

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20210521

Date:

20210521

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	0439141207	8inX8yd roll	160	
Sanidrem PU ROLL	0439141207	10.2X8yd roll	111	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
		Min:	Max:		min	max	
Preconditioning Temperature (°C)	50.0	Min: 53.6	Max: 53.6		40.0	60.0	Pass
Preconditioning Humidity	—	Min: 63.2	Max: 63.7		0.0	99.0	Pass
Preconditioning Time(KPa)	—	30			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)	1.5	1.4	BEF:-59.9 A:-58.5		0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	93.0	BEF:-58.8 A:34.2		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: 52.4		40.0	60.0	Pass
Humidity (RH) during EO exposure(% RH)	—	Min: 78.8	Max: 97.4		0.0	99.0	Pass
Pressure (P1) during EO exposure (Kpa)	—	Min: 32.8	Max: 56.9		—	—	Pass
EO dwell (min)	480	480			478	482	Pass
Numbers of air washes	3	4			1	5	Pass

Sterilization Process	Start time	End time	Time elapsed(min)
Heating	2021/5/21 13:12	2021/5/21 13:13	1
Precondition	2021/5/21 13:13	2021/5/21 13:43	30
Pre-vacuum	2021/5/21 13:43	2021/5/21 13:55	12
leak test	2021/5/21 13:55	2021/5/21 14:00	5
steam injection	2021/5/21 14:00	2021/5/21 14:06	6
EO injection	2021/5/21 14:06	2021/5/21 16:02	116
EO dwell	2021/5/21 16:02	2021/5/22 0:02	480
EO Removal	2021/5/22 0:02	2021/5/22 0:18	16
air washing	2021/5/22 0:18	2021/5/22 1:05	47
flushing	2021/5/22 1:05	2021/5/22 1:46	41

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20210615

Date:

20210615

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	0439141207	8inX8yd roll	84	
Sanidrem PU ROLL	0439141207	10.2inX8yd roll	294	



Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		min	max	
Preconditioning Temperature (°C)	50.0	Min: 54.5		Max: 54.6		40.0	60.0	Pass
Preconditioning Humidity	—	Min: 92.6		Max: 93.2		0.0	99.0	Pass
Preconditioning Time(KPa)	—	30				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)	—	0.3				0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	1.5	1.7		BEF:-59.7 A:-58.0		0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	84.8		BEF:-58.2 A:26.6		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: 54.9		40.0	60.0	Pass
Humidity (RH) during EO exposure(% RH)	—	Min: 97.3		Max: 97.4		0.0	99.0	Pass
Pressure (P1) during EO exposure (Kpa)	—	Min: 26.2		Max: 55.5		—	—	Pass
EO dwell (min)	480	480				478	482	Pass
Numbers of air washes	3	4				1	5	Pass

Sterilization Process	Start time	End time	Time elapsed(min)
Heating	2021/6/15 13:13	2021/6/15 13:13	0
Precondition	2021/6/15 13:13	2021/6/15 13:43	30
Pre-vacuum	2021/6/15 13:43	2021/6/15 13:55	12
leak test	2021/6/15 13:55	2021/6/15 14:00	5
steam injection	2021/6/15 14:00	2021/6/15 14:02	2
EO injection	2021/6/15 14:02	2021/6/15 14:45	43
EO dwell	2021/6/15 14:45	2021/6/15 22:45	480
EO Removal	2021/6/15 22:45	2021/6/15 23:01	16
air washing	2021/6/15 23:01	2021/6/15 23:47	46
flushing	2021/6/15 23:47	2021/6/16 0:27	40

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch: 20210812

Date:

20210812

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	0439141207	10.2inX2yd roll	288	



Process Parameters	Setting Value	Actual Value		Requirement		Pass/Fail
				min	max	
Preconditioning Temperature (°C)	50.0	Min: 54.0	Max: 54.9	40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.4	Max: 97.4	0.0	99.0	Pass
Preconditioning Time(KPa)	—	93		30.0	90.0	Fail
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)	1.5	1.4	BEF:-59.9 A:-58.5	0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	78.2	BEF:-58.8 A:19.4	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: 54.4	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: 19.4	Max: 49.6	—	—	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	2021/8/12 13:14	2021/8/12 13:15	1
Precondition	2021/8/12 13:15	2021/8/12 14:48	93
Pre-vacuum	2021/8/12 14:48	2021/8/12 14:55	7
leak test	2021/8/12 14:55	2021/8/12 15:00	5
steam injection	2021/8/12 15:00	2021/8/12 15:20	20
EO injection	2021/8/12 15:20	2021/8/12 16:12	52
EO dwell	2021/8/12 16:12	2021/8/13 0:13	481
EO Removal	2021/8/13 0:13	2021/8/13 0:28	15
air washing	2021/8/13 0:28	2021/8/13 1:05	37
flushing	2021/8/13 1:05	2021/8/13 1:34	29

