

Operator: Validation Manager
Process: Validation
Session Start: 26-11-2013 12:52:20
Session Stop: 26-11-2013 12:52:20
Session Name: Sterilization Validation
Session Text:

Vessel: Sterilizer
Product: Pharma Medical
Time Zone: UTC offset 01:00:00



Validation Report



Name: Validation Report
Description: 134,00 °C
Total Test Result **Passed**

Input parameters

Process Temperature : 134,00 °C
Process Temperature Band (K): 3,00
Max. Allowed Temperature Fluctuation (K): 1,00
Max. Allowed Difference Temperature (K): 2,00
Maximum Equilibration Time: 00:00:30
Minimum Holding Time: 00:03:00
Maximum Pressure Deviation: 0,1000 bar
Selected data series: 1, 2, 3, 4, 5, 6, Afløb, Tryklogger

Equilibration Time



Equilibration Start Time: 03-04-2008 13:12:46
Equilibration End Time: 03-04-2008 13:12:46
Equilibration Duration: 00:00:00
Max. allowed Equilibration Duration: 00:00:30
Equilibration Test Result: **Passed**

Process band



Holding Start Time: 03-04-2008 13:12:46
Holding End Time: 03-04-2008 13:21:21
Holding Duration: 00:08:35
Min. allowed Holding Duration: 00:03:00
Holding Test Result: **Passed**

Difference Band



Difference Temperature (K): 0,05
Max. Allowed Difference Temperature (K): 2,00
Difference Temperature Test Result: **Passed**

Fluctuation Band



Temperature Fluctuation (K): 0,86
Max. Allowed Temperature Fluctuation (K): 1,00
Temperature Fluctuation Test Result: **Passed**

Saturated Steam Analysis



Pressure Deviation: 0,0338 bar
Max. Pressure Deviation: 0,1000 bar
Pressure Deviation Test Result: **Passed**

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Summary Report

Name	Fluctuation (°C)	Deviation
1	0,82	0,0331 bar
2	0,84	0,0338 bar
3	0,83	0,0318 bar
4	0,84	0,0293 bar
5	0,86	0,0328 bar
6	0,83	0,0306 bar
Afløb	0,84	0,0313 bar

SAMPLE