



SECESPOL

P-LINE Heat Exchangers in the Pharmaceutical Industry

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Heat Exchangers in the Pharmaceutical Industry

Water is the most commonly used raw material in the pharmaceutical industry. Used not only as the main ingredient in the production of medicines and vaccines, it is also utilized for cleaning technological lines and rinsing of packages.

Water for injection (WFI) is produced from purified water that has been treated to eliminate substances harmful to the human body. In the production of medicines it plays the role of a solvent, substance for dilution of preparations, as well as means for sterilizing containers, equipment or systems.

Generation, storage, and distribution of WFI takes place in carefully designed systems. The required work parameters are usually determined at the design stage and depend on the parameters of the process for which a given medium is used.

Sanitary aspects in the pharmaceutical industry are extremely important. The WFI systems must meet strict hygiene requirements to prevent product contamination. In order to meet these requirements, SECESPOL offers specialised P-line heat exchangers that are ideal to be used in WFI generators, storage and distribution systems, and points of use.

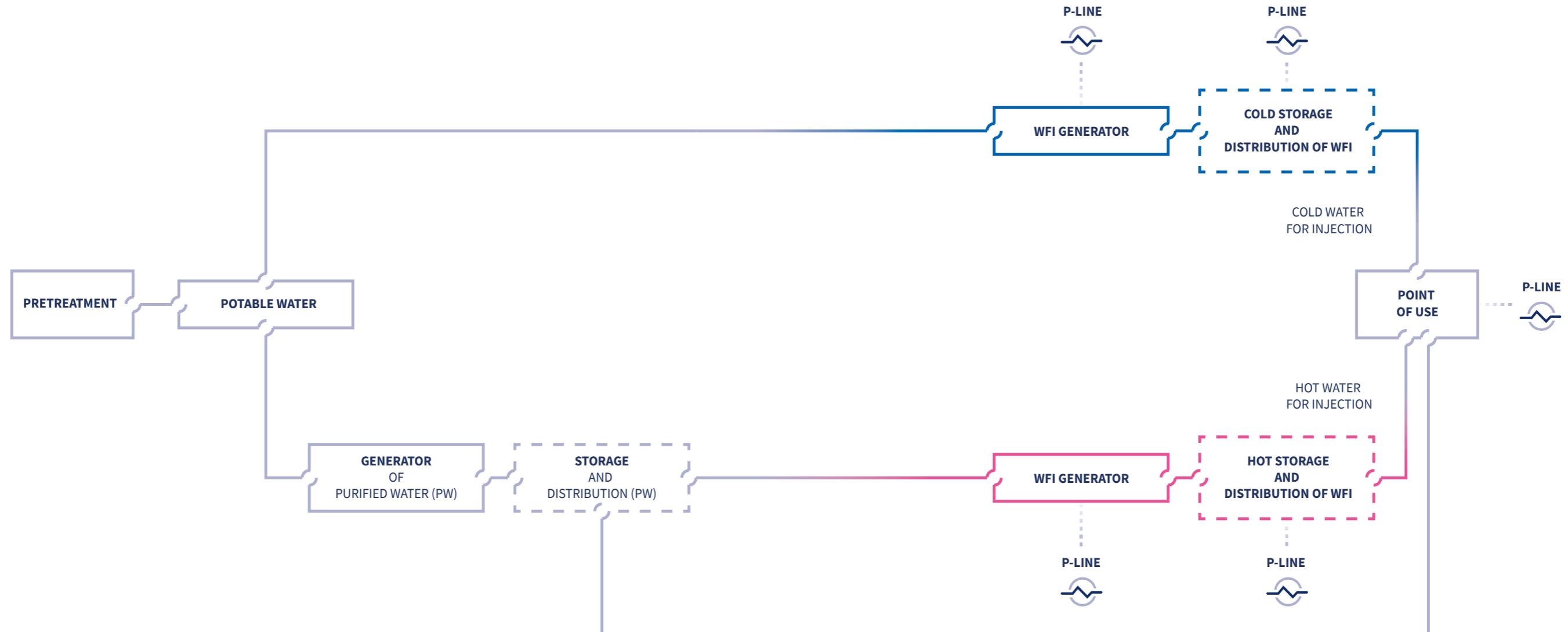


Figure 1. Diagram of PW and WFI systems with P-line heat exchangers

WFI – water for injection

PW – purified water

WFI applications

- Production of injectable drugs
- Production of high purity inhalation drugs
- Production of advanced therapy medicinal products (ATMP):
 - Gene therapy products
 - Somatic cell therapy medicinal products
 - Tissue engineering products
- Production of ophthalmic drugs and contact lenses
- Production of biotechnological preparations
- Production of diagnostic preparations
- Cleaning of containers, packaging and installations.



Heat exchangers in WFI generators

Thermal distillation is the most common method used to obtain water for injection (WFI). WFI generator consists of one or more distillation columns in which the process of repeated evaporation and condensation of purified water takes place. As the process is carried out at a high temperature, this method gives complete assurance of

the microbiological purity of the WFI water. P-line heat exchangers are used in the WFI generators for preheating, regenerative heating, as well as for final condensation of pure steam and cooling of generated water for injection.

