantity, multiple Wurster coating systems can be used to improve coating efficiency.

Dust concentration monitoring in exhaust system

In order to learn about the integrity of fluid bed filtering system in real time, a dust concentration monitor will be installed in air exhaust system at the back of filtering unit. Through the monitoring system, operator can learn about the concentration of particles in air exhaust system on HMI in real time. If an alarm is given in case of a broken filter bag, some measures can be taken timely to prevent further loss.

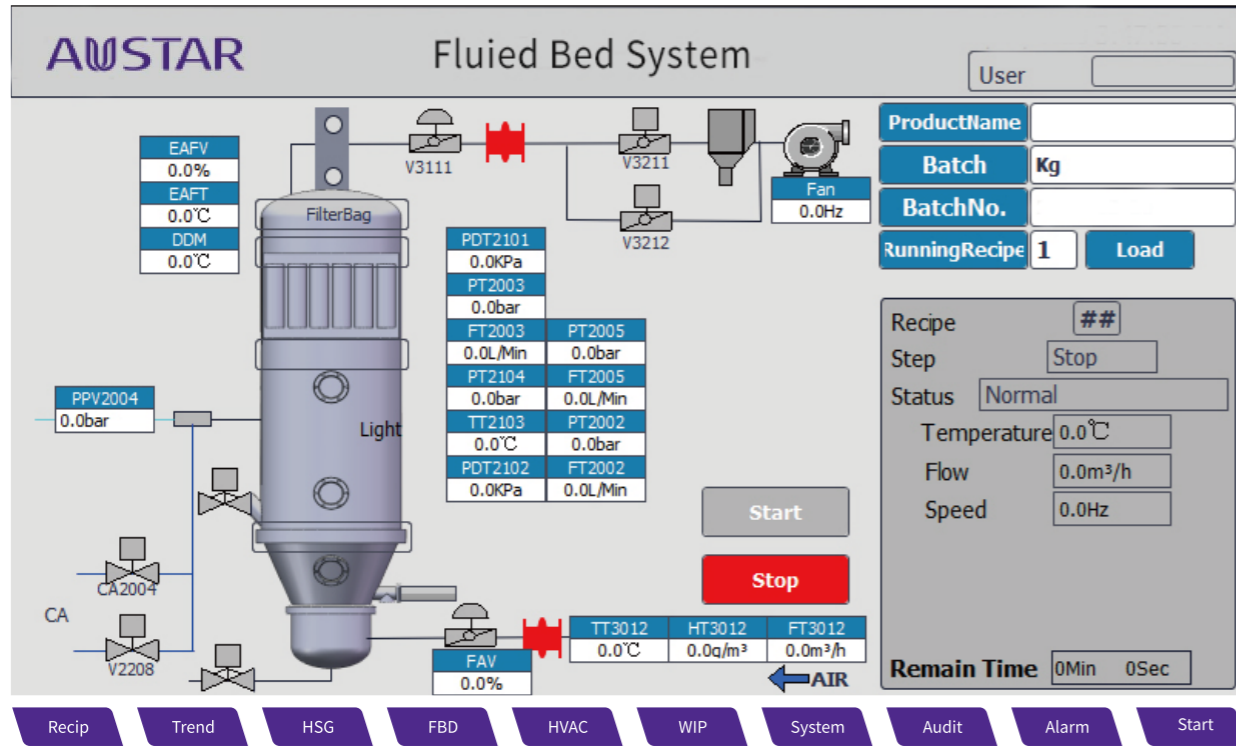
BIBO HEPA dust collector

If the drug supervision system or local regulation has higher concentration requirement for the discharging of a certain material, one HEPA H13 or H14 filter shall be added at the back of dust collector to realize higher level retaining of material and meet discharging requirement. BIBO technology can also be applied to HEPA dust collector to satisfy the requirements for equipment and facilities when highly potent and active products are produced, and the HEPA filter can be replaced in closed environment to protect the operator and surrounding environment.



HMI Control System

The complete unit of FBP could operate by PLC or IPC. The control system contains HMI control panel and control cabinets. The HMI will be installed in the production area close to the FBP. The control cabinets will be placed in the technical area. The whole software system is designed in accordance with GAMP5 regulations. The computer system based on visualization Wincc software is equipped with electric record, electronic signature, data audit trail, and authority management functions to meet the requirements of FDA 21 CFR Part 11: Electronic Record and Electronic Signature.



