SAFC Biosciences™
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Technical Bulletin

Quality Control Sterility Testing of Serum Products

SAFC Biosciences is an ISO 9001 certified company with a current Good Manufacturing Practice (cGMP) production facility. This compliance provides the customer with the assurance that they are receiving the highest quality of product possible. Our stringent Quality Control Department tests all raw materials and finished products to assure SAFC Biosciences' products meet specification prior to use or release. Crucial to the quality of any cell culture product, the sterility of product must be assured. To provide this assurance of sterility, SAFC Biosciences' testing procedure meets United States Pharmacopeia (USP) requirements.

Sterility testing is performed by membrane filtration. This method allows for the detection of yeast, mold, gram positive and gram negative bacteria. All test media and processes have been validated and growth promotion testing is performed on each lot of test media. Detection limits, specificity, accuracy and ruggedness of these testing processes are assured through our validation process. SAFC Biosciences meets the USP compliance requirements with regard to sterility testing. To meet the demand for international markets, SAFC Biosciences incorporates international guidelines when possible. SAFC Biosciences has identified the similarities and differences between testing according to United States, European and Japanese compendial guidelines. The table on the back outlines the various tests and SAFC Biosciences' procedures.

For more information about this subject or other SAFC Biosciences' products and services, please contact Technical Services.

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Method	SAFCB Testing	United States Pharmacopeia 24	European Pharmacopeia 2.6.1	Japanese Pharmacopeia 13 – 45
Pore size	0.45 µm	nominal 0.45 µm	not greater than 0.45 µm	nominal 0.45 µm or less
Membrane filter size	> 47 mm diameter	47 mm diameter	50 mm diameter	20-50 mm diameter
Volume tested	Entire contents up to 1000 mL	Entire contents up to 1000 mL	Half the contents of the container but not more than 20 mL	Entire contents of container up to 500 mL
Quantity tested based on number of units: Not more than 100 units	10% or 4 whichever is greater	10% or 4 whichever is greater	10% or 4 whichever is greater	Unspecified in this section
> 100 units but ≤ 500 units	10	10	10	
> 500 units	2% or 20 whichever is less	2% or 20 whichever is less	2% or 20 whichever is less	
Suitable test microorganisms for use in growth promotion of Fluid Thioglycollate media	*S.aureus* *B.subtilis* *Ps.aeruginosa* *Cl.soprogenes* *C.albicans*	*S.aureus/B.subtilis* *Ps.aeruginosa/* *M.luteus* *Cl.soprogenes/* *Bac.vulgatus*	*S.aureus* *B.subtilis* *Ps.aeruginosa* *Cl.soprogenes*	*B.subtilis/M.luteus* *C.albicans* *Bac.vulgatus*
Suitable test microorganisms for use in growth promotion of Trypticase Soy Broth media	*B.subtilis* *C.albicans* *Asp.niger*	*B.subtilis* *C.albicans* *Asp.niger*	*C.albicans* *Asp.niger*	*B.subtilis/M.luteus* *C.albicans*
Inoculum of test organisms	10 - 100 viable organisms	Less than 100 viable organisms	10 - 100 viable organisms	10 - 100 viable organisms
Length of growth promotion test	Bacteria – 3 days Fungi – 5 days	Not more than 5 days	Bacteria – not more than 3 days Fungi – not more than 5 days	Not more than 5 days

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