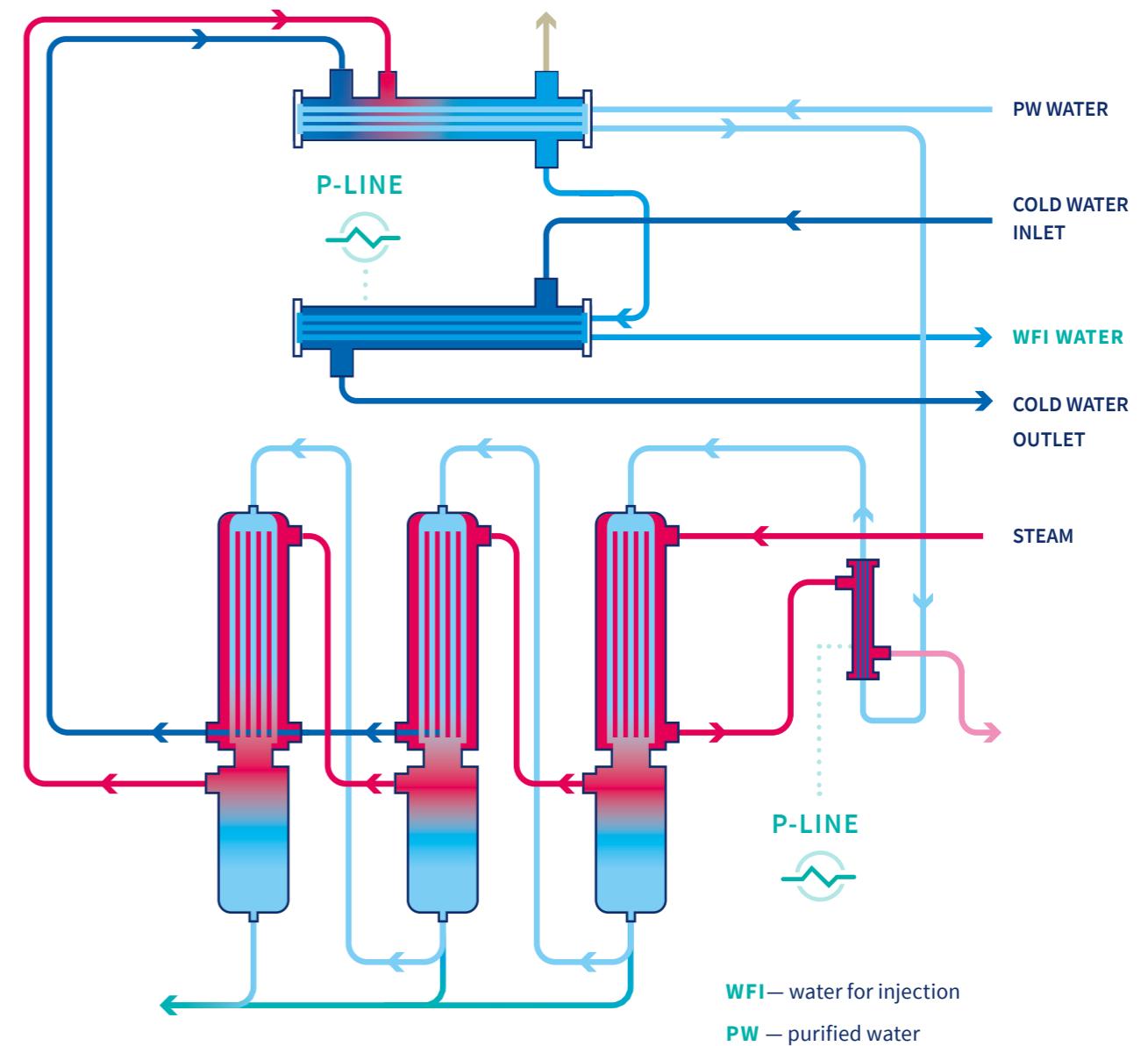


Figure 2. Diagram of the WFI generator with P-line heat exchangers

WFI cold storage and distribution system

The distilled water generated must be properly stored and distributed to the points of use.

In the cold water storage and distribution system, two P-line heat exchangers are installed. The first one is designed to keep the water temperature low (at 15-30°C) and cool the system. The second heat exchanger periodically heats the WFI water to sterilize the system.

WFI hot storage and distribution system

Another option is the system with only one P-line exchanger installed. It then performs both functions. Depending on whether cold water or technical steam flows through the shell, it cools or heats WFI.

Another method of storage and distribution is by keeping the water at a constant high temperature of 80°C - 85°C.

The task of the P-line heat exchanger installed in this system is to maintain the temperature using steam or hot water as a working medium.