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20210826

Date:

20210826

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	0439141207	10.2inX2yd roll	300	



Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.2		Max: 53.5		40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.4		Max: 97.4		0.0	99.0	Pass
Preconditioning Time(KPa)	—	25				30.0	90.0	Fail
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)	1.5	1.3	BEF:-59.9 A:-58.6			0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	91.0	BEF:-58.8 A:32.2			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: 54.8		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: 32.1		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	2021/8/26 19:53	2021/8/26 20:41	48
Precondition	2021/8/26 20:41	2021/8/26 21:06	25
Pre-vacuum	2021/8/26 21:06	2021/8/26 21:13	7
leak test	2021/8/26 21:13	2021/8/26 21:18	5
steam injection	2021/8/26 21:18	2021/8/26 21:21	3
EO injection	2021/8/26 21:21	2021/8/26 21:51	30
EO dwell	2021/8/26 21:51	2021/8/27 5:51	480
EO Removal	2021/8/27 5:51	2021/8/27 6:09	18
air washing	2021/8/27 6:09	2021/8/27 6:45	36
flushing	2021/8/27 6:45	2021/8/27 7:13	28

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20210828

Date:

20210828

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU dressing	0439141207	1inX3.5in	1	



Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
						min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.2	Max: 55.4	40.0	60.0	Pass		
Preconditioning Humidity	—	Min: 97.4	Max: 97.4	0.0	99.0	Pass		
Preconditioning Time(KPa)	—	31		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)	—	0.2		0.0	3.0	Pass		
Pressure change at end of steam injection (KPa)	1.5	1.4	BEF:-59.8 A:-58.4		0.5	3.0	Pass	
Pressure change at end of EO injection (KPa)	84.0	86.7	BEF:-58.9 A:27.8		0.0	150.0	Pass	
EO weight injected(Kg)	—			0.0	130.0	Pass		
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.9	Max: 57.2	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: 27.5	Max: 64.0	—	—	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	2021/8/28 9:21	2021/8/28 9:40	19
Precondition	2021/8/28 9:40	2021/8/28 10:11	31
Pre-vacuum	2021/8/28 10:11	2021/8/28 10:18	7
leak test	2021/8/28 10:18	2021/8/28 10:23	5
steam injection	2021/8/28 10:23	2021/8/28 10:25	2
EO injection	2021/8/28 10:25	2021/8/28 10:53	28
EO dwell	2021/8/28 10:53	2021/8/28 18:54	481
EO Removal	2021/8/28 18:54	2021/8/28 19:10	16
air washing	2021/8/28 19:10	2021/8/28 19:47	37
flushing	2021/8/28 19:47	2021/8/28 20:15	28

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20210829

Date:

20210829

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU dressing	0439141207	6inX8in	36	
Sanidrem PU dressing	0439141207	8inX10in	72	
Sanidrem PU dressing	0439141207	NO.9 4inX4in	25	
Sanidrem PU dressing	0439141207	NO.10 4inX4in	50	
Sanidrem PU dressing	0439141207	1inX3.5in	12	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
		Min:	Max:		min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.2	Max: 53.9		40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.4	Max: 97.4		0.0	99.0	Pass
Preconditioning Time(KPa)	—	15			30.0	90.0	Fail
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)	—	0.3			0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	1.5	1.6	BEF:-59.7 A:-58.1		0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	85.6	BEF:-58.9 A:26.7		0.0	150.0	Pass
EO weight injected(Kg)	—				0.0	130.0	Pass
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.9	Max: 56.3		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: 26.7	Max: 60.0		—	—	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	2021/8/29 9:31	2021/8/29 9:49	18
Precondition	2021/8/29 9:49	2021/8/29 10:04	15
Pre-vacuum	2021/8/29 10:04	2021/8/29 10:11	7
leak test	2021/8/29 10:11	2021/8/29 10:16	5
steam injection	2021/8/29 10:16	2021/8/29 10:18	2
EO injection	2021/8/29 10:18	2021/8/29 11:01	43
EO dwell	2021/8/29 11:01	2021/8/29 19:01	480
EO Removal	2021/8/29 19:01	2021/8/29 19:18	17
air washing	2021/8/29 19:18	2021/8/29 19:55	37
flushing	2021/8/29 19:55	2021/8/29 20:24	29

