



SAR HEALTHLINE (P) LTD

Human Serum Albumin (HSA)

For laboratory procedures only; other uses must be qualified by the end user .

Product Description	Catalogue Code	Unit Size
Quinn's Advantage™ HSA	ART-3001	12 x 5mL
Quinn's Advantage™ HSA	ART-3003	1 x 100mL

INTENDED USE

Human Serum Albumin (HSA) has been designed to be used as a tissue culture protein supplement in those applications requiring additional supplementation. Protein in the form of albumin, which makes up the bulk of the protein present in blood serum and reproductive tract fluid, is added to tissue culture media because it is thought to maintain the stability of cell membranes and chelate trace amounts of toxic components present in the culture water, media components, and containers and culture dishes. Protein, in the form of patient's serum or albumin, has been used extensively in media for IVF, GIFT, ICSI, embryo culture, embryo transfer, cryopreservation, and sperm washing for IUI.

DESCRIPTION

Product contains 100mg/mL total protein (weight/volume) in saline solution. Each lot of HSA is tested for pH (7.4±0.2), osmolality (280±10mOsm/kg water), sterility (no detectable contamination), and biocompatibility (>80% mouse zygote development to blastocysts) All donors used in its manufacture were individually tested and found to be non-reactive for hepatitis B surface antigen (HBsAG) and antibodies to hepatitis C virus (HCV) and Human Immunodeficiency Virus (HIV) by approved testing methods.

STORAGE INSTRUCTIONS AND STABILITY

Store unopened containers refrigerated at 2-8°C. Warm to ambient or incubator (37°C) temperature prior to use. Do not freeze or expose to temperatures greater than 39°C. The product is stable until the expiration date shown on the label or within 30 days of the Date of First Use provided that proper aseptic procedures have been observed by the user:

- A. Remove desired volume of product using aseptic procedures.
- B. Once product has been removed from the original container, reseal the container to ensure a tight seal. Write the date the product was first opened on the product label. Do not use product longer than 30 days after opening the container.
- C. Once removed, do not return any volume of product to the original container.
- D. Once the product has been opened, store the sealed container at 2-8°C.
- E. Do not use if the product becomes discoloured, cloudy, turbid, or shows any evidence of microbial contamination. One-cell MEA tested and passed with 80% or greater blastocyst. USP Endotoxin gel clot tested and passed with <1 EU/ml. A Certificate of Analysis is available for this product.

DIRECTIONS FOR USE

For sperm preparation and embryo culture: Use at 5mg/mL. For 10mL of medium, add 0.5mL of HSA solution to 9.5mL of bicarbonate-buffered medium (eg, Quinn's Advantage™ Fertilization (HTF)

Medium or Quinn's Advantage™ Cleavage Medium. *NOTE:* for washed sperm samples for IUI use QUINN'S® Sperm Washing Medium which already contains 5mg/mL Human Serum Albumin.

For embryo transfer: Use at 30mg/mL. For 10mL of medium add 3.0mL of HSA solution to 7.0mL of Quinn's Advantage™ Medium with HEPES.

For embryo cryopreservation: Use at 12mg/mL. For 10mL of medium add 1.2mL of HSA solution to 8.8mL of Quinn's Advantage™ Medium with HEPES.

For micromanipulation(ICSI and assisted hatching): Use at 5mg/mL. For 10mL of medium, add 0.5mL of HSA solution to 9.5mL of Quinn's Advantage™ Medium with HEPES.

Laboratories may establish through appropriate testing that higher or lower concentrations than those suggested above are optimal for specific applications.

NOT INTENDED FOR INJECTION BY USUAL PARENTERAL ROUTES IN HUMANS OR ANIMALS

Each laboratory should make its own determination of which medium and protocol to use for each particular procedure.

Information on specific aspects of IVF, embryo culture, and cryopreservation is available in our publication "IVF Laboratory Policy and Procedure Manual.

PRECAUTIONS AND WARNINGS

Do not use product that shows evidence of particulate matter. To avoid problems with contamination, aseptic technique should be used to remove aliquots of product from the container. Do not mix components of one container with another. Discard minimal amounts of excess product remaining in the bottle. This product contains albumin, a derivative of human blood. All donors used in its manufacture were individually tested and found to be nonreactive for hepatitis B surface antigen (HBsAG) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV) by approved testing methods. Donors of the source material have been screened for Creutzfeldt Jakob disease (CJD). Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of CJD is also considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.