

### Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20220520

Date:

20220520

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Saniderm PU ROLL	0440151308	8inX10in roll	180	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
		Min:		Max:	min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.2		Max: 53.0	40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.4		Max: 97.4	0.0	99.0	Pass
Preconditioning Time(KPa)	—	42			30.0	90.0	Pass
Vacuum value (KPa)	-60.0	-60			-61.0	-59.0	Pass
Leak test time(min)	5.0	5			1	10	Pass
Pressure change at end of leak test (KPa)	—	0.1			0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	0.0	1.6	BEF: 59.9	A: 58.3	0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	83.0	84.2	BEF: 59.0	A: 25.2	0.0	150.0	Pass
EO weight injected(Kg)	—				0.0	130.0	Pass
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.7		Max: 53.6	40.0	60.0	Pass
Humidity (RH) during EO exposure(% RH)	—	Min: 97.4		Max: 97.4	0.0	99.0	Pass
Pressure (P1) during EO exposure (Kpa)	—	Min: 26.0		Max: 74.2	—	—	Pass
EO dwell (min)	480	481			478	482	Pass
Numbers of air washes	3	3			1	5	Pass

Sterilization Process	Start time	End time	Time elapsed(min)
Heating	2022/5/20 12:53	2022/5/20 13:24	31
Precondition	2022/5/20 13:24	2022/5/20 14:06	42
Pre-vacuum	2022/5/20 14:06	2022/5/20 14:15	9
leak test	2022/5/20 14:15	2022/5/20 14:20	5
steam injection	2022/5/20 14:20	2022/5/20 14:22	2
EO injection	2022/5/20 14:22	2022/5/20 15:29	67
EO dwell	2022/5/20 15:29	2022/5/20 23:30	481
EO Removal	2022/5/20 23:30	2022/5/20 23:50	20
air washing	2022/5/20 23:50	2022/5/21 0:28	38
flushing	2022/5/21 0:28	2022/5/21 0:57	29

### Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20220523

Date:

20220523

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Saniderm PU ROLL	0440151308	8inX10in roll	180	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
					min	max	
Preconditioning Temperature (°C)	50.0	Min: 54.0	Max: 56.2	40.0	60.0	Pass	
Preconditioning Humidity	--	Min: 97.4	Max: 97.4	0.0	99.0	Pass	
Preconditioning Time(KPa)	--	37		30.0	90.0	Pass	
Vacuum value (KPa)	-60.0	-60		-61.0	-59.0	Pass	
Leak test time(min)	5.0	5		1	10	Pass	
Pressure change at end of leak test (KPa)	--	0.2		0.0	3.0	Pass	
Pressure change at end of steam injection (KPa)	0.0	1.7	BEF:-59.7 A:-58.0	0.5	3.0	Pass	
Pressure change at end of EO injection (KPa)	83.0	80.9	BEF:-58.6 A:22.3	0.0	150.0	Pass	
EO weight injected(Kg)	--			0.0	130.0	Pass	
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.6	Max: 55.4	40.0	60.0	Pass	
Humidity (RH) during EO exposure(% RH)	--	Min: 97.4	Max: 97.4	0.0	99.0	Pass	
Pressure (P1) during EO exposure (Kpa)	--	Min: 26.5	Max: 68.2	--	--	Pass	
EO dwell (min)	480	480		478	482	Pass	
Numbers of air washes	3	3		1	5	Pass	

Sterilization Process	Start time	End time	Time elapsed(min)
Heating	2022/5/23 13:52	2022/5/23 13:53	1
Precondition	2022/5/23 13:53	2022/5/23 14:30	37
Pre-vacuum	2022/5/23 14:30	2022/5/23 14:40	10
leak test	2022/5/23 14:40	2022/5/23 14:45	5
steam injection	2022/5/23 14:45	2022/5/23 14:47	2
EO injection	2022/5/23 14:47	2022/5/23 15:46	59
EO dwell	2022/5/23 15:46	2022/5/23 23:46	480
EO Removal	2022/5/23 23:46	2022/5/24 0:06	20
air washing	2022/5/24 0:06	2022/5/24 0:44	38
flushing	2022/5/24 0:44	2022/5/24 1:13	29



### Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20220518

Date:

20220518

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Saniderm PU ROLL	0440151308	8inX8yd roll	84	



Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.1		Max: 52.4		40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.4		Max: 97.4		0.0	99.0	Pass
Preconditioning Time(KPa)	—	36				30.0	90.0	Pass
Vacuum value (KPa)	-60.0	-60				-61.0	-59.0	Pass
Leak test time(min)	5.0	5				1	10	Pass
Pressure change at end of leak test (KPa)	—	0.2				0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	0.0	1.3	BEF:-59.8 A:-58.5			0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	83.0	83.2	BEF:-58.9 A:24.3			0.0	150.0	Pass
EO weight injected(Kg)	—					0.0	130.0	Pass
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.8		Max: 52.5		40.0	60.0	Pass
Humidity (RH) during EO exposure(% RH)	—	Min: 97.4		Max: 97.4		0.0	99.0	Pass
Pressure (P1) during EO exposure (Kpa)	—	Min: 26.2		Max: 65.4		—	—	Pass
EO dwell (min)	480	481				478	482	Pass
Numbers of air washes	3	3				1	5	Pass

