

Human Gamma Globulin, Powder

Catalog Number: HGG I000

Lot Number:

Storage: 2°C -8 °C
Expiration Date: <Lot Specific>
Filtration: 0.22 µm
Country of Origin: USA
Preservative: None
Source: Human Plasma
Manufacture Date: <Lot Specific>

Product Performance Specifications

Test	Specifications	Unit of Measure	Methodology
Purity	≥95%	Not Applicable	HPLC
Total Protein	≥4.5	g/dL	Biuret
Appearance	White to light blue	Not Applicable	Not Applicable
State	Lyophilized Powder	Not Applicable	Not Applicable
Sodium	50-200	mmol/L	ISE
Potassium	<1.0	mmol/L	ISE
Chloride	30-200	mmol/L	ISE
Calcium	<2	mg/dL	Arsenazo III
pH	6.0-8.0	Not Applicable	pH Meter
Microbial	≤100	CFU/mL	USP/BAM
Moisture	≤5%	Not Applicable	Protein Calculation
Solubility	<30 Minutes	Not Applicable	Not Applicable

*Analytes, solubility, filterability and stabilities are all based on a 5% solution.

Testing

Each unit of plasma used in the preparation of this material was tested and found negative or non-reactive for HIV 1/2, HBsAg, HCV, HIV-1 (NAT) and HCV (NAT) by FDA approved methods. Syphilis tested per FDA guidelines and found negative.

Caution

In-vitro use only. Products are intended for research or manufacturing of non-injectable products only. This material was tested as stated above in the testing section. Nevertheless, products of human origin should be considered potentially infectious and handled according to universal precautions. The safe and responsible handling of the product listed above is the responsibility of the customer. We accept no liability for injury or illness resulting from the use and/or handling of the product. The customer assumes responsibility for the proper disposal of all materials in accordance with Federal and State regulations.

Warranty

Golden West Diagnostics, LLC makes no claim or warranty that this product will perform or is suitable for use in a customer's application. It is the customer's responsibility to evaluate and qualify the product's suitability for the customer's intended use or application. Furthermore, this product is a biological material and lots may vary so it is the customer's responsibility to determine if an evaluation of each lot is warranted.



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