- Automatic control system is designed in compliance with international pharmaceutical regulations, such as EU GMP, US FDA, Chinese GMP, WHO, PIC/S, and TGA.
- Multi-level authority management is achieved.
- Computerized system validation service in compliance with GAMP 5 and FDA requirements can be provided.
- The software system with the functions of Batch Management, Electronic Record, Electronic Signature, Multi-level Authority Management and Audit Trail complies with data integrity requirements of FDA or EU GMP regulations.
- The existing recipes can be run automatically and new recipes can be created through the recipe management function. The operator needs system authority and relevant information will be recorded in real time with the help of audit-trail function.
- Cleaning recipe management : cleaning process recipes can be used and edited.
- Manual mode for preparation or commissioning tasks.
- Service mode for the control of all functions for trouble shooting or during maintenance.

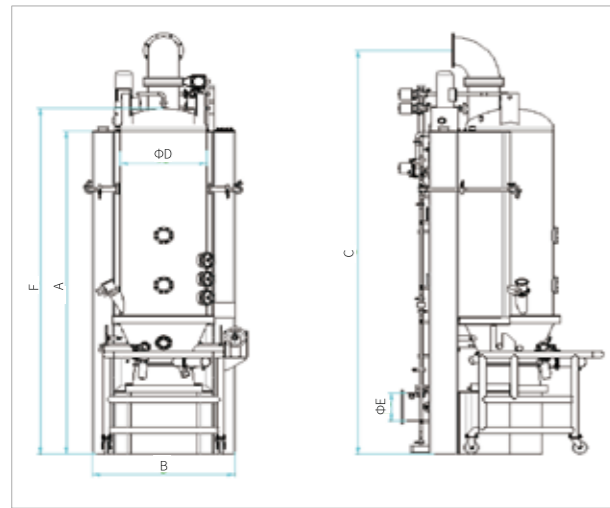
Lab Fluid Bed Processor

AUSTAR OSD formulation lab has fluid bed processor system which could be applied to scale up trial test. All equipments keep consistent to commercial model and have AHU,PLC control and HMI. With high similarity to commercial model, the uniformity of scale up research could be ensured. As a summary, the equipment is the ideal model for process and product R & D, especially for scale up test of small batch.

- Batch size from 0.3-3kg could be achieved on a single unit by interchangeable container.
- Top spray granulating & pellet coating process could be achieved by a single unit through the change of special container.
- Excellent Wurster coating system for high efficient and uniform coating process.
- The air unit and the controls are installed in machine housing, separated from the product area.
- PAT integration application to granulating and coating; critical process parameters, for instance, moisture content and particle size could be monitored online.



Product Parameters

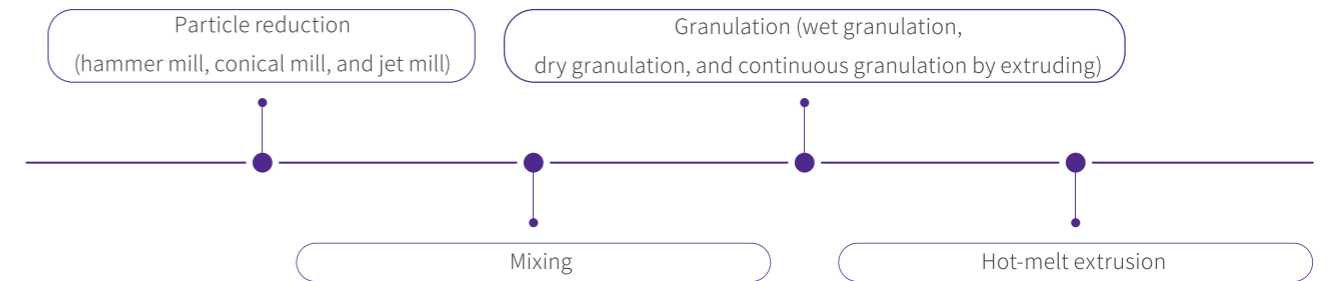


Parameter list		FBPL-1	FBPL-3	FBPL-5			
Volume	Drying/Granulating	Total Volume(L)	5	10	5	10	17
		Working Volume (30%-80%, L)	1.5 - 4	3 - 8	1.5 - 4	3 - 8	5.1 - 13.6
	Bottom-spray Coating	Total Volume(L)	2	6	10	20	40
		Working Volume (35%-85%, L)	1-2	2-5	4 - 9	7-17	14-34
Inlet Air handling Unit	Air Handling Volume (m ³ /h)	150	300	500			
	Filtering Grade	F8+H13	F8+H13	F8+H13			
Dust Collector	Filtering Grade	F9	F9	F9			
Air Fan	Power (kW)	2.2	4	5.5			
Compressed Air	Pressure (bar)	5.5 - 6.2					
	Consumption (m ³ /min)	0.98	0.98	0.98			