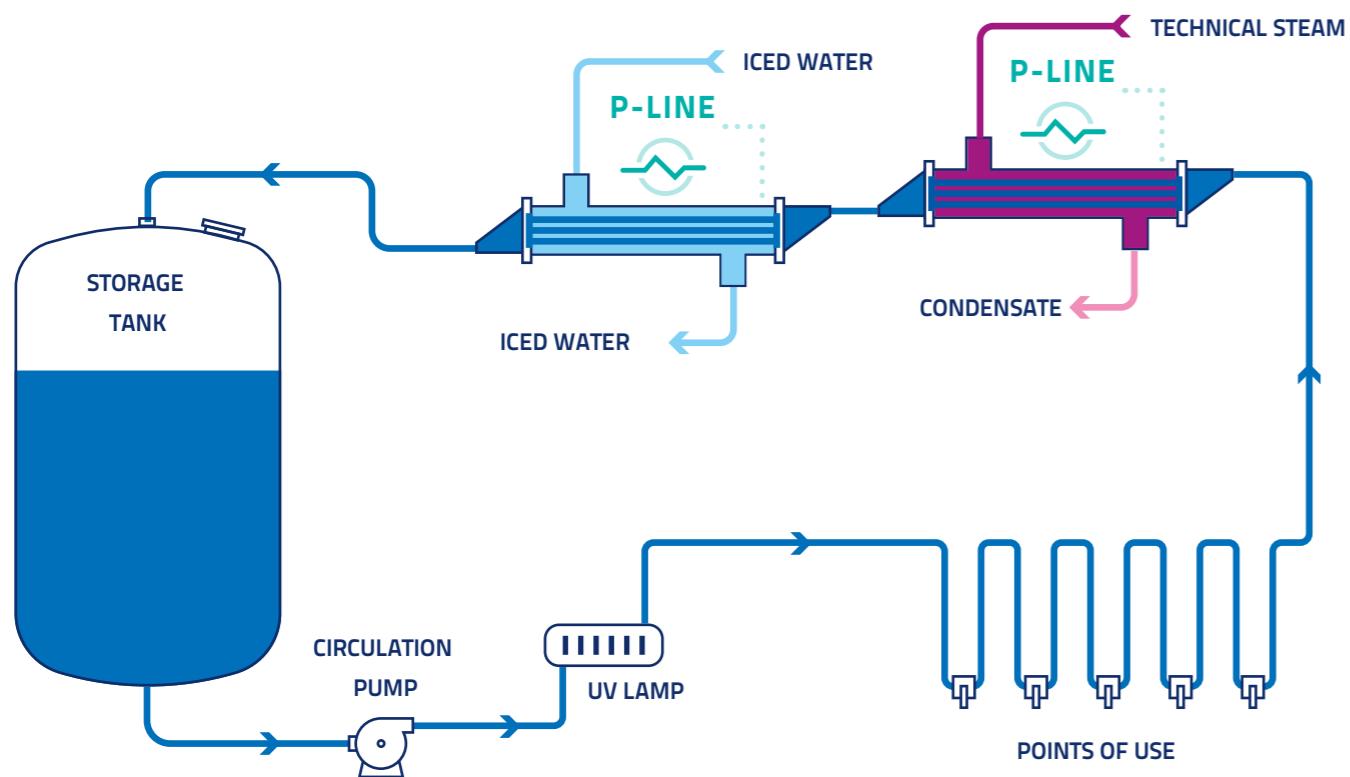


Figure 3. Diagram of the WFI cold water storage and distribution system with two P-line heat exchangers installed

WFI – water for injection

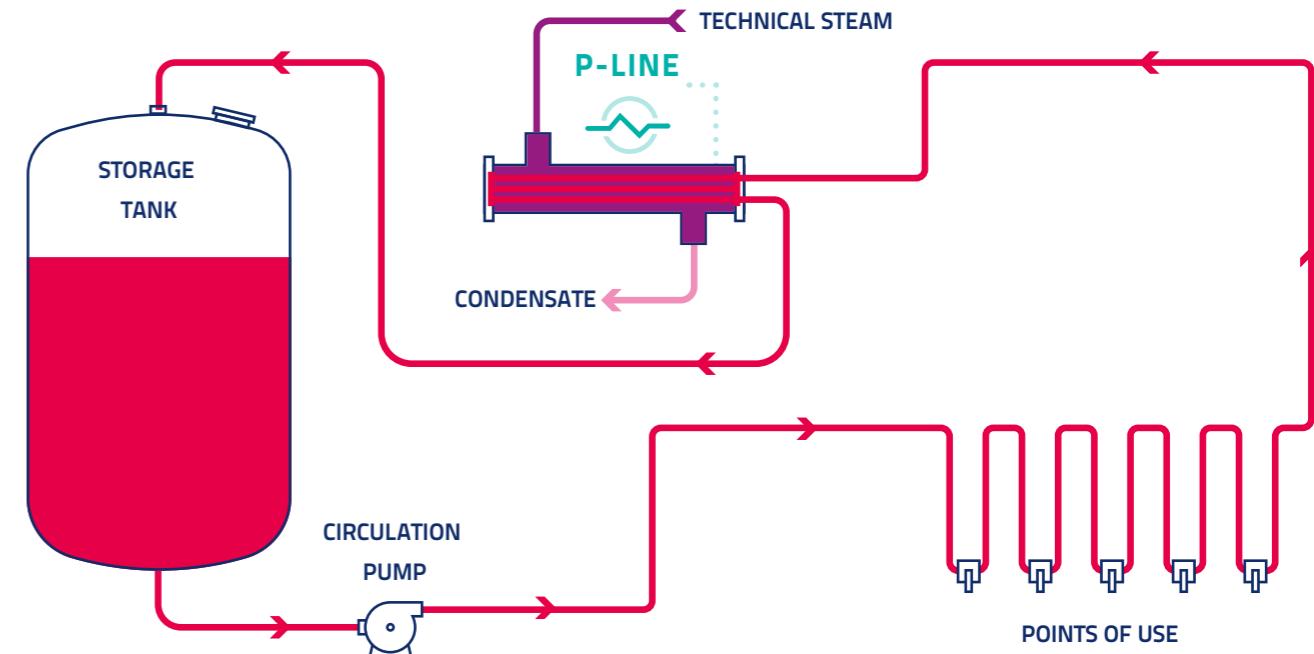


Figure 4. Diagram of hot storage and distribution system with a two-pass P-line heat exchanger installed

WFI – water for injection

WFI points of use

In order to use WFI it must be cooled to the application temperature, which is usually 25°C to 45°C.

If there are many points of use with the same temperature required, an additional circuit may be separated in the system in which the P-line heat exchanger is installed. Its task is to cool the water to the application temperature.

Another option is to place a heat exchanger just in front of the point of use (POU).

