

Ethylene Oxide Sterilization Process Record

Sterilizer: _____ Sterilization Batch: **20211111** Date: _____

20211111

Order: _____

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	06071440	4inX8yd roll	168	



Process Parameters	Setting Value	Actual Value		Requirement		Pass/Fail
				min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.1	Max: 54.0	40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.3	Max: 97.3	0.0	99.0	Pass
Preconditioning Time(KPa)	—	26		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)	—	0.2		0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	1.5	1.2	BEF:-59.7 A:-58.5	0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	94.2	BEF:-58.8 A:35.4	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: 53.3	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: 35.3	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	2021/11/11 13:03	2021/11/11 14:19	76
Precondition	2021/11/11 14:19	2021/11/11 14:45	26
Pre-vacuum	2021/11/11 14:45	2021/11/11 14:52	7
leak test	2021/11/11 14:52	2021/11/11 14:57	5
steam injection	2021/11/11 14:57	2021/11/11 14:59	2
EO injection	2021/11/11 14:59	2021/11/11 15:47	48
EO dwell	2021/11/11 15:47	2021/11/11 23:47	480
EO Removal	2021/11/11 23:47	2021/11/12 0:04	17
air washing	2021/11/12 0:04	2021/11/12 0:38	34
flushing	2021/11/12 0:38	2021/11/12 1:06	28

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20211112

Date:

20211112

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	06071440	6inX8yd roll	210	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
					min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.2	Max: 52.6	40.0	60.0	Pass	
Preconditioning Humidity	—	Min: 97.3	Max: 97.3	0.0	99.0	Pass	
Preconditioning Time(KPa)	—	26		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)	—	0.2		0.0	3.0	Pass	
Pressure change at end of steam injection (KPa)	1.5	1.1	BEF:-59.7 A:-58.6	0.5	3.0	Pass	
Pressure change at end of EO injection (KPa)	84.0	87.1	BEF:-58.9 A:28.2	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: 53.0	40.0	60.0	Pass	
Humidity (RH) during EO exposure(% RH)	—	Min: 97.3	Max: 97.3	0.0	99.0	Pass	
Pressure (P1) during EO exposure (Kpa)	—	Min: 27.9	Max: 75.7	—	—	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	2021/11/12 16:35	2021/11/12 17:22	47
Precondition	2021/11/12 17:22	2021/11/12 17:48	26
Pre-vacuum	2021/11/12 17:48	2021/11/12 17:55	7
leak test	2021/11/12 17:55	2021/11/12 18:00	5
steam injection	2021/11/12 18:00	2021/11/12 18:02	2
EO injection	2021/11/12 18:02	2021/11/12 18:31	29
EO dwell	2021/11/12 18:31	2021/11/13 2:31	480
EO Removal	2021/11/13 2:31	2021/11/13 2:48	17
air washing	2021/11/13 2:48	2021/11/13 3:22	34
flushing	2021/11/13 3:22	2021/11/13 3:51	29

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20211113

Date:

20211113

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	06071440	8inX8yd roll	168	



Process Parameters	Setting Value	Actual Value		Requirement		Pass/Fail
				min	max	
Preconditioning Temperature (°C)	50.0	Min: 49.6	Max: 51.8	40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.3	Max: 97.3	0.0	99.0	Pass
Preconditioning Time(KPa)	—	47		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	1.2	BEF:-59.8 A:-58.6	0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	90.8	BEF:-58.8 A:32.0	0.0	150.0	Pass
EO weight injected(Kg)	—			0.0	130.0	Pass
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.6	Max: 53.8	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: 32.0	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	2021/11/13 13:07	2021/11/13 13:08	1
Precondition	2021/11/13 13:08	2021/11/13 13:55	47
Pre-vacuum	2021/11/13 13:55	2021/11/13 14:02	7
leak test	2021/11/13 14:02	2021/11/13 14:07	5
steam injection	2021/11/13 14:07	2021/11/13 14:10	3
EO injection	2021/11/13 14:10	2021/11/13 15:36	86
EO dwell	2021/11/13 15:36	2021/11/13 23:36	480
EO Removal	2021/11/13 23:36	2021/11/13 23:53	17
air washing	2021/11/13 23:53	2021/11/14 0:28	35
flushing	2021/11/14 0:28	2021/11/14 0:57	29