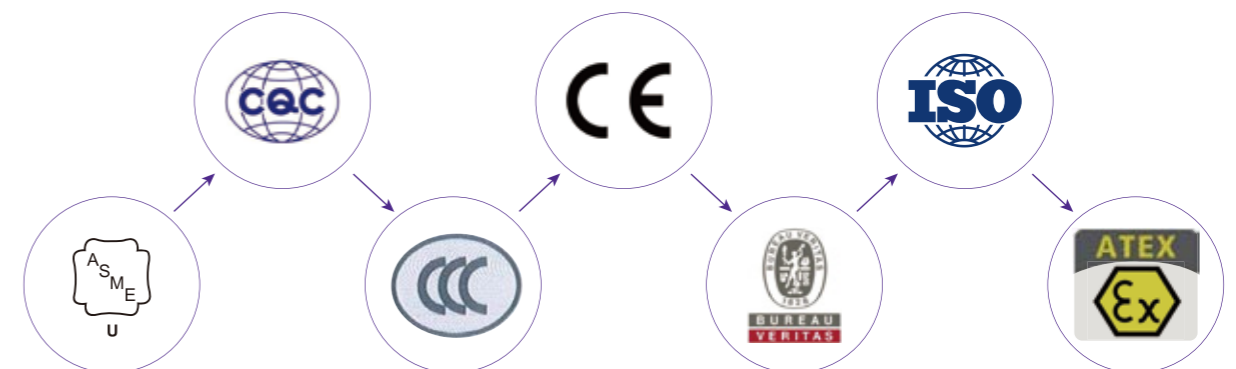
Parameter list		FBPL-10	FBPL-20	FBPL-30	FBPL-60	FBPL-120	FBPL-200	FBPL-300	FBPL-500	
Volume	Drying/Granulating	Total Volume(L)	30	60	100	180	400	680	1000	1500
		Working Volume (30%-80%, L)	9 - 24	18 - 48	30 - 80	54 - 144	120 - 320	204 - 540	300 - 800	450 - 1200
	Bottom-spray Coating	Total Volume(L)	35	50	90	280	405	460	880	1000
		Working Volume (35%-85%, L)	12-30	18-43	32-77	98-238	142-344	161-391	308-748	350-850
Inlet Air Handling Unit	Air Handling Volume(m ³ /h)	1000	1500	2000	3000	5000	6000	8000	10000	
	Filtering Grade	G4+F8+H13								
	Cooling Water Consumption(m ³ /h)	4.3	6.3	8.4	12.9	21.1	25.4	33.8	42.2	
	Steam Pressure(Mpa)	0.3-0.6								
	Steam consumption(kg/h)	47.1	70.6	94.1	141.1	235.2	282.3	376.4	470.5	
Dust Collector	Filtering grade	H13/H14								
Air Fan	Power (kW)	7.5	11	15	18.5	22	30	45	55	
Compressed Air	Pressure (bar)	5.5 - 6.2								
	Consumption (m ³ /min)	1.82	1.82	2.52	2.52	3.36	4.06	4.76	4.76	
Dimensions	A(mm)	1740	2590	3132	3815	4360	4710	5185	5630	
	B(mm)	900	1000	1140	1740	1870	2100	2390	2690	
	C(mm)	2196	3238	3889	4673	5213	5666	6100	6650	
	D(mm)	510	610	810	1010	1210	1410	1610	1810	
	E(mm)	150	200	250	250	300	400	400	500	
	F(mm)	1675	2775	3376	4160	4620	5130	5660	6180	
Weight(kg)		900	1200	1500	2600	3200	3600	4300	4900	

Process Service Abilities

AUSTAR Powder and Solid Process Research Center is equipped with advanced process equipment for particle analysis and process optimization service. Our experienced R&D and process engineers could assist the following processes:



AUSTAR Powder and Solid Process Research Center is completed with lab and pilot wet granulators for trial test and scale up research. The capacity of lab equipment can achieve 0.3-3kg/batch, and the pilot model could reach from 20-30kg/batch.



AUSTAR

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