

Anthrax Vaccine Adsorbed (AVA) (BioThrax™)

Catalog No. NR-2642

Product Description: Anthrax Vaccine Adsorbed (AVA) (BioThrax™) was produced from cell-free filtrates of microaerophilic cultures of an avirulent, nonencapsulated strain of *Bacillus anthracis*.

Lot: 57695650

Manufacturing Date: 18FEB2004

TEST	SPECIFICATIONS	RESULTS
Filtrate Appearance	Milky-white suspension	Milky-white suspension
Filtrate Analysis by Western Blot Protective antigen Lethal factor Edema factor	Positive Report results Report results	Positive Detectable Undetectable
SDS-PAGE of Filtrate for Protective Antigen	Predominant band of ~ 83 kDa	Predominant band of ~ 83 kDa
Total Protein of Filtrate (BSA Standard)	5 to 20 µg/mL	5 to 20 µg/mL
pH of Final Product	7.5 to 8.5	7.5 to 8.5
Relative Potency¹	0.53 to 1.79	0.53 to 1.79
Concentration of Additives in Final Product Aluminum Sodium chloride Benzethonium chloride Formaldehyde	0.8 to 1.5 mg/mL 0.75% to 0.95% (w/v) 0.0015% to 0.0030% (w/v) < 0.02% (w/v)	1.2 mg/mL 0.85% (w/v) 0.0025% (w/v) or 25 µg/mL 0.01% (w/v) or 100 µg/mL
Sterility²	Sterile	Sterile

¹When tested against the U.S. Reference Standard Anthrax Vaccine using guinea pig intracutaneous challenge models.

²Meets the requirements when tested as directed for *Direct Inoculation of the Culture Medium* method under *Test for Sterility of the Product to be Examined*.

Date: 08 OCT 2010

Signature: Signature on File

Title: Technical Manager, BEI Authentication or designee

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