

Biologicals Division

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Pel-Freez®

Analysis Certificate/Origin

PRODUCT: Bovine Gamma Globulin

CODE NO: 27005 **LOT NO:** 30135-A

DATE OF MANUFACTURE: October 28, 2013

ORIGIN: USA **STORAGE:** 2-8 °C

EXPIRATION: Suggested retest after 3 years.

EU

REQUIREMENTS: Product meets EU requirements for production of technical blood products

RECONSTITUTION: Reconstitute in at least 0.2% NaCl solution.

PROCEDURE: Bovine gamma globulin is purified from normal bovine serum or plasma collected in a USDA certified facility within the contiguous 48 states of the United States (documentation is on file). The processing of serum/plasma into gamma globulin was achieved exclusively at Pel-Freez Biologicals facilities using a combination of existing methods developed in our laboratory.

ASSAYS: This lot of Bovine Gamma Globulins contains 100% gamma globulin, which is less than 5% impurities as determined by serum protein electrophoresis (percent of the total protein present).

Protein by Weight - O.D. 280 nm $E^{1\%} = 1.39 = 91\%$. Residual salts, lipids, etc. comprise the rest of the weight.

Immunoelectrophoresis: At 10 mg/ml, the precipitin pattern observed was characteristic of bovine serum when tested with anti-whole bovine serum. The predominant band was in the IgG region.

Moisture Content: 4.06 % (FIO)

QUALITY ASSURANCE

Product Released on: November 22, 2013



Stephanie Whitmore
Quality Systems Technician

Meets or exceeds specifications✓

Does not meet or exceed specifications

FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES