

Pilot Freeze Dryer HDG-80Z10-50

- Haier Biomedical UK



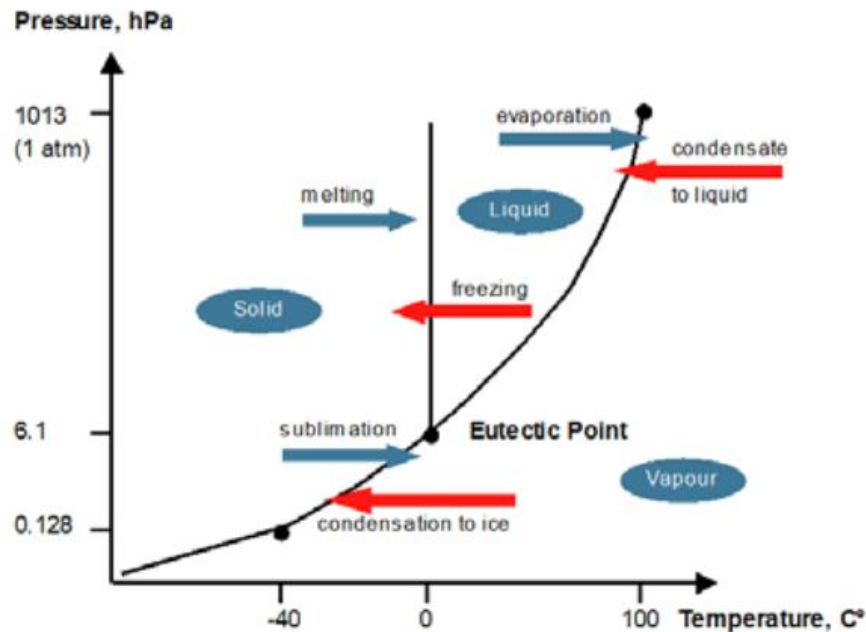
Why Freeze Drying?

- After the samples become freeze-dried preparations, they are more stable, especially for high temperature sensitive drugs, and most of them can be transported and stored at 0-4°C or even normal temperature after freeze-dried, **so the transportation and storage cost and inactivation risk are greatly reduced.**
- Compared with traditional drying methods, the bioactive materials can restore their pre-freeze-dried conformation and biological function after redissolution. Therefore, freeze-drying is the safest method with the least impact on the properties of the drying materials.
 - ✓ Heat-sensitive components, such as proteins, and microbial activity will be protected;
 - ✓ The action of microorganisms and enzymes is almost stopped, which can maintain the product with good physical shape.
 - ✓ The freeze-dried product has a large internal surface area, good resolubility and can be rapidly rehydrated.
 - ✓ Freeze drying can remove 95%~99% of the water, making the dried material maintained for a longer period of time

Principle of Freeze Drying

Freeze-drying: Under low temperature and low pressure, the water in the sample condenses into ice and sublimates into vapor to escape from the sample, so as to achieve the purpose of drying.

Freeze-drying can **keep the original physical and chemical properties and physiological activities** of the sample, and the loss of active ingredients is very small. In addition, the freeze-dried preparation has a unique loose porous structure, which can make the sample **easy to rehydrate and restore the activity**, and the freeze-dried preparation has low water content and is **easy to be stored stably for a long time**.



Vegetable & Fruit



Antibody / mRNA Vaccine



microorganism



IVD reagent



Cosmetics



Immunotherapy Drug

How to Choose Freeze Dryer

- **No requirements for controlling temperature rate in freeze drying process**

- ❑ Penicillin bottle storage: Gland type is recommended. Easy to encapsulate. Such as strains, drugs, etc;
- ❑ Need to increase sample during freeze-drying process: Multi-manifold is recommended. Such as chemical drugs, food, etc.
- ❑ Samples containing organic solvents: DG-65Z04-10A with -86°C cold trap is recommended, combined with pump + vacuum concentrator/rotary evaporator. Such as plant extracts, chemical catalysts, etc