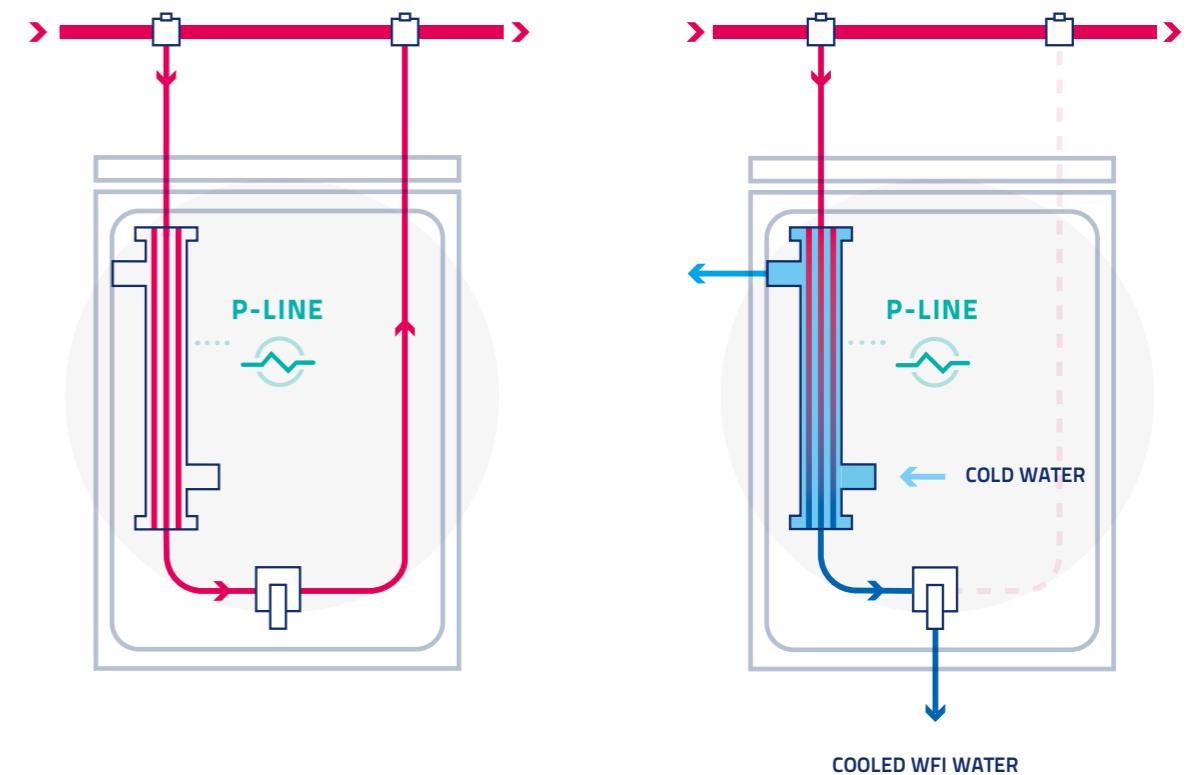


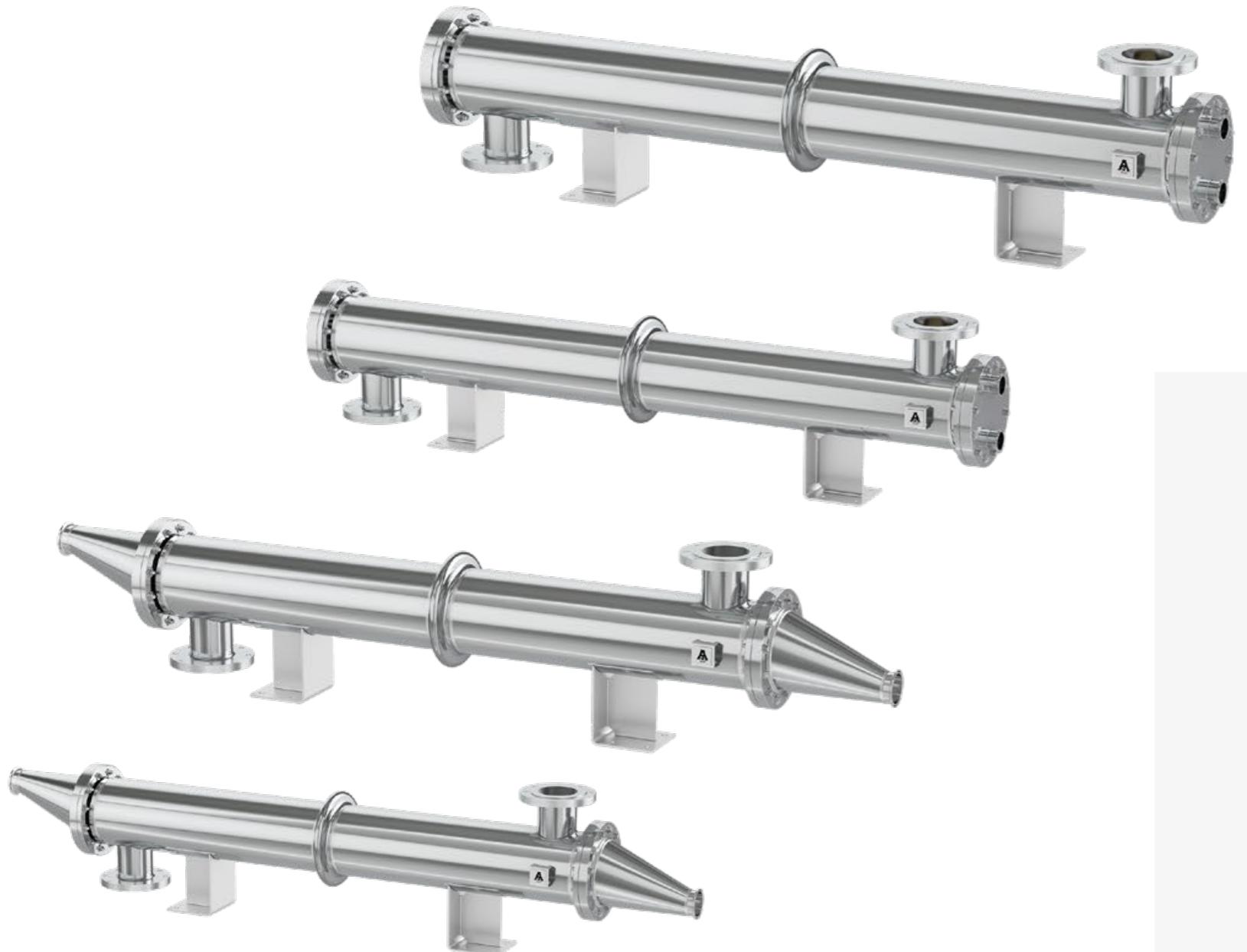
Figure 5. Diagram of the point of use (POU) with the P-line exchanger installed

WFI — water for injection

POU — point of use

Characteristics of the P-line heat exchangers

P-line heat exchangers meet the highest requirements of the pharmaceutical industry. At the same time, they meet its stringent hygiene standards imposed by inspection bodies. They have been designed to minimize the risk of contamination and to ensure safe and sterile work.



