

DEPYROGENATING TUNNELS

Steriline
PHARMACEUTICAL EQUIPMENTS



DEPYROGENATING TUNNELS

STERILINE **ST** series laminar flow depyrogenating tunnels have been designed to depyrogenize ampoules, vials and syringes with a continuous process maintaining an ISO5 environment throughout the length of the tunnel.

The depyrogenating tunnels consist of three chambers:

- the inlet chamber with its laminar flow unit keeps clean the transfer of glassware from the washing machine to the hot chamber, dries and preheats glassware and protects from the hot air back flow coming from hot chamber;
- the hot chamber subjects glassware to the thermal cycle for the depyrogenation (refer to below section);
- the cooling chamber cools glassware to the suitable temperature to be discharged into the sterile room/isolator;

The improved design allows higher production speeds, more compact dimensions, energy saving and a better control of the process parameters such as the air speed in the hot chamber and the pressure differential between the cooling chamber and the inlet chamber.

More than 18 models and a wide range of options including automatic air balance, air speed monitoring and automatic adjustment, conveyor belt cleaning system, doors position monitoring and automatic adjustment, pipes for D.E.H.S. test and particles control, sterilizable cooling chamber, automatic discharge of final vials are available to meet specific customer requirements.

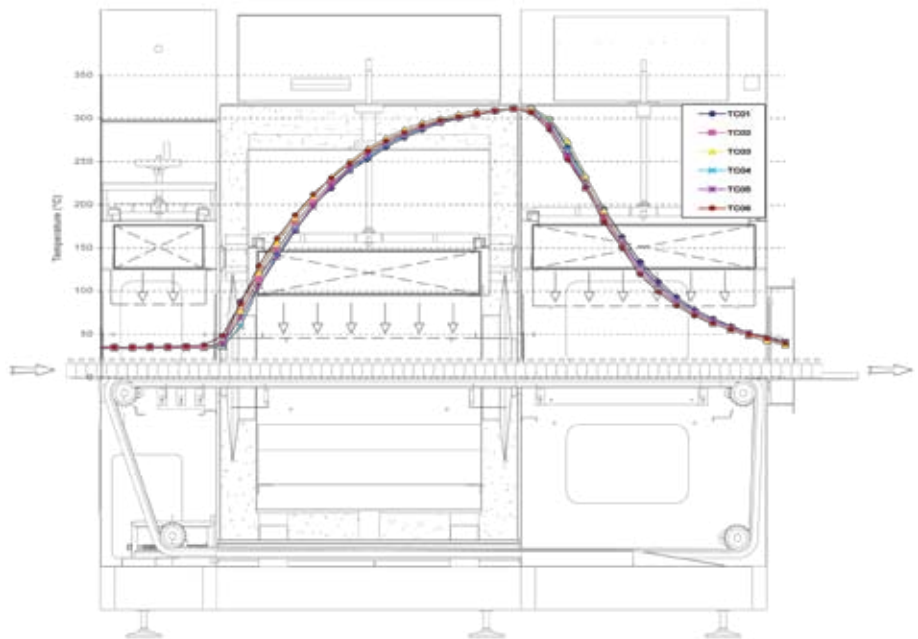
THERMAL CYCLE

The thermal cycle is designed to assure a pyrogens reduction of 10^{-3} (3 Log) or 10^{-6} (6 Log) in accordance with the following formula:

$$F_T = \int_0^t 10^{\frac{T-250}{46,4}} dt$$

and assuming a **D** value of 5 minutes and a **z** value of 46,4°C referred to E. Coli endotoxins. **D** and **z** values are defined respectively as the time required to reduce pyrogens by one logarithm at 250°C and the temperature increment to change the **D** value by a factor of 10. Thus the glassware is submitted to a thermal cycle equivalent to a 15 minutes (3 Log) or 30 minutes (6 Log) treatment at the constant temperature of 250°C. The microbial lethality delivered by a cycle designed for endotoxins inactivation provides a large margin of safety with regard to sterility.

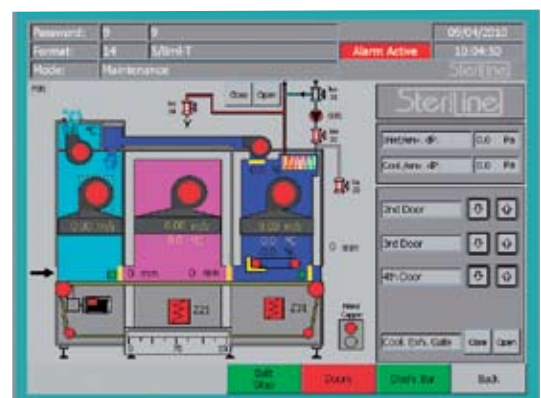
The perfect knowledge of heat exchange, sterilization and depyrogenation rules and the continuous parameters control guarantee the reproducibility and reliability of cycle.



HEAT PENETRATION IN VIALS

AUTOMATION

PLC controlled STERILINE depyrogenating tunnels are equipped with touch screen PC for operator interface. The PC with color graphics ensures easy access to statistics and control screens. 21CFR Part11 compliance is available. The data out screen features the set parameters and the current process parameters enabling the operator to control the operation of the tunnel. A diagnostic screen highlights alarm conditions of the tunnel to enable operator to minimize production downtime. The PC holds “recipes” for each type of glassware: once a format is selected all the tunnel process parameters change automatically by means of PLC without any other operation by the operator. The PC Hard Disk is capable of storing many months of operational process information i.e. process data trends, alarms history, batch reports, etc. STERILINE provides computer system validation documentation and testing in accordance with GAMP guideline.



STC25 - ST0 - ST1 - ST2 - ST3



ST1 TUNNEL

STERILINE offers a wide range of depyrogenating tunnels appropriate for any production requirement.

The models STC25, ST0, ST1, ST2, and ST3 features a variety of production capabilities for processing ampoules, small vials, and syringes.

This series is compact in design to fit even the tightest production spaces.

In addition to normal production facilities, these models are suitable for use by research and development laboratories.

ST SERIES	STC25	ST 0	ST 1	ST 2	ST 3
LENGTH mm	1382	1670	1980	2280	2280
WIDTH mm	1485	1260	1470	1470	1700
HEIGHT mm	2350	2400	2300	2300	2300
CONVEYOR BELTWIDTH mm	250	300	450	450	600
INLET AIR m ³ /h	200	242	348	348	455
EXHAUST AIR m ³ /h	0	205	294	294	382
COOLINGWATER CONSUMPTION* lt/h	1400	850	1600	2200	2800
TOTAL POWER kW	15	17	24	28	32

*ΔT cooling water 4 °C

ST4 - ST5 - ST6 - ST7 - ST8 - ST9



ST6 TUNNEL

STERILINE medium size depyrogenating tunnels, models ST4 through ST9, were specifically developed as a response to demand from pharmaceutical manufacturers for handling a wide range of container types and sizes. These extremely versatile, reliable, high performance machines can handle from 1 to 1000ml glassware in the same tunnel.

ST SERIES	ST 4	ST 5	ST 6	ST 7	ST 8	ST 9
LENGTH mm	2800	3075	2930	3260	3560	3870
WIDTH mm	1700	1700	1905	1905	1905	1905
HEIGHT mm	2300	2300	2350	2350	2350	2350
CONVEYOR BELTWIDTH mm	600	600	800	800	800	800
INLET AIR m ³ /h	455	455	597	597	597	597
EXHAUST AIR m ³ /h	382	382	500	500	500	500
COOLINGWATER CONSUMPTION* lt/h	3250	4250	4250	4600	5000	5500
TOTAL POWER kW	35	41	46	51	54	60

*ΔT cooling water 4 °C

ST12 - ST14 - ST15 - ST18 - ST19 - ST20



ST14 TUNNEL

STERILINE large size depyrogenating tunnels, models ST12, ST14, ST15 and ST18 through ST20, have been introduced to accommodate the ever increasing speeds demanded by today's modern production lines. These models are suitable for higher speed traditional glass processing. The STERILINE feature that is unique to these models is the utilization of two cooling chambers instead of one. Two cooling chambers with two different temperature set points reduces thermal shock normally encountered when cooling glassware too rapidly.