Ethylene Oxide Sterilization Process Record

Sterilizer: _____ Sterilization Batch: 20211115 Date: 20211115

20211115

Order: _____

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	06071440	10.2inX8yd roll	252	



Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
					min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.2	Max: 53.5	40.0	60.0	Pass	
Preconditioning Humidity	—	Min: 97.3	Max: 97.3	0.0	99.0	Pass	
Preconditioning Time(KPa)	—	27		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	1.3	BEF:-59.6 A:-58.3	0.5	3.0	Pass	
Pressure change at end of EO injection (KPa)	84.0	84.7	BEF:-58.6 A:26.1	0.0	150.0	Pass	
EO weight injected(Kg)	—			0.0	130.0	Pass	
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.6	Max: 52.9	40.0	60.0	Pass	
Humidity (RH) during EO exposure(% RH)	—	Min: 97.3	Max: 97.3	0.0	99.0	Pass	
Pressure (P1) during EO exposure (Kpa)	—	Min: 26.1	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	2021/11/15 13:02	2021/11/15 14:36	94
Precondition	2021/11/15 14:36	2021/11/15 15:03	27
Pre-vacuum	2021/11/15 15:03	2021/11/15 15:10	7
leak test	2021/11/15 15:10	2021/11/15 15:15	5
steam injection	2021/11/15 15:15	2021/11/15 15:18	3
EO injection	2021/11/15 15:18	2021/11/15 16:28	70
EO dwell	2021/11/15 16:28	2021/11/16 0:28	480
EO Removal	2021/11/16 0:28	2021/11/16 0:45	17
air washing	2021/11/16 0:45	2021/11/16 1:20	35
flushing	2021/11/16 1:20	2021/11/16 1:48	28

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20211116

Date:

20211116

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	06071440	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: 53.7		40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.3	Max: 97.3		0.0	99.0	Pass
Preconditioning Time(KPa)	—	41			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	1.5	BEF:-59.9 A:-58.4		0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	87.0	BEF:-58.8 A:28.2		0.0	150.0	Pass
EO weight injected(Kg)	—				0.0	130.0	Pass
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.6	Max: 53.5		40.0	60.0	Pass
Humidity (RH) during EO exposure(% RH)	—	Min: 97.3	Max: 97.3		0.0	99.0	Pass
Pressure (P1) during EO exposure (Kpa)	—	Min: 28.2	Max: 72.6		—	—	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	2021/11/16 13:00	2021/11/16 14:21	81
Precondition	2021/11/16 14:21	2021/11/16 15:01	40
Pre-vacuum	2021/11/16 15:01	2021/11/16 15:08	7
leak test	2021/11/16 15:08	2021/11/16 15:13	5
steam injection	2021/11/16 15:13	2021/11/16 15:16	3
EO injection	2021/11/16 15:16	2021/11/16 16:08	52
EO dwell	2021/11/16 16:08	2021/11/17 0:08	480
EO Removal	2021/11/17 0:08	2021/11/17 0:24	16
air washing	2021/11/17 0:24	2021/11/17 0:58	34
flushing	2021/11/17 0:58	2021/11/17 1:27	29

Ethylene Oxide Sterilization Process Record

Sterilizer: _____ Sterilization Batch: **20211118** Date: _____

20211118

Order: **1**

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	06071440	10.2inX2yd roll	210	



Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.1		Max: 51.9		40.0	60.0	Pass
Preconditioning Humidity	—	Min: 97.3		Max: 97.3		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)	—	0.1				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	85.6	BEF:-59.1	A:26.5		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: 97.3		Max: 97.4		0.0	99.0	Pass
Pressure (P1) during EO exposure (Kpa)	—	Min: 26.5		Max: 78.0		—	—	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	2021/11/18 17:49	2021/11/18 18:26	37
Precondition	2021/11/18 18:26	2021/11/18 18:41	15
Pre-vacuum	2021/11/18 18:41	2021/11/18 18:48	7
leak test	2021/11/18 18:48	2021/11/18 18:53	5
steam injection	2021/11/18 18:53	2021/11/18 18:55	2
EO injection	2021/11/18 18:55	2021/11/18 20:06	71
EO dwell	2021/11/18 20:06	2021/11/19 4:06	480
EO Removal	2021/11/19 4:06	2021/11/19 4:23	17
air washing	2021/11/19 4:23	2021/11/19 4:58	35
flushing	2021/11/19 4:58	2021/11/19 5:27	29