Application of P-line heat exchangers



Pharmaceutical industry

- Clean steam generation
- WFI generation
- WFI storage and distribution systems
- WFI point of use

Other

- Food industry
- Dairy industry
- Brewing industry

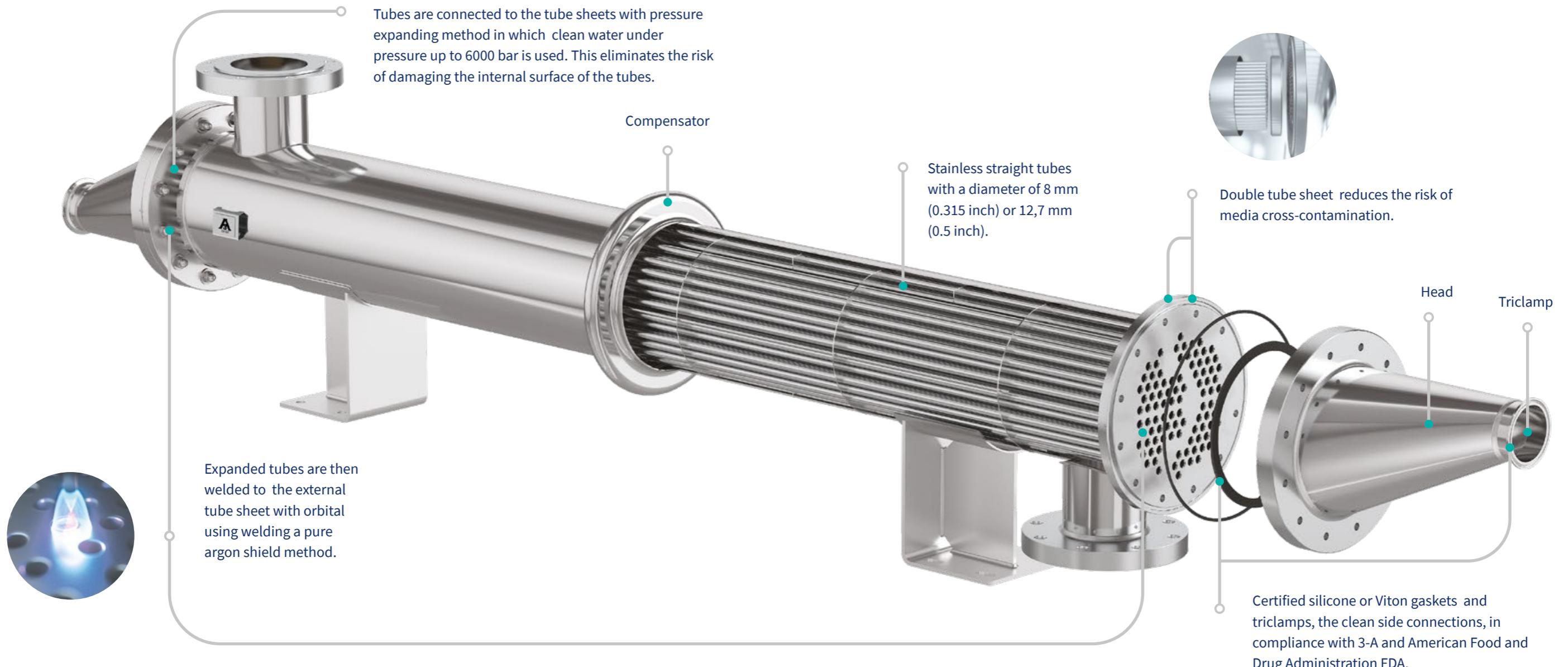
Media

- Shell side – water, steam, other consulted with the manufacturer
- Tube side – pharmaceutical product

CERTIFICATES AND STANDARDS

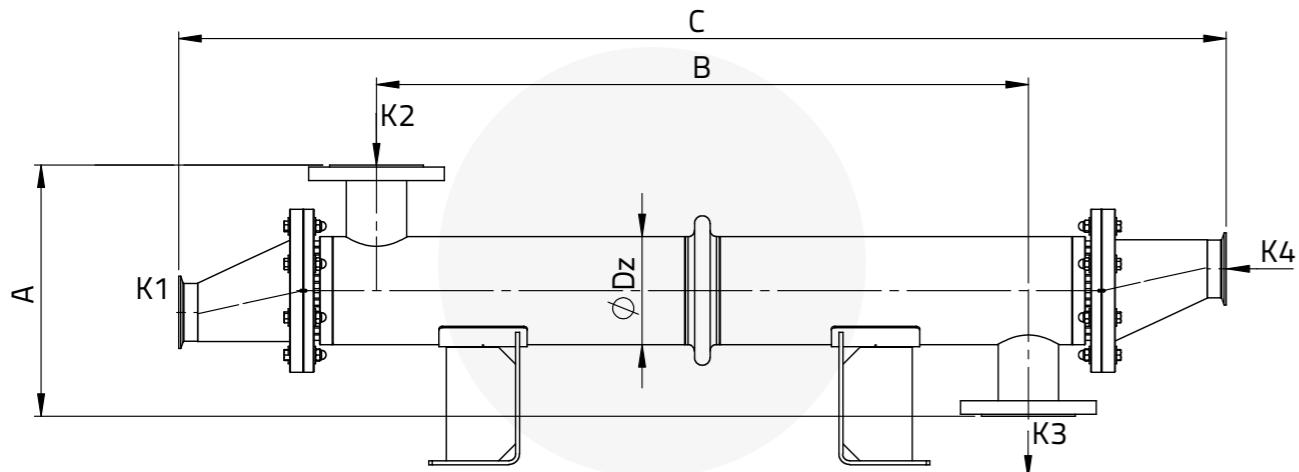
Manufactured in accordance with PED, ASME, 3-A Sanitary Standards, cGMP (FDA).

