



Product Overview

PRODUCT:	Human Gamma Globulin Powder, > 99%
PART NUMBER:	4840
FORM / APPEARANCE:	Off-white crystalline powder
FILTRATION:	0.22 micron-filtered
ADDITIVES:	No preservatives
STORAGE:	2 – 8 °C

Analytical Properties

ANALYTE	VALUE
TOTAL PROTEIN:	4.8 – 5.2 g/dL
PURITY:	> 99 %
MOISTURE:	< 5%
pH:	6.0 – 7.2
BIOBURDEN:	< 10 CFUs/mL

*Testing performed at a 5% solution with sterile DI H₂O

FOR IN VITRO DIAGNOSTIC MANUFACTURING USE ONLY

All human plasma units used to prepare this product have been tested by FDA approved tests and found to be non-reactive for HbsAg, Anti-HIV I/II, Anti-HCV, HIV-1 RNA, and HCV RNA. Donors of human plasma units used in the making of this product were tested and found negative for Syphilis according of FDA guidelines.

CAUTION: FOR USE IN RESEARCH OR REMANUFACTURE OF NON-INJECTABLE PRODUCTS NOT SUBJECT TO LICENSE UNDER PHS ACT SECTION 351, ONLY.

CAUTION: ALL BLOOD PRODUCTS SHOULD BE HANDLED AND TREATED AS POTENTIALLY INFECTIOUS