DG-65Z04-10A



DG-65Z04-10AR



Gland Type Multi-manifold Multi-manifold Gland Type

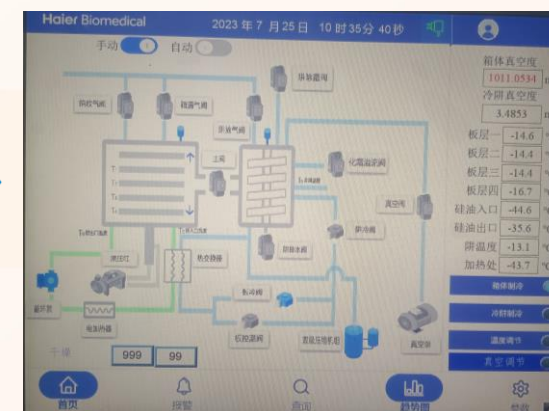
- **Strictly control of temperature rate, vacuum and batch consistency**

- ❑ Liposome drugs (SiRNA-LNP、mRNA-LNP, etc.)
- ❑ Antibody drugs (monoclonal antibody /ADC/ Specific antibody, etc.)
- ❑ IVD Freeze-dried preparations (PCR reagents, RNA/DNA preparations, etc.)
- ❑ Chemical drugs (synthetic drugs, antibiotics, etc.)
- ❑ Cytokines and immune drugs (interferon, lyophilized immunoglobulin for injection, etc.)
- ❑ Vaccine (mRNA vaccine)

Precise Process Control via Touch Screen



HDG-80Z10-50



Pilot Freeze Dryer Applications



Pharma

Protein/Antibody/enzyme
Company



Medical Research Center

Lyophilization in bio macromolecular
therapy (protein modification),
pharmaceutical, microbial research



IVD

IVD reagents (nucleic acid
diagnosis, protein diagnosis)



ADC

Freeze-drying treatment in antibody
coupling drug development research



Veterinary drugs

Freeze-drying treatment of veterinary
drugs, antibiotics and chemical drugs
and technological exploration



Vaccine Research

For research and development of
protein and mRNA vaccines, freeze-
dried for convenient storage and
transportation



Academy of Agri Sciences

Freeze-dried food research,
freeze-dried fully retain food
nutrition



Cosmetics

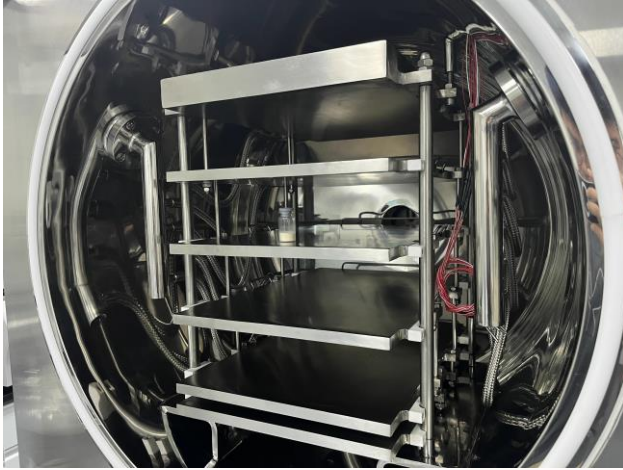
Preparation of lyophilized powder for skin
care ingredients such as oligopeptide,
collagen, plant extract and sodium
hyaluronate

HDG-80Z10-50 System Intro

1. Cascade dual system with Tecumseh compressors.
2. The hydraulic system includes hydraulic station, plate cylinder and other components, which are mainly used for shelf lifting movement and stopper.
3. Vacuum system includes rotary vane vacuum pump, electric evacuation valve and stainless-steel pipe road, chamber and cold trap are equipped with vacuum probe. The vacuum is controlled by the leak control valve, and the vacuum range is precisely controlled by PID regulation.
4. The circulating system includes circulating pump, heater, plate heat exchanger, expansion box and other components, and is connected through stainless steel tubes. Silicone oil (carrying refrigerant) transfers the heat and cold amount generated by the heater/plate heat exchanger to the shelf layer and products.
5. The control system is based on the PC-PLC double-layer structure independently developed in-house, and Siemens PLC is used to monitor equipment status, control equipment operation and execute related control chain. PC operation interface is available as well.



