

Product Overview

PRODUCT:	Human Gamma Globulin Powder
PART NUMBER:	2373
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:	> 96 %	
MOISTURE:	< 5%	
pH:	6.0 - 7.2	
BIOBURDEN:	< 10 CFUs/mL	

*Testing performed at a 5% solution with sterile DI H_2O

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