

Biologicals Division

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Pel-Freez®

Analysis Certificate

PRODUCT:



Citrate, Sterile

CODE NO: 31163

PO #:



STORAGE: -20 °C

DATE OF

MANUFACTURE: December 3, 2013

LOT NO: 33735

EU

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

PROCEDURE: Rabbit whole blood is collected from healthy young rabbits (New Zealand White, 8–12 weeks of age, either sex and fasted) at the time of slaughter, combined with 8.5% Sodium Citrate and processed per customer specifications. The specified amount of Sodium Chloride is added and allowed to mix until dissolution is complete. The plasma is then pre-filtered and passed through a 0.22-micron filter, bottled and stored at -20 °C.

ASSAYS:

Total Protein: 4.04 g/dl

Hemoglobin: 8.80 mg/dl

Final pH: 7.75 @ 50% aqueous solution

Bacterial Coagulase: All five strains of *S. aureus* +3 or greater at 6 hours.
S. epidermidis & *E. aerogenes* negative at 6 hours.

Optical Density: 0.237

Sterility: Passed, no growth at 14 days

QUALITY ASSURANCE

Quality Control Release Date: December 17, 2013

Amended by B. Crenshaw on January 9, 2014

Sarah Graves
Quality Systems Technician

Meets or exceeds specifications ✓

Does not meet specifications

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSE