NOVA BIOLOGICS, INC.
Your One Source for Biologic Products

BPL Human Serum Albumin
Excipient, USP/EP

HSA is found in human blood and is the most abundant protein in human blood plasma. HSA transports hormones, fatty acids, and other compounds, buffers pH, and maintains oncotic pressure, among other functions. HSA is used as a stabilizer in pharmaceutical and biologic products and is effective in drug delivery. It is also used in cryopreservation and cell culture applications.

For excipient use only. Not intended for therapeutic use.

Applications:

- Stabilizer of product potency during manufacturing, shipping, and storage
- Medium component in cell culture, cryopreservation, and stem cell expansion
- Carrier molecule/scaffold for drug delivery to transport therapeutic peptides and proteins
- Component in nanoparticle albumin-bound formulations
- Coating applications on medical devices

Concentrations & Fill Sizes

- 25% Solution x 100 mL
- 25% Solution x 50 mL

Extensive Plasma Testing:

- Every Plasma Donation:
  - Tested serologically (HBsAg, anti-HCV, anti-HIV)
  - NAT tested (HAV, HBV, HCV, HIV, parvovirus B19)
- Every Plasma Pool:
  - NAT tested by an approved external testing laboratory (HAV, HBV, HCV, HIV, parvovirus B19)
  - Tested serologically by BPL (HBsAg, anti-HIV)
- Tailored customer release documentation available

Product Attributes:

- Sterile, ready-for-use, clear, slightly viscous, almost colorless, yellow, amber, or slightly green aqueous solution made of the albumin component of the blood
- High purity product due to the chromatography 'polishing' step which reduces denatured impurities
- Prepared from the pooled plasma of US donors in FDA-licensed facilities in the US
- Dual stabilizers: caprylate (0.08 mmol/g albumin) and acetyltryptophanate (0.08 mmol/g albumin)
- Can be stored at room temperature (not above 30°C [86°F])
- Low aluminum content (<200 micrograms/L albumin)
- No preservatives and latex free

NOVA is the authorized distributor of Human Serum Albumin for excipient use, USP/EP manufactured by Bio Products Laboratory Ltd. (BPL) to the global market. Our HSA is manufactured using only US-sourced plasma from FDA-regulated and PPTA-approved collection centers that are subject to audit by BPL, and inspection by the UK Competent Authority (MHRA) or a European Union Competent Authority. BPL's state-of-the-art manufacturing facility in Elstree, UK, delivers consistent high-quality products manufactured under cGMP, and undergoes regular inspections and licensing by UK MHRA and international regulatory agencies. All batches are tested to ensure compliance with US, European Union, and Chinese Pharmacopoeial monographs, by performing relevant Pharmacopoeial tests as required by the FDA, EMEA, and CDE. Certificates of Analysis are generated for each tested batch. This HSA is acceptable for use as an excipient and/or for further manufacture of pharmaceutical and medical device products. We work together with BPL's knowledgeable regulatory, quality, and technical representatives to support our customers' needs for documentation and support from R&D to commercial approval. BPL's website is **www.bplgroup.com**

References: 1. BPL 25% (human albumin) Prescribing Information. Durham, NC: BPL Limited. 2. Matejtschuk P, Dash CH, Gascoigne EW. Production of human albumin solution: a continually developing colloid. Br J Anaesth. 2000;85(6):887-95. 3. Data on file: BPL-RD006-0220. Bio Products Laboratory Ltd.