

Ethylene Oxide Sterilization Process Record

Furnace No:

Sterilizer:

Sterilization Batch:

20230806-99

Date:

23/08/06

Orde

1

Article Name	Lot No	Specification	CTN/	Quantity
Saniderm PU roll	0341161409	10.2X2yd roll	234	

Production confirmation	
Doser:	
Operator:	
Supervisor:	
Quality control confirmation	
Inspector:	
Manager:	
Result Verification	
Check	<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified

Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		Min	Max	
Preconditioning Temperature(°C)	50.0	Min:	51.5	Max:	51.5	45.0	60.0	Pass
Preconditioning Humidity(%RH)	--	Min:	52.0	Max:	52.0	35.0	90.0	Pass
Preconditioning Time	--	15.0				10.0	90.0	Pass
Vaccum value(kPa)		-50.0				-60.0	59.0	Fail
Leak test time(Min)		5.0				1	10	Pass
Pressure change at end of leal test(kPa)	--	0.3				0.0	3.0	Pass
Pressure change at end of steam injection(kPa)	1.5	0.6	-49.7	To	-49.0	0.0	3.0	Pass
Pressure change at end of EO injection(kPa)	80.0	61.1	-49.0	To	12.1	0.0	150.0	Pass
EO weight injection(Kg)		0.0				0.0	130.0	Pass
Temperature(T1) during EO exposure(°C)	50.0	Min:	52.2	Max:	54.0	45.0	60.0	Pass
Humidity(RH) during EO exposure(%RH)	55.0	Min:	71.2	Max:	74.0	0.0	99.0	Pass
Pressure(P1) during EO exposure(kPa)	-50.0	Min:	0.0	Max:	0.0	--	--	Pass
EO dwell(Min)	480.0	480.0				478	482	Pass
Numbers of air washes	4.0	4.0				1	5	Pass

Sterilization Process	Start Time	End Time	Time elapsed
Heating	19:40:34	19:40:36	00:00:02
Precondition	19:40:34	19:40:36	00:00:02
Pre-vacuum	19:40:36	19:50:11	00:09:35
Leak test	19:50:11	19:55:15	00:05:04
Steam injection	19:55:15	19:57:18	00:02:03
EO Injection	19:57:18	20:50:09	00:52:51
EO dwell	21:05:09	05:05:13	08:00:04
EO Removal	05:05:15	05:17:26	00:12:11
Air washing	05:39:09	06:14:49	00:35:40
flushing	00:00:00	00:00:00	00:00:00



Ethylene Oxide Sterilization Process Record

Furnace No:

Sterilizer:

Sterilization Batch:

20230805-98

Date:

23/08/05

Orde

1

Article Name	Lot No	Specification	CTN/	Quantity
Saniderm PU ROLL	0341161409	4inX8yd roll	24	
Saniderm PU roll	0341161409	6inX8yd roll	20	
Saniderm PU dressing	0341161409	6inX8in	35	
Saniderm PU dressing	0341161409	4inX4in	50	

Production confirmation	
Doser:	
Operator:	
Supervisor:	
Quality control confirmation	
Inspector:	
Manager:	
Result Verification	
Check	<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified

Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min		Max		Min	Max	
Preconditioning Temperature(°C)	50.0	Min:	51.7	Max:	51.7	45.0	60.0	Pass
Preconditioning Humidity(%RH)	--	Min:	50.3	Max:	50.3	35.0	90.0	Pass
Preconditioning Time	--		15.0		10.0	90.0		Pass
Vacuum value(kPa)			-50.0		-60.0	59.0		Fail
Leak test time(Min)			5.0		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	0.6	-49.7	To	-49.0	0.0	3.0	Pass
Pressure change at end of EO injection(kPa)	80.0	61.2	-49.0	To	12.1	0.0	150.0	Pass
EO weight injection(Kg)			0.0		0.0	130.0		Pass
Temperature(T1) during EO exposure(°C)	50.0	Min:	52.2	Max:	52.8	45.0	60.0	Pass
Humidity(RH) during EO exposure(%RH)	55.0	Min:	74.5	Max:	76.4	0.0	99.0	Pass
Pressure(P1) during EO exposure(kPa)	-50.0	Min:	0.0	Max:	0.0	--	--	Pass
EO dwell(Min)	480.0		480.0		478	482		Pass
Numbers of air washes	4.0		4.0		1	5		Pass

Sterilization Process	Start Time	End Time	Time elapsed
Heating	17:35:13	17:35:16	00:00:03
Precondition	17:35:13	17:35:17	00:00:04
Pre-vacuum	17:35:17	17:44:46	00:09:29
Leak test	17:44:46	17:49:49	00:05:03
Steam injection	17:49:49	17:51:53	00:02:04
EO Injection	17:51:53	18:37:11	00:45:18
EO dwell	22:37:12	06:37:14	08:00:02
EO Removal	06:37:17	06:50:36	00:13:19
Air washing	07:12:26	07:48:11	00:35:45
flushing	00:00:00	00:00:00	00:00:00

