

# Polyvinylpyrrolidone (PVP) with HSA



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

- 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

- 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<sup>3</sup>) filtered and lyophilized.

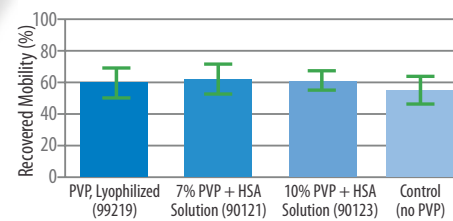
#### 10% Lyophilized PVP\*

- Available in kits of 10 x 1 mL.
- Requires aseptic reconstitution with an appropriate medium (such as sperm washing medium) 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° to 8°C.
- Does not contain protein supplement.

#### Features and Benefits

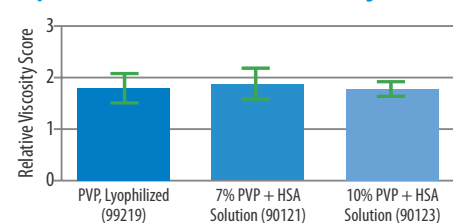
- Available with HSA (5mg/mL) for improved immobilization and manipulation of sperm.
- Yields greater control over fluid flow in the ICSI pipette.
- Prohibits the spermatozoa from sticking to the pipette.

### 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. Attee 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)



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## ASSISTED REPRODUCTIVE TECHNOLOGY

Each lot of Polyvinylpyrrolidone (PVP) with HSA receives a complete laboratory evaluation including mouse embryo testing, 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:  
+91 (0124) 4770707  
or write:  
infocbs@imvindia.com

90121 - 5 x 0.5 mL (7%)  
90123 - 5 x 0.5 mL (10%)

**Cryo Bio System**  
Groupe I.M.V. Technologies

www.cryobiosystem.com



**Cryo Bio System**  
Groupe I.M.V. Technologies

**Cryo Bio System India** (A Division of IMV India Pvt. Ltd.)

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# Multipurpose Handling Medium Complete (MHM)

Buffered medium for oocyte retrieval, embryo transfer, micro-manipulation and gamete washing.

## Multipurpose Handling Medium Complete (MHM)

- Available in 100 mL and 500 mL bottles
- MHM has a shelf life of 180 Days from date of manufacture

## Features and Benefits

First IVF medium using a combination buffering system of HEPES and MOPS to optimize pH buffering and stability at room atmosphere:

- Maintains pH across a broader range of temperatures
- Contains key amino acids, glycine and taurine, to help maintain cellular homeostasis
- Formulated to promote optimal cell growth by providing a safe and secure environment



Each lot of Multipurpose Handling Medium Complete (MHM) receives a complete laboratory evaluation including mouse embryo testing, endotoxin level, pH, osmolality and sterility testing. All results are provided in a lot-specific Certificate of Analysis.

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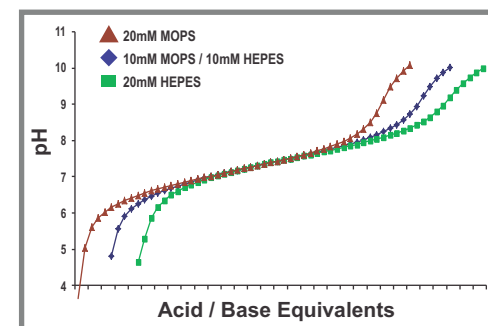
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90166 - 100 mL  
90166 - 500 mL  
MHM Complete

## The first multipurpose dual buffering medium for use with gametes and embryos

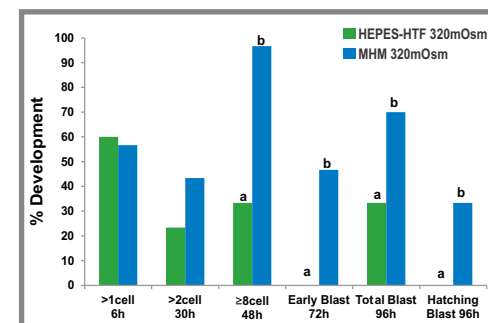
Minimizing stress imposed upon gametes and embryos and maintaining homeostasis during in vitro manipulations are important for optimizing ART success. A key to this endeavor is the use of an appropriate handling medium utilized for cellular manipulations outside of the laboratory incubator.

MHM maintains an appropriate and stable pH during gamete and embryo manipulation at room atmosphere by employing the first combination buffering system containing safe and effective pH buffers, HEPES and MOPS. By using these two proven pH buffers in specific ratios, pH buffering can be optimized for gametes and embryos and can lower amounts of each buffer utilized.



Use of a combination buffering system containing HEPES and MOPS, such as MHM allows adjustment of pKa, or optimal buffering capacity, not available in mono-buffered media. This permits formulation of a custom medium with a lower individual buffer concentration, with pH buffering optimized for use with gametes and embryos. This phenomenon is demonstrated by comparing pH titration curves.

MHM also contains key beneficial amino acids, glycine and taurine, which maintain cellular homeostasis, in part, by serving as potent osmolytes, thereby providing a safer environment for cellular manipulation.



Inclusion of evidence-based amino acids, glycine and taurine, found in MHM helps maintain cellular homeostasis, in part, by acting as potent osmolytes. These potent osmolytes in MHM provide added protection and permit embryo development in media with high osmolality that may be obtained via common laboratory practices during cell manipulation. Different superscripts within a developmental time point indicated a significant difference in development.