Construction of the P-line heat exchanger



- Full compliance with 3-A Sanitary Standards, 12-07 Tubular Heat Exchangers.
- Built entirely of stainless steel 316L (1.4404), polished mechanically, chemically etched and passivated.
- All surfaces in contact with the clean medium (e.g. internal surface of tubes, heads, etc.) electropolished to $Ra \leq 0,5 \mu\text{m}$ ($20 \mu\text{in}$)
- One-, two-, and four-pass types.

Technical parameters



WORKING PARAMETERS

	Gaskets	Max. pressure	Max. temp.	Min. temp.	
		bar psi	°C °F	°C °F	
Tubes	Viton	1 MPa 145 psi	140°C 284°F	-17°C* 1.4°F*	
	Silicone	1 MPa 145 psi	121°C* 249°F*	-25°C -13°F	

*Parameters for P-050: max. temp. (Silicone) 140°C (284°F), min. temp. (Viton) -25°C (-13°F).

All dimensions and technical data are approximate only and may be changed without further notice.

Technical drawing

Standard location of connections:
K4 / K1 – inlet/outlet tube side
(hygienic side)
K2 / K3 – inlet/outlet shell side
(service side)

Dimensions of P-line heat exchangers

Type	Dimensions												Flow types	Position options		
	A		B		C				Ø Dz							
	mm	in	mm	in	mm	in	mm	in	mm	in	mm	in				
P-050.070.08	176	6.93	709	27.91	880	34.65					60,3	2.37	1P	H,V		
P-050.110.08	176	6.93	1009	39.72	1180	46.46					60,3	2.37	1P	H,V		
P-050.140.08	176	6.93	1309	51.54	1480	58.27					60,3	2.37	1P	H,V		
P-080.070.08	300	11.81	518	20.39	1002	39.45					88,9	3.50	1P	H,V		
P-080.110.08	300	11.81	958	37.72	1442	56.77					88,9	3.50	1P	H,V		
P-080.140.08	300	11.81	1258	49.53	1742	68.58					88,9	3.50	1P	H,V		
P-100.070.08	325	12.80	518	20.39	1036,3	40.80					114,3	4.50	1P	H,V		
P-100.110.08	325	12.80	958	37.72	1476,3	58.12					114,3	4.50	1P	H,V		
P-100.140.08	325	12.80	1258	49.53	1776,3	69.93					114,3	4.50	1P	H,V		
P-125.110.08	350	13.78	958	37.72	1525,6	60.06	1269	49.96			139,7	5.50	1P,2P	H,V		
P-125.140.08	350	13.78	1258	49.53	1825,6	71.87	1569	61.77			139,7	5.50	1P,2P	H,V		
P-125.190.08	350	13.78	1728	68.03	2295,6	90.38	2039	80.28			139,7	5.50	1P,2P	H,V		
P-150.110.08	370	14.57	960	37.80	1546,8	60.90	1254,5	49.39			159	6.26	1P,2P	H,V		
P-150.140.08	370	14.57	1260	49.61	1846,8	72.71	1554,5	61.20			159	6.26	1P,2P	H,V		
P-150.190.08	370	14.57	1730	68.11	2316,8	91.21	2024,5	79.70			159	6.26	1P,2P	H,V		
P-200.110.08	460	18.11	924	36.38	1789,8	70.46	1262,5	49.70	1262,5	49.70	219,1	8.63	1P,2P,4P	H,V		
P-200.140.08	460	18.11	1224	48.19	2089,8	82.28	1562,5	61.52	1562,5	61.52	219,1	8.63	1P,2P,4P	H,V		
P-200.190.08	460	18.11	1694	66.69	2559,8	100.78	2032,5	80.02	2032,5	80.02	219,1	8.63	1P,2P,4P	H,V		
P-250.110.08	555	21.85	926	36.46	1953,2	76.90	1278	50.31	1271,5	50.06	273	10.75	1P,2P,4P	H,V		
P-250.140.08	555	21.85	1226	48.27	2253,2	88.71	1578	62.13	1571,5	61.87	273	10.75	1P,2P,4P	H,V		
P-250.190.08	555	21.85	1696	66.77	2732,2	107.57	2048	80.63	2041,5	80.37	273	10.75	1P,2P,4P	H,V		
P-050.070.12	176	6.93	709	27.91	880	34.65					60,3	2.37	1P	H,V		
P-050.110.12	176	6.93	1009	39.72	1180	46.46					60,3	2.37	1P	H,V		
P-050.140.12	176	6.93	1309	51.54	1480	58.27					60,3	2.37	1P	H,V		
P-080.070.12	300	11.81	518	20.39	1002	39.45					88,9	3.50	1P	H,V		
P-080.110.12	300	11.81	958	37.72	1442	56.77					88,9	3.50	1P	H,V		
P-080.140.12	300	11.81	1258	49.53	1742	68.58					88,9	3.50	1P	H,V		
P-100.070.12	325	12.80	518	20.39	1036,3	40.80					114,3	4.50	1P	H,V		
P-100.110.12	325	12.80	958	37.72	1476,3	58.12					114,3	4.50	1P	H,V		
P-100.140.12	325	12.80	1258	49.53	1776,3	69.93					114,3	4.50	1P	H,V		
P-125.110.12	350	13.78	958	37.72	1525,6	60.06	1269	49.96			139,7	5.50	1P,2P	H,V		
P-125.140.12	350	13.78	1258	49.53	1825,6	71.87	1569	61.77			139,7	5.50	1P,2P	H,V		
P-125.190.12	350	13.78	1728	68.03	2295,6	90.38	2039	80.28			139,7	5.50	1P,2P	H,V		
P-150.110.12	370	14.57	960	37.80	1546,8	60.90	1254,5	49.39			159	6.26	1P,2P	H,V		
P-150.140.12	370	14.57	1260	49.61	1846,8	72.71	1554,5	61.20			159	6.26	1P,2P	H,V		
P-150.190.12	370	14.57	1730	68.11	2316,8	91.21	2024,5	79.70			159	6.26	1P,2P	H,V		
P-200.110.12	460	18.11	924	36.38	1789,8	70.46	1262,5	49.70	1262,5	49.70	219,1	8.63	1P,2P,4P	H,V		
P-200.140.12	460	18.11	1224	48.19	2089,8	82.28	1562,5	61.52	1562,5	61.52	219,1	8.63	1P,2P,4P	H,V		
P-200.190.12	460	18.11	1694	66.69	2559,8	100.78	2032,5	80.02	2032,5	80.02	219,1	8.63	1P,2P,4P	H,V		
P-250.110.12	555	21.85	926	36.46	1953,2	76.90	1278	50.31	1271,5	50.06	273	10.75	1P,2P,4P	H,V		
P-250.140.12	555	21.85	1226	48.27	2253,2	88.71	1578	62.13	1571,5	61.87	273	10.75	1P,2P,4P	H,V		
P-250.190.12	555	21.85	1696	66.77	2732,2	107.57	2048	80.63	2041,5	80.37	273	10.75	1P,2P,4P	H,V		

