

Biologicals Division

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Pel-Freez®

Certificate of Analysis

PRODUCT: Goat Gamma Globulin

CODE NO: 22005

LOT NO: 11936

STORAGE: 2-8 °C

**DATE OF
MANUFACTURE:** December 02, 2013

COUNTRY OF ORIGIN: U.S.A.

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

RECONSTITUTION: Reconstitute in at least 0.2% NaCl solution.

PROCEDURE: The goat serum was obtained from USDA approved facility TX-TEC- 0004. The processing of the serum was performed at AR-TEC 0007. Goat gamma globulin is purified from normal goat serum using different fractionation procedures followed by extensive dialysis against low ionic strength buffer and finally lyophilization. To help eliminate diseases that might be carried in animal blood products, the pH of the gamma globulin is adjusted to <5.0 for a minimum of 3 hours during one of the fractionation processes.

ASSAYS: Serum Protein Electrophoresis
This lot of Goat Gamma contains 98% gamma globulin as determined by serum protein electrophoresis (percent of the total protein present).

Protein by Weight - O.D. 280 nm $E^{1\%}_{1\text{cm}}$ 1.39 is 87%
Residual salts, lipids, etc. comprise the rest of the weight.

Moisture: 3.90%

QUALITY ASSURANCE

Quality Control Release Date: May 2, 2014

Brenda Crenshaw

Brenda Crenshaw
Quality Systems Technician

Meets or exceeds specifications ✓

Does not meet specifications

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES