



GMP Configurable Freeze-Dryers

- **✓** Cost effective solution
- **✓** Controlled supply chain and traceability
- **✓** Standard validation package
- **✓** Addresses all pharmaceutical freeze-drying applications
- ✓ Broad range of standardized sub-systems enables flexible configuration



Equipment Basic Configuration

Configuration	Cylindrical or rectangular chamber with external cylindrical ice condenser. All components mounted on a single skid.
Drying chamber	All process surfaces AISI 316L mirror polished to better than 0.5 µm. Corners rounded for easy cleaning and bottom surfaces sloped towards the drain. All ports and piping connections are Tri-clamp sanitary type. Ports for validation and viewing (illuminated). Fully insulated and clad with AISI 304.
Access door	Hinged. Single silicone gasket. Viewing port. Fully insulated. Cover and fascia AISI 304 for clean room integration.
Shelves	Better than 0.5 μ m satin finish AISI 316L. Better than 0.5 mm/m flatness. Side and rear guides.
Ice condenser	Vertical or Horizontal configurations. Condensing surface consisting of multiple smooth coils, polished to better than 0.5 μ m., constructed from AISI 316L tube. Vessel sloped towards the drain. All ports and piping connections are Tri-clamp sanitary type. Ports for validation and viewing (illuminated). Fully insulated and clad with AISI 304.
Chamber-condenser isolation valve	Mirror finish butterfly type with EPDM gasket, pneumatically actuated.
Refrigeration system	2 stage reciprocating semi-hermetic, water-cooled compressors each with independent circuits. HFC refrigerant.
Shelf heat transfer system	Silicone oil fluid. Brazed plate heat exchangers. Canned type circulation pump. Multi-element electrical heater. Shelf temperature control within ± 1 °C. Shelf cooling to temperature lower than -55 °C. Shelf heating to temperature up to +80 °C
Condenser heat	Multiple independent coils with direct expansion of refrigerant. Condenser temperature lower
transfer system	than -75°C.
Temperature sensors	Double PT100 for fluid temperature control. PT100 for monitoring shelf, product and each condenser coil.
Vacuum system	Evacuation time from atmospheric to 0.1 mbar in less than 20 minutes provided by oil sealed rotary vane vacuum pump with redundant back-up (plus roots blower on some models). Antisuck back valves and oil mist filters. Ready-to-duct oil vapour exhaust manifold.

Equipment Basic Configuration

Leak tightness	Overall system pressure rise less than $2x10^{-2}$ mbar l/s. Largest individual leak less than $1x10^{-7}$ mbar l/s.
Vacuum measurement	Pirani type vacuum gauge at chamber (1) and at vacuum system (1).
Vacuum control	Via automatic opening and closing of the vacuum system valve.
Venting filter	0.22 μm
Internal CIP	Chamber and condenser internal piping and nozzles. Liquid ring vacuum pump.
Process valves	AISI 316L angle seat valves on process side. Pneumatic actuation.
Control system	Manual, semiautomatic and automatic operation. PLC controlled with touch screen interface and chart recorder. UPS included.
Internal testing	Execution of internal test protocols.
Standard	Instruction and maintenance manuals, as built drawings (layout, P&IDs, electrical and
documentation package	pneumatic diagrams, etc.), material and instrumentation calibration certificates.

Options and Accessories*

1	SIP	Pressure vessel. Sanitary diaphragm valves in process piping. Sterilizable filter. Liquid
		ring pump for condensate draining and drying. SIP temperature sensor PT100, pressure
		transducer and sterilizable chamber vacuum sensor. Door locking with peripheral pins. GB
		pressure directive.
2	PED directive	Design and construction of chamber and condenser.
3	Justice	Water circulation through chamber reinforcements for fast cooling after sterilization.
4	FSIP	Automatic filter sterilization in place (FSIP) and valves for manual WIT.
5	Independently	Configuration for filter sterilization cycle independent from equipment SIP.
	controlled FSIP	
6	Redundant filter	Second venting filter installed in series.
7	Internal CIP	Included in the basic unit. Customer to supply the water at the required flow and pressure.
		CIP control not included.
8	Integrated CIP	Condenser vessel is utilized as a water tank. Includes a sanitary centrifugal impulsion pump
	impulsion system	and integration with control system.
9	CIP external	Comprises an external skid with tanks, a sanitary centrifugal impulsion pump and a sanitary
	impulsion system	suction pump. Includes integration with control system.
10	Stoppering device	Hydraulically operated ram. Pressure applied at the shelves adjustable up to 1.5 kg/cm ² . Zero
		clearance system (shelves can be fully closed). Unbraided flexible hoses for thermal fluid.
11		Stainless steel 316L.
12		Automated bellows leak test integrated with the control system.
13	Constant height	Constant height loading and unloading system. Built-in position transducer for fine shelf
		height positioning.
14		Pneumatically operated mechanically linked set of peripheral pins. Automatic door latching.
	automatic locking	Position detectors to ensure correct locking.
15		Manual locking hinged slot door.
16		Automatic upward opening/downward closing slot door with mechanical locking device.
	locking	
17		Set of spacer rods to change the standard shelf interdistance by stacking two or more
	manual changeover	shelves, provided that stoppering device or shelf movement system is included.
18		Additional compressor operating in back-up mode.
19	Screw compressors	Replacement of the standard reciprocating compressors with screw type compressors.
		Includes variable frequency drives (VFD) for motors.
20		Replacement of the standard mechanical expansion valves with electronic type valves for
	valves (Coolstar)	improved accuracy and efficiency.
21		Installation of an additional circulation pump operating in back-up mode.
	circulation pump	
22	- · / · · · · · · · · · · · · · · · · ·	Replacement of the standard oil-sealed vacuum pumps by dry pumps.
23		Installation of an additional vacuum pump operating in back-up mode.
	pump	
24		Substitution of the standard vacuum control of on/off valve between vacuum system and
	control valve	condenser with a PID controlled microbleed valve.

