LYOTK Series Freeze-Dryer

Main application

The Freeze dryer is mainly used for the lyophilization of the products in the pharmaceutical industry, such as: biological products, chemical products, vial freeze drying, API freeze drying, natural medicine, heat sensitivity products, antibiotics, oral liquid lyophilized tablets etc.

Characteristics

LYOTK series and LYOTK LAB series has been developed to realize effective and economic freeze drying process. Maximum product security is considered during designing stage, it is suitable for all kinds of high value products; and it ensures operator and environmental safety. It supplies longer using life to customer through its variety and stability of design.

Freeze dryer combines the technology of freezing, drying and fluid dynamics together. It is composed of chamber, chamber door, ice condenser, shelf, refrigerating system, vacuume system, hydraulic system, recycling system and control system. It can increase some features according to customer's requirement, such as CIP/SIP, CIP cleaning station. The whole freeze drying cycle can be combined in below functional steps: loading, pre-freezing, evacuation, drying, pressure rise, pre-degassing, plugging, degassing, storage and unloading etc.; all those steps of the freeze drying cycle will be executed under the auto-running model.

Freeze dryer design is based on many existing and reliable technologies, and it adopts high quality materials and world renowned components which are widely accepted in the pharmaceutical industry; it adopts many proven technologies in manufacturing, which can guarantee the machine is in full compliance with requirement of EU cGMP, FDA, WHO, PIC/S etc.

Main technical parameter

Model	Main application	Shelf area	Condenser Ice capacity	Lyo batch capacity
LYOTK	Middle & Large Scale lyophilization production	1-40㎡	20-800kg	22mm(vial) 2000-90000pieces 16mm(vial) 4500-178000pieces
LYOTK LAB	R & D lyophilization	0.2-1㎡	4-20kg	22mm(vial) 400-2000pieces 16mm(vial) 800-4500pieces

Note: In above table, output is reverse to container size. That means smaller container size, larger output. For details, please take the reference of quotation.

System Composition

CHAMBER

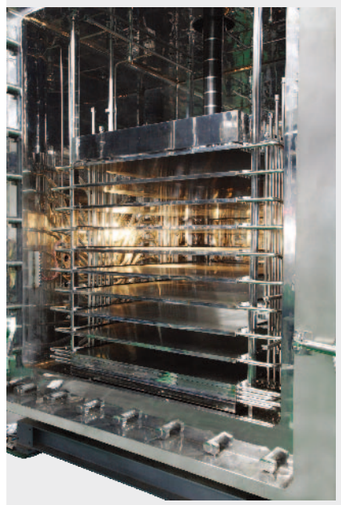
- The chamber is square shape. All the surface and holes are processed at one time through processing equipments, which meets current advanced international level;
- The internal corners of rectangular chambers have a radius >20mm;
- The bottom of the chamber is sloped towards one corner to ensure proper drainage;
- All internal materials adopt AISI 316L stainless steel;
- The internal surfaces of the chamber are mechanically polished to mirror polish <0.4mRa.

CONDENSER

- The ice condenser can be designed to be vertical type or horizontal type; customization is possible through placing it on the side, back, bottom of the chamber;
- Adopt mushroom valve design for best vapor flow and ice distribution;
- Condenser coils surface area and shelves area is 1:1, which ensures condenser has strong performance during a large quatity of sublimation.

CHAMBER DOOR

- Main door of the chamber adapts D-form gasket which can ensure good sealing effect;
- Special hinge design ensures easy opening of main door;
- Automatic main door locking system;
- According to customer's requirement, increase small loading door system. Servo motor drives sliding slot door to insure the minimum open during loading and it can work together with the automatic loading and unloading system.



PRODUCT SHELVES

- The shelves are made of AISI 316L stainless steel;
- Adopts special "internal welding" technology to ensure good flatness and sealing effect of the shelf;
- Adopt flexible 316L braided hose pipes;
- Surface polishing within the range of 0.4 - 0.6m Ra, with passivating treatment;
- Helium leak test for every shelf and shelf stack to ensure no leakage.

System Composition

REFRIGERATION SYSTEM

- The refrigeration system is designed and assembled precisely to ensure the performance specification;
- Compressor adopts R507 or R404A HFC refrigerants;
- All refrigeration circuits are configured to be able to serve either condenser or shelf cooling;
- All the key components are worldwide renowned brand;
- Good low temperature performance and minimum risk of leakage;
- According to customer's requirement, screw type compressor can be supplied as an option instead of piston compressor;
- According to customer's requirement, electronic expansion valve can be supplied as an option instead of thermo expansion valve.

VACUUM SYSTEM

- The vacuum system is composed of globally accepted brand vacuum pump and components;
- Booster pump can be supplied if necessary;
- According to customer's requirement, dry vacuum pump can be supplied as an option instead of normal oil sealed, rotary vane vacuum pump;
- According to customer's requirement, the MKS Capacitance type vacuum gauge can be supplied as an option instead of normal Pirani gauge;
- According to customer's requirement, a proportionally modulated gas admission valve can be supplied as an option instead of normal on/off style vacuum control.

HYDRAULIC SYSTEM

- Hydraulic system adopts original European brand;
- Provides AISI 316L bellows to cover hydraulic plugging cylinder with automatic integrity test function;
- Automatic shelf positioning hydraulic system can be supplied as an option with auto loading and unloading system;
- Automatic "shelf lifting" system will be supplied to prevent the shelf drifting during the cycle.

CIRCULATION SYSTEM

- Key components of circulation system adopt European brand;
- U.S.A imported 5CST silicone oil is adopted as heat transfer media;
- Adopt full welding design to minimize risk of the silicone oil leakage.

CIP/SIP SYSTEM

- Consisted of a series of fixed and rotary spray nozzles which are mounted on distributing manifolds of the chamber and condenser;
- All nozzles and pipes are AISI 316L /316stainless steel;
- All processing valves are sterile diaphragm valve with feedback signal;
- Two water media (PW&WFI) inlet can be provided as option;
- Pressure vessels can bear steam sterilization of 128℃(1.6barg);
- Perfect safety interlock can ensure the safety of the sterilization cycle;
- Sterile filter can be sterilized together with the chamber and condenser during SIP, simultaneously has the integrity testing of different options.

LYOTK production Freeze dryer technical parameter

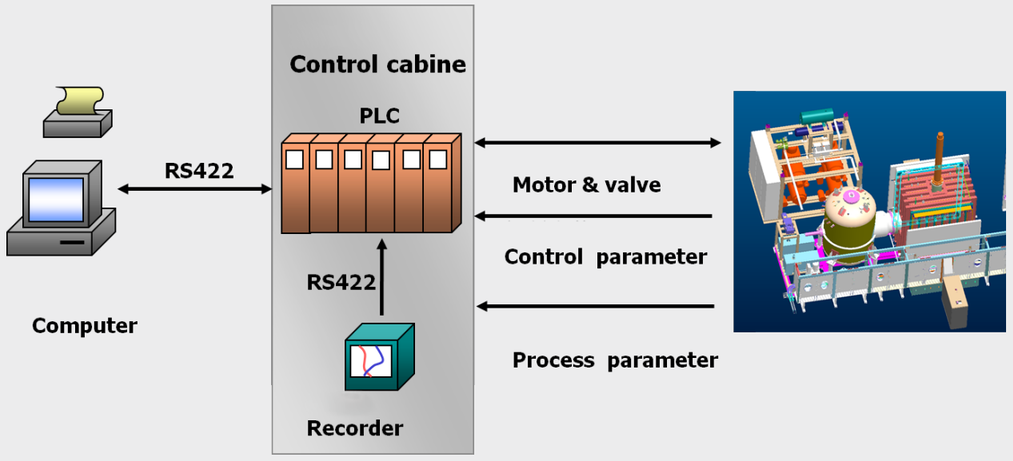
System Composition

CIP CLEANING STATION

- Auto control the local equipments, implement the CIP/ SIP;
- Implement remote composite control on Freeze-dryer;
- Manual control buffer tank water inlet and pipes water drainage;
- Reduce public utility duty, can provide CIP water source for several freeze dryers.

CONTROL & DOCUMENTATION SYSTEM

- SCADA control system based on the PLC+PC interface configuration;
- Adopt world renowned PLC brand and other control components;
- Fully comply with the FDA 21CFR PARTS 11 requirements;
- Can realize full cycle control function of LYOTK series freeze-dryer;
- Chart recorder for recording and store all processing data;
- E-signature and batch report function;
- Recipe edit and monitoring function;
- GAMP 5 documentation system is an option to ensure the product quality traceability, according to customer's requirement.



