

Material included in the package:

- 1 x 1 ml GM501 PVP 10 %
- 5 x 0.2 ml GM501 PVP 10 %

Material not included in the package:

- Incubator at 37°C (no CO<sub>2</sub>)
- Petri dishes
- LAF-bench (ISO Class 5)
- Microscope
- Pipettes
- Mineral Oil (e.g. GM501 Mineral Oil)
- HEPES-buffered sperm processing medium

Product code:

- 4 PVP 0001 (1 x 1 ml)
- 4 PVP 0001-5 (5 x 0.2 ml)

Used Abbreviations:

- ICSI - Intra cytoplasmic Sperm Injection
- PVP - Polyvinyl pyrrolidone

Composition:

- GM501 PVP is 10 % dialysed PhEur grade polyvinylpyrrolidone solved in an aqueous solution containing physiologic salts, HEPES, lactate, pyruvate, glucose and human albumin solution.

Intended use/Intended users

- GM501 PVP is a ready-to-use medium to reduce the motility of sperm, making it easier to catch them with an ICSI pipette.

- The intended users are IVF professionals (biologists, lab technicians, embryologists or medical doctors).

Instructions for use:

- *Evaporation of the PVP solution on the slide or dish and the presence of human albumin may occasionally cause a small amount of precipitation in the medium.*

Standard procedure:

1. Warm the PVP solution to 37°C.
2. Place a small drop of PVP solution (5 µl - 10 µl) in a dish and cover with GM501 MineralOil.
3. Add a small volume (1 µl - 2 µl) of washed sperm into the centre of the PVP droplet.
4. Wait for a few minutes to allow sperm to migrate to the periphery of the droplet.
5. Select and recover the spermatozoa for injection.

Alternative procedure (with extra washing step):

1. Warm the PVP solution and HEPES-buffered sperm processing medium to 37°C.
2. Place a small drop of PVP solution (5 µl - 10 µl) and 1 or more small drops HEPES-buffered sperm processing medium in a dish and cover with GM501 MineralOil.
3. Add a small volume (1 µl - 2 µl) of washed sperm into the centre of the PVP droplet.
4. Wait for a few minutes to allow sperm to migrate to the periphery of the droplet.
5. Select the spermatozoa for injection and nick (break) the tail of the spermatozoon with the tip of the pipette.
6. Transfer the spermatozoon into one of the HEPES-buffered sperm processing medium droplets and wash by transferring the sperm cell in and out of the sperm processing medium several times.
7. Aspirate the sperm cell into the pipette and use for ICSI procedure.

Product specifications and quality control:

- All raw materials are of highest available purity (European Pharmacopoeia and/or USP standard) if applicable.
- GM501 PVP has been evaluated by an independent test laboratory using the ISO 10993-5/USP30-NF25 Agar Diffusion test for cytotoxicity. The product was considered non-cytotoxic.
- A certificate of analysis is available for each batch upon request from our website with respective Lot number.
- The MSDS for the media are available upon request and can also be downloaded from our website.
- GM501 PVP is manufactured according to the following specifications:

pH	7.20-7.90 (Release criteria: 7.20-7.60)
Osmolality (mOsm/kg)	280-320
Sterility	sterile - SAL 10 <sup>-3</sup> (Sterility Assurance Level)
Endotoxins (EU/ml)	< 1.00
Viscosity at 25°C (cP)	> 170
MEA (Blastocysts after 96h in %)	≥ 80 after 30 min of exposure

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.

- GM501 PVP medium does not contain any antibiotics. Always work under strict hygienic conditions (e.g. LAF-bench, ISO Class 5) to avoid possible contamination.
- The long term safety of ICSI, including the use of PVP, on children born following this procedure is still under investigation.
- 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 9 month from time of manufacture.
- Store between 2-8°C.
- Do not freeze before use.
- Keep away from (sun)light.
- The product can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C.
- Do not use after expiry date.
- Stable after transport (max. 5 days) at elevated temperature ( $\leq 37^{\circ}\text{C}$ )



Consult instructions for use



Do not use if package is damaged



Temperature limitation



Sterilized using aseptic processing techniques (filtration)



Lot number



Use by



Keep away from (sun)light



Catalogue number

#### For technical support:



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