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IM0400 & IM0450

Enhanced Human Serum Albumin for Cell Culture and Microbiological Media

Description

Human Serum Albumin (HSA) is a proven substitute to animal serum in artificial media due to HSA’s superior chemical definition, control and regulatory acceptance. It is also an effective cryo-protectant and pharmaceutical delivery agent. The stabilizers found in current therapeutic grade HSA, however, can be detrimental to cell growth promotion and provide background interferences to sensitive diagnostic applications. Boval has developed a line of HSA products designed specifically for microbial and cell culture growth promotion where consistency and reliability are critical. These products are built from our knowledge of bovine serum albumin media applications and are the result of scientific understanding and product craftsmanship for enhanced growth promotion in a chemically-defined manner. Unlike other products that contain trace elements, these cell culture and microbiological grade products are produced by extensive processing of very pure and controlled HSA and modified with a stoichiometric lipid content in ratios determined to encourage productive growth of sensitive cells. The Industrial Microbiological HSA products are formulated in large homogenous lots using a controlled process in our facility under current Good Manufacturing Practices. Only human therapeutic grade HSA produced from U.S. Normal Source Plasma, drawn in select FDA- and GHA-approved centers, is used to manufacture these cell culture and microbiological grade products. Each human therapeutic grade HSA batch is manufactured in state-of-the-art fractionation facilities with full patient traceability and approved for use before entering the Boval manufacturing facility.

Product Features

- Highly purified product absent of chemical and microbial contamination
- Formulated either as a fatty acid free product or with an optimum lipid balance for growth promotion
- Complete traceability of raw materials and finished product
- Large homogenous lots
- Manufactured under cGMPs
- Each donor unit used in the preparation of the product was tested and found negative for Anti-HIV 1/2 and Anti-HCV and nonreactive for HBsAg, HIV-1 Antigen and RPR with kits approved by the FDA.

Typical Analyses

	IM0400 Fatty Acid Free HSA	IM0450 Lipid Enhanced HSA
Appearance	Clear straw solution or Cream powder	Clear straw solution or Cream powder
Protein Purity (HPLC)	NLT 95%	NLT 95.99%
pH	6.8 – 7.2	6.8 – 7.2
Moisture (powders only)	<5%	<5%
Solubility, (powders only)	< 0.150	< 0.150
Total Fatty Acids	NMT 0.05%	0.20%
Microbial Content	<3 CFU/g	<3 CFU/g
Preservative	Absent	Absent

Storage Recommendations

Store up to 3 years at 2-8 °C