Sterilization Process	Start time	End time	Time elapsed(min)
Heating	2022/5/18 13:15	2022/5/18 13:42	27
Precondition	2022/5/18 13:42	2022/5/18 14:18	36
Pre-vacuum	2022/5/18 14:18	2022/5/18 14:28	10
leak test	2022/5/18 14:28	2022/5/18 14:33	5
steam injection	2022/5/18 14:33	2022/5/18 14:35	2
EO injection	2022/5/18 14:35	2022/5/18 15:41	66
EO dwell	2022/5/18 15:41	2022/5/18 23:42	481
EO Removal	2022/5/18 23:42	2022/5/19 0:01	19
air washing	2022/5/19 0:01	2022/5/19 0:38	37
flushing	2022/5/19 0:38	2022/5/19 1:07	29

### Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20220517

Date:

20220517

班次 Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Saniderm PU ROLL	0440151308	6inX8in roll	180	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
		Min:		Max:	min	max	
Preconditioning Temperature (°C)	50.0	Min: 52.0		Max: 54.0	40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.4		Max: 97.4	0.0	99.0	Pass
Preconditioning Time(KPa)	—	36			30.0	90.0	Pass
Vacuum value (KPa)	-60.0	-60			-61.0	-59.0	Pass
Leak test time(min)	5.0	5			1	10	Pass
Pressure change at end of leak test (KPa)	—	0.2			0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	0.0	1.5	BEF:-59.8	A:-58.3	0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	83.0	77.3	BEF:-58.6	A:18.7	0.0	150.0	Pass
EO weight injected(Kg)	—				0.0	130.0	Pass
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.7		Max: 52.7	40.0	60.0	Pass
Humidity (RH) during EO exposure(% RH)	—	Min: 97.4		Max: 97.4	0.0	99.0	Pass
Pressure (P1) during EO exposure (Kpa)	—	Min: 25.8		Max: 54.0	—	—	Pass
EO dwell (min)	480	479			478	482	Pass
Numbers of air washes	3	3			1	5	Pass

Sterilization Process	Start time	End time	Time elapsed(min)
Heating	2022/5/17 13:44	2022/5/17 13:45	1
Precondition	2022/5/17 13:45	2022/5/17 14:22	37
Pre-vacuum	2022/5/17 14:22	2022/5/17 14:31	9
leak test	2022/5/17 14:31	2022/5/17 14:36	5
steam injection	2022/5/17 14:36	2022/5/17 14:39	3
EO injection	2022/5/17 14:39	2022/5/17 15:20	41
EO dwell	2022/5/17 15:20	2022/5/17 23:19	479
EO Removal	2022/5/17 23:19	2022/5/17 23:38	19
air washing	2022/5/17 23:38	2022/5/18 0:15	37
flushing	2022/5/18 0:15	2022/5/18 0:44	29



### Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20220516

Date:

20220516

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Saniderm PU ROLL	0440151308	6inX8in roll	180	



Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		min	max	
Preconditioning Temperature (°C)	50.0	Min: 51.9		Max: 53.4		40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.4		Max: 97.4		0.0	99.0	Pass
Preconditioning Time(KPa)	—	38				30.0	90.0	Pass
Vaccum value (KPa)	-60.0	-60				-61.0	-59.0	Pass
Leak test time(min)	5.0	5				1	10	Pass
Pressure change at end of leak test (KPa)	—	0.1				0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	0.0	1.4	BEF:-59.9	A:-58.5		0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	83.0	79.1	BEF:-59.0	A:20.1		0.0	150.0	Pass
EO weight injected(Kg)	—					0.0	130.0	Pass
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.7		Max: 52.5		40.0	60.0	Pass
Humidity (RH) during EO exposure(% RH)	—	Min: 97.4		Max: 97.4		0.0	99.0	Pass
Pressure (P1) during EO exposure (Kpa)	—	Min: 26.6		Max: 80.0		—	—	Pass
EO dwell (min)	480	480				478	482	Pass
Numbers of air washes	3	3				1	5	Pass

Sterilization Process	Start time	End time	Time elapsed(min)
Heating	2022/5/16 13:51	2022/5/16 13:52	1
Precondition	2022/5/16 13:52	2022/5/16 14:30	38
Pre-vacuum	2022/5/16 14:30	2022/5/16 14:39	9
leak test	2022/5/16 14:39	2022/5/16 14:44	5
steam injection	2022/5/16 14:44	2022/5/16 14:46	2
EO injection	2022/5/16 14:46	2022/5/16 15:42	56
EO dwell	2022/5/16 15:42	2022/5/16 23:42	480
EO Removal	2022/5/16 23:42	2022/5/17 0:01	19
air washing	2022/5/17 0:01	2022/5/17 0:38	37
flushing	2022/5/17 0:38	2022/5/17 1:06	28