

Polyclonal Anti-Vaccinia Virus (immune globulin, Human)

Catalog No. NR-2632

(DynPort Vaccine Company LLC Part No. 0062-0001)

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Product Description: Vaccinia Immune Globulin Intravenous (VIGIV) is an immune globulin preparation derived from pooled human plasma collected from donors who received booster immunizations with the Dryvax® smallpox vaccine.

Lot: 6804253

Manufacturing Date: 31OCT2002

TEST	SPECIFICATIONS	RESULTS
Appearance	Clear liquid essentially free of foreign particles	Clear liquid essentially free of foreign particles
Identity 50% plaque reduction neutralization titer	≥ 1:500	1:4175
Immunoglobulin G Content	≥ 90%	99.2%
Distribution of Molecular Size by HPLC Analysis	≥ 95% monomeric or dimeric < 2% polymeric < 3% fragment	93% monomeric; 6% dimeric 1% polymeric 0% fragment
Immunoglobulin Concentration	Report results	50 mg/mL
Sucrose Concentration (w/v)	Report results	4.9%
Human Albumin Concentration (w/v)	0.5 to 1.5%	1.4%
Sterility (21 CFR 610.12)	No growth after 14 days	No growth after 14 days
General Safety (21 CFR 610)	All animals survived No unexpected response No weight loss in guinea pig or mouse	All animals survived No unexpected response No weight loss in guinea pig or mouse
Pyrogen [21 CFR 610.13(b)]	Temperature rises for each individual rabbit is < 0.5°C Sum of maximum temperature rises for three individual rabbits is ≤ 1.2°C	Temperature rises for each individual rabbit is < 0.5°C Sum of maximum temperature rises for three individual rabbits is 0°C
Isoagglutinins Anti-A Anti-B Anti-D	≤ 1:32 ≤ 1:32 ≤ 1:8	1:4 1:2 None detected
Anti-Complementary Activity (CH₅₀)	≤ 5 CH ₅₀ Units/mg IgG	1.9 CH ₅₀ Units/mg IgG
Sodium Concentration	Report results	20.0 mEq/L
Prekallikrein Activator	≤ 70% of FDA reference Lot 3	< 2% of FDA reference Lot 3
Kallikrein Activity	< 20 mU/mL	1.8 mU/mL

TEST	SPECIFICATIONS	RESULTS
Hepatitis B Surface Antigen	Negative	Negative
Hepatitis C Virus RNA RT-PCR by Ultra-Qual Assay	Negative	Negative
Human Immunodeficiency Virus Type 1 RNA RT-PCR by Ultra-Qual Assay	Negative	Negative
pH	5.3 – 6.3	5.5
Heat Stability	No gelation after 4 hours at 57°C	No gelation after 4 hours at 57°C

Date: 22 FEB 2007

Signature: Signature on File

Title: Technical Manager, BEI Authentication

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