Technical parameters

Type	Tube diameter		Heat exchange area		Weight*				Tube side capacity						Shell side capacity			
					TYPE 1P		TYPE 2P		TYPE 4P		TYPE 1P		TYPE 2P		TYPE 4P			
	mm	in	m ²	ft ²	kg	lb	kg	lb	kg	lb	l	gal	l	gal	l	gal		
P-050.070.08	8	0.31	0,33	3.52	10,70	23.60			0,47	0.12			1,24	0.33				
P-050.110.08	8	0.31	0,45	4.86	12,64	27.87			0,63	0.17			1,69	0.45				
P-050.140.08	8	0.31	0,58	6.20	14,58	32.14			0,80	0.21			2,14	0.57				
P-080.070.08	8	0.31	0,45	4.89	33,33	73.49			1,31	0.35			2,94	0.78				
P-080.110.08	8	0.31	0,76	8.20	38,12	84.03			1,71	0.45			4,69	1.24				
P-080.140.08	8	0.31	0,97	10.46	41,37	91.21			1,98	0.52			5,88	1.55				
P-100.070.08	8	0.31	0,77	8.25	34,23	75.45			2,53	0.67			4,89	1.29				
P-100.110.08	8	0.31	1,29	13.84	41,36	91.19			3,20	0.85			7,85	2.07				
P-100.140.08	8	0.31	1,64	17.65	46,22	101.89			3,66	0.97			9,87	2.61				
P-125.110.08	8	0.31	1,95	21.01	61,30	135.13	64,89	143.05	5,26	1.39	3,22	0.85	11,55	3.05				
P-125.140.08	8	0.31	2,49	26.80	68,07	150.07	71,66	157.99	5,95	1.57	3,91	1.03	14,61	3.86				
P-125.190.08	8	0.31	3,33	35.86	79,53	175.34	83,12	183.25	7,18	1.90	5,14	1.36	19,15	5.06				
P-150.110.08	8	0.31	2,86	30.81	80,04	176.45	85,08	187.56	7,60	2.01	4,53	1.20	28,64	7.57				
P-150.140.08	8	0.31	3,65	39.27	90,31	199.10	95,35	210.21	8,62	2.28	5,55	1.47	30,79	8.13				
P-150.190.08	8	0.31	4,88	52.53	107,65	237.33	112,69	248.44	10,42	2.75	7,35	1.94	38,26	10.11				
P-200.110.08	8	0.31	4,24	45.60	125,54	276.78	130,23	287.12	131,07	288.97	15,83	4.18	6,98	1.84	6,87	1.82	31,69	8.37
P-200.140.08	8	0.31	5,39	58.01	140,91	310.65	145,60	320.99	146,44	322.85	17,33	4.58	8,48	2.24	8,37	2.21	39,60	10.46
P-200.190.08	8	0.31	7,20	77.46	165,00	363.77	169,69	374.11	170,53	375.96	19,66	5.19	10,81	2.86	10,70	2.83	51,98	13.73
P-250.110.08	8	0.31	7,83	84.30	185,24	408.40	202,41	446.25	203,65	448.98	31,53	8.33	12,77	3.37	12,51	3.30	44,93	11.87
P-250.140.08	8	0.31	9,97	107.30	211,27	465.77	228,44	503.62	229,68	506.36	34,30	9.06	15,54	4.10	15,28	4.04	56,46	14.92
P-250.190.08	8	0.31	13,32	143.32	252,09	555.78	269,26	593.63	270,50	596.36	38,63	10.20	19,87	5.25	19,61	5.18	74,52	19.69
P-050.070.12	12,7	0.50	0,19	2.05	10,63	23.43			0,43	0.11			1,30	0.34				
P-050.110.12	12,7	0.50	0,26	2.83	12,52	27.61			0,57	0.15			1,77	0.47				
P-050.140.12	12,7	0.50	0,34	3.61	14,42	31.79			0,72	0.19			2,24	0.59				
P-080.070.12	12,7	0.50	0,43	4.58	35,17	77.54			1,62	0.43			2,36	0.62				
P-080.110.12	12,7	0.50	0,71	7.68	41,28	91.00			2,20	0.58			3,75	0.99				
P-080.140.12	12,7	0.50	0,91	9.80	45,43	100.16			2,59	0.68			4,71	1.24				
P-100.070.12	12,7	0.50	0,58	6.27	35,67	78.64			2,74	0.72			4,46	1.18				
P-100.110.12	12,7	0.50	0,98	10.51	43,84	96.65			3,53	0.93			7,17	1.89				
P-100.140.12	12,7	0.50	1,25	13.40	49,40	108.91			4,07	1.08			9,02	2.38				
P-125.110.12	12,7	0.50	1,65	17.79	67,83	149.53	70,71	155.90	6,12	1.62	4,08	1.08	9,85	2.60				
P-125.140.12	12,7	0.50	2,11	22.68	76,28	168.17	79,17	174.54	7,04	1.86	4,99	1.32	12,47	3.30				
P-125.190.12	12,7	0.50	2,82	30.35	90,72	200.01	93,61	206.38	8,66	2.29	6,62	1.75	16,26	4.29				
P-150.110.12	12,7	0.50	2,03	21.87	83,46	183.98	88,50	195.09	8,02	2.12	4,95	1.31	27,69	7.32				
P-150.140.12	12,7	0.50	2,59	27.88	94,80	208.99	99,84	220.11	9,15	2.42	6,08	1.61	29,61	7.82				
P-150.190.12	12,7	0.50	3,46	37.29	114,03	251.40	119,07	262.51	11,13	2.94	8,06	2.13	36,65	9.68				
P-200.110.12	12,7	0.50	3,65	39.24	138,76	305.91	143,45	316.25	144,29	318.10	17,84	4.71	8,99	2.37	8,98	2.37	27,75	7.33
P-200.140.12	12,7	0.50	4,64	49.92	157,89	348.10	162,58	358.44	163,42	360.29	19,83	5.24	10,98	2.90	10,87	2.87	34,66	9.16
P-200.190.12	12,7	0.50	6,19	66.65	187,87	414.18	192,56	424.52	193,40	426.37	22,97	6.07	14,12	3.73	14,01	3.70	45,49	12.02
P-250.110.12	12,7	0.50	6,82	73.43	210,54	464.16	228,51	503.78	229,79	506.60	35,42	9.36	16,67	4.40	16,38	4.33	37,41	9.88
P-250.140.12	12,7	0.50	8,68	93.46	243,92	537.75	261,89	577.37	263,17									

