

Certificate of Analysis

PRODUCT: Goat Gamma Globulin

CODE NO: 22005

LOT NO: 01441

DATE OF MANUFACTURE: January 14, 2019

STORAGE: 2-8 °C

ORIGIN: U.S.A.

EU 142/2011: AR-TEC-0007

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

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.

RECONSTITUTION: Reconstitute in at least 0.2% NaCl solution.

ASSAYS:

Required Assays	Specification	Result
Serum Protein Electrophoresis	≥ 98%	98%
Protein by Weight, O.D. 280 nm E ^{1%} 1.39	≥ 85%	98%
Moisture Content	For information only	1.66%

QUALITY ASSURANCE

Quality Control Release Date: February 13, 2019



Sarah Graves
 Quality Systems Technician

Meets or exceeds specifications

Does not meet specifications

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES