

Polyvinylpyrrolidone (PVP) with HSA

ASSISTED
REPRODUCTIVE
TECHNOLOGY



Polyvinylpyrrolidone (PVP-K90) is a synthetic copolymer with a molecular weight of 360,000 Daltons. PVP is intended for use in ICSI procedures involving immobilization of sperm.

PVP with HSA solution is a ready-to-use PVP with HSA (5 mg/mL), reconstituted in an isotonic HEPES buffered HTF medium.

7% PVP with HSA Solution, Catalog #90121

31 p.d.

- Recommended for use with low quality or low motility sperm specimens
- Available in kits of 5 x 0.5 mL
- Has a shelf-life of 6 months from the date of manufacture when stored at the recommended temperature of 2° to 8°C.

10% PVP with HSA Solution, Catalog #90123

- Recommended for use with highly motile sperm specimens
- Available in kits of 5 x 0.5 mL
- Has a shelf-life of 6 months from the date of manufacture when stored at the recommended temperature of 2° to 8°C.

Lyophilized PVP* is composed of USP grade PVP which is dissolved in Water for Injection (WFI) grade water and then membrane (SAL 10⁻³) filtered and lyophilized.

10% Lyophilized PVP*, Catalog #99219

- Available in kits of 10 x 1 mL
- Requires aseptic reconstitution with an appropriate medium (such as sperm washing medium, catalog # 9983) prior to use
- Has a shelf life of 2 years from the date of manufacture, once reconstituted lyophilized PVP may be stored for up to 3 weeks when stored at the recommended temperature of 2-8°C
- Does not contain protein supplement

Features and Benefits

- Available with HSA (5mg/mL) for improved immobilization and manipulation of sperm.
- Yields greater control over fluid flow in the ICSI pipette.
- Prohibits the spermatozoa from sticking to the pipette.

Sperm Mobility Recovery Assay

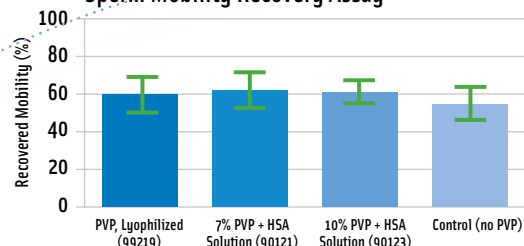


Figure 1. Sperm Mobility Recovery Assay. Several lots of PVP (lyophilized or solutions) were evaluated for biocompatibility with human sperm. Freshly obtained normal semen specimens were washed 2 times, exposed to PVP (test) or Control medium (sperm wash medium without PVP) for 1 hour, then washed twice and pelleted. Sperm pellets were then gently layered with sperm wash medium and the motile fraction was separated by swim up for 30 minutes. The percent (%) recovered motility was determined compared to the initial raw semen specimen. The results show that there is no toxic effect of PVP on sperm within a 1 hour exposure and that sperm motility can be recovered to the same level as control medium without PVP. Each bar represents the average (\pm S.D.) of at least 3 lots of PVP tested in duplicate assays versus control medium.

Sperm Immobilization Assay

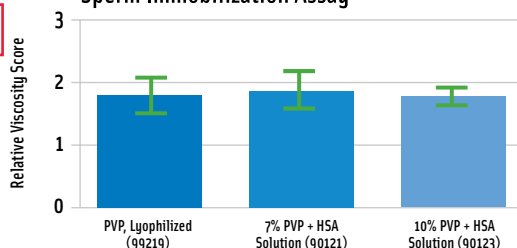


Figure 2. Sperm Immobilization Assay. Freshly obtained normal specimens were divided into two aliquots. One was used to obtain seminal fluid (without sperm) as the control medium and the other aliquot was used as the source of semen. Capillary tubes were filled with each PVP (test) medium or control medium and exposed at the same time to a control sperm sample for 30 minutes while incubated at 37°C. The distance traveled (in mm) by the leading spermatozoa is recorded for each test and control tubes and the Relative Viscosity Score (RVS) is determined as the distance traveled by the sperm in seminal (control) fluid divided by the distance traveled by the sperm in PVP (test) medium. Each bar represents the average (\pm S.D.) of at least 3 lots of PVP product.

References

1. Atiee S, Pool T, Martin J: A Simple Approach to Intracytoplasmic Sperm Injection. *Fertil Steril* 63.3, 652-665, 1995.
2. Van Steirteghen A C, et. al.: High Fertilization and Implantation Rates After Intracytoplasmic Sperm Injection. *Human Reproduction* 8:7, 1061-1066, 1993.

*Lyophilized PVP does not contain HSA (protein supplement)

Each lot of PVP receives a complete laboratory evaluation including endotoxin level, pH, osmolality and sterility testing. All results are provided in a lot-specific Certificate of Analysis.

Irvine Scientific's commitment to excellence is demonstrated by our products' performance and adherence to the industry's highest quality standards. We were one of the first companies in the USA to receive ISO 13485:2003 quality systems certification, the new rigorous international quality assurance standard designed specifically for Medical Devices.

Always refer to product insert for complete instructions for use. For more information on all of our Reproductive Products, call 1 (800) 437 5706.



CATALOG #90121 & 90123 Rev.4

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