MHM is recommended for in vitro procedures involving manipulation of gametes and embryos at room atmosphere, such as sperm washing, oocyte recovery, micromanipulation and embryo transfer to maintain a stable and appropriate pH. MHM should be supplemented with protein and warmed to ~37°C prior to use.

# Hyaluronidase Solution

Hyaluronidase Solution is a convenient, ready-to-use solution designed for removing cumulus cells surrounding freshly retrieved oocytes prior to ICSI or other ART procedures.

This solution consists of 80 IU/mL of Hyaluronidase enzyme in a HEPES buffered HTF medium with therapeutic - grade human serum albumin (5mg/mL) and the antibiotic gentamicin sulfate (10µg/mL).

Irvine Scientific has performed extensive efficacy testing on Hyaluronidase Solution using freshly retrieved mouse oocytes and one-cell embryos.

The performance of Irvine Scientific's Hyaluronidase Solution was equivalent to control hyaluronidase solutions, and no toxicity was observed to mouse oocytes and embryos. The development of one-cell embryos to blastocysts was equivalent after exposure to Hyaluronidase Solution as compared to non exposed controls (in growth medium only). The lot-to-lot performance of Hyaluronidase Solution was consistent for enzyme activity and the removal of cumulus cells from freshly retrieved oocytes within 2 minutes.

In addition to the mouse oocyte and embryo bioassays, Hyaluronidase Solution is also tested for enzyme activity using a standard enzymatic assay for Hyaluronidase. This permits verification of actual enzyme activity, in addition to the functional bioassay of cumulus cell removal and lack of toxicity.

Moreover, stability studies have been conducted to determine the enzymatic activity of Irvine Scientific's Hyaluronidase Solution after storage at several temperatures. The results (Figure 4) indicate that greater than 95% of the initial enzymatic activity (80 IU/mL) remains after storage for 2 months at 6°C (refrigerated) or 6 months frozen (-10°C).

The recommended storage temperature for this product is frozen (<- 10°C) to assure a shelf life of at least 6 months. Repeated freeze/thaw cycles of Hyaluronidase Solution (no more than 3) did not adversely affect the enzymatic activity (data not shown).

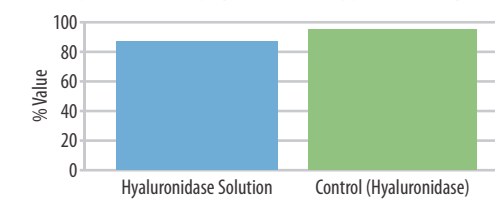
## Hyaluronidase Solution

- Available in kits of 5 X 1.0 mL.
- The shelf life is 6 months when stored sealed at the recommended temperature of <-10°C.
- Gentamicin sulfate is included as the antibiotic.

## Features and Benefits

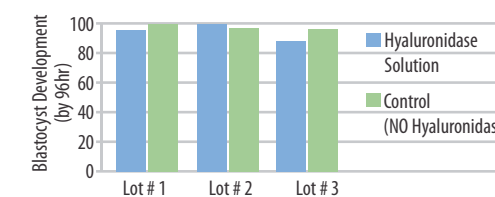
- Convenient ready-to-use solution for denuding oocytes of cumulus cells prior to ICSI or other ART procedures. Refer to product insert for detailed usage instructions.
- This solution contains HEPES buffered HTF medium to maintain proper pH during cumulus cell removal at ambient atmosphere conditions.

## Oocyte Viability (Morphology at 24 hr)



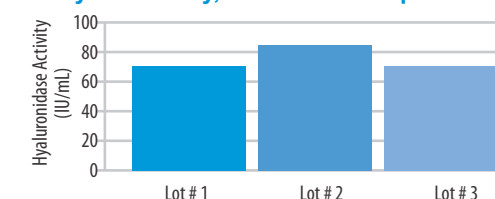
**Figure 1.** Freshly retrieved mouse oocytes were exposed to Hyaluronidase Solution (IS) or Control Hyaluronidase (in house) for 1-2 minutes with gentle pipetting to remove cumulus cells. Cumulus cells were dissociated within 2 minutes of exposure. Oocytes were then transferred to culture medium (HTF + 0.5% BSA) and viability was evaluated morphologically after 24 hours. The data is expressed as the % of oocytes that appeared normal after 24 hr incubation. Each bar represents the average (± SEM) of at least 5 experiments (n=150 embryos total for each condition).

## Lot-to-Lot Comparison



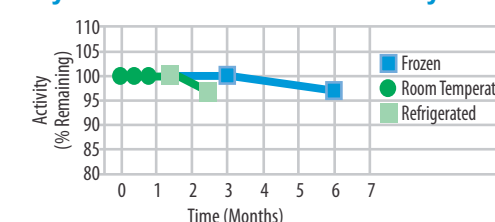
**Figure 2.** Fresh one-cell mouse embryos were retrieved and exposed to Hyaluronidase Solution for 1-2 minutes with gentle pipetting. Embryos were then washed and cultured in growth medium (HTF + 0.5% BSA) to the blastocyst stage. The data represents the rate of blastocyst development by 96 hours post retrieval for three different lots of Hyaluronidase Solution (n=31 embryos for each lot). Controls were exposed to, and cultured in, growth medium only (no hyaluronidase).

## Enzyme Activity, Lot-to-Lot Comparison



**Figure 3.** Samples of Hyaluronidase Solution were evaluated by a standard turbidimetric assay to determine specific activity of the enzyme.

## Hyaluronidase Solution Stability



**Figure 4.** Hyaluronidase activity was determined following different storage conditions.



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

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90101 - 5 x 1 mL