

Report Test

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LOT No : 0621/2023

Date : 31 May 2023

Determination of Sterilization Operation Specification

Item Detail	Specification	Setting	Result
Chamber Setting Temperature	40.0-55.5 °C	45.0 °C	
Vacuum pressure	40-60 kPa	60 kPa	
Vacuum Time	50-60 min	60 min	
Humidification			
Humidity	50.0-90.0%	20.2 %	
Sterilization			
Sterilization Temperature	40.0-55.5 °C	43.5 °C	
Gas Injection			
Final pressure	0-10 kPa	4 kPa	
Final temperature of vaporizer	40.0-55.5 °C	44.8 °C	
Exposure			
Temperature at start point of Exposure time period	40.0-55.5 °C	43.3 °C	
Temperature at finish point of Exposure time period	40.0-55.5 °C	46.0 °C	
Exposure Time	120-240 min	180 min	
Exhaust			
Exhaust Time	60-80 min	75 min	
First Vacuum pressure	0-2 kPa	1.5 kPa	
Second Vacuum pressure	0-2 kPa	1.5 kPa	
Third Vacuum pressure	0-2 kPa	1.5 kPa	
Fourth Vacuum pressure	0-2 kPa	1.5 kPa	
Fifth Vacuum pressure	0-2 kPa	1.5 kPa	
Storage			
Storage Time	≥ 48 hour	≥ 48 hour	
Chemical Test			
EO sterilization temperature 40-55°C, Time Sterilization by EO 3hours	Blue	Red	Pass
Biological Test			
EZ Test Biological Indicator	Green	Green	Pass

(*Malairak Lappho*)

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