

CHECKLIST FOR STERILITY TEST

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

Routine Sterility test		
1.	Sterility Test	Method Procedure for protocol analysis of sterility test should consist of: a) Quantity and volume of sample b) Method used (Membrane filtration/Direct Inoculation) c) Open System or Closed System (if membrane filtration method used) d) Type and volume of rinsing fluid used for each membrane (membrane filtration) e) List of media and reagents 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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