



Certification of Analysis for LifeGlobal® Protein Supplement

(Catalogue Numbers: LGPS-005, LGPS-605, LGPS-020, LGPS-050, LGPS-100, LGPS-250)

Lot Number: LGPS-170424U
Expiry Date: 2018-04-24
 yyyy-mm-dd
Production Date: 2017-04-24
 yyyy-mm-dd

Indications for Use: For use in assisted reproductive procedures that require protein supplementation. These procedures include in vitro fertilization, embryo culture and growth, and embryo cryopreservation.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

This product contains a total protein concentration of 50 mg/ml, comprising 44 mg/ml human serum albumin and 6 mg/ml human α - and β -globulins from therapeutic-grade source material, in a sterile saline. The human serum albumin and α - and β -globulins used in the preparation of this product have been heated at 60°C for ten hours.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBc, HCV, and HTLV I/II and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Do not use the product for longer than 30 days after opening the container. Do not use after expiry date. Devices are not intended for resterilization.

Instructions for Use: See LifeGlobal® Protein Supplement Instructions for Use.

Storage Requirements: Store at 2-8°C and protected from light. When stored unopened at 2-8°C and protected from light, the product is stable until the expiration date shown on the bottle label.

Raw Materials

Chemicals used by LifeGlobal meet ASC, USP, or NF standards.

We certify that this product has been manufactured according to current Good Manufacturing Practice (cGMP). The quality of this particular batch was tested and evaluated by stringent quality control procedures. On the basis of superior test results, the batch was considered suitable for the use intended.

Assay (performed for each batch)	Specification	Results
Physicochemical Tests		
pH	7.2-7.4	7.33
Osmolality	250-270 mOsM	268 mOsM
Biological Tests		
Endotoxin (LAL)	≤ 1.0 EU/ml	< 0.03 EU/ml
Sterility Test (bacterial and fungal screen, SAL 10 ⁻³)	PASS	PASS
Biological Assays		
1-cell Mouse Embryo Assay (% expanded blastocysts at 96 h of culture)	≥ 80%	92 %