Ethylene Oxide Sterilization Process Record

Sterilizer:

Sterilization Batch:

20211117

Date:

20211117

Order:

1

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU ROLL	06071440	10.2inX2yd roll	300	

Process Parameters	Setting Value	Actual Value			Requirement		Pass/Fail
					min	max	
Preconditioning Temperature (°C)	50.0	Min: 50.2	Max: 52.6	40.0	60.0	Pass	
Preconditioning Humidity	—	Min: 97.3	Max: 97.3	0.0	99.0	Pass	
Preconditioning Time(KPa)	—	16		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	85.3	BEF:-58.5 A:26.8	0.0	150.0	Pass	
EO weight injected(Kg)	—			0.0	130.0	Pass	
Temperature (T1) during EO exposure(°C)	50.0	Min: 49.6	Max: 53.5	40.0	60.0	Pass	
Humidity (RH) during EO exposure(% RH)	—	Min: 97.3	Max: 97.3	0.0	99.0	Pass	
Pressure (P1) during EO exposure (Kpa)	—	Min: 26.7	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	2021/11/17 16:31	2021/11/17 17:38	67
Precondition	2021/11/17 17:38	2021/11/17 17:54	16
Pre-vacuum	2021/11/17 17:54	2021/11/17 18:01	7
leak test	2021/11/17 18:01	2021/11/17 18:06	5
steam injection	2021/11/17 18:06	2021/11/17 18:08	2
EO injection	2021/11/17 18:08	2021/11/17 18:46	38
EO dwell	2021/11/17 18:46	2021/11/18 2:46	480
EO Removal	2021/11/18 2:46	2021/11/18 3:03	17
air washing	2021/11/18 3:03	2021/11/18 3:38	35
flushing	2021/11/18 3:38	2021/11/18 4:07	29

Ethylene Oxide Sterilization Process Record

Sterilizer: _____ Sterilization Batch: **20211119** Date: **20211119** Order: **1**

Article Name	Lot No.	Specification	CTN/NO;	Quantity
Sanidrem PU dressing	06071440	6inX8in	43	
Sanidrem PU dressing	06071440	10inX14in	65	



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: 97.3	Max: 97.3		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)	—	0.2			0.0	3.0	Pass
Pressure change at end of steam injection (KPa)	1.5	1.2	BEF:-59.9 A:-58.7		0.5	3.0	Pass
Pressure change at end of EO injection (KPa)	84.0	84.6	BEF:-59.1 A:25.5		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: 54.7		40.0	60.0	Pass
Humidity (RH) during EO exposure(% RH)	—	Min: 97.3	Max: 97.3		0.0	99.0	Pass
Pressure (P1) during EO exposure (Kpa)	—	Min: 25.5	Max: 79.3		—	—	Pass
EO dwell (min)	490	479			478	482	Pass
Numbers of air washes	3	3			1	5	Pass

Sterilization Process	Start time	End time	Time elapsed(min)
Heating	2021/11/19 9:26	2021/11/19 9:59	33
Precondition	2021/11/19 9:59	2021/11/19 10:14	15
Pre-vacuum	2021/11/19 10:14	2021/11/19 10:21	7
leak test	2021/11/19 10:21	2021/11/19 10:26	5
steam injection	2021/11/19 10:26	2021/11/19 10:28	2
EO injection	2021/11/19 10:28	2021/11/19 11:27	59
EO dwell	2021/11/19 11:27	2021/11/19 19:26	479
EO Removal	2021/11/19 19:26	2021/11/19 19:43	17
air washing	2021/11/19 19:43	2021/11/19 20:19	36
flushing	2021/11/19 20:19	2021/11/19 20:47	28