^{*}Tick your selections

Options and Accesories*

25	Capacitance	Substitution of the chamber Pirani vacuum gauge by a capacitance manometer.
	vacuum gauge	
26	Loading/unloading automation	Manual and semi-automatic solutions for bulk and vial applications.
	(Lyogistics)	
27	Product trays	Set of AISI 316L stainless steel internally polished trays for vial or bulk applications.
28	SCADA package	Substitution of the touch screen HMI by a PC and SCADA control system with user-friendly graphical interface.

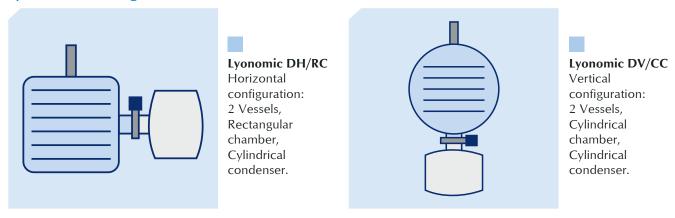
Documentation and Validation Options*

29	FAT	Includes a one-week FAT at Telstar's premises in Shanghai, China with client present (upon
		request FAT can be performed in Europe).
		request in can be performed in Europe).
30	System qualification	Generation and delivery of the QPP, FS and generation of DQ and FAT protocols compiled
	documentation (QPP,	and executed by Telstar in accordance with GAMP 5.
	FS, DQ and FAT)	
31	System qualification	Generation and delivery of the QPP, FS; generation of DQ and FAT protocols compiled
	documentation (QPP,	and executed by Telstar in accordance with GAMP 5 and preparation of IQ/OQ protocol
	FS, DQ, FAT and IQ/	templates.
	OQ protocols)	
32	IQ/OQ execution	To complement the system qualification documentation option, IQ/OQ protocols are
		executed at customer site by Telstar.
2.2	Software validation	,
33	Software validation	Generation of a complete set of documentation qualifying design and testing of the software
	documentation	modules in accordance to GAMP 5.

Service Options*

Freeze-drying Development and/or optimization of freeze drying recipes available upon request. support services

Lyonomic Configurations*



Remarks & Comments

^{*}Tick your selections

Technical Data (select your model)