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20210830

Date:

20210830

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	0439141207	4inX8yd roll	84	
Sanidrem PU ROLL	0439141207	6inX8yd roll	90	
Sanidrem PU ROLL	0439141207	8inX8yd roll	50	



Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.2		Max: 53.1		40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.4		Max: 97.4		0.0	99.0	Pass
Preconditioning Time(KPa)	—	15				30.0	90.0	Fail
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)	—	0.3				0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	1.5	1.7	BEF:-59.6 A:	57.9		0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	83.6	BEF:-58.6 A:	25.0		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: 54.8		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: 25.0		Max: 61.4		—	—	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	2021/8/30 9:20	2021/8/30 9:49	29
Precondition	2021/8/30 9:49	2021/8/30 10:04	15
Pre-vacuum	2021/8/30 10:04	2021/8/30 10:11	7
leak test	2021/8/30 10:11	2021/8/30 10:16	5
steam injection	2021/8/30 10:16	2021/8/30 10:18	2
EO injection	2021/8/30 10:18	2021/8/30 10:58	40
EO dwell	2021/8/30 10:58	2021/8/30 18:58	480
EO Removal	2021/8/30 18:58	2021/8/30 19:15	17
air washing	2021/8/30 19:15	2021/8/30 19:51	36
flushing	2021/8/30 19:51	2021/8/30 20:20	29

Ethylene Oxide Sterilization Process Record

Sterilizer: _____ Sterilization Batch: **20210831** Date: **20210831** Order: **1**

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	0439141207	10.2inX8yd roll	183	
Sanidrem PU ROLL	0439141207	10.2inX2yd roll	20	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
		Min:	Max:		min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.2	Max: 56.4		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
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)	1.5	1.3	BEF:-59.9 A:-58.6		0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	85.0	BEF:-59.0 A:26.0		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: 56.3		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: 62.9		—	—	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	2021/8/31 9:43	2021/8/31 9:58	15
Precondition	2021/8/31 9:58	2021/8/31 10:35	37
Pre-vacuum	2021/8/31 10:35	2021/8/31 10:42	7
leak test	2021/8/31 10:42	2021/8/31 10:47	5
steam injection	2021/8/31 10:47	2021/8/31 10:50	3
EO injection	2021/8/31 10:50	2021/8/31 11:43	53
EO dwell	2021/8/31 11:43	2021/8/31 19:42	479
EO Removal	2021/8/31 19:42	2021/8/31 19:59	17
air washing	2021/8/31 19:59	2021/8/31 20:35	36
flushing	2021/8/31 20:35	2021/8/31 21:03	28

Ethylene Oxide Sterilization Process Record

Sterilizer: _____ Sterilization Batch: **20210901** Date: _____

20210901

Order: _____

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	0439141207	10.2inX2yd roll	300	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
		Min:		Max:	min	max	
Preconditioning Temperature (°C)	50.0	Min: 55.3		Max: 57.3	40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.4		Max: 97.4	0.0	99.0	Pass
Preconditioning Time(KPa)	—	55			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)	—	0.2			0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	1.5	1.6	BEF:-59.8	A:-58.2	0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	86.5	BEF:-58.9	A:27.6	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: 56.6	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: 27.0		Max: 62.0	—	—	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	2021/9/1 11:03	2021/9/1 11:04	1
Precondition	2021/9/1 11:04	2021/9/1 11:59	55
Pre-vacuum	2021/9/1 11:59	2021/9/1 12:07	8
leak test	2021/9/1 12:07	2021/9/1 12:12	5
steam injection	2021/9/1 12:12	2021/9/1 12:14	2
EO injection	2021/9/1 12:14	2021/9/1 12:35	21
EO dwell	2021/9/1 12:35	2021/9/1 20:35	480
EO Removal	2021/9/1 20:35	2021/9/1 20:52	17
air washing	2021/9/1 20:52	2021/9/1 21:28	36
flushing	2021/9/1 21:28	2021/9/1 21:56	28

