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M/C : SHINVA

Document No. : TR-EO-033060516

MODEL : XG 1 SERIES

Date : 6/5/2016

SERIAL No. : 070997

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PRODUCT : ORDER NO. 2145876

Determination of Sterilization Specification

Item Detail	Specification	Setting	Result
Chamber Setting Temperature	55.0 - 59.0 (°C)	59 (°C)	-
Vacuum Level	5-12 kPa	9 kPa	-
Vacuum Time (min)	50-60 min	60 min	-
<b>Humidification</b>			
Humidity (%)	50%-90%	87%	-
<b>Sterilization</b>			
Steri Temp	55.0 - 59.0 (°C)	55.0 (°C)	-
Jacket Temp	60.0 - 65.0 (°C)	65.0 (°C)	-
<b>Gas Injection</b>			
Final pressure (kpa(abs))	0.21-0.23 kPa	0.21 kPa	-
Final temperature of vaporizer,Temp 10 (°C)	55.0 - 59.0 (°C)	55 (°C)	-
<b>Exposure</b>			
Temperature at strat point of Exposure time period Temp. 1 (°C)	55.0 - 59.0 (°C)	60 (°C)	-
Temperature at finish point of Exposure time period Temp. 1 (°C)	55.0 - 59.0 (°C)	55 (°C)	-
Exposure Time (min)	390-420 min	420 min	-
<b>Exhaust</b>			
Exhaust Time (hour)	≥ 4 hour	4 hour	-
First Vacuum Level (kPa)	5-12 kPa	9 kPa	-
Second Vacuum Level (kPa)	5-12 kPa	9 kPa	-
Third Vacuum Level (kPa)	5-12 kPa	9 kPa	-
<b>Storage</b>			
Storage Time	≥ 48 hour	≥ 48 hour	-
<b>Chemical tested, Sterile Strip</b>			
EO sterilization temperatures 55-60 C° Time sterile by EO 7 hours .	Brown	Brown	Pass
<b>Biological Test</b>			
EZ Test Biological Indicator	Brown	Brown	Pass
24 hour results for EO	Red	Red	Pass

Technical Chamber

Quality Manager