ST SERIES	ST 12	ST 12.1	ST 14	ST 15	ST 18	ST 19	ST 20
LENGTH mm	3160	3460	4220	4560	4680	6325	7720
WIDTH mm	2440	2440	2440	2440	2795	2795	2795
HEIGHT mm	2400	2400	2400	2400	2400	2400	2400
CONVEYOR BELTWIDTH mm	1250	1250	1250	1250	1600	1600	1600
INLET AIR m ³ /h	1270	1270	1270	1270	1615	2066	2066
EXHAUST AIR m ³ /h	1118	1118	1118	1118	1480	1871	1871
COOLINGWATER CONSUMPTION* lt/h	4820	5500	6910	6600	8510	10650	13950
TOTAL POWER kW	63	71	83	83	94	124	156

*ΔT cooling water 4 °C

STERILIZABLE COOLING CHAMBER



COOLING CHAMBER HEATING ELEMENTS



AUTOMATIC TIGHT DOOR



HIGH TEMPERATURE RESISTANT INFLATABLE GASKETS



AUTOMATIC DISCHARGE BAR

The depyrogenating tunnels with sterilizable cooling chamber have the following features:

- Heating elements for sterilizing the cooling chamber by means of dry heat;
- Cooling chamber insulation to provide protection at temperatures up to 230°C;
- Insulated airtight door at the tunnel exit, equipped with high temperature resistant inflatable gaskets, to protect the isolator during the cooling chamber sterilization and to enable the isolator to be sterilized without any leak of VHP into the tunnel.

The cooling chamber is sterilized by HEPA filtered hot air at a temperature of approximately 200°C.

The cycle time is defined during the pre-testing phase at Steriline, calculated in order to ensure the coldest point sterilization.

The minimum surface temperature anywhere in the cooling chamber on any material should be above 170°C.

The coldest point shall stay at a temperature of 170°C as long as necessary to achieve bacterial reduction of 6 log according to the following formula:

$$F_H = \int_0^t 10^{\frac{T-170}{20}} dt$$

Once the cooling chamber sterilization cycle has been started:

- The airtight door closes and the insulated gaskets inflate;
- The cooling water circuit drains;
- All tunnel heaters start;
- The cooling chamber temperature raises up to the predefined set point, that is maintained for the predefined sterilization time.

AUTOMATIC DISCHARGE OF FINAL VIALS

In presence of isolator it is difficult for the operator to manually remove the remaining vials at the end of the batch.

Therefore the depyrogenating tunnels are equipped with the automatic discharge bar to fully discharge the glassware at the end of the process.

TUNNELS OUTPUT

(for a Pyrogens reduction by 3 Log)

AMPOULES-DIN 58377				THOUSANDS / HOUR																			
V	D	H	W	STC25	ST0	ST1	ST2	ST3	ST4	ST5	ST6	ST7	ST8	ST9	ST12	ST12.1	ST12.2	ST14	ST15	ST18	ST19	ST20	
[ml]	[mm]	[mm]	[g]																				
1	10,75	67	-	8	16	23	30	45	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	10,75	79	-	8	16	23	30	45	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	12,75	82	-	6	12	17	25	34	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	14,75	90	-	4,5	9	12	18	24	36	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	17,75	109	-	3	6	8	12	16	24	32	-	-	-	-	-	-	-	-	-	-	-	-	-
20	22,50	120	-	-	3,5	5	7,5	10	15	20	-	-	-	-	-	-	-	-	-	-	-	-	-
25	22,55	135	-	-	3,5	5	7,5	10	15	20	-	-	-	-	-	-	-	-	-	-	-	-	-
30	22,55	160	-	-	3,5	5	7,5	10	15	20	-	-	-	-	-	-	-	-	-	-	-	-	-