Model		LYOTK1	LYOTK3	LYOTK5	LYOTK7	LYOTK10	LYOTK15	LYOTK20	LYOTK25	LYOTK30	LYOTK35	LYOTK40
Shelf area (㎡)		1	3	5	7	10	15	20	25	30	35	40
Effective shelf area (㎡)		1.0	2.88	5.66	7	10.18	15.01	20	24.65	29.93	35.37	40.81
Max.Vial loading Qty.	Piece/ Φ16mm	4264	12730	25080	30096	45144	66000	88275	104325	133386	157638	181890
	Piece/ Φ18mm	3404	9735	19500	23400	35100	52260	70015	82745	104082	123006	141930
	Piece/ Φ22mm	2280	6480	13120	15744	23616	34560	45738	54054	69564	82212	94860
Shelf size	Width (mm)	455	644	944	944	944	1244	1244	1244	1544	1544	1544
	Depth (mm)	615	970	1270	1270	1270	1270	1524	1524	1830	1830	1830
Shelf Qty.(piece)		4+1	5+1	4+1	6+1	9+1	10+1	11+1	13+1	11+1	13+1	15+1
Shelf Space(mm)		80～130										
Shelf temp. scope (℃)		(-55℃～+80℃)										
Condenser ultimate tempertature (℃)		≤-75℃										
Ultimate vacuum (mbar)		0.005										
Compressed air		>6BarG										
Condenser Ice capacity (kg)		25	65	105	140	220	290	400	530	640	750	850
length (mm)		2000	3000	4000	4800	5800	6200	6500	6600	6800	6800	7000
width (mm)		1200	1800	2300	2600	2500	2500	2600	2600	2600	2700	2700
height (mm)		2000	3000	3700	3000	3400	4100	4100	4300	4600	4800	4800
Weight (kg)		3900	5400	10000	12000	16000	21000	23000	26000	30000	32000	34000
Main Power (kw)		15	30	43	55	72	103	141	151	182	212	222
Cooling water (m3/h)		5	7	11	16	18	25	37	37	42	50	50
Pure steam consumption (kg/h)		40	60	100	150	210	260	300	320	380	380	450
P.W/WFI QTY (l/min)		60	90	120	150	160	200	230	260	280	280	300

The above data is only for reference, the final data is subject to the quotation or contract.

LALUTK Auto Loading & Unloading System

Characteristics

- Two types of Auto Loading & Unloading systems from Truking: Row by Row (RBR) and Automatic Guided Vehicle (AGV), which can be selected separately or synthetically by customer according to the processing;
- Auto Loading & Unloading System composed of infeed joint system, front pusher system, back pusher system, outfeed system, sterile isolation system and control system etc. The whole cycle of equipment is divided into: vial convey, buffer, vial infeed counting, shelf joint, loading, shelf joint, unloading, vial outfeed and so on; the whole loading & unloading cycle will be done automatically according to the
- above steps under automatic operation mode;
  Improve sterile assurance level, reduce quality control risk;
  Reduce operators in sterile room to reduce the microbe load in the room;
- Adopt integrated control system, to realize the interlocking between loading and unloading system, freeze dryer, filling machine and capping machine;
- Complete electric safety circuit, reliable detecting data analysis and alarm function;
- User friendly HMI, flexible control model, editable production recipe, and tracable operation record.

Main application

It is mainly used for sterile transferring the half plugging vials from filling machine to Freeze-dryer and from Freeze-dryer to capping machine, with advanced integrated infeed and outfeed structure, and it can realize the product automatic transferring without operator.

Main technical parameter

Model & Capacity		LALUTK-06	LALUTK-09	LALUTK-12	LALUTK-15
Vial size (Body Dia.× height)	2ml(φ16×35)	12000 pcs/h	18000 pcs/h	24000 pcs/h	30000 pcs/h
	10ml(φ22×49.7)	11000 pcs/h	15000 pcs/h	21000 pcs/h	25300 pcs/h
	20ml(φ27×58)	7000 pcs/h	10000 pcs/h	12000 pcs/h	20000 pcs/h
	30ml(φ32×70)	5500 pcs/h	7200 pcs/h	9000 pcs/h	16500 pcs/h
	50ml(φ42.5×73)	/	/	5000 pcs/h	/
	100ml(φ51.6×94.5)	/	/	3000 pcs/h	/

