

CHECKLIST FOR STERILITY TEST

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

Routine Sterility test		
1.	Sterility Test	Method
		Detailed test procedure for sterility test a) Quantity or volume of sample used. b) Method used (Membrane filtration/Direct Inoculation) c) Open System or Closed System (if Membrane filtration method used) d) Volume of rinsing fluid used for each membrane (membrane filtration) e) List of media and reagents used. g) List of neutralizing agent used (if any)
		Result (raw data)*
		- Must show observation for 14 days
2.	Growth Promotion Test	Method
		Result (raw data)*
3.	Test for Media Sterility	Method
		Result (raw data)*
		- Must show observation for 14 days
4.	Preparation of media	Method
		Result (copy of logbook for preparation of media or any relevant document)

*Raw data must include: Name & Strength of product/ media, Batch No of product/media, microorganisms used, date of test started and ended, observation in every interval period, wherever applicable. Applicant must provide actual data

Updated: 26th July 2017