

Yersinia pestis* F1-V Fusion Protein, Recombinant from *Escherichia coli
Catalog No. NR-4526
Product Description: *Yersinia pestis* (*Y. pestis*) recombinant F1-V fusion protein was expressed in *Escherichia coli* and purified by conventional chromatography.

Lot¹: FIN-0229
Manufacturing Date: 16JUN2006

TEST	SPECIFICATIONS	RESULTS
Appearance	Clear to slightly turbid, colorless liquid that may contain fine amorphous particles or aggregates	Clear, colorless liquid containing fine amorphous particles
Identification by Western Blot Antibody to F1-V protein	Major band at ~ 53 kDa	Major band at ~ 53 kDa
LDS-PAGE	Major band at ~ 53 kDa	Major band at ~ 53 kDa
Concentration by Spectrophotometer at OD₂₈₀	0.3 mg/mL to 3.0 mg/mL	2.1 mg/mL
Potency Immunogenicity in mice with Protollin	Report result	Immune response in 100% of mice > 39 to 1357 fold higher than with unformulated F1-V ²
pH (post-vialing)	7.0 to 7.8	7.4
pI	Report result	~ 5.3
General Safety (21 CFR 610.11)	Meets requirements	Meets requirements
Endotoxin Content Limulus Amoebocyte Lysate assay, USP<85>	< 100 EU/mg protein	4.3 EU/mg protein
Sterility (21 CFR 610.12)	No growth	No growth

¹The cardboard storage box for Lot FIN-0229 may have been exposed to mold. All vials were disinfected prior to release.

²Two doses of NPV containing 0.1 to 1 µg of Protollin and 0.3 to 10 µg F-1V, adjuvant:antigen ratios of 3.3:1 to 1:100 were used.

Date: 29 JAN 2009

Signature: Signature on File

Title: Technical Manager, BEI Authentication or designee

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