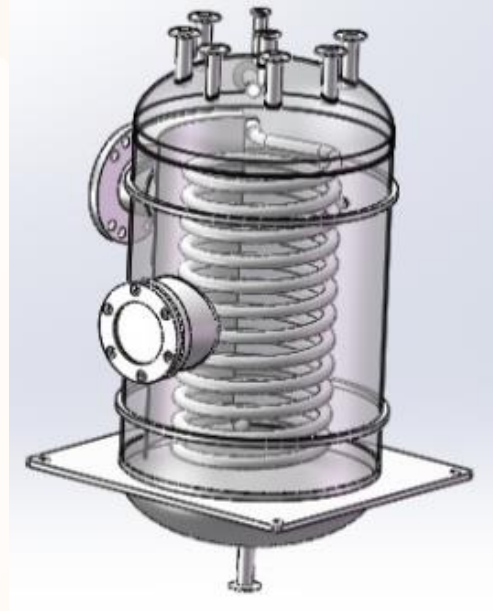
HDG-80Z10-50 Core Features



Precise Shelves Temperature Control

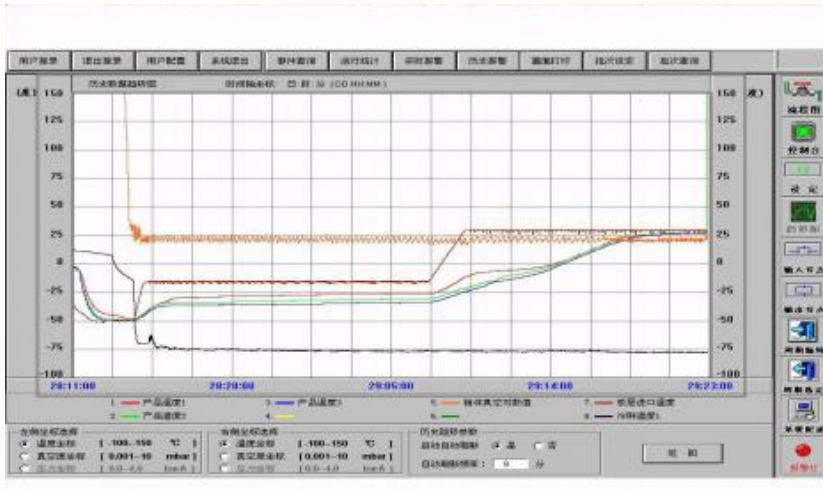
- $\pm 0.5^{\circ}\text{C}$ shelf temperature accuracy;
- $\pm 1^{\circ}\text{C}$ uniformity for all shelves

The cold trap



Industry-leading cooling performance

- From $+20^{\circ}\text{C}$ to -80°C only in 30min!



PLC control, user-friendly control interface

- Editable automatic programs, multi-temperature segment control, in line with the requirements of fine process;
- Touch screen is easy to operate, and can be connected to a PC.

HDG-80Z10-50 Benefits

Suitable for Small batch production & Pilot Run

- Shelf total size: 0.54m²
- Capacity: Circa. 2,046 Penicillin bottles Φ16mm.

Excellent temperature Uniformity Control

- $\pm 0.5^{\circ}\text{C}$ shelf temperature accuracy;
- $\pm 1^{\circ}\text{C}$ uniformity for all shelves

Superb Cooling Performance

- From $+20^{\circ}\text{C}$ to -80°C only in 30min!

Sample Safety

- Emergency protection function as standard




Complete Compliance documents

- CE, FDA 21 CFR part 11, GMP, SAT, SAT, 3Q.




HDG-80Z10-50 Spec

Product Model		HDG-80Z10-500	
Shelf Size	0.54m ² Penicillin Φ12mm: Circa. 3690pcs; Penicillin Φ16mm: Circa. 2046pcs; Penicillin Φ22mm: Circa. 1056pcs	Control System	PLC control (touch screen as standard, okay to connect with PC)
Cold trap temperature (℃)	-75/-80	Vacuum control	leak control valve
Cold trap cooling speed	From +20 ℃ to -80 ℃ in 30min	Freeze drying curve & records	YES
Ice condenser capacity (kg)	10	Automated program	YES (okay manually)
Shelf temperature uniformity (℃)	±0.5℃ on same shelf ±1℃ for all shelves	Penicillin lid press	YES(Hydraulic)
Ultimate vacuum (mbar)	0.005	N2 Back fill system	Optional
Shelf dimension (mm)	300*450	Automatic drainage	YES
Shelf qty	4+1	Frost	Heated gas frost
Shelf distance (mm)	80	Wireless monitoring	YES
Shelf temperature (℃)	-55 ~ 80	Sample emergency protection	Constantly cooling the sample when vacuum exceeds limit
Power (KW)	5	FDA 21 CFR Part 11	Compliance
Power consumption (kWh/day)	120	Drying end point judgment	Optional
Ext. dimension (W*D*H)(mm)	900*1750*1950	Eutectic point test	Optional
Weight (kg)	800	Sterilization	Optional for H2O2 Sterilizer
Input Power	Single phase 220V/50Hz	IQ/OQ Confirmation	Optional

