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Certificate of Analysis

Product Name Gamma globulin, human

 Glentham Code
 GE4986

 CAS Number
 9007-83-4

 MDL Number
 MFCD00164089

 Batch Number
 074AJE

Molecular Weight Molecular Formula Storage Temp. +4°C

Property	Specification	Batch 074AJE
Physical Description	White to almost white powder	White powder
pH (5% in water)	6.0 - 8.0	6.5
Protein	4.5 - 5.5 g/100ml (5% solution)	4.7g/100ml
Water	≤ 5%	Conforms
Sodium (Na)	≤ 200mmol/L (5% solution)	≤ 50mmol/L
Chloride (CI)	≤ 200mmol/L (5% solution)	≤ 50mmol/L
Potassium (K)	≤ 2mmol/L (5% solution)	≤ 1mmol/L
Calcium (Ca)	≤ 2mg/100ml (5% solution)	≤ 1mg/100ml
Microbiological Counts	≤ 100CFU/ml (5% solution)	≤ 1CFU/ml
Purity (SDS-PAGE)	≥ 98%	≥ 98%
Source	Human plasma	Conforms
Additional Testing	Negative for HBsAg, HCV, HIV1/2, HIV-1 (NAT) and HCV (NAT)	Conforms

Specification Version v1.1

Manufacture Date 2023-08-01

Re-Test Date 2031-08-30

Glentham Life Sciences confirm that the above referenced product conformed to the information displayed in this document on the quality release date. Please check www.glentham.com or contact us using the details above for the current version of this document.

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Page 1 of 1 Printed: 2025-05-15 03:19:29