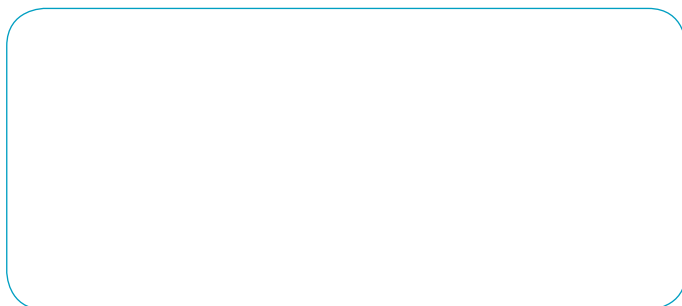
TUBE VIALS-DIN/ISO 8362-1				THOUSANDS / HOUR																			
Size	D	H	W	STC25	ST0	ST1	ST2	ST3	ST4	ST5	ST6	ST7	ST8	ST9	ST12	ST12.1	ST12.2	ST14	ST15	ST18	ST19	ST20	
	[mm]	[mm]	[g]																				
2R	16	35	5	4	7,78	14,76	17,8	23,74	28,93	33	38,54	44	-	-	-	-	-	-	-	-	-	-	-
4R	16	45	6,1	4	7,78	14,76	17,8	23,74	28,93	33	38,54	44	-	-	-	-	-	-	-	-	-	-	-
6R	22	40	8,3	2,2	4,07	7,71	9,3	12,41	15,12	17,25	20,15	23	25,85	28,7	31,5	35,9	40,3	44,8	-	-	-	-	-
8R	22	45	9,4	2,2	4,07	7,71	9,3	12,41	15,12	17,25	20,15	23	25,85	28,7	31,5	35,9	40,3	44,8	-	-	-	-	-
10R	24	45	10,2	1,8	3,36	6,37	7,68	10,25	12,49	14,25	16,64	19	21,36	23,71	26	29,6	33,3	37	40,7	-	-	-	-
15R	24	60	12,8	1,8	3,36	6,37	7,68	10,25	12,49	14,25	16,64	19	21,36	23,71	26	29,6	33,3	37	40,7	-	-	-	-
20R	30	55	17,4	1,1	2,12	4,02	4,85	6,48	7,89	9	10,51	12	13,49	14,98	16,4	18,7	21	23,4	25,7	32,9	-	-	-
25R	30	65	20,2	1,1	2,12	4,02	4,85	6,48	7,89	9	10,51	12	13,49	14,98	16,4	18,7	21	23,4	25,7	32,9	-	-	-
30R	30	75	22,7	1,1	2,12	4,02	4,85	6,48	7,89	9	10,51	12	13,49	14,98	16,4	18,7	21	23,4	25,7	32,9	-	-	-

MOLDED VIALS-DIN/ISO 8362-4				THOUSANDS / HOUR																			
Size	D	H	W	STC25	ST0	ST1	ST2	ST3	ST4	ST5	ST6	ST7	ST8	ST9	ST12	ST12.1	ST12.2	ST14	ST15	ST18	ST19	ST20	
	[mm]	[mm]	[g]																				
5H	20,8	41,3	14	2,2	4,16	7,88	9,51	12,68	15,45	17,63	20,59	23,5	26,41	29,33	32,1	36,7	41,2	-	-	-	-	-	-
7H	22,1	40,8	13	2	3,63	6,88	8,29	11,06	13,48	15,38	17,96	20,5	23,04	25,58	28	32	36	40	43,9	-	-	-	-
8H	23	46,8	16	1,8	3,45	6,54	7,89	10,52	12,82	14,63	17,08	19,5	21,92	24,34	26,7	30,4	34,2	38	41,8	-	-	-	-
10H	25,4	53,5	21	1,3	2,21	4,19	5,06	6,75	8,22	9,38	10,95	12,5	14,05	15,6	17,1	19,5	21,9	24,3	26,8	34,3	-	-	-
15H	26,5	58,8	24	1	1,96	3,72	4,49	5,99	7,3	8,33	9,72	11,1	12,48	13,85	15,2	17,3	19,4	21,6	23,8	30,4	42,5	-	-
20H	32	58	29	0,7	1,29	2,45	2,95	3,94	4,8	5,48	6,39	7,3	8,21	9,11	10	11,4	12,8	14,2	15,6	20	27,9	35,2	-
25H	36	58	30	0,5	1,03	1,95	2,35	3,13	3,81	4,35	5,08	5,8	6,52	7,24	7,9	9	10,1	11,3	12,4	15,9	22,2	27,9	-
30H	36	62,8	35	0,45	0,97	1,84	2,22	2,97	3,62	4,13	4,82	5,5	6,18	6,86	7,5	8,5	9,6	10,7	11,7	15	21	26,5	-
50H	42,5	73	50	0,35	0,67	1,27	1,54	2,05	2,5	2,85	3,33	3,8	4,27	4,74	5,2	5,9	6,6	7,4	8,1	10,4	14,5	18,3	-
100H	51,6	94,5	89	0,17	0,37	0,7	0,85	1,13	1,38	1,58	1,84	2,1	2,36	2,62	2,8	3,2	3,6	4,1	4,5	5,7	8	10,1	-

LIGHT INFUSION BOTTLES-ISO 8536-1				THOUSANDS / HOUR																			
V	D	H	W	STC25	ST0	ST1	ST2	ST3	ST4	ST5	ST6	ST7	ST8	ST9	ST12	ST12.1	ST12.1	ST14	ST15	ST18	ST19	ST20	
[ml]	[mm]	[mm]	[g]																				
50	46	68	55	0,3	0,48	0,91	1,09	1,46	1,78	2,03	2,37	2,7	3	3,3	3,7	4,2	4,7	5,2	5,7	7,4	10,3	13	-
100	49	104	95	0,18	0,41	0,77	0,93	1,24	1,51	1,73	2	2,3	2,5	2,8	3,1	3,5	4	4,4	4,9	6,3	8,8	11,1	-
250	68	125	170	-	0,20	0,39	0,47	0,62	0,76	0,86	1	1,15	1,29	1,4	1,7	1,8	2	2,2	2,4	3,1	4,4	5,5	-
500	78	177	290	-	0,15	0,28	0,33	0,44	0,54	0,62	0,72	0,82	0,92	1	1,1	1,2	1,4	1,6	1,7	2,2	3,1	3,9	-
1000	95	230	510	-	0,08	0,15	0,18	0,24	0,3	0,34	0,4	0,46	0,5	0,56	0,62	0,7	0,8	0,88	0,98	1,2	1,7	2,2	-

INFUSION BOTTLES-DIN 58363-1				THOUSANDS / HOUR																			
V	D	H	W	STC25	ST0	ST1	ST2	ST3	ST4	ST5	ST6	ST7	ST8	ST9	ST12	ST12.1	ST12.1	ST14	ST15	ST18	ST19	ST20	
[ml]	[mm]	[mm]	[g]																				
100	49	108	120	-	-	-	-	1,1	1,28	1,45	1,6	1,8	2,2	2,4	2,8	3,3	3,6	4,4	4,8	6,2	8,4	10,2	-
250	66	140	230	-	-	-	-	0,56	0,65	0,75	0,85	0,95	1,1	1,2	1,4	1,6	1,8	2,1	2,4	3	4	5	-
500	78	188	375	-	-	-	-	0,4	0,46	0,52	0,6	0,66	0,8	0,85	1	1,2	1,4	1,6	1,75	2,2	3	3,8	-
1000	95	238	600	-	-	-	-	-	-	-	-	-	-	-	0,6	0,7	0,8	0,9	1,2	1,7	1,8	2,4	-

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