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20210902

Date:

20210902

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	0439141207	10.2inX2yd roll	300	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
		min	max		min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.2	Max: 51.7		40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.3	Max: 97.4		0.0	99.0	Pass
Preconditioning Time(KPa)	—	15			30.0	90.0	Fail
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)	—	0.3			0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	1.5	1.5	BEF:-59.7	A:-58.2	0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	88.1	BEF:-58.7	A:29.4	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: 52.9		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: 29.2	Max: 71.2		—	—	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	2021/9/2 19:36	2021/9/2 20:05	29
Precondition	2021/9/2 20:05	2021/9/2 20:21	16
Pre-vacuum	2021/9/2 20:21	2021/9/2 20:28	7
leak test	2021/9/2 20:28	2021/9/2 20:33	5
steam injection	2021/9/2 20:33	2021/9/2 20:35	2
EO injection	2021/9/2 20:35	2021/9/2 21:39	64
EO dwell	2021/9/2 21:39	2021/9/3 5:39	480
EO Removal	2021/9/3 5:39	2021/9/3 5:56	17
air washing	2021/9/3 5:56	2021/9/3 6:33	37
flushing	2021/9/3 6:33	2021/9/3 7:01	28

Ethylene Oxide Sterilization Process Record

Sterilizer: SC050

Sterilization Batch: 20210917

Date:

20210917

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	0439141207	10.2inX2yd roll	300	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
					min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.1	Max: 55.2	40.0	60.0	Pass	
Preconditioning Humidity	—	Min: 97.4	Max: 97.4	0.0	99.0	Pass	
Preconditioning Time(KPa)	—	73		30.0	90.0	Pass	
Vaccum value (KPa)	-60.0	-60		-61.0	-59.0	Pass	
Leak test time(min)	5.0	63		1	10	Fail	
Pressure change at end of leak test (KPa)	—	0.3		0.0	3.0	Pass	
Pressure change at end of steam injection (KPa)	1.5	1.4	BEF:-59.9 A:-58.5	0.5	3.0	Pass	
Pressure change at end of EO injection (KPa)	84.0	83.9	BEF:-58.8 A:25.1	0.0	150.0	Pass	
EO weight injected(Kg)	—			0.0	130.0	Pass	
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.8	Max: 54.2	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: 24.4	Max: 62.6	—	—	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	2021/9/17 12:59	2021/9/17 14:24	85
Precondition	2021/9/17 13:42	2021/9/17 14:55	73
Pre-vacuum	2021/9/17 13:57	2021/9/17 15:02	65
leak test	2021/9/17 14:04	2021/9/17 15:07	63
steam injection	2021/9/17 14:09	2021/9/17 15:10	61
EO injection	2021/9/17 14:12	2021/9/17 15:43	91
EO dwell	2021/9/17 15:43	2021/9/17 23:44	481
EO Removal	2021/9/17 23:44	2021/9/18 0:01	17
air washing	2021/9/18 0:01	2021/9/18 0:37	36
flushing	2021/9/18 0:37	2021/9/18 1:06	29

Ethylene Oxide Sterilization Process Record

Sterilizer: _____ Sterilization Batch: **20210918** Date: **20210918** Order: _____ 1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	0439141207	10.2inX2yd roll	112	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
		Min:		Max:	min	max	
Preconditioning Temperature (°C)	50.0	Min: 51.9		Max: 53.8	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)	—	0.2			0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	1.5	1.6	BEF:-59.9	A:-58.3	0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	82.6	BEF:-59.0	A:23.6	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: 54.0	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: 30.1		Max: 67.1	—	—	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	2021/9/18 13:44	2021/9/18 13:45	1
Precondition	2021/9/18 13:45	2021/9/18 14:24	39
Pre-vacuum	2021/9/18 14:24	2021/9/18 14:31	7
leak test	2021/9/18 14:31	2021/9/18 14:36	5
steam injection	2021/9/18 14:36	2021/9/18 14:38	2
EO injection	2021/9/18 14:38	2021/9/18 15:42	64
EO dwell	2021/9/18 15:42	2021/9/18 23:42	480
EO Removal	2021/9/18 23:42	2021/9/18 23:59	17
air washing	2021/9/18 23:59	2021/9/19 0:35	36
flushing	2021/9/19 0:35	2021/9/19 1:03	28