



Human Gamma globulin, Lyophilized

Product # PS980

- Made from plasma of US origin collected from qualified human whole blood or source plasma donors at Blood Establishments with a current valid FDA Registration Certificate, collected according to FDA guidelines.
- Material manufactured according to documented procedures and GMP guidelines.
- Material may be out-dated or expired for therapeutic use.
- Labeling: Product name, lot number, grams/volume, storage temperature
- Appearance: White powder, free of particulate matter.
- Included with each shipment:
 - Signed Certificate of Compliance with the following information:
 - Certification of testing:

Each donor unit used in the production of the product has been tested by an FDA licensed laboratory with FDA licensed test kits.

Test results Negative or Non-Reactive for HBsAg, anti-HBc, anti-HIV 1/2, anti-HTLV I/II, anti-HCV, and Syphilis, HIV -1 RNA and HCV RNA. Results for other viral tests if performed such as HBV NAT, West Nile Virus and Chagas (T. cruzi) Negative or Non-Reactive.

In addition, the plasma used for manufacture may be tested by PCR for HAV, HBV, HCV, HIV and Parvo B-19.
 - Certification of Storage Temperature: The product has been stored at 2 - 8 C.
 - Certificate of Analysis with the following information:
 - Manufacture date, Batch number, pH, total protein, albumin and globulin levels
- Packaging: Plastic or glass bottles
- Shipping: Depends on customer specification.
Shipped refrigerated or at ambient temperature
- Order Lead Time: Depends on required quantity. Contracts and Standing Orders available.