

First Priority Manufacturing
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Certificate of Analysis

Product Code: 6153R9	Lot Number: R987B	Date of Manufacture: Nov 2021
Master Batch Record Name: Hypo-Gest (250) Tab Bottling MBR		
Product Label Name: Hypo-Gest™		
Net Quantity of Contents: 250 Tablets	Serving Size: 3 Tablets	Stability Testing Not Complete

Ingredient	Results per Tablet
Betaine Hydrochloride 98%	220mg
L-Glutamic Acid	220mg
Pepsin 1:3000 3000 FCC units/mg	200mg
Pancreatin 8x, including: Amylase ≥ 200 U USP/mg Lipase ≥ 33 U USP/mg Protease ≥ 200 U USP/mg	133mg
Fungal Protease Mixture (from Aspergillus spp.) 2000 SAP/g 200 LAP/g	100mg
Papain 3000 USP units/mg	100mg
Perilla (Leaf) (Perilla frutescens L.) Extract 8:1	100mg
Ox Bile Extract 45% Cholic Acid	80mg
Pancrelipase	67mg
Bromelain 2400 GDU/g, 3600MCU/g	67mg
Amylase 25,000 SKB/g	40mg
AVERAGE FINISHED TABLET WEIGHT	2,083 MG

Other Ingredients: dicalcium phosphate, stearic acid, silicon dioxide, sodium sulfate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, methylcellulose, dextrin, calcium lactate, lactose, saccharose, sodium chloride

This product does not contain any of the 8 major allergens as defined by the Food Allergen Labeling and Consumer Protection Act (FALCPA). FALCPA defines the 8 major food allergens as: milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.

Assay	Method	Specification	Results
Total Aerobic Plate Count	FPM 5.01	AHPA ≤ 10 ⁷ CFU/G	Pass
Enterobacteriaceae	FPM 14.01	AHPA ≤ 10 ⁴ CFU/G	Pass
Appearance	FPM 3.01	Small Oval Tablet	Conforms
NIR	FPM 1.01	Positive	Pass
Composition Analysis	FPM 17.01	Conforms	Pass
Arsenic (As)	FPM 10.01	< 4ppm	Pass
Cadmium (Cd)	FPM 10.01	< 2ppm	Pass
Mercury (Hg)	FPM 10.01	< 5ppm	Pass
Lead (Pb)	FPM 10.01	< 2ppm	Pass
Disintegration	FPM 11.01	≤ 120 Minutes	Pass

