

Certificate of Analysis

PRODUCT: Bovine Gamma Globulin

CODE NO: 27005

LOT NO: 35041

DATE OF MANUFACTURE: December 16, 2019

STORAGE: 2-8 °C

ORIGIN: U.S.A.

EU 142/2011: AR TEC 0007

RECONSTITUTION: Reconstitute in at least 0.2% NaCl solution.

EU REQUIREMENTS: Product meets European Union requirements for treated technical blood products: pH is lowered to ≤ 5 for a minimum of 2 hours.

HEALTHY ANIMAL STATEMENT: This product is made from raw materials that were collected from animals found free from obvious signs of infectious and contagious disease.

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:

Required Assays	Specification	Result
Serum Protein Electrophoresis	$\geq 98\%$	>99%
Protein by Weight, O.D. 280 nm $E^{1\%1.39}$	$\geq 85\%$	94%
Moisture Content	For information only	2.13%

QUALITY ASSURANCE

Quality Control Release Date: April 9, 2020



Sarah Graves
 Quality Systems Technician

Meets or exceeds specifications

Does not meet specifications

Amended by S. Graves on 14May2020: correction to moisture result.

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES