

Bio Clamp™

Sterilization Test Summary

Testing was undertaken to compare the effects of Autoclaving and Gamma Irradiation sterilization on the in-use performance of the Bio Clamp™. The durability and robustness was tested before and after the different types of sterilization across the available range of Bio Clamp™ sizes.



Conclusion

From the testing that has been carried on the individual sizes of the Bio Clamp™, it may be determined that the process of autoclaving & gamma sterilisation has no negative effect on the durability and robustness.

Results Table

| | Test 1 Ambient Pressure Test Results | Test 2 Heat & Pressure Test Results | Test 3 Average Handle Torque Test Results per Size (Nm) | Test 4 Steam & Pressure Test Results |
|---|---|---|---|---|
| Batch 1 Virgin Clamps | All Clamps Passed Acceptance Criteria. No Leaks Observed. | All Clamps Passed Acceptance Criteria. No Leaks Observed. | 0.75"=7.200 1.5"=8.633 2.0"=7.266 2.5"=9.466 3.0"=8.833 | All Clamps Passed Acceptance Criteria. No Leaks Observed. |
| Batch 2 Autoclaved Clamps | All Clamps Passed Acceptance Criteria. No Leaks Observed. | All Clamps Passed Acceptance Criteria. No Leaks Observed. | 0.75"=7.200 1.5"=8.633 2.0"=7.266 2.5"=9.466 3.0"=8.833 | All Clamps Passed Acceptance Criteria. No Leaks Observed. |
| Batch 3 Gamma Irradiated Clamps | All Clamps Passed Acceptance Criteria. No Leaks Observed. | All Clamps Passed Acceptance Criteria. No Leaks Observed. | 0.75"=7.200 1.5"=8.633 2.0"=7.266 2.5"=9.466 3.0"=8.833 | All Clamps Passed Acceptance Criteria. No Leaks Observed. |

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Test 1

Test 1 involved attaching the Bio Clamps™ to an appropriately sized stainless steel sanitary flange connection enclosing a silicone gasket. The system was pressurized to 10 bar using water at room temperature. Once the system had stabilized the pressure drop was monitored over a 30 second period with a digital pressure gauge and recorded. Visual examination was also conducted to look for signs of leakage.

Test 2

Test 2 involved heating the Bio Clamps™ to 121°C for a minimum period of 20 minutes in a heating cabinet. The Bio Clamps™ were then attached to an appropriately sized stainless steel sanitary flange connection enclosing a silicone gasket. The system was then pressurized to 10 bar using water. Once the system had stabilised the pressure drop was monitored over a 30 second period with a digital

pressure gauge and recorded. Visual examination was also conducted to look for signs of leakage.

Test 3

Test 3 involved the destructive testing of the Bio Clamp™ handles. Each handle was torque tested to the point of failure and the results recorded.

Test 4

Test 4 involved the in-line steam heating of the most popular size of Bio Clamp™ (1.5"). The whole sanitary flange/Bio Clamp™ connection was heated to 121°C for a period of 20 minutes. The system was then pressurized to 10 bar using water at room temperature. Once the system had stabilised the pressure drop was monitored over a 30 second period with a digital pressure gauge and recorded. Visual examination was also conducted to look for signs of leakage.

Test Matrix

| | Test 1 | Test 2 | Test 3 | Test 4 |
|---|--|--|--|---|
| Batch 1 Virgin Clamps | 5 Sizes of Clamp 15 Samples per Size 5 x 15 = 75 Tests | 5 Sizes of Clamp 15 Samples per Size 5 x 15 = 75 Tests | 6 Sizes of Clamp 15 Samples per Size 5 x 15 = 75 Tests | 1 Size of Clamp - 1.5" 5 Samples per Size 5 x 1 = 5 Tests |
| Batch 2 Autoclaved Clamps | 5 Sizes of Clamp 15 Samples per Size 5 x 15 = 75 Tests | 5 Sizes of Clamp 15 Samples per Size 5 x 15 = 75 Tests | 6 Sizes of Clamp 15 Samples per Size 5 x 15 = 75 Tests | 1 Size of Clamp - 1.5" 5 Samples per Size 5 x 1 = 5 Tests |
| Batch 3 Gamma Irradiated Clamps | 5 Sizes of Clamp 15 Samples per Size 5 x 15 = 75 Tests | 5 Sizes of Clamp 15 Samples per Size 5 x 15 = 75 Tests | 6 Sizes of Clamp 15 Samples per Size 5 x 15 = 75 Tests | 1 Size of Clamp - 1.5" 5 Samples per Size 5 x 1 = 5 Tests |
| | | | | Total Number of Tests = 690 |

Batch 1 was made up of un-treated Bio Clamps™

Batch 2 was made up of Bio Clamps™ that were Autoclaved at 135°C for 30 minutes

Batch 3 was made up of Bio Clamps™ that were Gamma Irradiated with a minimum dose of 25 kGy. (Maximum 40 kGy)

The Bio Clamps™ tested are available in the following sizes:
0.75", 1.5", 2.0", 2.5", 3.0"



Your pharmaceutical manufacturing specialist

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