

FCE: \_\_\_\_\_

**BOTH WORKSHEETS MUST BE COMPLETED**

Sup SID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ / \_\_\_\_\_

Aseptic Filler: \_\_\_\_\_

Number	Critical Control Point	Sterilizing Medium Used	Control/Description	Unit	Limit	Threshold	Corrective Action	Record	Frequency
1	Compressed Air Filter Sterilization	Steam	Time and Temperature						
1.1	Sterilization Temperature		TT1	[°C]	min	121	Filter Sterilization has to be repeated	Strip Chart	Continuous
1.2	Sterilization Time		PLC Timer	[sec]	min	30			
2	Aseptic chamber pre-heat	Hot Air	Time and Temperature						
2.1	Pre-heat Temperature		TT2	[°C]	min	230	None		
2.2	Pre-heat Time		PLC Timer	[sec]	min	20			
3	Aseptic Chamber Sterilization	H2O2	Time, Temp, % H2O2, Pressure						
3.1	Sterilization Temperature		TT3	[°C]	min	75	Pre-heat and chamber sterilization has to be repeated	Operator Log	1 hr
3.2	Sterilization Time		PLC Timer	[sec]	min	20			
3.3	H2O2 Concentration		Manual QC 1	[%]	min	32			
3.4	Sterile air overpressure		P-1	[Pa]	min	10			
4	Production	H2O2	Time, Temp, % H2O2, Pressure						
4.1	Air Knife Temperature		TT4	[°C]	min	250	Sterility is lost and production is stopped. Repeat CIP and SIP cycles.		
4.2	H2O2 Bath Temperature		TT5	[°C]	min	75			
4.3	H2O2 Concentration		Manual	[%]	min	32			
4.4	Film Speed		PLC	[m/min]	max	20			
4.5	Sterile air overpressure		P-1	[Pa]	min	10			

**ONCE COMPLETED, GO TO PRODUCT STERILIZER - TANK WORKSHEET AND COMPLETE**

**BOTH WORKSHEETS MUST BE COMPLETED**

Product Sterilizer: \_\_\_\_\_

Number	Critical Control Point	Sterilizing Medium Used	Control/Description	Unit	Limit	Threshold	Corrective Action	Record	Frequency
1	Product Sterilizer	Steam	Time and Temperature						
1.1	Sterilization Temperature			[°F]	min				
1.2	Sterilization Time			[sec]	min				
1.3	Sterilization Back Pressure			[psig]	min				
2	Aseptic Tank	Steam	Time and Temperature						
2.1	Sterilization Temperature			[°F]	min				
2.2	Sterilization Time			[sec]	min				
2.3	Sterilization Back Pressure			[psig]	min				