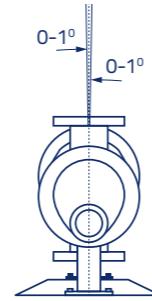
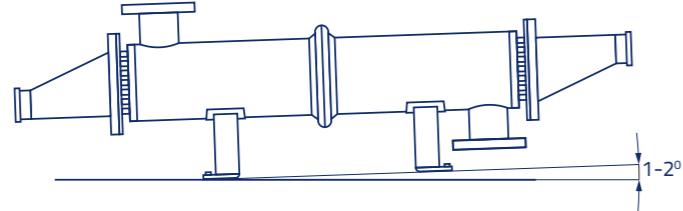
Mounting

P-line heat exchangers can be installed vertically or horizontally depending on the application and available space.

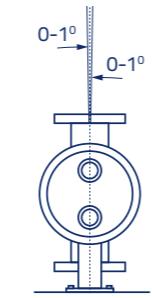
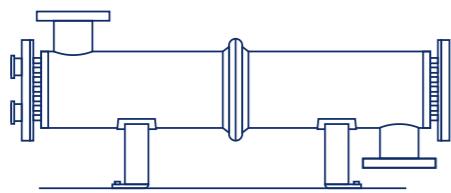


Horizontal mounting

1P heat exchanger



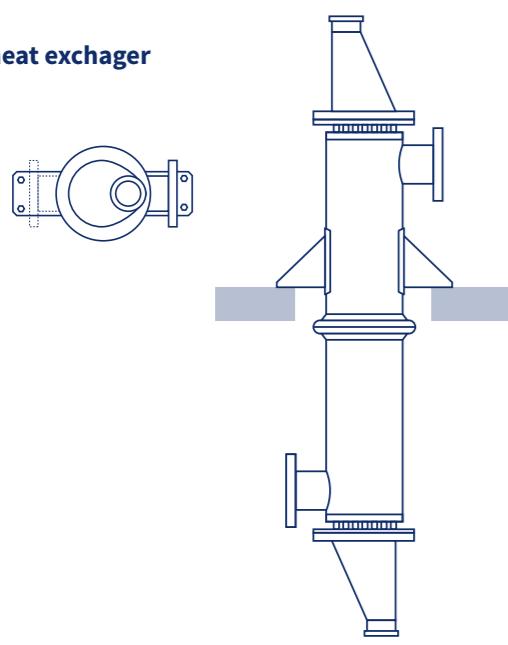
2P and 4P heat exchanger



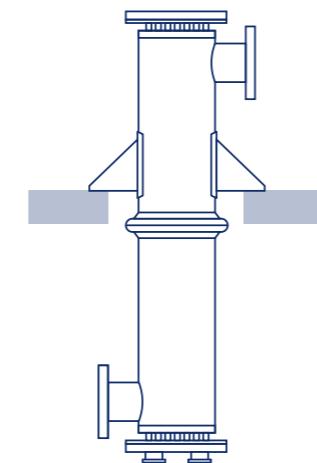
Vertical mounting



1P heat exchanger



2P heat exchanger



1P - One-pass

2P - Two-pass

4P - Four-pass

Exemplar designation



P-080.070.08.H-1P.F

heat exchanger type

P-

shell nominal diameter

080.

approximate shell length [cm]

070.

tube external diameter [mm]

08.

mounting position (H- horizontal, V-vertical)

H-

number of passes (1, 2 or 4)

1P.

gasket material (F- Viton, S- Silicone)

F

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Астрахань (8512)99-46-04
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