

GM501 HSA**Material included in the package:**

- 5 ml GM501 HSA (10 % human serum albumin)

Material not included in the package:

- CO₂-incubator at 37°C
- LAF-bench (ISO5 environment)

Product code:

- 4 HSA-0005

Composition:

- 10 % (100mg/ml) GM501 HSA in saline buffer.

Intended use/Intended users:

- GM501 HSA (10 % human serum albumin) is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of GM501 HSA solution as a supplement for culture medium.
- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

Instructions for use:

- To supplement the 50 ml culture medium (e.g. GM501 Basic or GM501 Basic with Gentamicin) with GM501 HSA to a protein end concentration of 1 %. Keep 45 ml culture medium in the bottle and add 5 ml of GM501 HSA. Mix well.

Product specifications and quality control:

- GM501 HSA is obtained from blood of donors of certified blood banks according to international guidelines. The HSA is dialyzed and subsequently solved in saline buffer.

- The protein supplement is manufactured using the modified Cohn-Oncley cold ethanol fractionation process. The final product is sterilized by filtration and additionally heated for 10-11 hours at 60°C.
- All raw materials are of highest available purity (European Pharmacopoeia and/or USP standard), if applicable.
- A certificate of analysis is available for each batch upon request from our website with respective lot number.
- The MSDS for GM501 HSA is available upon request and can also be downloaded from our website.
- GM501 HSA is manufactured and tested according to the following specifications:









pH (at 37°C, 6 % CO ₂)	7.20-7.40
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Osmolality (mOsm/kg)	265-285
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Sterility	sterile - SAL 10 ⁻³ (Sterility Assurance Level)
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Endotoxins (EU/ml)	< 1.00
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MEA (Blastocysts after 96h in %)	≥ 80
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	Consult instructions for use		Do not use if package is damaged
	Temperature limitation		Sterilized using aseptic processing techniques (filtration)
	Lot number		Keep away from sunlight
	Use by		Catalogue number

Precautions and warnings:

- Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot totally be excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of proven virus transmissions with albumin, manufactured to European Pharmacopoeia specifications by established processes.
- Therefore, handle all specimens as if capable of transmitting HIV or hepatitis. Always wear protective clothing when handling specimens.
- Always work under strict hygienic conditions (ISO 5 environment, e.g. LAF-bench) to avoid possible contamination.
- Only for the intended use.

Pre-use checks:

- Do not use the product if bottle, seal of the container or package is opened or defect when the product is delivered.
- Do not use the product if it becomes discoloured, cloudy or shows any evidence of microbial contamination.

Storage instructions and stability:

- The shelf life is 12 month from time of manufacture.
- Store between 2-8°C.
- Do not freeze before use.
- Keep away from (sun) light.
- After opening the container do not use the product longer than 7 days.
- Do not use after expiry date.

For technical support:

GYNEMED Medizinprodukte GmbH & Co. KG,
Lübecker Straße 9, 23738 Lensahn - Germany
Phone: +49 (0) 4363 90 32 90 - **Fax:** +49 (0) 4363 90 32 91-9
Email: info@gynemed.de - **http:** //www.gynemed.de

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