

CERTIFICATE OF ANALYSIS
CERTIFICATE OF ORIGIN

Albumin bovine, Low Endotoxin biotechnology grade, lyophil.	Cat.No.: 47321 Contr.No.: 190777
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Parameter	Method	Specification	Result
Molecular weight		ca. 67 000	
Appearance		ivory colored lyophil.	corresponds
Protein (%) (protein factor 6.22)	Nitrogen Analyzer dry weight basis	96 – 100	97
Purity (%) (albumin, 7% solution)	Cellulose Acetate Electrophoresis	97 – 100	100
pH	7% solution	5.0 – 6.0	5.8
Sodium (mg/g)	Flame Photometer	0 – 10.0	7.6
Chloride (mg/g)	Coulometric Titrator	0 – 12.0	6.1
Endotoxin (EU/mg)	Limulus Ameboocyte Lysate	0 – 10.0	0.4
IgG	Radialimmunodiffusion	not detectable	not detected
Moisture (%)	KF	0 – 8.0	< 8.0
Minimum shelf life			31.08.2022
Storage (°C)			-15 to -25

The product has been subjected to a heat treatment at a temperature of at least 65 °C for a period of at least 3 hours and subjected to pH 5 or lower for a period of at least 3 hours.

It is certified that the product is derived from bovine blood collected from US sourced cattle slaughtered at a USDA licensed establishment located in the USA. The bovine plasma/serum was derived from US sourced animals under 30 months of age that were not stunned using a penetrating device that injects air into the cranial cavity. During the collection process appropriate precautions were taken not to contaminate the serum/plasma with specified risk materials (SRM) as defined by the USDA. The material does not contain, nor is derived from SRM as defined in REGULATION (EC) 999/2001. All cattle received ante- and post mortem health inspection under a veterinarian's supervision at the abattoir and were apparently free from infectious and contagious diseases and injurious parasites. Ruminant materials used in the manufacture of this product are not originated from BSE related herds. The record of each raw material collection is incorporated into the manufacturing records and veterinary certificates are maintained on file at the manufacturing site. At the time of manufacture of this lot of material, the US is classified as an OIE negligible BSE risk country in accordance with Chapter 11.4 of the Terrestrial Code and is free from Rinderpest, foot-and-mouth disease, and contagious bovine pleuropneumonia.

Each lot is tested for mycoplasma by the method of Barile and Kern and certified that none was detected.

Each lot is also tested for the bovine viruses BVD, IBR, PI3, bovine adenoviruses, Rabies virus, Bluetongue virus, Parvo and Reo by the Code of Federal Regulations 9 CFR 113 and certified that none was detected.

Die Eignung des Produktes für spezielle Anwendungszwecke wird nicht zugesichert.

Dieses Dokument entbindet nicht von einer branchenüblichen Eingangskontrolle.

We do not guarantee that the product can be used for a special application.

This document does not release you from performing the standard control upon receipt of incoming goods.

SERVA Electrophoresis GmbH
Qualitätskontrolle/ Quality Control

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