	•	,						Lyonomic													
Feature	Unit		1			2			3			4			5			6		7	
Useable surface area	m^2	0,81	1,08	1,35	1,44	1,8	2,16	2,7	3,24	3,78	3,24	3,78	4,,32	5,4	6,48	7,56	6,48	7,56	8,64	8,64	
No of useable shelves	ud	3	4	5	4	5	6	5	6	7	6	7	8	5	6	7	6	7	8	8	
Shelf clearance*	mm	180	120	100	120	100	80	140	110	93	110	93	80	150	125	100	125	100	90	145	
Shelf dimensions w x d**	mm	450	450	450	450	450	450	600	600	600	600	600	600	900	900	900	900	900	900	900	
	mm	600	600	600	800	800	800	900	900	900	900	900	900	1200	1200	1200	1200	1200	1200	120	
Condenser capacity	kg	30	30	30	30	30	30	65	65	65	100	100	100	140	140	140	216	216	216	216	
Shelf temperature range	°C							< -5	5º up to	+80											
Final condenser temp.	°C		<-75																		
Approximate footprint **	mm	12	60 x 30	000	12	60 x 32	50	50 2000 x 4000 2000 x 5600													
Approximate weight	kg		2000			2500		4000							60	000	00				
Vial Capacity***	Approx.																1			100	
16 mm Ø 2R-4R	4440/m ²	3596	4795	5994	6394	7992	9590	11988	14386	16783	14386	16783	19181	23976	28771	33566	28771	33566	38362	383	
22 mm Ø 6R-8R	2340/m ²	1895	2527	3159	3370	4212	5054	6318	7582	8845	7582	8845	10109	12636	15163	17690	15163	17690	20218	202	
24 mm Ø 10R-15R	1970/m ²	1596	2128	2660	2837	3546	4255	5319	6383	7447	6383	7447	8510	10638	12766	14893	12766	14893	17021	170	
30 mm Ø 20R-25R	1250/m ²	1013	1350	1688	1800	2250	2700	3375	4050	4725	4050	4725	5400	6750	8100	9450	8100	9450	10800	1080	
30 Min 92 201423K	1230/111	1015	1550	1000	1000	2230	2700	33/3	4030	4/23	4030	4/23	3400	0/30	0100	9430	0100	9430	10000	1000	
Lyonomic																					
Feature	Unit		7				8				9			1	10			1	1		
Useable surface area	m^2	9,72	10,8	11,88	10,8	11,88	12,96	14,04	10,8	12,6	14,4	16,2	14,4	16,2	18	19,8	18	19,8	21,6	23,	
No of useable shelves	ud	9	10	11	10	11	12	13	6	7	8	9	8	9	10	11	10	11	12	13	
Shelf clearance*	mm	125	110	100	110	100	90	80	160	135	110	95	150	130	115	100	160	145	130	11	
Shelf dimensions w x d**	mm	900	900	900	900	900	900	900	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	120	
	mm	1200	1200	1200	1200	1200	1200	1200	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	150	
Condenser capacity	kg	216	216	216	288	288	288	288	288	288	288	288	360	360	360	360	468	468	468	46	
Shelf temperature range	°C							<-5	5º up to												
Final condenser temp.	°C								<-75												
Approximate footprint **	mm			200	00 x 58	00						2200	x 6000					2200 :	x 6800		
Approximate weight	kg		10000					120	000					13000					200 / 0000		
Vial Capacity***	Approx.													15000							
16 mm Ø 2R-4R	4440/m ²	43157	47952	52747	47952	52747	57542	62338	47952	55944	63936	71928	63936	71928	79920	87912	79920	87912	95904	1038	
22 mm Ø 6R-8R	2340/m ²	22745	25272	27799	25272	27799	30326	32854	25272	29484	33696	37908	33696	37908	42120	46332	42120	46332	50544	5475	
24 mm Ø 10R-15R	1970/m ²	19148	21276	23404	21276	23404	25531	27659	21276	24822	28368	31914	28368	31914	35460	39006	35460	39006	42552	4609	
30 mm Ø 20R-25R	1250/m ²	12150	13500	14850	13500	14850	16200		13500		18000	20250	18000	20250		24750					
30 Hill & 20K25K	1230/111	12130	13300	1 1050	13300	1 1050	10200	17550	13300	13730	10000	20230	10000	20230	22300	21/30	22500	21/30	27000	272	
								L	yonomi	c											
Feature	Unit			12						13							14				
Useable surface area	- m ²	23,4	25,2	27	28,8	30,6	24,3	27	29,7	32,4	35,1	37,8	40,5	37,8	40,5	43,2	45,9	48,6	51,3	54	
No of useable shelves	ud	13	14	15	16	17	9	10	11	12	13	14	15	14	15	16	17	18	19	20	
Shelf clearance*	mm	115	105	100	90	85	150	130	115	105	95	85	80	130	120	110	104	95	90	85	
Shelf dimensions w x d**	mm	1200	1200	1200	1200	1200	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	150	
	mm	1500	1500	1500	1500	1500	1800	1800	1800	1800	1800	1800	1800	1800	1800	1800	1800	1800	1800	180	
Condenser capacity	kg	586	586	586	586	586	780	780	780	780	780	780	780	975	975	975	975	975	975	97	
Shelf temperature range	.℃								5º up to						_						
Final condenser temp.	°C								<-75												
Approximate footprint **	mm		22	00 x 68	00				.,,				26	2600 x 8200							
Approximate weight	kg			16000	00					21000			20	00 X 02	00		21000				
										_1000				21000							
16 mm Ø 2R-4R	Approx. 4440/m ²	102900	111000	110000	127072	125064	107902	110000	121060	1/2056	155044	167022	170920	167832	170020	101900	202700	215794	22772	220	
16 mm Ø 2R-4R 22 mm Ø 6R-8R	2340/m ²	54756	58968	119880 63180	127872 67392	135864 71604	107892 56862	63180	131868 69498	75816	155844 82134	167832 88452	179820 94770	88452	179820 94770			215784 113724			
	1970/m ²	46098	49644	53190		60282	47871	53190	58509	63828	69147		79785		79785	85104	90423		101061		
24 mm Ø 10R-15R	19/0/111	40098	49044	22120	56736	00202	4/0/I	22120	20209	03028	0914/	74466	/9/05	74466	/9/05	05104	90423	33/42	101001	1003	

^{*} Shelf clearance values for Comfortable Loading Height machines. For Constant Height machines these values will change **Width x Depth

^{***} These values are for guidance only and represent the estimated capacity available when using various product trays or loading systems



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1250/m² 29250 31500 33750 36000 38250 30375 33750 37125 40500 43875 47250 50625 47250 50625 54000 57375 60750 64125 67500

ISO 9001: Certified Company

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