Spec Comparison

Manufacture		Christ	IMA Edwards	Haier
	Product Model	Epsilon2-10D LSC plus	Minifast 04	HDG-80Z10-50
Main Spec	Picture			
	GMP Certified?	No	Yes	Yes
Main Spec	Shelf Size (m ²)	0.7	0.54	0.54
	Cold Trap Temperature (°C)	-88	-70	-80
	Cold Trap Cooling speed	From +20 °C to -80 °C in 60 min	From +20 °C to -40 °C in 30 min	From +20 °C to -80 °C in 30 min
	Ice condenser capacity (kg)	10	8	10
	Shelf temperature range (°C)	-60 ~ 60	-40 ~ 40	-55 ~ 80
	Shelf temperature accuracy (°C)	±0.5	±0.1	±0.5
	Shelf temperature Uniformity(°C)	±1	±1	±1
	Shelf temperature pull up / down speed	≤45min(from +20°C to -40°C); ≤45min(from -40°C to +20°C)	From +20°C to -40°C/ < 60min (standard)	≤60min(from +20°C to -40°C); ≤60min(from -40°C to +20°C)
	Ultimate Vacuum(Pa)	0.1	0.5	0.5
	Touch Screen	LCD touch screen	LCD touch screen, available to connect PC	LCD touch screen, available to connect PC
	Cooling system	Compressor directly cooling + shelf indirect cooling (Silicone Oil)	Single compressor series + shelf indirect cooling (Silicone Oil)	Dual stage cooling + shelf indirect cooling (Silicone Oil)
	Eutectic point test	LC plus system, temperature resistance integrated sample probe, generate the eutectic point / test curve to obtain the sample eutectic point		Optional

Spec Comparison

		Christ	IMA Edwards	Haier
	Product Model	Epsilon2-10D LSC plus	Minifast 04	HDG-80Z10-50
	Picture			
Main Spec	Freeze Drying curve & records	Yes	Yes	Yes
	Automated program	Yes	Yes	Yes
	Vacuum Control	Auto	Auto	Auto, PLC control vacuum valve
	Sample emergency protection	Yes	Yes	Yes
Other Spec	Drying end point judgment	Optional, Lyo Balance weighing system Range: 0.001~500g Accuracy: ± 0.005 g	Yes, pressure rise method	Optional Industrial speculum can be retrofitted
	Freeze-drying traceability	Optional, online imaging system, picture, video, freeze-drying curve recording	Yes, by freeze drying curve	Yes, by freeze drying curve
	N2 back fill	Yes	Yes	Yes
	Frost	Heated gas frost	Heated water frost	Heated gas frost
	Automatic drainage	Yes	Yes	Yes
	Penicillin lid press	Yes	Yes	Yes
	Power input	3-phase 380V, 50Hz	Single phase 220V, 50Hz	Single phase 220V, 50Hz
	Wireless monitoring	/	/	Optional

1. Is filling equipment available? – **Yes.**
2. Is gradient cooling possible? Precise multi-stage temperature control? -- **Yes. You can set up freely on the program. In the meanwhile, Haier Biomedical owns a professional process design team who can support you improve your freeze drying process.**
3. What's the capacity for one batch?
**Penicillin Φ12mm: Circa. 3690pcs;
Penicillin Φ16mm: Circa. 2046pcs;
Penicillin Φ22mm: Circa. 1056pcs**
4. Is drying end point judgment possible? -- **Yes, this is an optional function.**
5. Is HDG-80Z10-50 able to monitor eutectic point? – **Yes. We can supply a eutectic point detection device. In the meanwhile, our technical team can help you to find out!**

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