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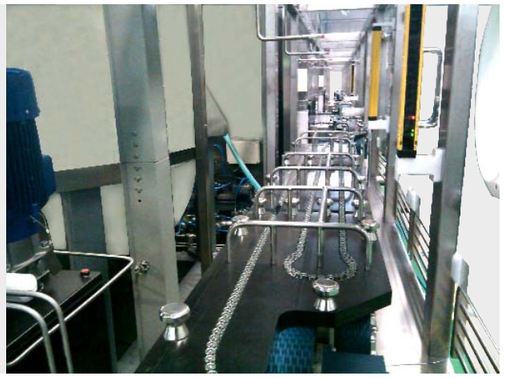
System Composition

INFEED JOINT SYSTEM

- Equip infeed transit integrated conveyor belt, joint with the upstream machine flexibly;
- High efficiency and convenient buffer for vial to realize the filling speed match with Freeze-dryer Loading speed;
- LAF protection for mechanical parts, easy cleaning design without dead angle.

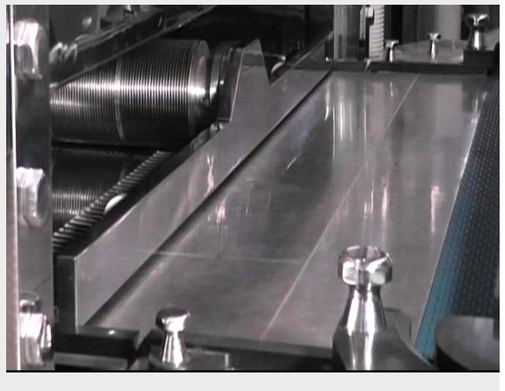


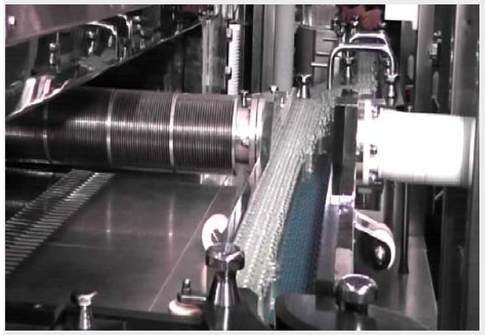
FRONT PUSHER SYSTEM

- Flexible loading control, push the vials onto the shelves;
- Integrate safety monitoring for pusher position;
- Loading types: single row loading, row by rows loading, full pack loading.

BACK PUSHER SYSTEM

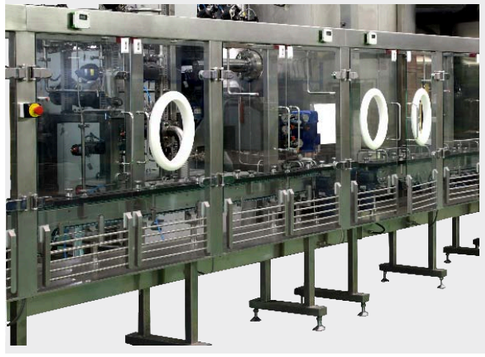
- Multi-model movement control, realize safety transferring of the outfeed pusher control data;
- TRUKING's patent of air-sealing structure for the outfeed pusher;
- Integrate safety monitoring for pusher position.





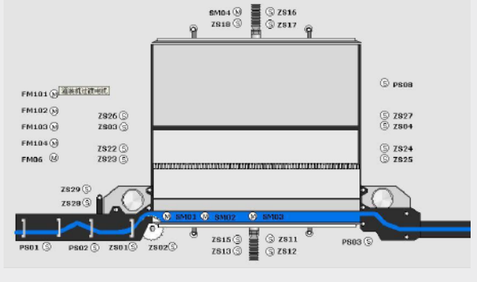
OUTFEED SYSTEM

- Equip with vial moving detection device for the outfeed;
- Outfeed transit integrated conveyor belt, to realize the joint with capping machine.



STERILE ISOLATION SYSTEM

- ORABS and CRABS system is optional;
- Equipped with safety door sensor, emergency button etc. Other optional functions are as follows: LAF device, on line particle monitoring device, on line velocity monitoring, settlement and airborne bacterial collecting and optical sensor etc.



CONTROL AND DOCUMENTATION SYSTEM

- User friendly HMI, using world brand PLC and motion servo control system, operation in the sterile room;
- Data transferring and sharing with Freeze-dryer, and interlocking with filling machine and capping machine;
- Batch number record function, error recovers function;
- Integration with RABS and other isolation system;
- GAMP5 documentation system is provided as option to ensure quality traceability.