**CHECKLIST FOR STERILITY TEST**

| Validation test | | |
|---|---|---|
| 1. | Bacteriostasis & Fungistasis Test | **Method**<br>Procedure for validation of sterility test should consist of:<br><br>a) Quantity and volume of sample<br>b) Method used (Membrane filtration/Direct Inoculation)<br>c) Open System or Closed System (if membrane filtration method used)<br>d) Type and volume of rinsing fluid used for each membrane (membrane filtration)<br>e) List of media and reagents<br>f) List of neutralizing agent (if any)<br>g) Microorganisms used and size of inoculum |
| | | **Result** (raw data)*<br>Validation for Sterility Test (Bacteriostasis and fungistasis test) |

| Routine Sterility test | | |
|---|---|---|
| 1. | Sterility Test | Method |
| | | Procedure for validation of sterility test should consist of:<br><br>a) Quantity and volume of sample<br>b) Method used (Membrane filtration/Direct Inoculation)<br>c) Open System or Closed System (if membrane filtration method used)<br>d) Type and volume of rinsing fluid used for each membrane (membrane filtration)<br>e) List of media and reagents<br>h) List of neutralizing agent (if any) |

*Raw data must comprise name and strength of product, type of media, batch no of product/media, types of microorganisms, date of test commencement and completion, observation in every interval period, wherever applicable. Actual data must be provided.

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